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(71) Applicant: KCI LICENSING, INC. [US/US]; Post Office Box 659508, San Antonio, Texas 78265 (US).

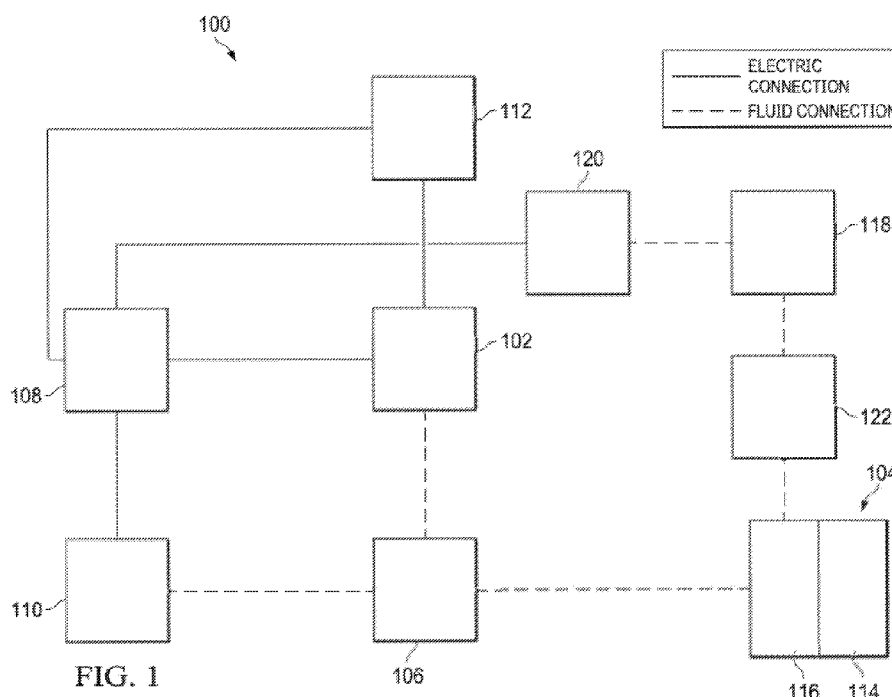
(72) Inventors: LOCKE, Christopher Brian; Post Office Box 659508, San Antonio, Texas 78265 (US). ROBINSON,

Timothy Mark; Post Office Box 659508, San Antonio, Texas 78265 (US).

(74) Agent: ADAMSON, Trisha D., et al.; 3M Center, Office of Intellectual Property Counsel, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US).

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(54) Title: TISSUE INTERFACE WITH FLUID BRIDGES BETWEEN SEPARABLE SECTIONS



(57) Abstract: Disclosed embodiments relate to dressings for treating a tissue site with negative pressure. Dressing embodiments may comprise a tissue interface having a manifold sandwiched between two polymer film layers. In some embodiments, the tissue interface may be configured with separable sections. For example, seams bonding the two polymer film layers together may subdivide the manifold into a plurality of separable sections. In some embodiments, the seams may be configured to allow separation of the separable sections without exposing the manifold sections. Some embodiments may further comprise one or more fluid bridges pneumatically linking adjacent separable sections across intervening seams, which may improve manifolding. The fluid bridges in some embodiments may be configured to minimize risk of in-growth.

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TISSUE INTERFACE WITH FLUID BRIDGES BETWEEN SEPARABLE SECTIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Provisional Application No. 62/884,549, filed on August 8, 2019, which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The invention set forth in the appended claims relates generally to tissue treatment systems and more particularly, but without limitation, to systems, dressings, and fillers for negative-pressure tissue treatment, and methods of using systems, dressings, and fillers for negative-pressure tissue treatment.

BACKGROUND

[0003] Clinical studies and practice have shown that reducing pressure in proximity to a tissue site can augment and accelerate growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but it has proven particularly advantageous for treating wounds. Regardless of the etiology of a wound, whether trauma, surgery, or another cause, proper care of the wound is important to the outcome. Treatment of wounds or other tissue with 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.

[0004] There is also widespread acceptance that cleansing a tissue site can be highly beneficial for new tissue growth. For example, a wound or a cavity can be washed out with 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.

[0005] 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

[0006] 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.

