

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 2018280128 B2**

(54) Title
Composite dressings for improved granulation and reduced maceration with negative-pressure treatment

(51) International Patent Classification(s)
A61M 1/00 (2006.01) **A61F 13/02** (2006.01)
A61F 13/00 (2006.01)

(21) Application No: **2018280128** (22) Date of Filing: **2018.06.05**

(87) WIPO No: **WO18/226705**

(30) Priority Data

(31) Number	(32) Date	(33) Country
62/516,550	2017.06.07	US
62/516,540	2017.06.07	US
62/516,566	2017.06.07	US

(43) Publication Date: **2018.12.13**

(44) Accepted Journal Date: **2024.04.18**

(71) Applicant(s)
Solventum Intellectual Properties Company

(72) Inventor(s)
Locke, Christopher Brian;Robinson, Timothy Mark

(74) Agent / Attorney
Spruson & Ferguson, GPO Box 3898, Sydney, NSW, 2001, AU

(56) Related Art
WO 2015/193257 A1
US 2011/0213287 A1
WO 01/85248 A1



- (51) International Patent Classification:
A61M 1/00 (2006.01) *A61F 13/02* (2006.01)
A61F 13/00 (2006.01)
- (21) International Application Number:
PCT/US2018/036074
- (22) International Filing Date:
05 June 2018 (05.06.2018)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
62/516,540 07 June 2017 (07.06.2017) US
62/516,550 07 June 2017 (07.06.2017) US
62/516,566 07 June 2017 (07.06.2017) US
- (71) Applicant: **KCI LICENSING, INC.** [US/US]; Legal Department-Intellectual Property, P.O. Box 659508, San Antonio, TX 78265-9508 (US).
- (72) Inventors: **LOCKE, Christopher, Brian**; 6 Bosworth Mews, Bournemouth BH9 3SD (GB). **ROBINSON, Timothy, Mark**; 19 Wessex Avenue, Shillingstone DT11 0TG (GB).
- (74) Agent: **WELCH, Gerald, T.** et al.; Harness, Dickey & Pierce, P.L.C., 5445 Corporate Drive, Suite 200, Troy, MI 48098 (US).
- (81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(54) Title: COMPOSITE DRESSINGS FOR IMPROVED GRANULATION AND REDUCED MACERATION WITH NEGATIVE-PRESSURE TREATMENT

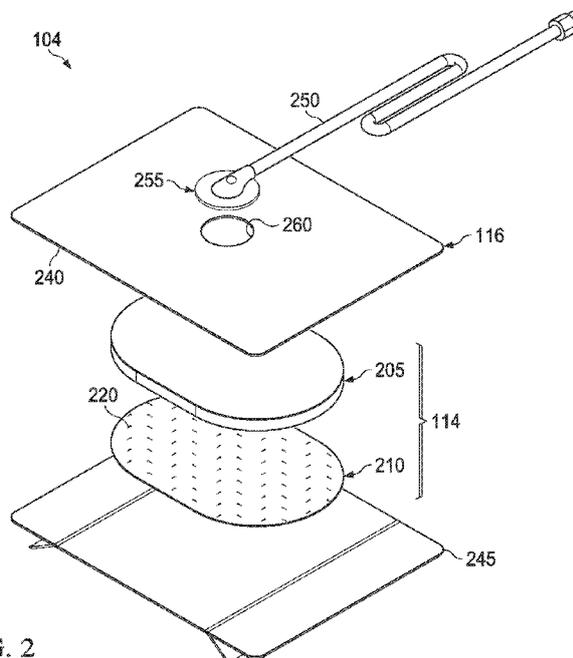


FIG. 2

(57) Abstract: A dressing may comprise a manifold having a first planar surface and a second planar surface opposite the first planar surface, and a first layer adjacent to the first planar surface and a second layer adjacent to the second planar surface. The first layer and the second layer may be laminated to the first planar surface and the second planar surface, respectively. Pressure-responsive fluid restrictions through at least one of the first layer and the second layer may be adjacent to the manifold. The first layer and the second layer may also form a sleeve or an envelope around the manifold in some embodiments. At least one of the first layer and the second layer may be configured to be disposed between the manifold and a tissue site in use. In some examples, the dressing may have a smooth or matte surface configured to contact a tissue site.



(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

20 Nov 2023
2018280128

COMPOSITE DRESSINGS FOR IMPROVED GRANULATION AND REDUCED MACERATION WITH NEGATIVE-PRESSURE TREATMENT

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 dressings for tissue treatment and methods of using the dressings for tissue treatment.

BACKGROUND

[0003] Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

[0004] 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 reduced pressure may be commonly referred to as "negative-pressure therapy," but is also known by other names, including "negative-pressure wound therapy," "reduced-pressure therapy," "vacuum therapy," "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.

[0005] There is also widespread acceptance that cleansing a tissue site can be highly beneficial for new tissue growth. For example, a wound can be washed out with a stream of liquid solution, or a cavity can be washed out using a liquid solution for therapeutic purposes. These practices are commonly referred to as "irrigation" and "lavage" respectively. "Instillation" is another practice that generally refers to a process of slowly introducing fluid to a tissue site and leaving the fluid for a prescribed period of time before removing the fluid. For example, instillation of topical treatment solutions over a wound bed can be combined with negative-pressure therapy to further promote wound healing by loosening soluble contaminants in a wound bed and removing infectious material. As a result, soluble bacterial burden can be decreased, contaminants removed, and the wound cleansed.

[0006] While the clinical benefits of negative-pressure therapy and/or instillation therapy are widely known, improvements to therapy systems, components, and processes may benefit healthcare providers and patients.

BRIEF SUMMARY

[0007] New and useful systems, apparatuses, and methods for treating tissue in a negative-pressure therapy environment 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.

[0008] According to one aspect of the present invention, there is provided a dressing for treating a tissue site with negative pressure, the dressing comprising: a manifold comprising a first surface and a second surface opposite the first surface; a first layer adjacent to the first surface and a second layer adjacent to the second surface, the first layer and the second layer each comprising a polymer film; a plurality of fluid restrictions in the polymer film of both the first layer and the second layer; and a sealing layer adjacent to at least one of the first layer and the second layer, the sealing layer having a plurality of apertures fluidly coupled to the fluid restrictions, wherein one or more of the plurality of apertures is sized to expose both the fluid restrictions and a portion of the polymer film around the fluid

restrictions to the tissue site through the sealing layer, and wherein a dimension of one or more of the fluid restrictions in the polymer film exceeds a dimension of one or more of the plurality of apertures.

[0009] Unless the context clearly requires otherwise, throughout the description and the claims, the words “comprise”, “comprising”, and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of “including, but not limited to”.

[0010] For example, in some embodiments, a dressing for treating tissue may be a composite of dressing layers, including a release film, a perforated polymer film, open-cell foam, and an adhesive drape. Some dressings may also include a bonded silicone having perforations. The perforation pattern of the polymer film can be aligned with the perforation pattern of at least a central area of the silicone. In some embodiments, the perforations may be slits or slots. The open-cell foam may be a reticulated foam in some examples, and may be relatively thin and hydrophobic to reduce the fluid hold capacity of the dressing. The foam may also be thin to reduce the dressing profile and increase flexibility, which can enable it to conform to wound beds and other tissue sites under negative pressure.

[0011] More generally, some embodiments of a dressing may comprise a manifold having a first surface and a second surface opposite the first surface, and a first layer adjacent to the first surface and a second layer adjacent to the second surface. In some examples, the first layer and the second layer may be laminated to the first surface and the second surface, respectively. Fluid restrictions through at least one of the first layer and the second layer may be adjacent to the manifold. The first layer and the second layer may also form a sleeve or an envelope around the manifold in some embodiments. At least one of the first layer and the second layer may be configured to be disposed between the manifold and a tissue site in use. In some examples, the dressing may have a smooth or matte surface configured to contact a tissue site.

[0012] The first layer and the second layer may each comprise or consist essentially of a polymer film in some examples. In more specific examples, the polymer film may be hydrophobic, and may have a contact angle with water greater than 90 degrees. Examples of suitable polymer films may include, without limitation, polythene, polyurethane, acrylics, polyolefines, polyacetates, polyamides, polyesters, polyether block amide, thermoplastic vulcanizates, polyethers, and polyvinyl alcohol.

[0013] In some embodiments, the fluid restrictions may comprise or consist essentially of elastic passages in the polymer film. In further embodiments, the elastic passages are normally closed, for example, closed in the absence of a pressure gradient. For example, the elastic passages are responsive to a pressure gradient. For example, the fluid restrictions may comprise or consist essentially of fenestrations, slits, or slots in the polymer film that open or expand in response to a pressure gradient.

[0014] In some embodiments, the manifold may comprise a foam, and in more particular examples, may comprise or consist essentially of a reticulated polymer foam. A hydrophobic manifold having a thickness of less than 7 millimeters and a free volume of at least 90% may be suitable for many therapeutic applications.

[0015] In some embodiments, a dressing may comprise a manifold formed from a hydrophobic material, a film substantially enclosing the manifold, and a plurality of fluid passages through the film. The film may be formed from a hydrophobic material, and the plurality of fluid passages may be configured to expand in response to a pressure gradient across the film.

[0016] Some embodiments of a dressing may comprise a first layer of film, a second layer comprising a manifold adjacent to the first layer, a third layer of film adjacent to the manifold opposite the first layer, and a plurality of fluid restrictions through the film of at least one of the first layer and the third layer. The films of the first layer and the third layer may each have a flat surface texture, and the plurality of fluid restrictions may be configured to be responsive to a pressure gradient across the fluid restrictions.

[0017] An apparatus for treating a tissue site with negative pressure is also described herein, wherein some example embodiments include a tissue interface comprising a manifold and a film covering at least two sides of the manifold, the manifold and the film formed from a hydrophobic material; a plurality of elastomeric valves through the film, the plurality of elastomeric valves configured to expand in response to a pressure gradient across the film; and a cover configured to be attached to the tissue site. The cover and the tissue interface may be assembled in a stacked relationship with the cover configured to be attached to an attachment surface adjacent to the tissue site. The tissue interface may further comprises a sealing layer in some embodiments, which may be disposed adjacent to the film and configured to contact the tissue site. At least one aperture in the sealing layer may be fluidly coupled to at least one of the elastomeric valves in the film. Some embodiments of the

apparatus may additionally include a negative-pressure source fluidly coupled to the tissue interface.

[0018] In other examples, a method of promoting granulation in a surface wound may comprise applying a dressing to the surface wound, wherein the dressing comprises a cover, a manifold having a first planar surface and a second planar surface opposite the first planar surface, and a perforated polymer film covering at least the first planar surface and the second planar surface. The perforated polymer film may be sealed to the surface wound and cover at least a portion of a periwound adjacent to the surface wound. The cover may be attached to epidermis around the perforated polymer film. The dressing may be fluidly coupled to a negative-pressure source, and negative pressure from the negative-pressure source may be applied to the dressing.

[0019] Advantages of the claimed subject matter may include: (1) increased formation of granulation tissue (i.e. faster healing), (2) reduced peel force required to remove the dressing (i.e. ease of use, less pain during dressing changes), (3) reduced time to apply the dressing (i.e. ease of use), and/or (4) reduced risk of maceration of the periwound area during treatment, any or all of which may enable a 7-day dressing (versus 48 hour dressing changes), increase therapy compliance, and decrease costs of care. Other 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

[0020] Figure 1 is a functional block diagram of an example embodiment of a therapy system that can provide tissue treatment in accordance with this specification;

[0021] Figure 2 is an assembly view of an example of a dressing, illustrating additional details that may be associated with some example embodiments of the therapy system of Figure 1;

[0022] Figure 3 is a schematic view of an example configuration of fluid restrictions in a layer that may be associated with some embodiments of the dressing of Figure 2;

[0023] Figure 4 is an assembly view of another example of a dressing, illustrating additional details that may be associated with some example embodiment of the therapy system of Figure 1;

[0024] Figure 5 is a schematic view of an example configuration of apertures in a layer that may be associated with some embodiments of the dressing of Figure 4;

[0025] Figure 6 is a schematic view of the example layer of Figure 5 overlaid on the example layer of Figure 3;

[0026] Figure 7 is a schematic view of another example of a layer that may be associated with some embodiments of a dressing;

[0027] Figure 8 and Figure 9 illustrate other example configurations of fluid restrictions that may be associated with some embodiments of layers of the dressing of Figure 2 or Figure 4;

[0028] Figure 10 is an assembly view illustrating an example of a tissue interface that may be associated with some embodiments of the therapy system of Figure 1;

[0029] Figure 11 is a perspective view of another example configuration of layers that may be associated with some embodiments of a dressing in the therapy system of Figure 1;

[0030] Figure 12 is a partial cutaway view of another example configuration of layers that may be associated with some embodiments of a dressing in the therapy system of Figure 1;

[0031] Figure 13 is a graphical representation of maximum peel force measurements (N) on day 7 following dressing application and removal of each test and control dressing;

[0032] Figure 14 is a graphical representation of tissue ingrowth measurements. Thickness (mm) is measured for each test and control dressing;

[0033] Figure 15 is an optical micrograph picture demonstrating granulation tissue thickness for each test and control dressing; and

[0034] Figure 16 is a graphical representation of Figure 15 demonstrating quantitative morphometry granulation tissue thickness for each test and control dressing.

DESCRIPTION OF EXAMPLE EMBODIMENTS

[0035] 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, and may omit certain details already well-known in the art. The following detailed description is, therefore, to be taken as illustrative and not limiting.

[0036] 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.

[0037] Figure 1 is a simplified functional block diagram of an example embodiment of a therapy system 100 that can provide negative-pressure therapy with instillation of topical treatment solutions to a tissue site in accordance with this specification.

[0038] The term “tissue site” in this context broadly refers to a wound, defect, or other treatment target located on or within tissue, including but not limited to, a surface wound, bone tissue, adipose tissue, muscle tissue, neural tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, or ligaments. 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 applied to a tissue site to grow additional tissue that may be harvested and transplanted. A surface wound, as used herein, is a wound on the surface of a body that is exposed to the outer surface of the body, such an injury or damage to the epidermis, dermis, and/or subcutaneous layers. Surface wounds may include ulcers or closed incisions, for example. A surface wound, as used herein, does not include wounds within an intra-abdominal cavity. 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.

[0039] The therapy system 100 may include a source or supply of negative pressure, such as a negative-pressure source 102, a dressing 104, a fluid container, such as a container 106, and a regulator or controller, such as a controller 108, for example. Additionally, the therapy system 100 may include sensors to measure operating parameters and provide

feedback signals to the controller 108 indicative of the operating parameters. As illustrated in Figure 1, for example, the therapy system 100 may include a pressure sensor 110, an electric sensor 112, or both, coupled to the controller 108. As illustrated in the example of Figure 1, the dressing 104 may comprise or consist essentially of one or more dressing layers, such as a tissue interface 114, a cover 116, or both in some embodiments.

[0040] The therapy system 100 may also include a source of instillation solution, such as saline, for example. For example, a solution source 118 may be fluidly coupled to the dressing 104, as illustrated in the example embodiment of Figure 1. The solution source 118 may be fluidly coupled to a positive-pressure source such as the positive-pressure source 120, a negative-pressure source such as the negative-pressure source 102, or both in some embodiments. A regulator, such as an instillation regulator 122, may also be fluidly coupled to the solution source 118 and the dressing 104 to ensure proper dosage of instillation solution to a tissue site. For example, the instillation regulator 122 may comprise a piston that can be pneumatically actuated by the negative-pressure source 102 to draw instillation solution from the solution source during a negative-pressure interval and to instill the solution to a dressing during a venting interval. Additionally or alternatively, the controller 108 may be coupled to the negative-pressure source 102, the positive-pressure source 120, or both, to control dosage of instillation solution to a tissue site. In some embodiments, the instillation regulator 122 may also be fluidly coupled to the negative-pressure source 102 through the dressing 104, as illustrated in the example of Figure 1.

[0041] Some components of the therapy system 100 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 102 may be combined with the solution source 118, the controller 108 and other components into a therapy unit.

[0042] In general, components of the therapy system 100 may be coupled directly or indirectly. For example, the negative-pressure source 102 may be directly coupled to the container 106, and may be indirectly coupled to the dressing 104 through the container 106. Coupling may include fluid, mechanical, thermal, electrical, or chemical coupling (such as a chemical bond), or some combination of coupling in some contexts. For example, the negative-pressure source 102 may be electrically coupled to the controller 108. The negative-pressure source may be fluidly coupled to one or more distribution components, which provide a fluid path to a tissue site. In some embodiments, components may also be coupled

by virtue of physical proximity, being integral to a single structure, or being formed from the same piece of material. For example, the tissue interface 114 and the cover 116 may be discrete layers disposed adjacent to each other, and may be joined together in some embodiments.