[0007] For example, in some embodiments, a dressing or filler for treating a tissue site with negative-pressure may include a manifold and a barrier. For example, a thin sheet of reticulated foam may be a suitable manifold for some embodiments, and a suitable barrier may comprise two layers of polymer film enclosing the manifold. Suitable films may include, for example, polythene, polyurethane, or ethyl methyl acrylate. Some embodiments of the film may have fluid restrictions, such as fluid valves, perforations, or fenestrations, formed over the surface. The manifold may be formed in sections in some embodiments. For example, the manifold sections may be formed by bonding the film layer to form seams around and defining the manifold sections. The composite dressing or filler may resemble a quilted structure in some configurations, for example with pillows of manifold foam bounded by and/or held within pockets formed by the seams. Sections may be folded, cut, or otherwise separated to shape and size the dressing or filler for optimal placement, and exposure of the manifold section foam may be avoided or minimized by folding or separating the sections along the seams between sections.

[0008] In some embodiments, the separable sections may be pneumatically connected by fluid communication bridges, which may span at least some of the seams. The fluid bridges may be configured to increase “cross-talk”, for example pressure or fluid communication, between separable sections. For example, the seams may be formed by welding the two layers of polymer film together. In some embodiments, small sections of the seams may not be fully welded, and these small sections may form the fluid bridges. For example, the fluid bridges may be formed when partial welding of the film layers results in the film layers being fused to the foam of the manifold by the partial welding process at these small sections, and the foam within such fluid bridges may be locally felted.

[0009] In some embodiments, the fluid bridges may provide improved pneumatic connection between adjacent sections of the manifold. In some embodiments, the fluid bridges may be configured to allow use of separated sections without significant risk of tissue growth into the manifold. For example, the fluid bridges may be configured to allow separation of sections at the seams without exposing un-felted foam to the wound. The fluid bridges may operate to expose a small cross-section of compressed and/or felted foam upon separation of one or more separable sections (e.g. at the seams).

In some embodiments, the separable sections remain substantially closed to prevent in-growth, even when an edge of the separable section with a fluid bridge is placed in contact with the wound bed.

[0010] More generally, some embodiments may relate to dressings for treating a tissue site with negative pressure, and the dressing embodiments may comprise: 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 adjacent to at least the first surface; a plurality of bonds between the first layer and the second layer, the plurality of bonds forming seams defining separable sections of the manifold; and one or more fluid bridges through and/or across at least some of the seams. For example, in some embodiments, one or more fluid bridges may span each seam between adjacent separable sections. In some embodiments, the plurality of bonds may form a seal between adjacent separable sections of the manifold; and the one or more fluid bridges may be configured to provide fluid communication and/or pneumatic connection through the seal and/or across the seam. In some embodiments, the one or more fluid bridges may be configured to provide substantially more fluid communication between adjacent separable sections than provided by the seams.

[0011] In some embodiments, the plurality of bonds may comprise welds between the first layer and the second layer; and the one or more fluid bridges may be disposed between welds. For example, the one or more fluid bridges may be formed by gaps in the welds. In some embodiments, the one or more fluid bridges may be formed by portions of the seam that are partially welded and/or not fully welded. In other examples, the one or more fluid bridges may be formed by portions of the seam that are not welded at all. In some embodiments, the welds may locally compress the manifold at the seams. In some embodiments, the manifold may comprise foam; and the one or more fluid bridges may comprise portions of the manifold that are felted. For example, the one or more fluid bridges may have a felted foam firmness ranging from 2 to 10 (e.g. 2 to 3, 3 to 10, 2 to 5, 3 to 5, 5 to 7, 5 to 10, or about 5). In some embodiments, the one or more fluid bridges may each have a width ranging from about 1-5 millimeters and a thickness ranging from about 1-5 millimeters. For example, the one or more fluid bridges may each have a width of about 2 millimeters and a thickness of about 1.5 millimeters.

[0012] In some embodiments, the first layer and the second layer may each comprise polyurethane film. In some embodiments, the fluid restrictions may be located in both the first layer and the second layer. In some embodiments, the welds between the first layer and the second layer may comprise portions of the manifold between the first layer and the second layer at the seams. In some embodiments, each separable section may be bounded by the seams; and the portion of the manifold between the seams may form a plurality of manifold sections. For example, the seams may be

configured to allow separation of the separable sections without exposing the manifold sections and/or unfelted foam.

[0013] In some embodiments, fluid bridges may fluidly couple two or more separable sections. For example, at least two fluid bridges may span each seam between adjacent separable sections. In some embodiments, each separable section may be in fluid communication with at least two other adjacent separable sections via fluid bridges. In some embodiments, each seam between adjacent separable sections may comprise a perforation line located approximately along a centerline of the seam between the adjacent separable sections. In some embodiments, the one or more fluid bridges may each comprise a plurality of holes in the seam that are cratered spaced, for example at about 3 to about 4 millimeter pitches.

[0014] Some dressing embodiments may comprise: a manifold comprising a first surface and a second surface opposite the first surface; a plurality of fluid valves adjacent to at least the first surface; a plurality of bonds between the first surface and the second surface, the plurality of bonds forming seams defining separable sections of the manifold; and one or more fluid bridges through at least some of the seams. In some embodiments, the plurality of bonds may form a seal between adjacent separable sections of the manifold; and the one or more fluid bridges may be configured to provide fluid communication through the seal and/or across the seams. The plurality of bonds in some embodiments may comprise welds between the first surface and the second surface; and the one or more fluid bridges may be formed by portions of the seam that are only partially welded. In some embodiments, the manifold may comprise foam; and the one or more fluid bridges may comprise portions of the manifold that are felted. For example, portions of the manifold that are only partially welded during formation of the seams may form the one or more felted fluid bridges. In some embodiments, the one or more fluid bridges may have a felted foam firmness ranging from 2 to 5 or 5 to 7. The manifold of some embodiments may further comprise an integral barrier on at least the first surface. Alternative embodiments may have one or more separate barriers, which may be joined to or used with the manifold to form the tissue interface. For example, the tissue interface may further comprise 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, the fluid valves being located in the polymer film, and the plurality of bonds joining the first layer and the second layer. In some embodiments, the manifold may comprise a spacer manifold disposed between the first layer and the second layer.

[0015] A method of forming a tissue interface for a dressing is also described herein, wherein some example embodiments may include: providing a manifold, a first polymer film layer, and a second polymer film layer; positioning the manifold between the first polymer film layer and the second polymer film layer; bonding the first polymer film layer to the second polymer film layer to form seams defining separable sections of the manifold and one or more fluid bridges through each seam between adjacent separable sections. In some embodiments, the step of bonding the first polymer film layer to

the second polymer film layer may comprise welding the first polymer film layer to the second polymer film layer. In some embodiments, the manifold may comprise foam; and the fluid bridges may be formed by felting portions of the foam within the seams. For example, during the step of bonding the first polymer film layer to the second polymer film layer to form seams, the fluid bridges may be formed by partially welding the first polymer film layer to the second polymer film layer with the manifold between the first polymer film layer and the second polymer film layer. The partial welding may result in formation of felted foam within the fluid bridges. In another example, forming the one or more fluid bridges may comprises leaving gaps in the welds of the seams, for example during the step of bonding the first polymer film layer to the second polymer film layer to form seams. In some embodiments, forming the one or more fluid bridges may comprise configuring a bonding tool to define the fluid bridges when forming the seams. In some alternative embodiments, forming the one or more fluid bridges may comprise forming a plurality of holes in the seams that are cratered spaced, for example at about 3 to about 4 millimeter pitches.

[0016] Some embodiments may further comprise perforating the seams to form perforation lines between adjacent separable sections. For example, the perforation lines may be located approximately along the centerline of the relevant seam. Some embodiments may further comprise forming a plurality of fluid restrictions in the first polymer film layer and/or forming a plurality of fluid restrictions in the second polymer film layer. In some embodiments, each separable section may be bounded by the seams, and the portion of the manifold between the seams may form a plurality of manifold sections. In some embodiments, the fluid restrictions may be coextensive with the manifold sections. In some embodiments, the step of forming the plurality of fluid restrictions may occur after bonding the first polymer film layer to the second polymer film layer.

[0017] A method for treating a tissue site using a dressing having a manifold is also described herein, and the method embodiments may comprise the steps of: excising separable sections of the dressing based upon at least one of a size and shape of the tissue site, wherein excising separable sections does not expose unfelted foam of the manifold; applying the dressing to fill or cover the tissue site; sealing the dressing to epidermis adjacent to the tissue site; fluidly coupling the dressing to a negative-pressure source; and applying negative pressure from the negative-pressure source to the dressing. In some embodiments, excising separable sections may comprise cutting or tearing a seam between the separable sections along a perforation line within the seam.