[0043] A distribution component is preferably detachable, and may be disposable, reusable, or recyclable. The dressing 104 and the container 106 are illustrative of distribution components. A fluid conductor is another illustrative example of a distribution component. A "fluid conductor," in this context, broadly includes a tube, pipe, hose, conduit, or other structure with one or more lumina or open pathways 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. Moreover, some fluid conductors may be molded into or otherwise integrally combined with other components. Distribution components may also include or comprise interfaces or fluid ports to facilitate coupling and de-coupling other components, including sensors and data communication devices. In some embodiments, for example, a dressing interface may facilitate coupling a fluid conductor to the dressing 104. For example, such a dressing interface may be a SENSAT.R.A.C.TM Pad available from KCI of San Antonio, Texas.

[0044] A negative-pressure supply, such as the negative-pressure source 102, may be a reservoir of air at a negative pressure, or may be a manual or electrically-powered device, such as a vacuum pump, a suction pump, a wall suction port available at many healthcare facilities, or a micro-pump, for example. "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. 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. 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 -50 mm Hg (-9.9 kPa) and -300 mm Hg (-39.9 kPa).

[0045] The container 106 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.

[0046] A controller, such as the controller 108, may be a microprocessor or computer programmed to operate one or more components of the therapy system 100, such as the negative-pressure source 102. In some embodiments, for example, the controller 108 may be a microcontroller, which generally comprises an integrated circuit containing a processor core and a memory programmed to directly or indirectly control one or more operating parameters of the therapy system 100. Operating parameters may include the power applied to the negative-pressure source 102, the pressure generated by the negative-pressure source 102, or the pressure distributed to the tissue interface 114, for example. The controller 108 is also preferably configured to receive one or more input signals, such as a feedback signal, and programmed to modify one or more operating parameters based on the input signals.

[0047] Sensors, such as the pressure sensor 110 or the electric sensor 112, are generally known in the art as any apparatus operable to detect or measure a physical phenomenon or property, and generally provide a signal indicative of the phenomenon or property that is detected or measured. For example, the pressure sensor 110 and the electric sensor 112 may be configured to measure one or more operating parameters of the therapy system 100. In some embodiments, the pressure sensor 110 may be a transducer configured to measure pressure in a pneumatic pathway and convert the measurement to a signal indicative of the pressure measured. In some embodiments, for example, the pressure sensor 110 may be a piezo-resistive strain gauge. The electric sensor 112 may optionally measure operating parameters of the negative-pressure source 102, such as the voltage or current, in some embodiments. Preferably, the signals from the pressure sensor 110 and the electric sensor 112 are suitable as an input signal to the controller 108, but some signal conditioning may be appropriate in some embodiments. For example, the signal may need to be filtered or amplified before it can be processed by the controller 108. Typically, the signal is an electrical signal, but may be represented in other forms, such as an optical signal.

[0048] The tissue interface 114 can be generally adapted to contact a tissue site. The tissue interface 114 may be partially or fully in contact with the tissue site. If the tissue site is

a wound, for example, the tissue interface 114 may partially or completely fill the wound, or may be placed over the wound. The tissue interface 114 may take many forms and have more than one layer in some embodiments. The tissue interface 114 may also 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 tissue interface 114 may be adapted to the contours of deep and irregular shaped tissue sites.

[0049] In some embodiments, the cover 116 may provide a bacterial barrier and protection from physical trauma. The cover 116 may also be constructed from a material that can reduce evaporative losses and provide a fluid seal between two components or two environments, such as between a therapeutic environment and a local external environment. The cover 116 may be, for example, an elastomeric film or membrane that can provide a seal adequate to maintain a negative pressure at a tissue site for a given negative-pressure source. The cover 116 may have a high moisture-vapor transmission rate (MVTR) in some applications. For example, the MVTR may be at least 300 g/m² per twenty-four hours in some embodiments. In some example embodiments, the cover 116 may be a polymer drape, such as a polyurethane film, that is permeable to water vapor but impermeable to liquid. Such drapes typically have a thickness in the range of 25-50 microns. For permeable materials, the permeability generally should be low enough that a desired negative pressure may be maintained. The cover 116 may comprise, for example, one or more of the following materials: hydrophilic polyurethane; cellulotics; hydrophilic polyamides; polyvinyl alcohol; polyvinyl pyrrolidone; hydrophilic acrylics; hydrophilic silicone elastomers; an INSPIRE 2301 material from Coveris Advanced Coatings of Wrexham, United Kingdom having, for example, an MVTR (inverted cup technique) of 14400 g/m²/24 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 Glendale, California; polyether block polyamide copolymer (PEBAX), for example, from Arkema, France; INSPIRE 2327; or other appropriate material.

[0050] An attachment device may be used to attach the cover 116 to an attachment surface, such as undamaged epidermis, a gasket, or another cover. The attachment device

may take many forms. For example, an attachment device may be a medically-acceptable, pressure-sensitive adhesive configured to bond the cover 116 to epidermis around a tissue site, such as a surface wound. In some embodiments, for example, some or all of the cover 116 may be coated with an adhesive, such as an acrylic adhesive, which may have 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.

[0051] The solution source 118 may also be representative of a container, canister, pouch, bag, or other storage component, which can provide a solution for instillation therapy. Compositions of solutions may vary according to a prescribed therapy, but examples of solutions that may be suitable for some prescriptions include hypochlorite-based solutions, silver nitrate (0.5%), sulfur-based solutions, biguanides, cationic solutions, and isotonic solutions.

[0052] 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 and instillation 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.

[0053] In general, exudates and other fluids flow toward lower pressure along a fluid path. Thus, the term “downstream” typically implies something in a fluid path relatively closer to a source of negative pressure or further away from a source of positive pressure. Conversely, the term “upstream” implies something relatively further away from a source of negative pressure or closer to a source of positive pressure. 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 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.

[0054] Figure 2 is an assembly view of an example of the dressing 104 of Figure 1, illustrating additional details that may be associated with some embodiments in which the tissue interface 114 comprises more than one layer. In the example of Figure 2, the tissue

interface 114 comprises a first layer 205 and a second layer 210. In some embodiments, the first layer 205 may be disposed adjacent to the second layer 210. For example, the first layer 205 and the second layer 210 may be stacked so that the first layer 205 is in contact with the second layer 210. The first layer 205 may also be bonded to the second layer 210 in some embodiments.

[0055] The first layer 205 generally comprises or consists essentially of a manifold or a manifold layer, which provides a means for collecting or distributing fluid across the tissue interface 114 under pressure. For example, the first layer 205 may be adapted to receive negative pressure from a source and distribute negative pressure through multiple apertures across the tissue interface 114, which may have the effect of collecting fluid from across a tissue site and drawing the fluid toward the source. In some embodiments, the fluid path may be reversed or a secondary fluid path may be provided to facilitate delivering fluid, such as from a source of instillation solution, across the tissue interface 114.

[0056] In some illustrative embodiments, the pathways of the first layer 205 may be interconnected to improve distribution or collection of fluids. In some illustrative embodiments, the first layer 205 may comprise or consist essentially of a porous material having interconnected fluid pathways. For example, 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. Other suitable materials may include a 3D textile (Baltex, Muller, Heathcoates), non-woven (Libeltex, Freudenberg), a 3D polymeric structure (molded polymers, embossed and formed films, and fusion bonded films [Supracore]), and mesh, for example. Liquids, gels, and other foams may also include or be cured to include apertures and fluid pathways. In some embodiments, the first layer 205 may additionally or alternatively comprise projections that form interconnected fluid pathways. For example, the first layer 205 may be molded to provide surface projections that define interconnected fluid pathways. Any or all of the surfaces of the first layer 205 may have an uneven, coarse, or jagged profile

[0057] In some embodiments, the first layer 205 may comprise or consist essentially of a reticulated foam having pore sizes and free volume that may vary according to needs of a prescribed therapy. For example, a reticulated foam having a free volume of at least 90% may be suitable for many therapy applications, and a foam having an average pore size in a range of 400-600 microns may be particularly suitable for some types of therapy. The tensile strength of the first layer 205 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. The 25% compression load deflection of the first layer 205 may be at least 0.35 pounds per square inch, and the 65% compression load deflection may be at least 0.43 pounds per square inch. In some embodiments, the tensile strength of the first layer 205 may be at least 10 pounds per square inch. The first layer 205 may have a tear strength of at least 2.5 pounds per inch. In some embodiments, the first layer 205 may be a foam comprised of polyols such as polyester or polyether, isocyanate such as toluene diisocyanate, and polymerization modifiers such as amines and tin compounds. In one non-limiting example, the first layer 205 may be a reticulated polyurethane foam such as used in GRANUFOAM™ dressing or V.A.C. VERAFLOR™ dressing, both available from KCI of San Antonio, Texas.

[0058] The first layer 205 generally has a first planar surface and a second planar surface opposite the first planar surface. The thickness of the first layer 205 between the first planar surface and the second planar surface may also vary according to needs of a prescribed therapy. For example, the thickness of the first layer 205 may be decreased to relieve stress on other layers and to reduce tension on peripheral tissue. The thickness of the first layer 205 can also affect the conformability of the first layer 205. In some embodiments, a thickness in a range of about 5 millimeters to 10 millimeters may be suitable.

[0059] The second layer 210 may comprise or consist essentially of a means for controlling or managing fluid flow. In some embodiments, the second layer 210 may comprise or consist essentially of a liquid-impermeable, elastomeric material. For example, the second layer 210 may comprise or consist essentially of a polymer film. The second layer 210 may also have a smooth or matte surface texture in some embodiments. A glossy or shiny finish better or equal to a grade B3 according to the SPI (Society of the Plastics Industry) standards may be particularly advantageous for some applications. In some embodiments, variations in surface height may be limited to acceptable tolerances. For example, the surface of the second layer may have a substantially flat surface, with height variations limited to 0.2 millimeters over a centimeter.

[0060] In some embodiments, the second layer 210 may be hydrophobic. The hydrophobicity of the second layer 210 may vary, but may have a contact angle with water of at least ninety degrees in some embodiments. In some embodiments the second layer 210 may have a contact angle with water of no more than 150 degrees. For example, in some embodiments, the contact angle of the second layer 210 may be in a range of at least 90 degrees to about 120 degrees, or in a range of at least 120 degrees to 150 degrees. Water

contact angles can be measured using any standard apparatus. Although manual goniometers can be used to visually approximate contact angles, contact angle measuring instruments can often include an integrated system involving a level stage, liquid dropper such as a syringe, camera, and software designed to calculate contact angles more accurately and precisely, among other things. Non-limiting examples of such integrated systems may include the FTÅ125, FTÅ200, FTÅ2000, and FTÅ4000 systems, all commercially available from First Ten Angstroms, Inc., of Portsmouth, VA, and the DTA25, DTA30, and DTA100 systems, all commercially available from Kruss GmbH of Hamburg, Germany. Unless otherwise specified, water contact angles herein are measured using deionized and distilled water on a level sample surface for a sessile drop added from a height of no more than 5 cm in air at 20-25°C and 20-50% relative humidity. Contact angles reported herein represent averages of 5-9 measured values, discarding both the highest and lowest measured values. The hydrophobicity of the second layer 210 may be further enhanced with a hydrophobic coating of other materials, such as silicones and fluorocarbons, either as coated from a liquid, or plasma coated.

[0061] The second layer 210 may also be suitable for welding to other layers, including the first layer 205. For example, the second layer 210 may be adapted for welding to polyurethane foams using heat, radio frequency (RF) welding, or other methods to generate heat such as ultrasonic welding. RF welding may be particularly suitable for more polar materials, such as polyurethane, polyamides, polyesters and acrylates. Sacrificial polar interfaces may be used to facilitate RF welding of less polar film materials, such as polyethylene.

[0062] The area density of the second layer 210 may vary according to a prescribed therapy or application. In some embodiments, an area density of less than 40 grams per square meter may be suitable, and an area density of about 20-30 grams per square meter may be particularly advantageous for some applications.

[0063] In some embodiments, for example, the second layer 210 may comprise or consist essentially of a hydrophobic polymer, such as a polyethylene film. The simple and inert structure of polyethylene can provide a surface that interacts little, if any, with biological tissues and fluids, providing a surface that may encourage the free flow of liquids and low adherence, which can be particularly advantageous for many applications. Other suitable polymeric films include polyurethanes, acrylics, polyolefin (such as cyclic olefin copolymers), polyacetates, polyamides, polyesters, copolyesters, PEBAX block copolymers,

thermoplastic elastomers, thermoplastic vulcanizates, polyethers, polyvinyl alcohols, polypropylene, polymethylpentene, polycarbonate, styreneics, silicones, fluoropolymers, and acetates. A thickness between 20 microns and 100 microns may be suitable for many applications. Films may be clear, colored, or printed. More polar films suitable for laminating to a polyethylene film include polyamide, co-polyesters, ionomers, and acrylics. To aid in the bond between a polyethylene and polar film, tie layers may be used, such as ethylene vinyl acetate, or modified polyurethanes. An ethyl methyl acrylate (EMA) film may also have suitable hydrophobic and welding properties for some configurations.

[0064] As illustrated in the example of Figure 2, the second layer 210 may have one or more fluid restrictions 220, which can be distributed uniformly or randomly across the second layer 210. The fluid restrictions 220 may be bi-directional and pressure-responsive. For example, each of the fluid restrictions 220 generally may comprise or consist essentially of an elastic passage that is normally unstrained to substantially reduce liquid flow, and can expand or open in response to a pressure gradient. In some embodiments, the fluid restrictions 220 may comprise or consist essentially of perforations in the second layer 210. Perforations may be formed by removing material from the second layer 210. For example, perforations may be formed by cutting through the second layer 210, which may also deform the edges of the perforations in some embodiments. In the absence of a pressure gradient across the perforations, the passages may be sufficiently small to form a seal or fluid restriction, which can substantially reduce or prevent liquid flow. Additionally or alternatively, one or more of the fluid restrictions 220 may be an elastomeric valve that is normally closed when unstrained to substantially prevent liquid flow, and can open in response to a pressure gradient. A fenestration in the second layer 210 may be a suitable valve for some applications. Fenestrations may also be formed by removing material from the second layer 210, but the amount of material removed and the resulting dimensions of the fenestrations may be an order of magnitude less than perforations, and may not deform the edges.

[0065] For example, some embodiments of the fluid restrictions 220 may comprise or consist essentially of one or more slits, slots or combinations of slits and slots in the second layer 210. In some examples, the fluid restrictions 220 may comprise or consist of linear slots having a length less than 4 millimeters and a width less than 1 millimeter. The length may be at least 2 millimeters, and the width may be at least 0.4 millimeters in some embodiments. A length of about 3 millimeters and a width of about 0.8 millimeters may be

particularly suitable for many applications, and a tolerance of about 0.1 millimeter may also be acceptable. Such dimensions and tolerances may be achieved with a laser cutter, for example. Slots of such configurations may function as imperfect valves that substantially reduce liquid flow in a normally closed or resting state. For example, such slots may form a flow restriction without being completely closed or sealed. The slots can expand or open wider in response to a pressure gradient to allow increased liquid flow.

[0066] In the example of Figure 2, the dressing 104 may further include an attachment device, such as an adhesive 240. The adhesive 240 may be, for example, a medically-acceptable, pressure-sensitive adhesive that extends about a periphery, a portion, or the entire cover 116. In some embodiments, for example, the adhesive 240 may be 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. In some embodiments, such a layer of the adhesive 240 may be continuous or discontinuous. Discontinuities in the adhesive 240 may be provided by apertures or holes (not shown) in the adhesive 240. The apertures or holes in the adhesive 240 may be formed after application of the adhesive 240 or by coating the adhesive 240 in patterns on a carrier layer, such as, for example, a side of the cover 116. Apertures or holes in the adhesive 240 may also be sized to enhance the MVTR of the dressing 104 in some example embodiments.

[0067] As illustrated in the example of Figure 2, in some embodiments, the dressing 104 may include a release liner 245 to protect the adhesive 240 prior to use. The release liner 245 may also provide stiffness to assist with, for example, deployment of the dressing 104. The release liner 245 may be, for example, a casting paper, a film, or polyethylene. Further, in some embodiments, the release liner 245 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 245 may substantially preclude wrinkling or other deformation of the dressing 104. 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 104, or when subjected to temperature or environmental variations, or sterilization. Further, a release agent may be disposed on a side of the release liner 245 that is configured to contact the second layer 210. For example, the release agent may be a silicone coating and may have a release factor suitable to facilitate removal of the release liner 245 by hand and without damaging or

deforming the dressing 104. In some embodiments, the release agent may be a fluorocarbon or a fluorosilicone, for example. In other embodiments, the release liner 245 may be uncoated or otherwise used without a release agent.