[0018] 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

[0019] Figure 1 is a functional block diagram of an example embodiment of a therapy system that can provide negative-pressure treatment in accordance with this specification;

[0020] Figure 2 is an exploded view of a dressing that may be associated with an example embodiment of the therapy system of Figure 1;

[0021] Figure 3 is a top view of a tissue interface of the dressing of Figure 2;

[0022] Figure 4 is a cross-sectional view of the tissue interface of Figure 3;

[0023] Figure 5 is an assembly view of exemplary layers of an embodiment of the tissue interface of Figure 3;

[0024] Figure 6 is top view of another tissue interface embodiment of the dressing of Figure 2;

[0025] Figure 7 is a top view of yet another tissue interface embodiment of the dressing of Figure 2;

[0026] Figure 8 is a top view of still another tissue interface embodiment of the dressing of Figure 2;

[0027] Figure 9 is a top view of another tissue interface embodiment of the dressing of Figure 2;

[0028] Figure 10 is a schematic cross-sectional view of the tissue interface of Figure 9;

[0029] Figure 11 is another schematic cross-sectional view of the tissue interface of Figure 9;

[0030] Figure 12 is yet another schematic cross-sectional view of the tissue interface of Figure 9;

[0031] Figure 13 is a chart showing pressure through an exemplary tissue interface having separable sections with welded seams therebetween; and

[0032] Figure 14 is a chart showing pressure through another exemplary tissue interface, similar to that of Figure 13 but which additionally has fluid bridges across the seams between adjacent separable sections.

DESCRIPTION OF EXAMPLE EMBODIMENTS

[0033] The following description of example embodiments provides information that enables a person skilled in the art to make and use the subject matter set forth in the appended claims, but it may omit certain details already well-known in the art. The following detailed description is, therefore, to be taken as illustrative and not limiting.

[0034] 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.

[0035] 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.

[0036] 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 dehiscent wounds, partial-thickness burns, ulcers (such as diabetic, pressure, or venous insufficiency ulcers), flaps, and grafts, for example.

[0037] 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, the therapy system 100 may include one or more sensors, for example 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 a tissue interface 114, a cover 116, or both in some embodiments.

[0038] The therapy system 100 may also include a source of instillation solution. 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 (e.g. saline) 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.

[0039] 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.

[0040] 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, and may be fluidly coupled to one or more distribution components to 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.

[0041] 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. 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 Kinetic Concepts, Inc. of San Antonio, Texas.

[0042] 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 (-6.7 kPa) and -300 mm Hg (-39.9 kPa).

[0043] 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.

[0044] 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.

[0045] 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 piezoresistive 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.

[0046] The tissue interface 114 can be generally adapted to partially or fully contact a tissue site. The tissue interface 114 may take many forms, and may have many sizes, shapes, or thicknesses depending on a variety of factors, such as the type of treatment being implemented or the nature and size of a tissue site. For example, the size and shape of the tissue interface 114 may be adapted to the contours of deep and irregular shaped tissue sites. Any or all of the surfaces of the tissue interface 114 may have an uneven, coarse, or jagged profile.

[0047] In some embodiments, the tissue interface 114 may comprise or consist essentially of a manifold. A manifold in this context may comprise or consist essentially of a means for collecting or distributing fluid across the tissue interface 114 under pressure. For example, a manifold 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 fluid from a source of instillation solution, across a tissue site.

[0048] In some illustrative embodiments, a manifold may comprise a plurality of pathways, which can be interconnected to improve distribution or collection of fluids. In some illustrative embodiments, a manifold may comprise or consist essentially of a porous material having interconnected fluid pathways. Examples of suitable porous material that can be adapted to form interconnected fluid pathways (e.g., channels) may include cellular foam, including open-cell foam such as reticulated foam; porous tissue collections; and other porous material such as gauze or felted mat that generally include pores, edges, and/or walls. Liquids, gels, and other foams may also include or be cured to include apertures and fluid pathways. In some embodiments, a manifold may additionally or alternatively comprise projections that form interconnected fluid pathways. For example, a manifold may be molded to provide surface projections that define interconnected fluid pathways.

[0049] In some embodiments, the tissue interface 114 may comprise or consist essentially of reticulated foam having pore sizes and free volume that may vary according to needs of a prescribed therapy. For example, reticulated foam having a free volume of at least 90% may be suitable for many therapy applications, and foam having an average pore size in a range of 400-600 microns (40-50 pores per inch) may be particularly suitable for some types of therapy. The tensile strength of the tissue interface 114 may also vary according to needs of a prescribed therapy. For example, the tensile strength of foam may be increased for instillation of topical treatment solutions. The 25% compression load deflection of the tissue interface 114 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 tissue interface 114 may be at least 10 pounds per square inch. The tissue interface 114 may have a tear strength of at least 2.5 pounds per inch. In some embodiments, the tissue interface may be foam comprised of polyols such as polyester or polyether, isocyanate such as toluene

diisocyanate, and polymerization modifiers such as amines and tin compounds. In some examples, the tissue interface 114 may comprise or consist essentially of reticulated polyurethane foam such as found in GRANUFOAM™ dressing or V.A.C. VERAFLOR™ dressing, both available from Kinetic Concepts, Inc. of San Antonio, Texas.

5 **[0050]** The thickness of the tissue interface 114 may also vary according to needs of a prescribed therapy. For example, the thickness of the tissue interface may be decreased to reduce tension on peripheral tissue. The thickness of the tissue interface 114 can also affect the conformability of the tissue interface 114. In some embodiments, a thickness in a range of about 5 millimeters to 10 millimeters may be suitable.

10 **[0051]** The tissue interface 114 may be either hydrophobic or hydrophilic. In an example in which the tissue interface 114 may be hydrophilic, the tissue interface 114 may also wick fluid away from a tissue site, while continuing to distribute negative pressure to the tissue site. The wicking properties of the tissue interface 114 may draw fluid away from a tissue site by capillary flow or other wicking mechanisms. An example of a hydrophilic material that may be suitable is a polyvinyl alcohol,
15 open-cell foam such as V.A.C. WHITEFOAM™ dressing available from Kinetic Concepts, Inc. of San Antonio, Texas. Other hydrophilic foams may include those made from polyether. Other foams that may exhibit hydrophilic characteristics include hydrophobic foams that have been treated or coated to provide hydrophilicity.

20 **[0052]** In some embodiments, the tissue interface 114 may be constructed from bioresorbable materials. Suitable bioresorbable materials may include, without limitation, a polymeric blend of polylactic acid (PLA) and polyglycolic acid (PGA). The polymeric blend may also include, without limitation, polycarbonates, polyfumarates, and caprolactones. The tissue interface 114 may further serve as a scaffold for new cell-growth, or a scaffold material may be used in conjunction with the tissue interface 114 to promote cell-growth. A scaffold is generally a substance or structure used to enhance
25 or promote the growth of cells or formation of tissue, such as a three-dimensional porous structure that provides a template for cell growth. Illustrative examples of scaffold materials include calcium phosphate, collagen, PLA/PGA, coral hydroxy apatites, carbonates, or processed allograft materials.

30 **[0053]** 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 comprise or consist of, 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
35 least 250 g/m² per twenty-four hours in some embodiments, measured using an upright cup technique according to ASTM E96/E96M Upright Cup Method at 38 degrees Celsius and 10% relative humidity.

In some embodiments, an MVTR up to 5,000 grams per square meter per twenty-four hours may provide effective breathability and mechanical properties. 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.

[0054] The cover 116 may comprise, for example, one or more of the following materials: polyurethane (PU), such as hydrophilic polyurethane; cellulotics; hydrophilic polyamides; polyvinyl alcohol; polyvinyl pyrrolidone; hydrophilic acrylics; silicones, such as hydrophilic silicone elastomers; an INSPIRE 2301 and INSPIRE 2327 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; ethylene vinyl acetate (EVA); 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.

[0055] 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. 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.

[0056] 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.

[0057] In operation, the tissue interface 114 may be placed within, over, on, or otherwise proximate to a tissue site. If the tissue site is a wound, for example, the tissue interface 114 may partially or completely fill the wound, or it may be placed over the wound. The cover 116 (e.g. a separate drape) may be placed over the tissue interface 114 and sealed to an attachment surface near a tissue site. For

example, the cover 116 may be sealed to undamaged epidermis peripheral to a tissue site. Thus, the dressing 104 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 pressure in the sealed therapeutic environment. A port may be applied to the cover, providing fluid communication between the external environment (e.g. the negative-pressure source 102) and the manifold of the dressing.

[0058] 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.

[0059] 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.

[0060] 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 separable sections. For example, the tissue interface 114 of Figure 2 comprises one or more interface sections 205, which are configured to be separable. Each of the interface sections 205 may be bounded by one or more seams 210. In some examples, the seams 210 may be formed between and/or may define the interface sections 205. For example, the seams 210 may span the perimeter of the interface sections 205, and adjacent interface sections 205 may have a seam 210 therebetween.

[0061] As illustrated in the example of Figure 2, the tissue interface 114 may have one or more fluid restrictions 220, which can be distributed uniformly or randomly across the tissue interface 114. 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.

[0062] 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 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. In some embodiments, the fluid restrictions 220 may be formed by ultrasonics or other heat means. 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.