[0068] Figure 2 also illustrates one example of a fluid conductor 250 and a dressing interface 255. As shown in the example of Figure 2, the fluid conductor 250 may be a flexible tube, which can be fluidly coupled on one end to the dressing interface 255. The dressing interface 255 may be an elbow connector, as shown in the example of Figure 2, which can be placed over an aperture 260 in the cover 116 to provide a fluid path between the fluid conductor 250 and the tissue interface 114.

[0069] Figure 3 is a schematic view of an example of the second layer 210, illustrating additional details that may be associated with some embodiments. As illustrated in the example of Figure 3, the fluid restrictions 220 may each consist essentially of one or more linear slots having a length of about 3 millimeters. Figure 3 additionally illustrates an example of a uniform distribution pattern of the fluid restrictions 220. In Figure 3, the fluid restrictions 220 are substantially coextensive with the second layer 210, and are distributed across the second layer 210 in a grid of parallel rows and columns, in which the slots are also mutually parallel to each other. In some embodiments, the rows may be spaced about 3 millimeters on center, and the fluid restrictions 220 within each of the rows may be spaced about 3 millimeters on center as illustrated in the example of Figure 3. The fluid restrictions 220 in adjacent rows may be aligned or offset. For example, adjacent rows may be offset, as illustrated in Figure 3, so that the fluid restrictions 220 are aligned in alternating rows and separated by about 6 millimeters. The spacing of the fluid restrictions 220 may vary in some embodiments to increase the density of the fluid restrictions 220 according to therapeutic requirements.

[0070] One or more of the components of the dressing 104 may additionally be treated with an antimicrobial agent in some embodiments. For example, the first layer 205 may be a foam, mesh, or non-woven coated with an antimicrobial agent. In some embodiments, the first layer may comprise antimicrobial elements, such as fibers coated with an antimicrobial agent. Additionally or alternatively, some embodiments of the second layer 210 may be a polymer coated or mixed with an antimicrobial agent. In other examples, the fluid conductor 250 may additionally or alternatively be treated with one or more antimicrobial agents. Suitable antimicrobial agents may include, for example, metallic silver,

PHMB, iodine or its complexes and mixes such as povidone iodine, copper metal compounds, chlorhexidine, or some combination of these materials.

[0071] Additionally or alternatively, one or more of the components may be coated with a mixture that may include citric acid and collagen, which can reduce bio-films and infections. For example, the first layer 205 may be a foam coated with such a mixture.

[0072] Individual components of the dressing 104 may be bonded or otherwise secured to one another with a solvent or non-solvent adhesive, or with thermal welding, for example, without adversely affecting fluid management.

[0073] The cover 116, the first layer 205, and the second layer 210, or various combinations may be assembled before application or *in situ*. For example, the cover 116 may be laminated to the first layer 205, and the second layer 210 may be laminated to the first layer 205 opposite the cover 116 in some embodiments. The second layer 210 may provide a smooth surface opposite the first layer 205. In some embodiments, one or more layers of the tissue interface 114 may coextensive. For example, the second layer 210 may be cut flush with the edge of the first layer 205, exposing the edge of the first layer 205, as illustrated in the embodiment of Figure 2. In other embodiments, the second layer 210 may overlap the edge of the first layer 205. In some embodiments, the dressing 104 may be provided as a single, composite dressing. For example, the second layer 210 may be coupled to the cover 116 to enclose the first layer 205, wherein the second layer 210 is configured to face a tissue site.

[0074] In use, the release liner 245 (if included) may be removed to expose the second layer 210, which may be placed within, over, on, or otherwise proximate to a tissue site, particularly a surface tissue site and adjacent epidermis. The second layer 210 may be interposed between the first layer 205 and the tissue site and adjacent epidermis, which can substantially reduce or eliminate adverse interaction with the first layer 205. For example, the second layer 210 may be placed over a surface wound (including edges of the wound) and undamaged epidermis to prevent direct contact with the first layer 205. Treatment of a surface wound or placement of the dressing 104 on a surface wound includes placing the dressing 104 immediately adjacent to the surface of the body or extending over at least a portion of the surface of the body. Treatment of a surface wound does not include placing the dressing 104 wholly within the body or wholly under the surface of the body, such as placing a dressing within an abdominal cavity. The cover 116 may be sealed to an attachment

surface, such as epidermis peripheral to a tissue site, around the first layer 205 and the second layer 210.

[0075] The geometry and dimensions of the tissue interface 114, the cover 116, or both may vary to suit a particular application or anatomy. For example, the geometry or dimensions of the tissue interface 114 and the cover 116 may be adapted to provide an effective and reliable seal against challenging anatomical surfaces, such as an elbow or heel, at and around a tissue site. Additionally or alternatively, the dimensions may be modified to increase the surface area for the second layer 210 to enhance the movement and proliferation of epithelial cells at a tissue site and reduce the likelihood of granulation tissue in-growth.

[0076] Thus, the dressing 104 in the example of Figure 2 can provide a sealed therapeutic environment proximate to a tissue site, substantially isolated from the external environment, and the negative-pressure source 102 can reduce the pressure in the sealed therapeutic environment. Negative pressure in the sealed environment may compress the first layer 205 into the second layer 210, which can deform the surface of the second layer 210 to provide an uneven, coarse, or jagged profile that can induce macrostrain and micro-strain in the tissue site in some embodiments. Negative pressure applied through the tissue interface 114 can also create a negative pressure differential across the fluid restrictions 220 in the second layer 210, which can open the fluid restrictions 220 to allow exudate and other liquid movement through the fluid restrictions 220 into the first layer 205 and the container 106. For example, in some embodiments in which the fluid restrictions 220 may comprise perforations through the second layer 210, a pressure gradient across the perforations can strain the adjacent material of the second layer 210 and increase the dimensions of the perforations to allow liquid movement through them, similar to the operation of a duckbill valve.

[0077] In some embodiments, the first layer 205 may be hydrophobic to minimize retention or storage of liquid in the dressing 104. In other embodiments, the first layer 205 may be hydrophilic. In an example in which the first layer 205 may be hydrophilic, the first layer 205 may also wick fluid away from a tissue site, while continuing to distribute negative pressure to the tissue site. The wicking properties of the first layer 205 may draw fluid away from a tissue site by capillary flow or other wicking mechanisms, for example. An example of a hydrophilic first layer 205 is a polyvinyl alcohol, open-cell foam such as V.A.C. WHITEFOAM™ dressing available from KCI 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.

[0078] If the negative-pressure source 102 is removed or turned-off, the pressure differential across the fluid restrictions 220 can dissipate, allowing the fluid restrictions 220 to return to an unstrained or resting state and prevent or reduce the return rate of exudate or other liquid moving to the tissue site through the second layer 210.

[0079] In some applications, a filler may also be disposed between a tissue site and the second layer 210. For example, if the tissue site is a surface wound, a wound filler may be applied interior to the periwound, and the second layer 210 may be disposed over the periwound and the wound filler. In some embodiments, the filler may be a manifold, such as an open-cell foam. The filler may comprise or consist essentially of the same material as the first layer 205 in some embodiments.

[0080] Additionally or alternatively, the tissue interface 114 may be formed into strips suitable for use as bridges or to fill tunnel wounds, for example. Strips having a width of about 5 millimeters to 30 millimeters may be suitable for some embodiments.

[0081] Additionally or alternatively, the second layer 210 may comprise reinforcing fibers to increase its tensile strength, which may be advantageous for use in tunnel wounds.

[0082] Additionally or alternatively, instillation solution or other fluid may be distributed to the dressing 104, which can increase the pressure in the tissue interface 114. The increased pressure in the tissue interface 114 can create a positive pressure differential across the fluid restrictions 220 in the second layer 210, which can open or expand the fluid restrictions 220 from their resting state to allow the instillation solution or other fluid to be distributed to the tissue site.

[0083] Figure 4 is an assembly view of another example of the dressing 104 of Figure 1, illustrating additional details that may be associated with some embodiments in which the tissue interface 114 may comprise additional layers. In the example of Figure 4, the tissue interface 114 comprises a third layer 405 in addition to the first layer 205 and the second layer 210. In some embodiments, the third layer 405 may be adjacent to the second layer 210 opposite the first layer 205. The third layer 405 may also be bonded to the second layer 210 in some embodiments.

[0084] The third layer 405 may comprise or consist essentially of a sealing layer formed from a soft, pliable material suitable for providing a fluid seal with a tissue site, and may have a substantially flat surface. For example, the third layer 405 may comprise,

without limitation, 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, polyurethane, polyolefin, or hydrogenated styrenic copolymers. In some embodiments, the third layer 405 may have a thickness between about 200 microns (μm) and about 1000 microns (μm). In some embodiments, the third layer 405 may have a hardness between about 5 Shore OO and about 80 Shore OO. Further, the third layer 405 may be comprised of hydrophobic or hydrophilic materials.

[0085] In some embodiments, the third layer 405 may be a hydrophobic-coated material. For example, the third layer 405 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.

[0086] The third layer 405 may have a periphery 410 surrounding or around an interior portion 415, and apertures 420 disposed through the periphery 410 and the interior portion 415. The interior portion 230 may correspond to a surface area of the first layer 205 in some examples. The third layer 405 may also have corners 425 and edges 430. The corners 425 and the edges 430 may be part of the periphery 410. The third layer 405 may have an interior border 435 around the interior portion 415, disposed between the interior portion 415 and the periphery 410. The interior border 435 may be substantially free of the apertures 420, as illustrated in the example of Figure 3. In some examples, as illustrated in Figure 3, the interior portion 415 may be symmetrical and centrally disposed in the third layer 405.

[0087] The apertures 420 may be formed by cutting or by application of local RF or ultrasonic energy, for example, or by other suitable techniques for forming an opening. The apertures 420 may have a uniform distribution pattern, or may be randomly distributed on the third layer 405. The apertures 420 in the third layer 405 may have many shapes, including circles, squares, stars, ovals, polygons, slits, complex curves, rectilinear shapes, triangles, for example, or may have some combination of such shapes.

[0088] Each of the apertures 420 may have uniform or similar geometric properties. For example, in some embodiments, each of the apertures 420 may be circular apertures, having substantially the same diameter. In some embodiments, the diameter of each of the apertures 420 may be between about 1 millimeter to about 50 millimeters. In other

embodiments, the diameter of each of the apertures 420 may be between about 1 millimeter to about 20 millimeters.

[0089] In other embodiments, geometric properties of the apertures 420 may vary. For example, the diameter of the apertures 420 may vary depending on the position of the apertures 420 in the third layer 405, as illustrated in Figure 4. In some embodiments, the diameter of the apertures 420 in the periphery 410 of the third layer 405 may be larger than the diameter of the apertures 420 in the interior portion 415 of the third layer 405. For example, in some embodiments, the apertures 420 disposed in the periphery 410 may have a diameter between about 9.8 millimeters to about 10.2 millimeters. In some embodiments, the apertures 420 disposed in the corners 425 may have a diameter between about 7.75 millimeters to about 8.75 millimeters. In some embodiments, the apertures 420 disposed in the interior portion 415 may have a diameter between about 1.8 millimeters to about 2.2 millimeters.

[0090] At least one of the apertures 420 in the periphery 410 of the third layer 405 may be positioned at the edges 430 of the periphery 410, and may have an interior cut open or exposed at the edges 430 that is in fluid communication in a lateral direction with the edges 430. The lateral direction may refer to a direction toward the edges 430 and in the same plane as the third layer 405. As shown in the example of Figure 4, the apertures 420 in the periphery 410 may be positioned proximate to or at the edges 430 and in fluid communication in a lateral direction with the edges 430. The apertures 420 positioned proximate to or at the edges 430 may be spaced substantially equidistant around the periphery 410 as shown in the example of Figure 3. Alternatively, the spacing of the apertures 420 proximate to or at the edges 430 may be irregular.

[0091] As illustrated in the example of Figure 4, in some embodiments, the release liner 245 may be attached to or positioned adjacent to the third layer 405 to protect the adhesive 240 prior to use. In some embodiments, the release liner 245 may have a surface texture that may be imprinted on an adjacent layer, such as the third layer 405. Further, a release agent may be disposed on a side of the release liner 245 that is configured to contact the third layer 405.

[0092] Figure 5 is a schematic view of an example configuration of the apertures 420, illustrating additional details that may be associated with some embodiments of the third layer 405. In some embodiments, the apertures 420 illustrated in Figure 5 may be associated only with the interior portion 415. In the example of Figure 5, the apertures 420 are generally

circular and have a diameter of about 2 millimeters. Figure 5 also illustrates an example of a uniform distribution pattern of the apertures 420 in the interior portion 415. In Figure 5, the apertures 420 are distributed across the interior portion 415 in a grid of parallel rows and columns. Within each row and column, the apertures 420 may be equidistant from each other, as illustrated in the example of Figure 5. Figure 5 illustrates one example configuration that may be particularly suitable for many applications, in which the apertures 420 are spaced about 6 millimeters apart along each row and column, with a 3 millimeter offset.

[0093] Figure 6 is a schematic view of the example third layer 405 of Figure 5 overlaid on the second layer 210 of Figure 3, illustrating additional details that may be associated with some example embodiments of the tissue interface 114. For example, as illustrated in Figure 6, the fluid restrictions 220 may be aligned, overlapping, in registration with, or otherwise fluidly coupled to the apertures 420 in some embodiments. In some embodiments, one or more of the fluid restrictions 220 may be registered with the apertures 420 only in the interior portion 415, or only partially registered with the apertures 420. The fluid restrictions 220 in the example of Figure 6 are generally configured so that each of the fluid restrictions 220 is registered with only one of the apertures 420. In other examples, one or more of the fluid restrictions 220 may be registered with more than one of the apertures 420. For example, any one or more of the fluid restrictions 220 may be a perforation or a fenestration that extends across two or more of the apertures 420. Additionally or alternatively, one or more of the fluid restrictions 220 may not be registered with any of the apertures 420.

[0094] As illustrated in the example of Figure 6, the apertures 420 may be sized to expose a portion of the second layer 210, the fluid restrictions 220, or both through the third layer 405. In some embodiments, one or more of the apertures 235 may be sized to expose more than one of the fluid restrictions 220. For example, some or all of the apertures 235 may be sized to expose two or three of the fluid restrictions 220. In some examples, the length of each of the fluid restrictions 220 may be substantially equal to the diameter of each of the apertures 420. More generally, the average dimensions of the fluid restrictions 220 are substantially similar to the average dimensions of the apertures 420. For example, the apertures 420 may be elliptical in some embodiments, and the length of each of the fluid restrictions 220 may be substantially equal to the major axis or the minor axis. In some embodiments, though, the dimensions of the fluid restrictions 220 may exceed the dimensions

of the apertures 420, and the size of the apertures 420 may limit the effective size of the fluid restrictions 220 exposed to the lower surface of the dressing 104.

[0095] Individual components of the dressing 104 in the example of Figure 4 may be bonded or otherwise secured to one another with a solvent or non-solvent adhesive, or with thermal welding, for example, without adversely affecting fluid management. Further, the second layer 210 or the first layer 205 may be coupled to the border 435 of the third layer 405 in any suitable manner, such as with a weld or an adhesive, for example.

[0096] The cover 116, the first layer 205, the second layer 210, the third layer 405, or various combinations may be assembled before application or *in situ*. For example, the cover 116 may be laminated to the first layer 205, and the second layer 210 may be laminated to the first layer 205 opposite the cover 116 in some embodiments. The third layer 405 may also be coupled to the second layer 210 opposite the first layer 205 in some embodiments. In some embodiments, one or more layers of the tissue interface 114 may coextensive. For example, the second layer 210, the third layer 405, or both may be cut flush with the edge of the first layer 205, exposing the edge of the first layer 205, as illustrated in the embodiment of Figure 4. In other embodiments, the second layer 210, the third layer 405, or both may overlap the edge of the first layer 205. In some embodiments, the dressing 104 may be provided as a single, composite dressing. For example, the third layer 405 may be coupled to the cover 116 to enclose the first layer 205 and the second layer 210, wherein the third layer 405 is configured to face a tissue site. Additionally or alternatively, the second layer 210, the third layer 405, or both may be disposed on both sides of the first layer 205 and bonded together to enclose the first layer 205.

[0097] In use, the release liner 245 (if included) may be removed to expose the third layer 405 of the example of Figure 4, which may be placed within, over, on, or otherwise proximate to a tissue site, particularly a surface tissue site and adjacent epidermis. The third layer 405 and the second layer 210 may be interposed between the first layer 205 and the tissue site, which can substantially reduce or eliminate adverse interaction with the first layer 205. For example, the third layer 405 may be placed over a surface wound (including edges of the wound) and undamaged epidermis to prevent direct contact with the first layer 205. In some applications, the interior portion 415 of the third layer 405 may be positioned adjacent to, proximate to, or covering a tissue site. In some applications, at least some portion of the second layer 210, the fluid restrictions 220, or both may be exposed to a tissue site through the third layer 405. The periphery 410 of the third layer 405 may be positioned adjacent to or

proximate to tissue around or surrounding the tissue site. The third layer 405 may be sufficiently tacky to hold the dressing 104 in position, while also allowing the dressing 104 to be removed or re-positioned without trauma to the tissue site.

[0098] Removing the release liner 245 in the example of Figure 4 can also expose the adhesive 240 and the cover 116 may be attached to an attachment surface, such as epidermis peripheral to a tissue site, around the first layer 205 and the second layer 210. For example, the adhesive 240 may be in fluid communication with an attachment surface through the apertures 420 in at least the periphery 410 of the third layer 405. The adhesive 240 may also be in fluid communication with the edges 430 through the apertures 420 exposed at the edges 430.

[0099] Once the dressing 104 is in the desired position, the adhesive 240 may be pressed through the apertures 420 to bond the dressing 104 to the attachment surface. The apertures 420 at the edges 430 may permit the adhesive 240 to flow around the edges 430 for enhancing the adhesion of the edges 430 to an attachment surface.

[00100] In some embodiments, apertures or holes in the third layer 405 may be sized to control the amount of the adhesive 240 in fluid communication with the apertures 420. For a given geometry of the corners 425, the relative sizes of the apertures 420 may be configured to maximize the surface area of the adhesive 240 exposed and in fluid communication through the apertures 420 at the corners 425. For example, as shown in Figure 3, the edges 430 may intersect at substantially a right angle, or about 90 degrees, to define the corners 425. In some embodiments, the corners 425 may have a radius of about 10 millimeters. Further, in some embodiments, three of the apertures 420 having a diameter between about 7.75 millimeters to about 8.75 millimeters may be positioned in a triangular configuration at the corners 425 to maximize the exposed surface area for the adhesive 240. In other embodiments, the size and number of the apertures 420 in the corners 425 may be adjusted as necessary, depending on the chosen geometry of the corners 425, to maximize the exposed surface area of the adhesive 240. Further, the apertures 420 at the corners 425 may be fully housed within the third layer 405, substantially precluding fluid communication in a lateral direction exterior to the corners 425. The apertures 420 at the corners 425 being fully housed within the third layer 405 may substantially preclude fluid communication of the adhesive 240 exterior to the corners 425, and may provide improved handling of the dressing 104 during deployment at a tissue site. Further, the exterior of the corners 425 being

substantially free of the adhesive 240 may increase the flexibility of the corners 425 to enhance comfort.

[00101] In some embodiments, the bond strength of the adhesive 240 may vary in different locations of the dressing 104. For example, the adhesive 240 may have a lower bond strength in locations adjacent to the third layer 405 where the apertures 420 are relatively larger, and may have a higher bond strength where the apertures 420 are smaller. Adhesive 240 with lower bond strength in combination with larger apertures 420 may provide a bond comparable to adhesive 240 with higher bond strength in locations having smaller apertures 420.

[00102] The geometry and dimensions of the tissue interface 114, the cover 116, or both may vary to suit a particular application or anatomy. For example, the geometry or dimensions of the tissue interface 114 and the cover 116 may be adapted to provide an effective and reliable seal against challenging anatomical surfaces, such as an elbow or heel, at and around a tissue site. Additionally or alternatively, the dimensions may be modified to increase the surface area for the third layer 405 to enhance the movement and proliferation of epithelial cells at a tissue site and reduce the likelihood of granulation tissue in-growth.

[00103] Further, the dressing 104 may permit re-application or re-positioning to reduce or eliminate leaks, which can be caused by creases and other discontinuities in the dressing 104 or a tissue site. The ability to rectify leaks may increase the reliability of the therapy and reduce power consumption in some embodiments.

[00104] Thus, the dressing 104 in the example of Figure 4 can provide a sealed therapeutic environment proximate to a tissue site, substantially isolated from the external environment, and the negative-pressure source 102 can reduce the pressure in the sealed therapeutic environment. The third layer 405 may provide an effective and reliable seal against challenging anatomical surfaces, such as an elbow or heel, at and around a tissue site. Further, the dressing 104 may permit re-application or re-positioning, to correct air leaks caused by creases and other discontinuities in the dressing 104, for example. The ability to rectify leaks may increase the efficacy of the therapy and reduce power consumption in some embodiments.

[00105] If not already configured, the dressing interface 255 may be disposed over the aperture 260 and attached to the cover 116. The fluid conductor 250 may be fluidly coupled to the dressing interface 255 and to the negative-pressure source 102.

[00106] Negative pressure applied through the tissue interface 114 can create a negative pressure differential across the fluid restrictions 220 in the second layer 210, which can open or expand the fluid restrictions 220. For example, in some embodiments in which the fluid restrictions 220 may comprise substantially closed fenestrations through the second layer 210, a pressure gradient across the fenestrations can strain the adjacent material of the second layer 210 and increase the dimensions of the fenestrations to allow liquid movement through them, similar to the operation of a duckbill valve. Opening the fluid restrictions 220 can allow exudate and other liquid movement through the fluid restrictions 220 into the first layer 205 and the container 106. Changes in pressure can also cause the first layer 205 to expand and contract, and the interior border 435 may protect the epidermis from irritation. The second layer 210 and the third layer 405 can also substantially reduce or prevent exposure of tissue to the first layer 205, which can inhibit growth of tissue into the first layer 205.

[00107] If the negative-pressure source 102 is removed or turned off, the pressure differential across the fluid restrictions 220 can dissipate, allowing the fluid restrictions 220 to close and prevent exudate or other liquid from returning to the tissue site through the second layer 210.

[00108] In some applications, a filler may also be disposed between a tissue site and the third layer 405. For example, if the tissue site is a surface wound, a wound filler may be applied interior to the periwound, and the third layer 405 may be disposed over the periwound and the wound filler. In some embodiments, the filler may be a manifold, such as an open-cell foam. The filler may comprise or consist essentially of the same material as the first layer 205 in some embodiments.

[00109] Additionally or alternatively, instillation solution or other fluid may be distributed to the dressing 104, which can increase the pressure in the tissue interface 114. The increased pressure in the tissue interface 114 can create a positive pressure differential across the fluid restrictions 220 in the second layer 210, which can open the fluid restrictions 220 to allow the instillation solution or other fluid to be distributed to the tissue site.

[00110] Figure 7 is a top view of another example the third layer 405, illustrating additional details that may be associated with some embodiments. As shown in the example of Figure 7, the third layer 405 may have one or more elastomeric valves 705 instead of or in addition to the apertures 420 in the interior portion 415. The valves 705 may be included in the third layer 405 in addition to or instead of the second layer 210. In some

embodiments in which the third layer 405 includes one or more of the valves 705, the second layer 210 may be omitted. For example, in some embodiments, the tissue interface 114 may consist essentially of the first layer 205 and the third layer 405 of Figure 7 with the valves 705 disposed in the interior portion 415.

[00111] Figure 8 and Figure 9 illustrate other example configurations of the valves 705, in which the valves 705 each generally comprise a combination of intersecting slits or cross-slits.

[00112] Figure 10 is an assembly view of another example of the tissue interface 114 of Figure 1. In the example of Figure 10, the second layer 210 is disposed adjacent to two sides of the first layer 205. In some embodiments, for example, the second layer 210 may be laminated or otherwise mechanically bonded to two sides of the first layer 205. Additionally or alternatively, the third layer 405 may be disposed adjacent to one or more sides of the first layer 205, or may be disposed adjacent to the second layer 210 as shown in the example of Figure 10. In some embodiments, the third layer 405 may form a sleeve or envelope around the first layer 205, the second layer 210, or both.

[00113] Figure 11 is a perspective view of another example configuration of the first layer 205 and the second layer 210. In the example of Figure 11, the second layer 210 may form a sleeve around the first layer 205. For example, the second layer 210 may be folded or rolled around the first layer 205, and edges of the second layer 210 may be attached to each other. In other examples, the edges may be attached to form a sleeve before inserting the first layer 205, or the edges may be attached to the first layer 205. The second layer 210 may leave one or more edges of the first layer 205 exposed, as illustrated in the example of Figure 11. The example configuration of Figure 11 may be used in combination with or instead of other configurations of the first layer 205 and the second layer 210 described above.

[00114] Figure 12 is a partial cutaway view of another example configuration of the first layer and the second layer 210. In the example of Figure 12, the second layer 210 may form an envelope around the first layer 205. For example, the second layer 210 may be disposed on two sides of the first layer 205, and the edges may be mechanically coupled to each other around the first layer 205 to form an envelope. The example configuration of Figure 12 may be used in combination with or instead of other configurations of the first layer 205 and the second layer 210 described above.

[00115] The systems, apparatuses, and methods described herein may provide significant advantages over prior dressings. For example, some dressings for negative-pressure therapy can require time and skill to be properly sized and applied to achieve a good fit and seal. In contrast, some embodiments of the dressing 104 provide a negative-pressure dressing that is simple to apply, reducing the time to apply and remove. In some embodiments, for example, the dressing 104 may be a fully-integrated negative-pressure therapy dressing that can be applied to a tissue site (including on the periwound) in one step, without being cut to size, while still providing or improving many benefits of other negative-pressure therapy dressings that require sizing. Such benefits may include good manifolding, beneficial granulation, protection of the peripheral tissue from maceration, protection of the tissue site from shedding materials, and a low-trauma and high-seal bond. These characteristics may be particularly advantageous for surface wounds having moderate depth and medium-to-high levels of exudate. Some embodiments of the dressing 104 may remain on the tissue site for at least 5 days, and some embodiments may remain for at least 7 days. Antimicrobial agents in the dressing 104 may extend the usable life of the dressing 104 by reducing or eliminating infection risks that may be associated with extended use, particularly use with infected or highly exuding wounds.

EXAMPLES

[00116] Some of the advantages associated with the systems, apparatuses, and methods described herein may be further demonstrated by the following non-limiting example.

[00117] Example 1 – Evaluation of Dressing in a Swine Model of Full Thickness Excisional Wounds

Objective

[00118] The primary objective of this study was to evaluate an embodiment of a dressing having features described above (designated as “GM” for purposes of the study), in conjunction with V.A.C.® Therapy and V.A.C. VERAFLOR™ Therapy as compared to traditional V.A.C.® Therapy with GRANUFOAM™ dressing and to other Advanced Wound Care dressings without V.A.C.® Therapy. Wounds were assessed for granulation tissue formation, presence of maceration in periwound skin and ease of dressing removal as determined by:

- i. Histological assessment for granulation tissue thickness
- ii. Peel strength testing

- iii. Visual assessment of bleeding
- iv. Visual assessment of dressing particles left in wound bed after removal of dressing
- v. Histological assessment for dressing particles, necrosis, bleeding, edema and inflammation
- vi. Maceration (tissue water content) of intact skin
- vii. Histological assessment of intact skin for bacteria, edema and inflammation

Test and Control Articles

Test Article 1 (TA)

Description	GM dressing
Size	10cm x 8cm foam with 12.5cm x 11cm border
Storage	Test article stored between 15°C and 30°C (59°F and 86°F).

Control Article 1 (CA1)

Description	V.A.C.® GRANUFOAM™ Dressing
Size	~7.5cm x 3cm (cut to fit from larger piece)
Storage	Control article stored between 15°C and 30°C (59°F and 86°F).

Control Article 2 (CA2)

Description	TIELLE™ non-adhesive advanced wound dressing (AWD)
Size	10cm x 10cm
Storage	Control article stored between 15°C and 30°C (59°F and 86°F).

Control Article 3 (CA3)

Description	V.A.C. VERAFLOR™ Dressing
Size	~ 7.5cm x 3cm (cut to fit from larger piece)
Storage	Control article stored between 15°C and 30°C (59°F and 86°F).

Animal Model

[00119] This study was conducted using the animal model outlined below:

Species	Sus scrofa scrofa (Porcine)
Breed	1/2 Duroc, 1/4 Landrace cross, 1/4 Yorkshire
Source	Oak Hill Genetics, Ewing, IL
Age at Procedure	Appropriate to weight
Weight at Procedure	50 - 70 kg or alternate weight as approved by the Study Director
Gender	Female (nulliparous and non-pregnant)
Number of Animals	8 + 0 spare

Study Design

[00120] Table 1. Study Design

Group	Number of Animals	Maximum Number of Excisional Wounds Created on Day 0	Maximum NPWT Sites per Animal	Maximum AWD (Sites per Animal)	Dressing Changes	Peel Testing, Visual Assessment, TEWL	Scheduled Time of Euthanasia
1	1	n=10/animal	n=8	n=2	None	Day 4	Day 4
2	3	n=10/animal	n=8	n=2	None	Day 4	Day 4
3	4	n=10/animal	n=10	n=02	Day 4	Day 4 and Day 7	Day 7

TEWL = transepidermal water loss analysis using Delfin moisture meter; AWD = Advanced Wound Dressing

[00121] Table 2. Description of Treatment Regimens and Dressings

Therapy/Treatment Number	Treatment Abbreviation	Test Material	Therapy
1	TANPT ^a	TA	Continuous V.A.C.® Therapy
2	TANPTI ^a	TA	V.A.C. VERAFLOR TM with saline
3	NPT	CA1	Continuous V.A.C.® Therapy
4	AWD	CA2	None
5	NPTI	CA3	V.A.C. VERAFLOR TM with saline

^a With conductive wires placed on top on intact skin under dressing as appropriate

Surgical Procedures

Excisional Wound Creation – Day 0

[00122] The initial pilot animal (Group 1) underwent all wound creation and therapy prior to scheduling procedures on the additional Group 2 and 3 animals. Up to Ten (10) full thickness skin excisional wounds (~3 x 7.5 cm) were created on each animal (up to 5 wounds on each side of the spine) with the aid of a sterile template. There was spacing between each of the wounds (approximately 6 cm or more from wound edge to wound edge between adjacent wounds, and sufficient spacing between all wounds to provide enough space to properly place the dressings and the drape. If the length of the back of the animal did not provide enough space for 10 wounds and dressings (determined on Day 0) then 8 wounds (4 on each side of spine) was created. A scalpel blade was used to surgically create the wound down to the subcutaneous fascial layer (just over the muscle) but without disrupting it. If disruption of the subcutaneous fascial layer occurred, it was documented in the study records. Care was taken during wound creation so as not to undermine the perimeter of the wound. The wounds were prepared in two paraspinal columns with efforts made to keep the columns between the crest of the shoulders and the coccygeal tuberosity. Direct pressure with sterile gauze was utilized to obtain hemostasis. In the event of excessive bleeding that did not subside with direct pressure, a hemostat was used to clamp the source of bleeding. Wound sites were kept moist with sterile 0.9% saline-soaked gauze during the creation of other wounds. Wounds were photographed.

Application of Dressings and Negative Pressure Therapy

[00123] Following the creation of wounds (Day 0) all wounds received Test or Control Article. On Day 4 (Group 3 only), those wounds undergoing dressing removal received Test or Control Article.

[00124] On the designated dressing change day (after peel testing, TEWL, visual observations and photographs), the periwound area was wiped clean with sterile 0.9% saline-soaked gauze and allowed to dry. Dressings were applied to the individual wound sites per a randomization scheme.

[00125] An adhesive such as benzoin was placed on the skin surrounding the very perimeter of the test article edges, regardless of the type of dressing for a particular wound, so that the periwound area was framed with adhesive leaving a ~1cm perimeter of periwound free of benzoin. This means that the immediate periwound skin cannot have benzoin adhesive applied as this may affect the EpiD readings. The adhesive was placed on the skin in any area that V.A.C.® Drape was applied. Alternatively (or in addition to), Hollister (a medical grade silicone adhesive) was applied as an extra adhesive to help maintain a seal.