[0063] 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 comprise 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.

[0064] Figure 3 is a top view of the tissue interface 114 of Figure 2, illustrating additional details that may be associated with some examples. Each of the interface sections 205 may have the same shape or a different shape. As shown in the example of Figure 3, the interface sections 205 may have similar shapes. In some embodiments, each of the interface sections 205 may have a tessellate shape, such as the generally square shape in the example of Figure 3, with sides having a length ranging from about 10 mm to about 30 mm (e.g., about 15 mm to about 25 mm or about 18 mm to about 22 mm). For example, the interface sections 205 may be squares having dimensions of about 20 mm by about 20 mm.

[0065] Figure 4 is a section view of the tissue interface 114 of Figure 3 taken along line 4-4, illustrating additional details that may be associated with some embodiments. In the example of Figure 4, the tissue interface 114 comprises a first layer 405, a second layer 410, and a spacer manifold 415 may be disposed between the first layer 405 and the second layer 410. In some embodiments, the first layer 405 and the second layer 410 may be disposed adjacent to the spacer manifold 415 as shown in the example of Figure 4. Also as shown in the example of Figure 4, the seams 210 may be formed by one or more bonds, which can define substantially discrete manifold sections 420 of the spacer manifold 415. In some examples, the bonds may couple the first layer 405 and the second layer 410 to the spacer manifold 415, or the bonds may couple the first layer 405 to the second layer 410 through the spacer manifold 415. The bonds may be continuous or discrete. In some embodiments, some seams 210 may span an area between adjacent manifold sections 420, and some seams 210 may define exterior edges of the manifold sections 420 (e.g. where there are no adjacent separable sections) with bonds between the first layer 405 and the second layer 410. In some embodiments, each separable interface section 205 may comprise the manifold section 420 of spacer manifold 415 material enclosed by the first layer

405, the second layer 410, and the seams 210 about its perimeter. Each of the seams 210 between adjacent interface sections 205 may have a width W1 ranging from about 2 mm to about 5mm, and may be wide enough to allow for the interface sections 205 to be separated along the seams 210 without exposing any portion of the manifold sections 420.

5 **[0066]** The manifold sections 420 may comprise or consist of foam in some embodiments. For example, the foam may be open-cell foam, such as reticulated foam. In some embodiments, the foam may be polyurethane foam. The foam may also be relatively thin and hydrophobic to reduce the fluid hold capacity of the dressing, which can encourage exudate and other fluid to pass quickly to external storage. The foam layer may also be thin to reduce the dressing profile and increase flexibility, which
10 can enable it to conform to wound beds and other tissue sites under negative pressure. In some embodiments, the manifold sections 420 may be formed of 3-dimensional textiles, non-woven wicking material, vacuum-formed texture surfaces, and composites thereof. A hydrophobic manifold having a thickness of 10 millimeters or less and a free volume of at least 90% may be suitable for many therapeutic applications. In some embodiments, the manifold sections 420 may be formed of colored
15 material. Each of the manifold sections 420 may be a same color or a different color. In some embodiments, the manifold sections 420 may jointly form a manifold layer of the tissue interface 114.

[0067] The first layer 405 and the second layer 410 may comprise or consist essentially of a barrier. In some embodiments, the barrier may comprise a means for controlling or managing fluid flow. In some embodiments, the barrier may comprise or consist essentially of a tissue barrier, which
20 may be configured to prevent or substantially reduce growth of tissue into the tissue interface 114. Oftentimes, the barrier may do both. In some embodiments, the first layer 405 and the second layer 410 may comprise or consist essentially of an elastomeric material that is impermeable to liquid and/or that prevents or substantially reduces growth of tissue into the tissue interface 114. For example, the first layer 405 and the second layer 410 may comprise or consist essentially of a polymer film. The
25 first layer 405 and the second layer 410 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
30 millimeters over a centimeter.

[0068] In some embodiments, the first layer 405 and the second layer 410 may comprise or consist essentially of a hydrophobic material. The hydrophobicity may vary, but may have a contact angle with water of at least ninety degrees in some embodiments. In some embodiments the hydrophobic material may have a contact angle with water of no more than 150 degrees. For example,
35 in some embodiments, the contact angle 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 first layer 405, the second layer 410, or both 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.

[0069] The first layer 405 and the second layer 410 may also be suitable for bonding to other layers, including each other. For example, the first layer 405, the second layer 410, or both 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. The first layer 405 and the second layer 410 may include hot melt films.