[00126] For the test article wound pair (test article with V.A.C.® Therapy), and/or the test article with V.A.C. VERAFLOR™ Therapy (test article using V.A.C. VERAFLOR™ Therapy with saline) wounds, a pair of electrodes (e.g. aluminum sheet or wire) was applied so it rested in the peri-wound area (under test article but on top of periwound skin).

[00127] As applicable, the skin underneath the strips of the foam bridge were covered with V.A.C.® Drape to protect it. Each bridged wound group was covered with the V.A.C.® Drape included in the dressing kit, one hole will be made in the drape, and a SENSAT.R.A.C.™ Pad or a V.A.C. VERAT.R.A.C.™ Pad (as applicable) was attached directly above the hole as per instructions for use (IFU). Each of the pads was framed with V.A.C.® Drape along each side to keep it in place and to make sure there was a seal.

[00128] A V.A.C.ULTA™ unit was present in the surgical suite on the day of wound creation and was appropriately connected to each pad to verify that each wound group had been sealed properly following the application.

[00129] To check the seal around the wounds, negative-pressure wound therapy (NPWT) began at a continuous vacuum pressure of -125 mmHg using the SEAL CHECK™ function on the V.A.C.ULTA™ Unit. Upon verification of a proper seal, the V.A.C.ULTA™

unit was turned off and this procedure was repeated as applicable. Following verification of all seals, additional layers of V.A.C.® Drape was placed around the edges to reinforce the seals and prevent leaks.

[00130] For wounds receiving V.A.C. VERAFLOR™ Therapy the Fill Assist feature was used to determine the volume of fluid (i.e. saline) required to saturate the dressings in the paired wounds. These determinations were made for wound pairs at each dressing change, as appropriate. V.A.C. VERAFLOR™ Therapy NPWT was begun at a continuous vacuum pressure of -125 mmHg using the SEAL CHECK™ function on the V.A.C.ULTA™ Unit. Upon verification of a proper seal, the V.A.C.ULTA™ unit was turned off and this procedure was repeated as applicable. Following verification of all seals, additional layers of V.A.C.® Drape were placed around the edges to reinforce the seals and prevent leaks. The soak/dwell time per cycle was 10 minutes, NPWT time per cycle was 3.5 hours with a target pressure of -125 mmHg.

[00131] The entire V.A.C.® Drape-covered area was draped with a tear-resistant mesh (e.g. organza material) secured with V.A.C.® Drape, Elastikon® or equivalent to prevent dislodgement of the dressings.

Interim Dressing Change – Day 4 Group 3 Only

[00132] Resistance readings from under the dressings were performed. Peel force testing for wounds were performed on one wound from each treatment pair. The dressings were removed by hand for the other half of each wound pair, unless dressings were intended to stay in place (i.e. TANPT and TANPTI (n=2 animals)). Wound assessments were performed (as applicable) and photographs taken.

Peel Testing and Observations

[00133] Peel force testing was performed on one wound from each treatment pair (same wounds as dressing change, if applicable). For wounds where the dressing had been removed, TEWL was performed, wound assessments were performed and photographs taken.

[00134] For Groups 1 & 2, (Day 4), peel force testing, TEWL and assessments were performed on 5 wounds. The remaining 5 wounds were collected with dressings in situ for histopathology processing and evaluation.

[00135] For Group 3 (Day 7), peel force testing, TEWL and assessments were performed on 5 wounds. The remaining 5 wounds were collected with dressings in situ for histopathology processing and evaluation.

[00136] Peel force testing was performed on a tilting operating table. The peel force test was performed using a device that peels back the test material edge while measuring the force that is required to peel the dressing from the wound at an angle of $\sim 180^\circ$ relative to the peel tester. A digital protractor was used to confirm the angle. The peel strength values indicate the ease with which the test materials can be removed from the wound bed. Removal of the test materials was performed using a 20N Shimpo Digital Force Gauge that was mounted onto a Shimpo Motorized Test Stand and controlled via a computer equipped with LabView.

[00137] The drape over the control articles for peel testing was gently circumscribed with a scalpel, taking care to not disrupt the tissue ingrowth into the sides of the dressing. On treatments with the test article for peel testing, a scalpel was used to remove the excess dressing that was not in contact with the wound. This was done by cutting the dressing along the sides, bottom and top where the margins of the wound are visible after negative pressure therapy. The medial end of the dressing or dressing tab was attached to the force gauge with the clip (no circumscribing of the dressing will be performed). The dressing was then pulled from the wound (medial to lateral) at a constant rate from a medial to lateral direction. After the peel force measurements were taken, assessments were performed. Continuous peel force readings were recorded through LabView via the Force Gauge and saved for each wound. Following peel testing, the dressings were saved for analysis of the tissue that remains within the dressing.

[00138] Fig. 13 demonstrates the results of maximum peel force measurements (N) on day 7 following dressing application and removal of test articles (designated as “TANPT” and TANPTI) and control dressings. As can be seen, the test article with and without V.A.C. VERAFLORTM Therapy required significantly less peel force.

[00139] After peel force testing and TEWL measurements, two biopsy punches (5mm, or not to exceed 8 mm each) were collected from the center of each wound as applicable.

Transepidermal Water Loss

[00140] Determination of the level of moisture at the dressing-skin (intact) interface was performed using a Moisture Meter the EpiD Compact from Delfin Technologies (Kuopio, Finland). This measurement was done immediately after wound creation on Day 0, at the dressing change day (as applicable), and at termination prior to euthanasia. To measure the dielectric constant of the skin, the EpiD Compact instrument was

turned used. On the day of wound creation (Day 0), four consecutive measurements of moisture was collected from intact skin on each animal approximating midway between the wound and edge of the wound pad of where the test article and the advanced wound dressings were. On dressing change day and at termination (as applicable), four consecutive measurements of moisture were collected. These measurements were repeated on each of the available wound sites for each animal. All of the measurements/data was recorded.

Wound Assessments

Gross Observations

[00141] Wound observations were performed and documented at the dressing change and/or at the termination procedure as follows:

- Wound bleeding – None, Minor, Moderate, or Significant.
- Gross observations – Dry (dull/not shiny), Moist (glistening in appearance), Wet (presence of fluid), Eschar (tissue appearing dark and leathery), Slough (removable yellowish layer) and its location(s) in the wound site.
- Discharge – None, Serous (thin, watery, clear) Serosanguineous (thin, pale red to pink), Sanguineous (thin, bright red), Purulent (opaque tan to yellow, thin or thick).

Dressing and Tissue Retention

[00142] Dressing retention (small particles and large pieces) was assessed following dressing removal or peel testing. After removal of the dressings from the wound, dressing retention in the wound was visually assessed and documented. All removed dressings was visually assessed for tissue retention and digitally photographed.

[00143] Figure 14 demonstrates that there was a significant reduction in tissue ingrowth with TANPT and TANPTI.

Histopathology

[00144] If wound sites were in 70% ethanol they were immediately processed and if received in NBF wounds were transferred to 70% ethanol for a period of time before further processing per Histopathology Test Site standard procedures. The wound site + dressings (if intact), were embedded in oversized paraffin blocks, entire *en bloc* site was cross sectioned once at ~5 µm thickness and resulting slides stained with Hematoxylin and Eosin (H&E). Gross images were taken of the cut surface of the specimens prior to processing and embedding in paraffin. In order to accommodate the entire tissue section with border of non-affected skin on all sides, oversized slides were used.

[00145] The histopathological response was scored semi-quantitatively by a board-certified veterinary pathologist, on a scale of 1-5 where 1=minimal, 2=mild, 3=moderate, 4= marked and 5=severe, except where otherwise specified. Microscopic evaluation of all stained sections for morphological changes for the wound including, but not limited to, granulation tissue thickness and character, amount of granulation tissue embedded in dressing (if possible), tissue inflammation, edema, vascularity (if possible), presence of bacteria, necrosis and other relevant factors as determined by the pathologist. The peri-wound area was evaluated for characteristics consistent with maceration as determined by the pathologist.

2D photographs of individual wound sites

[00146] Two dimensional (2-D) photographs of the individual wound sites were taken at the following time points:

- Day 0 (freshly created wounds) – all wounds
- Day 4 (day of dressing change or termination as applicable) after dressing removal and before application of new dressings – all wounds
 - 2-D photographs of the freshly removed dressing next to the wound were taken.
- Day 7 after dressing removal and before euthanasia.
 - 2-D photographs of the freshly removed dressing next to the wound were taken.

Histopathological assessment of individual wound sites

[00147] The optical micrographs pictures in Fig. 15 demonstrate that TANPT had significantly more granulation than NPT and NPTI.

[00148] Further Fig. 16 is a graphical representation comparing the Day 7 granulation tissue thickness between the test and control treatments. TANPT and TANPTI showed significantly higher granulation tissue thickness.

Study Conclusions

[00149] The data demonstrate that the test article had surprisingly positive results, with improvement when combined with V.A.C. VERAFLORTM Therapy. The test article with V.A.C. VERAFLORTM Therapy performed superiorly by showing an increase in granulation tissue thickness, a reduction in tissue ingrowth, percent epithelialization and average vascularization score.

[00150] Additionally, by Day 7, all treatments with the test article showed significantly greater granulation tissue than NPT and NPTI. The percent increase in granulation depth using the test article (measured after a 7 day treatment period) was at least 75% for NPT, and 200% for NPTI. No evidence of adverse events or safety concerns were found. Periwound tissue moisture decreased over time (all treatment groups) reducing risk of maceration.

[00151] All treatments with the test article also showed surprising reductions in tissue in-growth, as evidenced by the significant reductions in peel force. After 7 days of either continuous V.A.C.® Therapy or V.A.C. VERAFLOR™ Therapy with no dressing change, a peel force of less than 2N was needed to remove the test article. Specifically, a peel force of 1.8N was used to remove the TANPTI test article, and a peel force of 1.5N was used to remove the TANPT test article. Compared to CA1 with V.A.C.® Therapy, the peel force was reduced by 87% and 89%, respectively.

[00152] 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 that fall within the scope of the appended claims. Moreover, descriptions of various alternatives using terms such as “or” do not require mutual exclusivity unless clearly required by the context, and the indefinite articles “a” or “an” do not limit the subject to a single instance unless clearly required by the context.

[00153] Features, elements, and aspects described in the context of some embodiments may also be omitted, 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. For example, one or more of the features of some layers may be combined with features of other layers to provide an equivalent function. Alternatively or additionally, one or more of the fluid restrictions 220 may have shapes similar to shapes described as exemplary for the valves 705. In other examples, the second layer 210, the third layer 405, or some combination of the second layer 210 and the third layer 405 may be coupled to both sides of the first layer 205.

[00154] Components may be also be combined or eliminated in various configurations for purposes of sale, manufacture, assembly, or use. For example, in some configurations the dressing 104, the container 106, or both may be eliminated or separated from other components for manufacture or sale. In other example configurations,

components of the dressing 104 may also be manufactured, configured, assembled, or sold independently or as a kit.

[00155] 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 in the context of some embodiments may also be omitted, 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

1. A dressing for treating a tissue site with negative pressure, the dressing comprising:
 - a manifold comprising a first surface and a second surface opposite the first surface;
 - a first layer adjacent to the first surface and a second layer adjacent to the second surface, the first layer and the second layer each comprising a polymer film;
 - a plurality of fluid restrictions in the polymer film of both the first layer and the second layer; and
 - a sealing layer adjacent to at least one of the first layer and the second layer, the sealing layer having a plurality of apertures fluidly coupled to the fluid restrictions, wherein one or more of the plurality of apertures is sized to expose both the fluid restrictions and a portion of the polymer film around the fluid restrictions to the tissue site through the sealing layer, and wherein a dimension of one or more of the fluid restrictions in the polymer film exceeds a dimension of one or more of the plurality of apertures.
2. The dressing of claim 1, wherein the polymer film is hydrophobic.
3. The dressing of any of claims 1-2, wherein the polymer film is selected from a group consisting of polythene, polyurethane, acrylics, polyolefines, polyacetates, polyamides, polyesters, polyether block amide, thermoplastic vulcanizates, polyethers, and polyvinyl alcohol.
4. The dressing of any of claims 1-2, wherein the polymer film is a polyethylene film having an area density of less than 30 grams per square meter.
5. The dressing of any of claims 1-4, wherein the fluid restrictions comprise a plurality of slots configured to permit fluid flow and inhibit exposure of the manifold to the tissue site.

6. The dressing of any of claims 1-4, wherein the fluid restrictions comprise or consist essentially of elastomeric valves in the polymer film that are normally closed.
7. The dressing of claim 6, wherein the elastomeric valves are fenestrations.
8. The dressing of claim 6, wherein the elastomeric valves are slits.
9. The dressing of any of claims 1-6, wherein the fluid restrictions comprise a plurality of slits in the polymer film, each of the slits having a length less than 4 millimeters.
10. The dressing of any one of claims 1-9, wherein the plurality of fluid restrictions in the polymer film are adjacent to the first surface and to the second surface.
11. The dressing of any one of claims 1-10, wherein the first layer and the second layer are laminated to the manifold.
12. The dressing of any one of claims 1-10, wherein the first layer and the second layer form a sleeve around the manifold.
13. The dressing of claim 12, wherein at least one edge of the manifold is exposed through the sleeve.
14. The dressing of any one of claims 12-13, wherein the sleeve is configured to be interposed between the manifold and the tissue site.
15. The dressing of any of claims 1-14, wherein the manifold comprises a foam.
16. The dressing of any of claims 1-15, wherein the manifold is hydrophobic.
17. The dressing of any one of claims 1-16, wherein:
 - the fluid restrictions are distributed across the polymer film in parallel rows and columns;
 - the rows are spaced about 3 millimeters on center; and
 - the fluid restrictions in each of the rows are spaced about 3 millimeters on center.
18. The dressing of claim 17, wherein the fluid restrictions in adjacent rows are offset.
19. The dressing of claim 1, further comprising:

- a drape configured to be disposed over the manifold; and
a fluid port configured to be coupled to the drape and fluidly coupled to the manifold through the drape and the polymer film of at least one of the first layer and the second layer.
20. The dressing of any one of claims 1-19, the sealing layer comprising a hydrophobic gel having a plurality of apertures in registration with at least some of the plurality of fluid restrictions.
 21. The dressing of any one of claims 1-19, the sealing layer comprising a hydrophobic gel having a plurality of apertures coextensive with the sealing layer and substantially all the plurality of apertures are in registration with the plurality of fluid restrictions.
 22. The dressing of claim 1, wherein the sealing layer comprises a silicone gel.
 23. The dressing of any one of claims 1-19, the sealing layer having a plurality of apertures adjacent to the fluid restrictions and an area density less than 300 grams per square meter.
 24. The dressing of any one of claim 1, wherein the sealing layer has a hardness of between about 5 Shore OO and about 80 Shore OO.
 25. The dressing of any one of claim 1, wherein the sealing layer is configured to be interposed between the manifold and the tissue site.
 26. The dressing of claim 1, wherein the dimension of the one or more of the fluid restrictions comprises a length that exceeds the dimension of the one or more of the plurality of apertures such that the length overlaps an edge of the one or more of the plurality of apertures.
 27. The dressing of claim 19, wherein the drape and the sealing layer enclose the first layer, the second layer, and the manifold.
 28. A system for treating a tissue site, the system comprising:
 - the dressing or apparatus of claim 1; and
 - a negative-pressure source fluidly coupled to the dressing or apparatus.

29. The system of claim 28, further comprising a fluid container fluidly coupled between the dressing and the negative-pressure source.

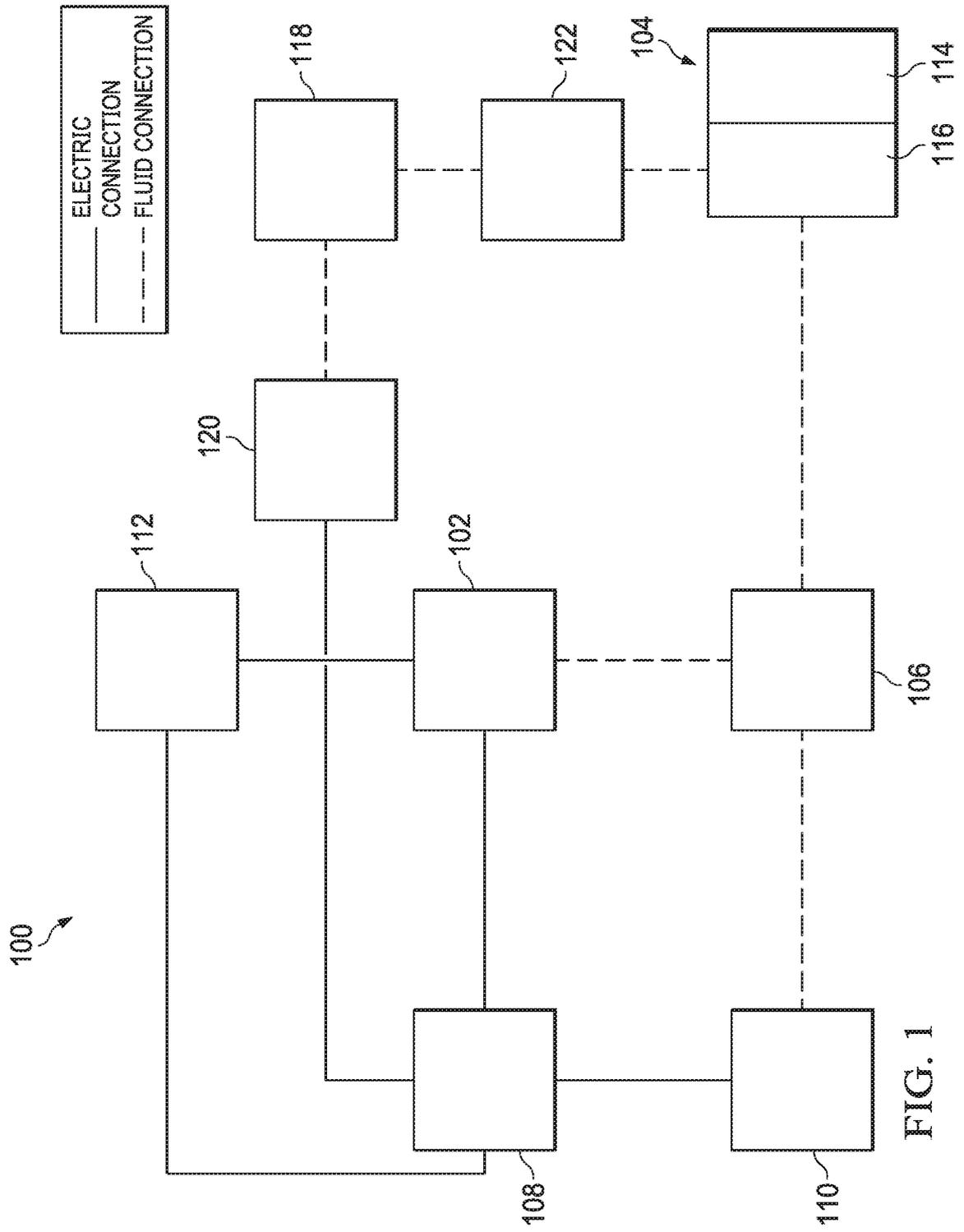


FIG. 1

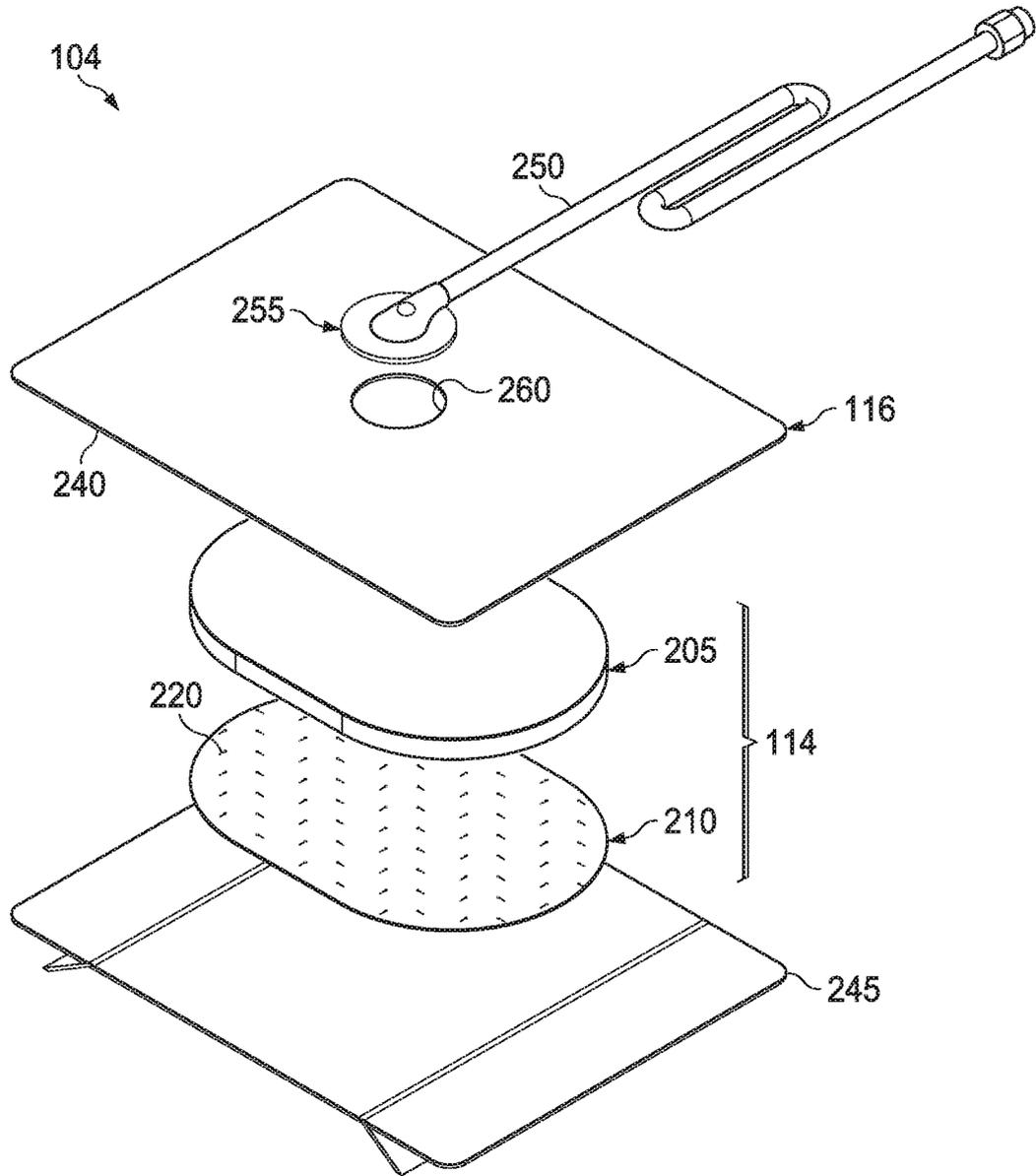


FIG. 2

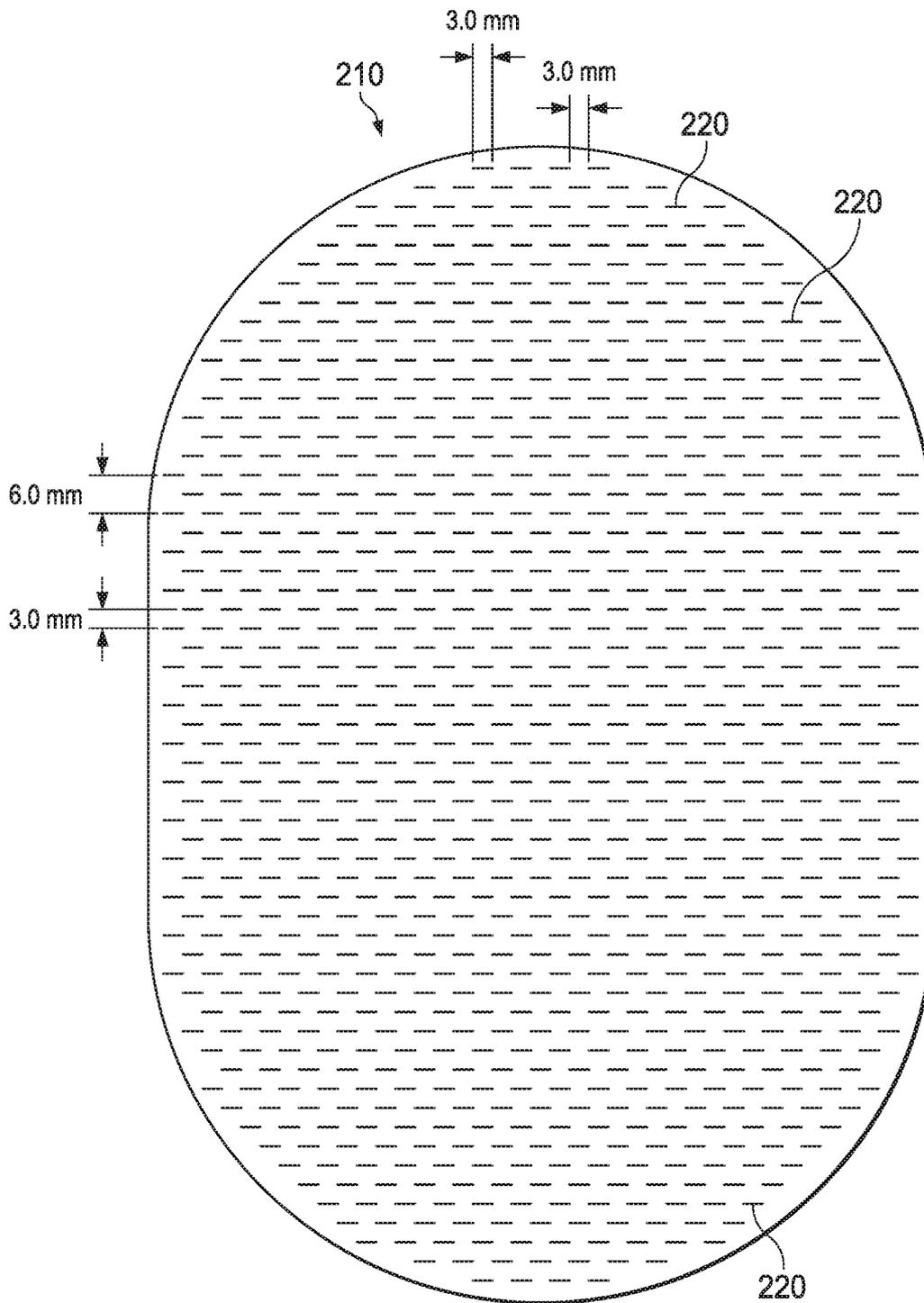


FIG. 3

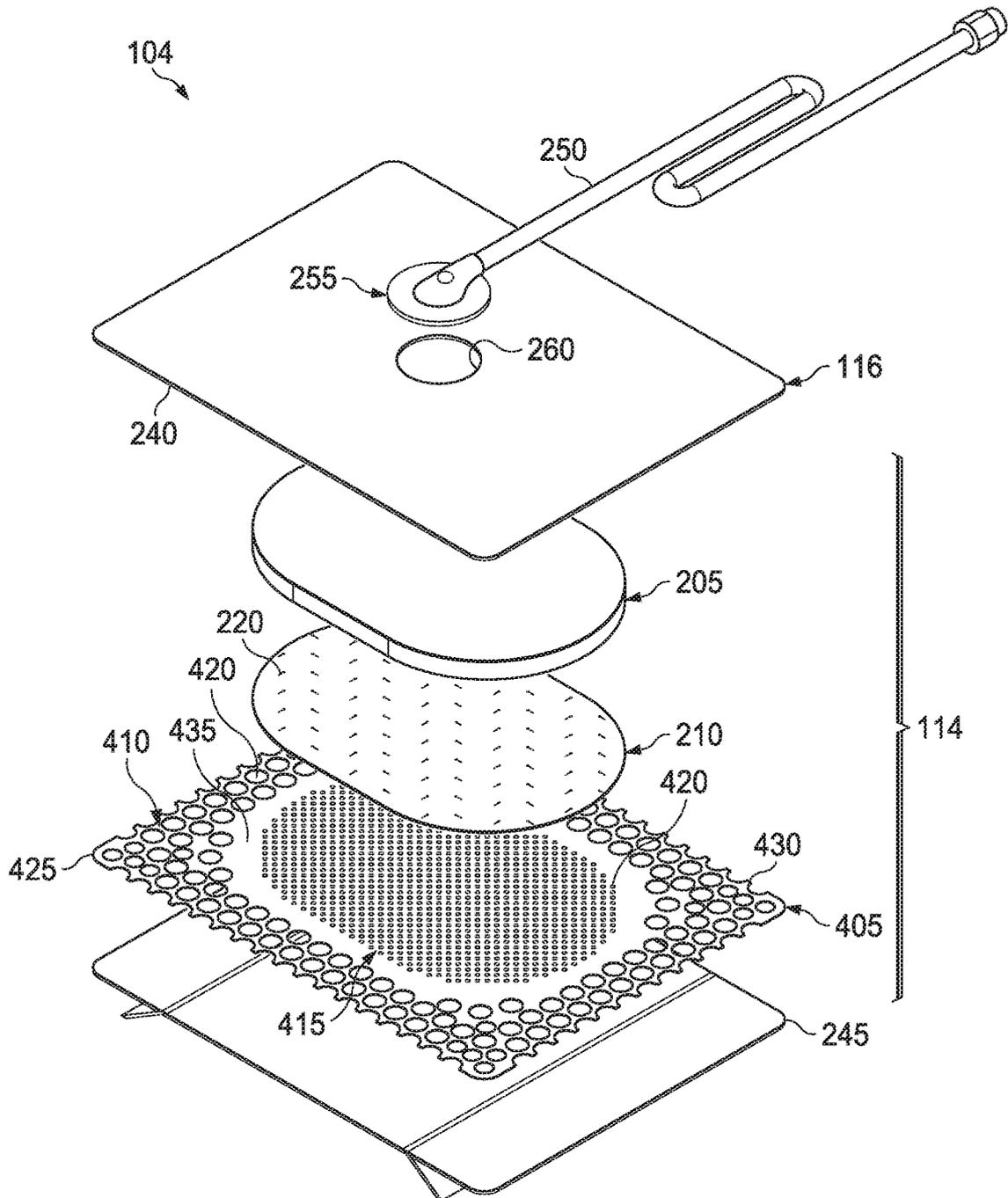


FIG. 4

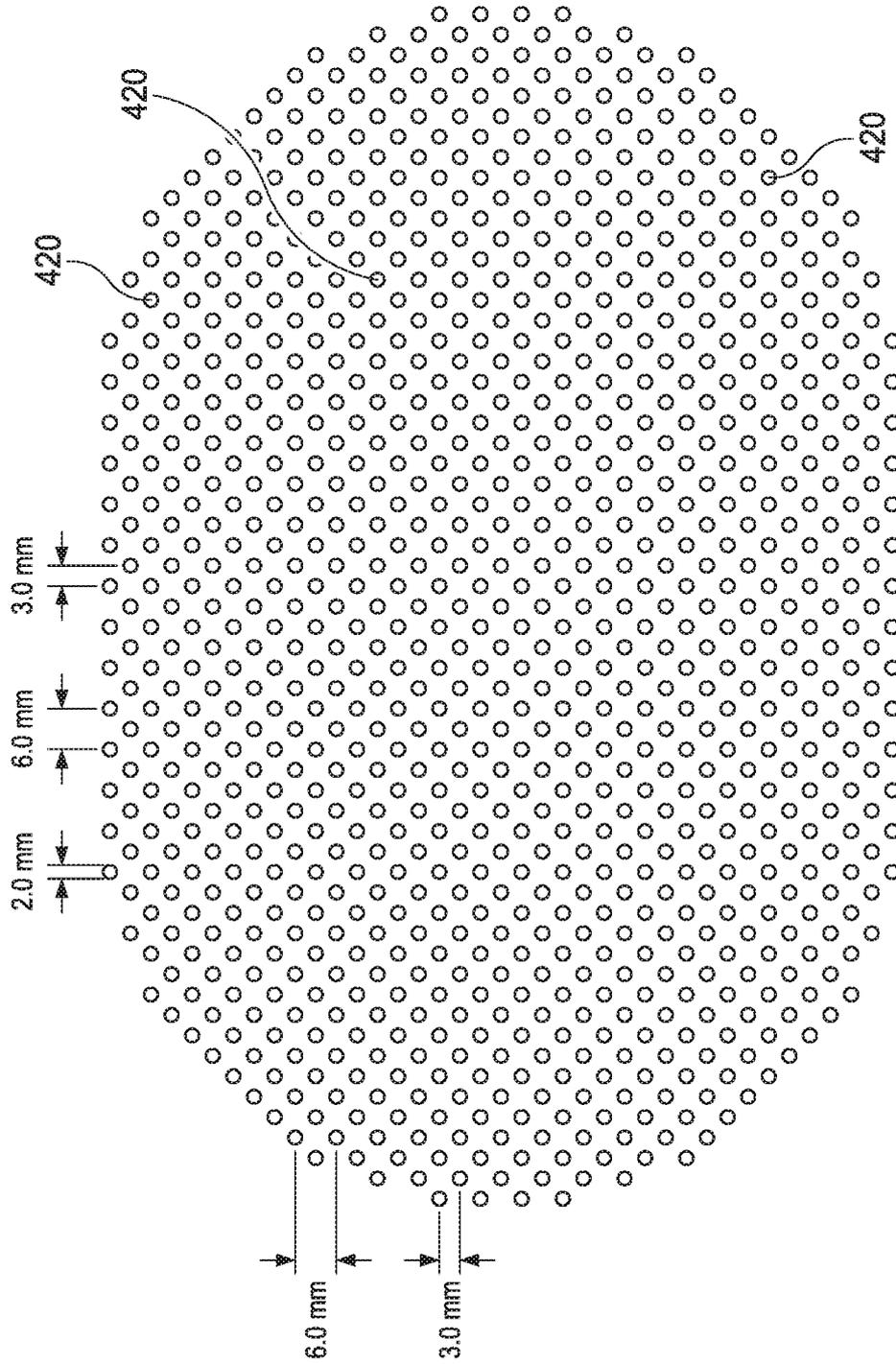


FIG. 5