[0070] The area density of the first layer 405 and the second layer 410 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.

[0071] In some embodiments, for example, the first layer 405, the second layer 410, or both 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. For example, the first layer 405 and the second layer 410 may each have a thickness of about 75 microns. 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.

[0072] In some embodiments, the fluid restrictions 220 may comprise or consist essentially of perforations in at least one of the first layer 405 and the second layer 410. Perforations may be formed by removing material from the first layer 405, the second layer 410, or both. For example, perforations may be formed by cutting through the material, 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 material may be a suitable valve for some applications. Fenestrations may also be formed by removing material, 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. In some embodiments, the fluid restrictions 220 extend through both the first layer 405 and the second layer 410, and the fluid restrictions 220 may be coextensive with at least one of the first layer 405 and the second layer 410. As illustrated in the example of Figure 4, both the first layer 405 and the second layer 410 may have fluid restrictions 220, and the fluid restrictions 220 in the first layer 405 may align with the fluid restrictions 220 in the second layer 410. In some embodiments, the fluid restrictions may be coextensive with at least the first layer. In some embodiments, the fluid restrictions 220 may be coextensive with the manifold sections 420. In some embodiments, the fluid restrictions 220 may at least partially penetrate the underlying manifold sections 420.

[0073] Each of the manifold sections 420 in Figure 4 has a length L_1 , which can be in a range from about 10 mm to about 30 mm (e.g., about 15 mm to about 25 mm or about 18 mm to about 22 mm). For example, each of the manifold sections 420 may have a length of about 20 mm. In some embodiments, the manifold sections 420 may be spaced apart by a distance D_1 of about 5 mm to about 15 mm. For example, a distance D_1 of about 10 mm may be particularly advantageous for some embodiments.

[0074] In some embodiments, each of the manifold sections 420 in the tissue interface 114 may be the same size. In other embodiments, one or more of the manifold sections 420 in the tissue interface 114 may have a different size.

[0075] In some embodiments, the tissue interface 114 has a thickness T_1 ranging from about 5 mm to about 20 mm (e.g., about 8 mm to about 18 mm, or about 10 mm to about 15 mm). For example, the tissue interface 114 may have a thickness T_1 of about 8 mm. The thickness T_1 of the tissue interface 114 may vary depending upon a thickness of the manifold sections 420 used to form the

tissue interface 114. For example, each of the manifold sections 420 may have a thickness ranging from about 5 mm to about 15 mm (e.g., about 8 mm to about 12 mm).

[0076] One or more of the interface sections 205 may be separated or excised by cutting or tearing within the width W1 of the seams 210, with portions of the seams 210 bounding the interface sections 205 remaining intact to substantially reduce or prevent exposure of the manifold sections 420.

[0077] In some embodiments, the first layer 405 and the second layer 410 may be formed of a transparent polymer to aid in cutting the interface sections 205 apart along the seams 210.

[0078] Figure 5 is an assembly view of exemplary layers that may form an embodiment of the tissue interface 114 shown in Figure 3. In some embodiments, the spacer manifold 415 may be formed from an integral manifold material, such as a sheet or layer of foam. In some embodiments, bonds between the first layer 405 and the second layer 410 may extend through the spacer manifold 415 to define the interface sections 205. For example, formation of the seams 210 by bonding may result in the initially uniform spacer manifold 415 being subdivided by the seams 210 to form the manifold sections 420 shown in Figure 4. The pattern of the seams 210 may define individual sections of the spacer manifold 415. Some embodiments of the spacer manifold 415 may have a thickness T2 ranging from about 5 mm to about 12 mm (e.g. about 10 mm), and at least one of the first layer 405 and the second layer 410 may melt through or weld to portions of the spacer manifold 415 during welding to form the seams 210. In some embodiments, bonding the first layer 405 to the second layer 410 to form the seams 210 may comprise bonding the first layer 405 to the spacer manifold 415 and bonding the second layer 410 to the spacer manifold 415. In some embodiments, welding to form the seams 210 may join, compress, and/or alter the layers to form a unitary weld.

[0079] Additionally or alternatively, a unitary manifold material can be perforated and cut to define the manifold sections 420 in a variety of suitable shapes and patterns. In some embodiments, the seams 210 may align with perforations between the manifold sections 420. In some examples, sacrificial joints may be left between the manifold sections 420 to maintain the spacer manifold 415 together as a single unit. Maintaining the integrity of the spacer manifold 415 as a single unit can allow for easier assembly of the tissue interface 114. In some embodiments, either or both of the first layer 405 and the second layer 410 may also be bonded to other portions of the spacer manifold 415 for additional stability.