6/14

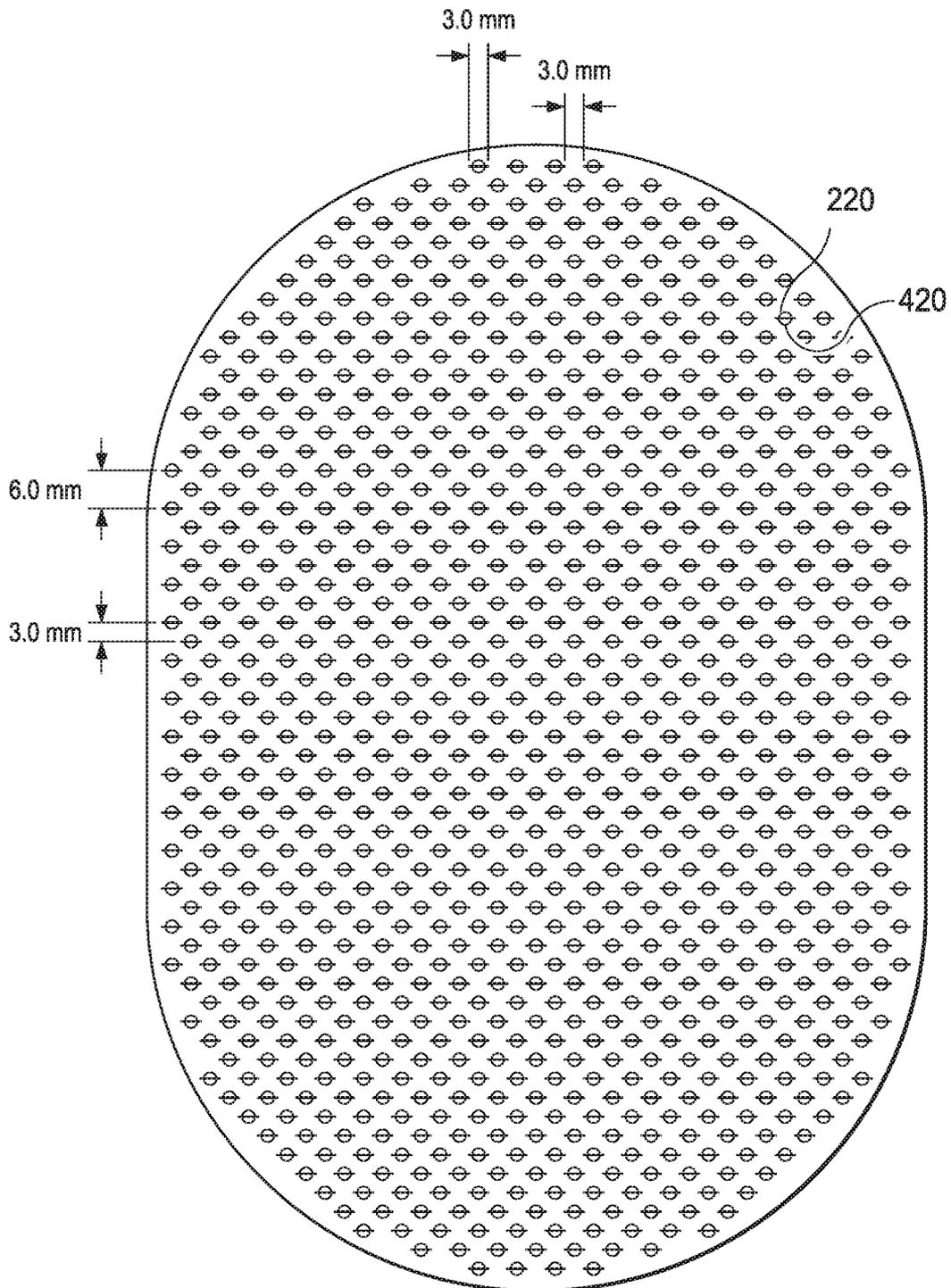


FIG. 6

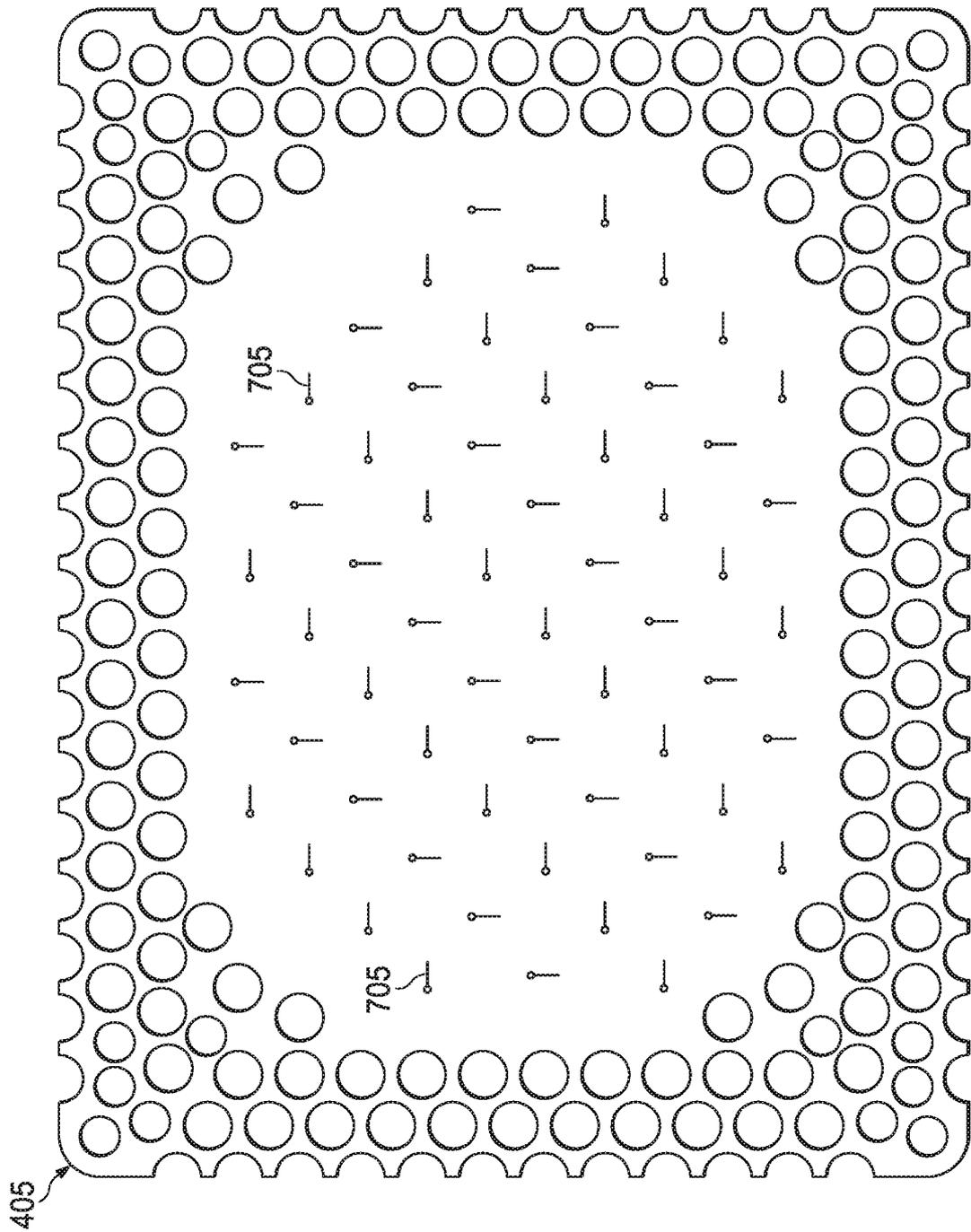


FIG. 7

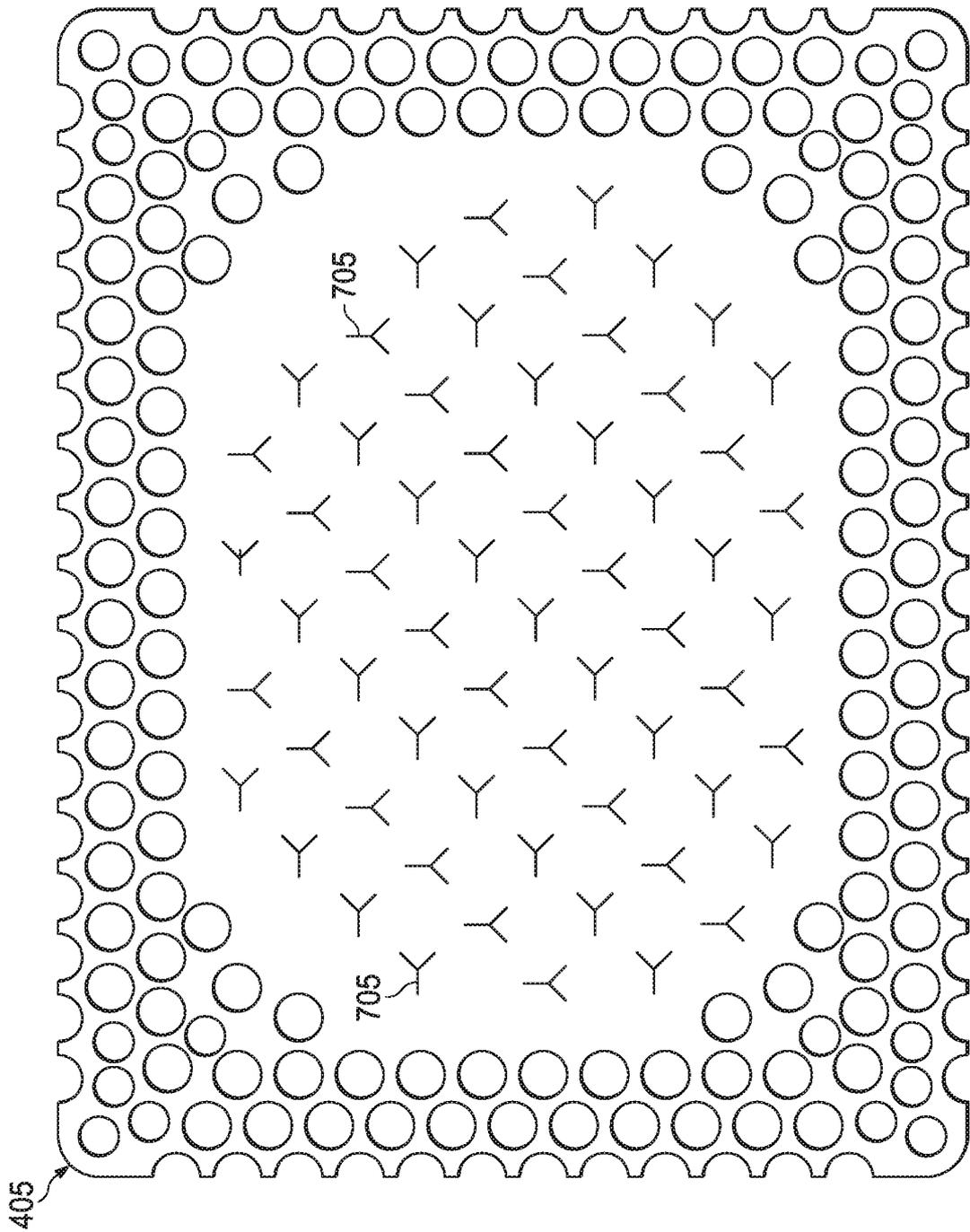


FIG. 8

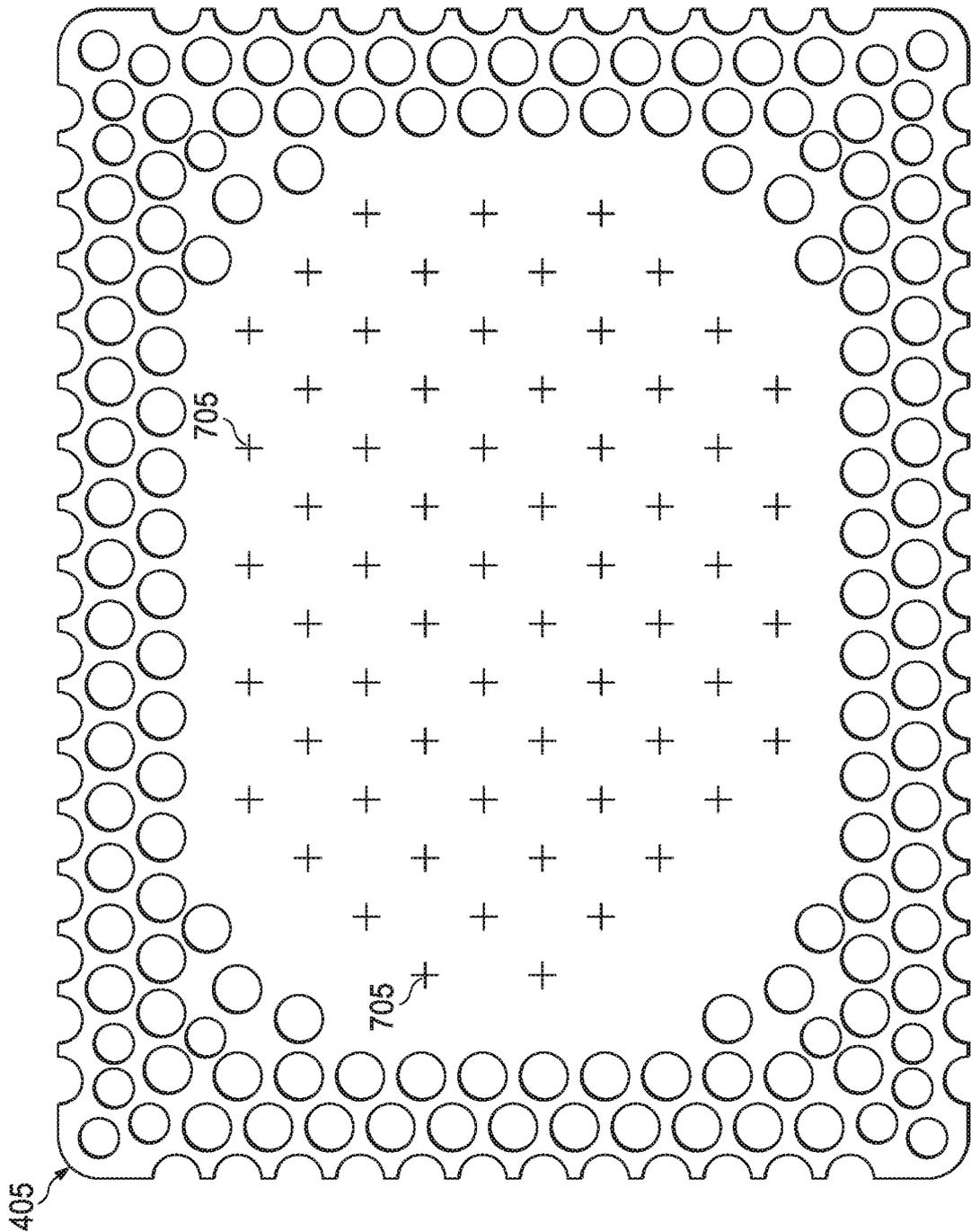


FIG. 9

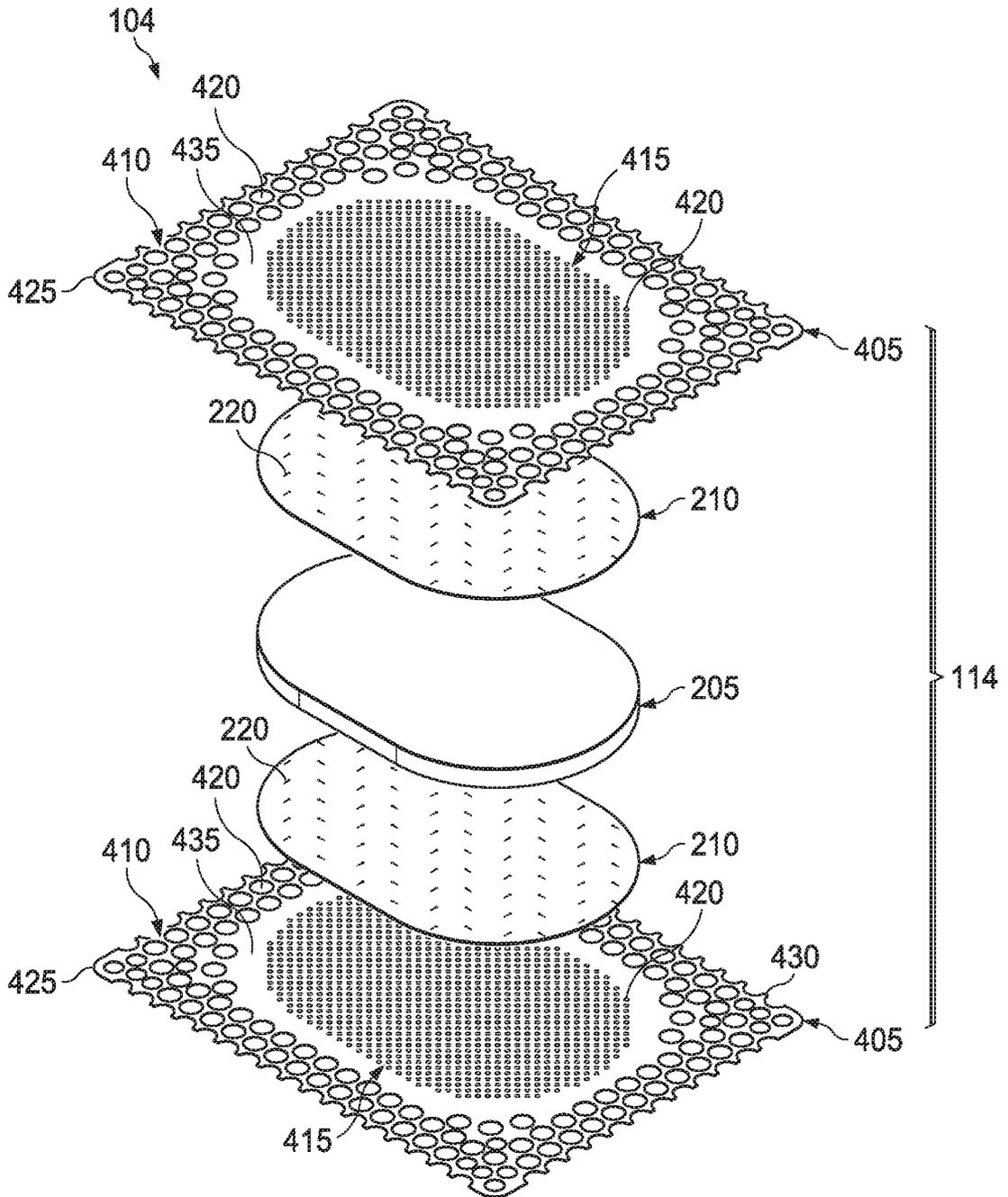


FIG. 10

11/14

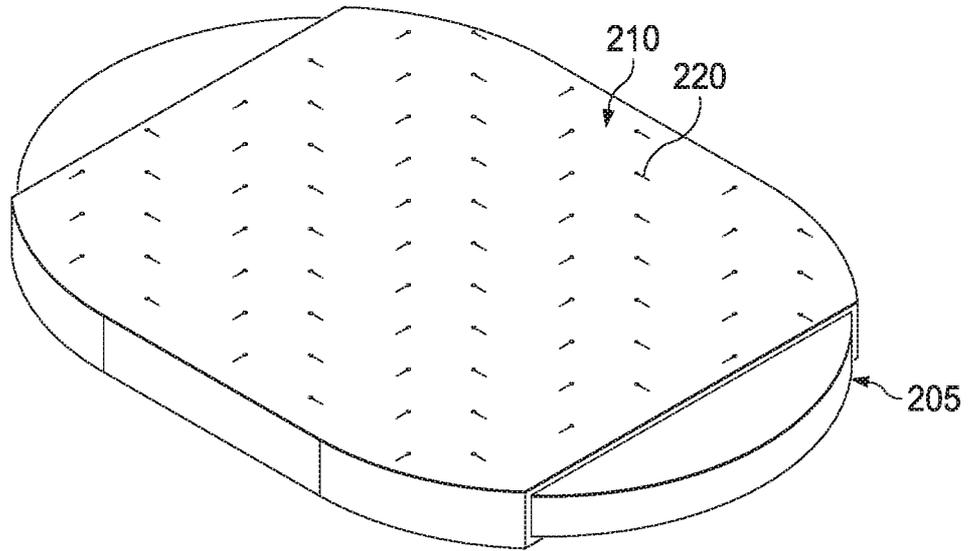


FIG. 11

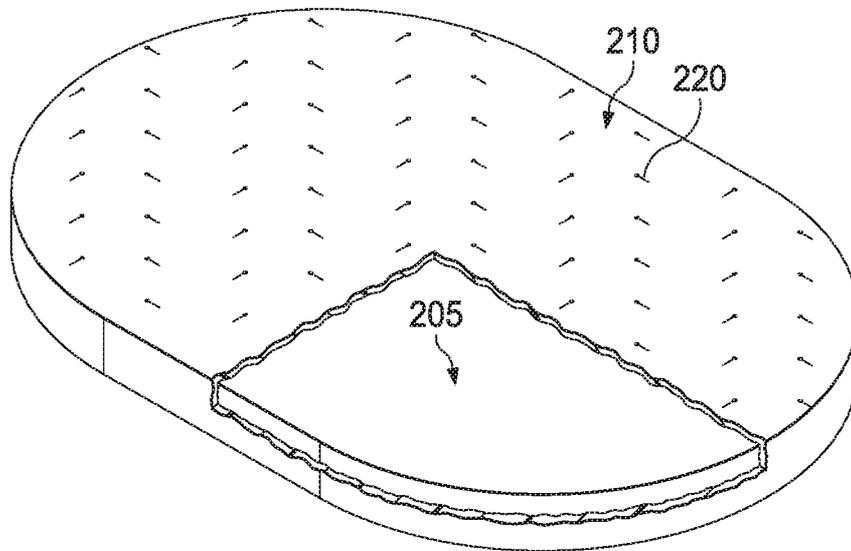
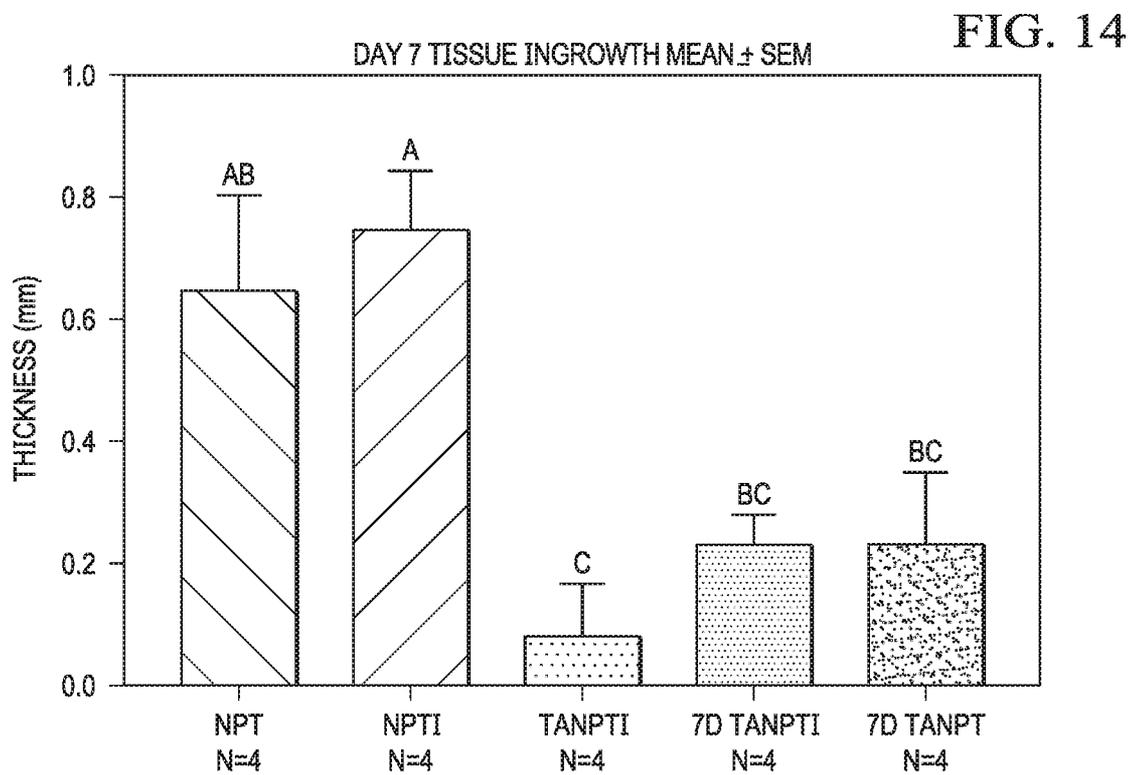
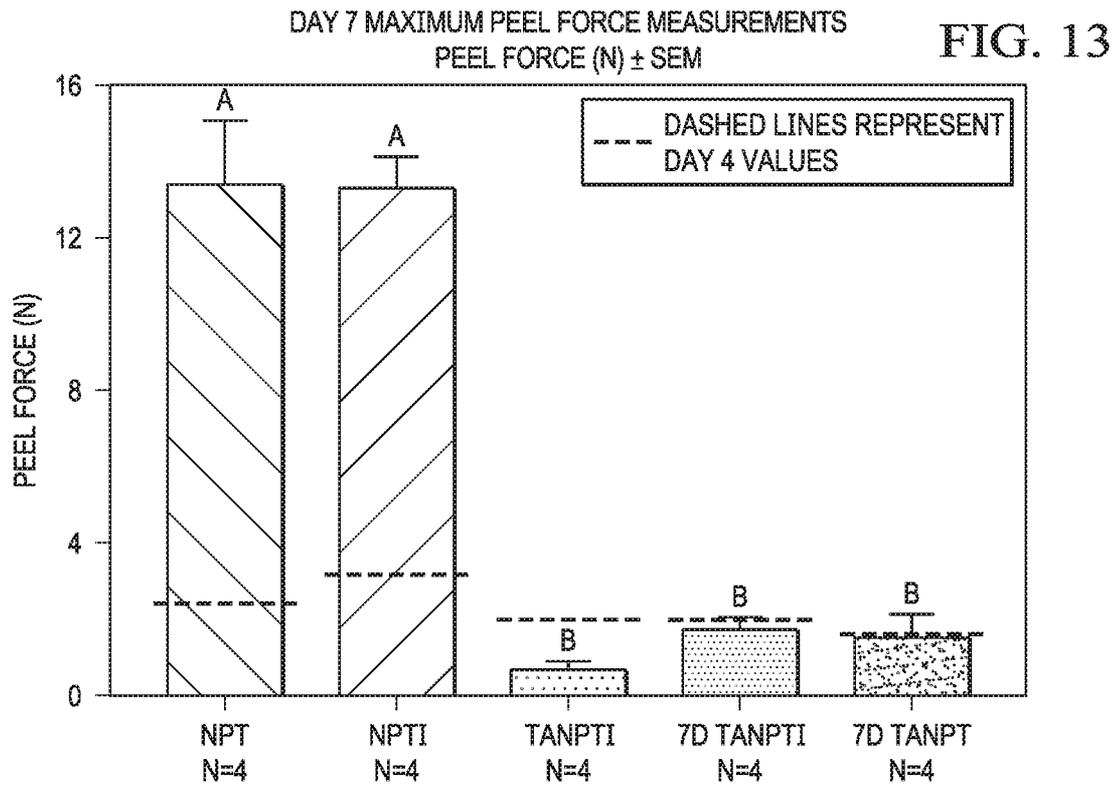


FIG. 12

12/14



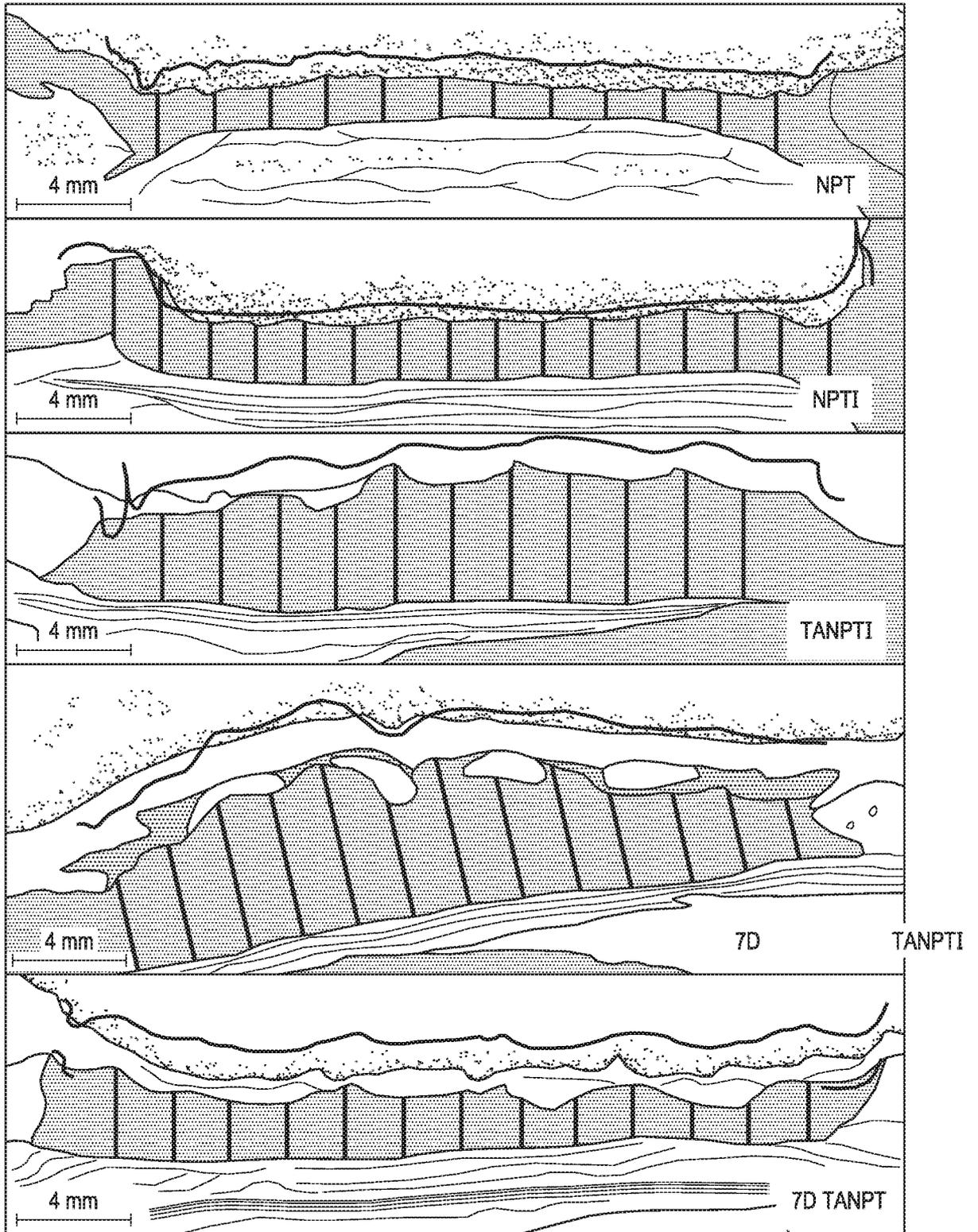


FIG. 15