[0080] In some embodiments, the spacer manifold 415 may comprise an aggregate of discrete manifold sections. For example, the tissue interface 114 can be formed by spacing discrete manifold sections apart, placing the first layer 405 of polymer film over the manifold sections, placing the second layer 410 under the manifold sections, and bonding the first layer 405 to the second layer 410, forming the seams 210 between the manifold sections. Suitable means for bonding the first layer 405 to the second layer 410 may include, for example, an adhesive such as an acrylic, and welding, such as heat, radio frequency (RF), or ultrasonic welding. In some embodiments, sacrificial materials may be

disposed between the first layer 405 and the second layer 410 to facilitate welding. Suitable sacrificial materials may include, for example, hot melt films supplied by Bayer (such as H2, HU2, and H5 films), Cornelius (Collano film), or Prochimir (such as TC203 or TC206 film).

[0081] Figure 6 is a top view of another example of the tissue interface 114, illustrating additional details that may be associated with some embodiments. In the example of Figure 6, the interface sections 205 have generally triangular shapes. In some embodiments, the manifold sections 420 within the interface sections 205 also have generally triangular shapes. The triangular shapes may be equilateral triangles, isosceles triangles, or scalene triangles, for example. One or more sacrificial joints 600 may couple the manifold sections 420 together in some embodiments. For example, in some embodiments the spacer manifold 415 may be shaped and perforated to form the manifold sections 420, leaving the sacrificial joints 600 between the manifold sections 420. In the example of Figure 6, the sacrificial joints 600 comprise extensions 605, which may have a generally triangular shape. The extensions 605 of Figure 6 are joined at a common apex, which can minimize potential exposure of manifold material if the interface sections 205 are separated. The first layer 405 can be bonded to the second layer 410 around and/or through the extensions 605 so as to form the seams 210 between the interface sections 205.

[0082] In some example embodiments, the tissue interface 114 may have a generally hexagonal shape. One or more sides of the tissue interface 114 may have a same length or a different length.

[0083] The tissue interface 114 may include eight interface sections 205, as illustrated in the example of Figure 6. In some embodiments, the tissue interface 114 may include one or more of the interface sections 205, depending on dimensions of each of the interface sections 205.

[0084] Figure 7 is a top view of another example of the tissue interface 114, illustrating additional details that may be associated with some embodiments. In the example of Figure 7, the tissue interface 114 has a generally square shape and each of the interface sections 205 in the tissue interface 114 has a generally triangular shape. The tissue interface 114 of Figure 6 includes eight of the interface sections 205.

[0085] Figure 8 is a top view of another example of the tissue interface 114, illustrating additional details that may be associated with some embodiments. In the example of Figure 8, the interface sections 205 have generally square shapes. Each of the manifold sections 420 also has a generally square shape, and can be attached to adjacent manifold sections 420 by the sacrificial joints 600. The tissue interface 114 of Figure 7 includes nine of the interface sections 205.

[0086] In other embodiments, the tissue interface 114 may include more or fewer of the interface sections 205. Each of the interface sections 205 may have a different size or a same size. Each of the interface sections 205 may have a same shape or a different shape. For example, the interface

sections 205 may be in the form of equilateral polygons, which may have sides not exceeding about 20 millimeters and having an area less than about 400 square millimeters.

[0087] Figure 9 is a top view of another example of the tissue interface 114, illustrating additional details that may be associated with some embodiments. The tissue interface 114 of Figure 9 may be similar to that shown in Figure 3, with the addition of one or more fluid bridges 905 through or across at least some of the seams 210 separating the interface sections 205. In some embodiments, one or more fluid bridges 905 may span each seam 210 between adjacent interface sections 205, to provide fluid communication between adjacent manifold sections 420. For example, the interface sections 205 of the tissue interface 114 may be pneumatically connected by the fluid bridges 905. In some embodiments, the fluid bridges 905 may be configured to provide substantially more fluid communication between interface sections 205 than provided by the seams 210. In some embodiments, the plurality of bonds forming the seams 210 may restrict fluid flow across the seams 210 and/or may form a seal between the interface sections 205, and the fluid bridges 905 may provide fluid communication across the seams 210. In some embodiments, the fluid bridges 905 may extend substantially perpendicularly to a longitudinal centerline of the seam 210 being traversed.

[0088] The fluid bridges 905 may provide a fluid path between interface sections 205. For example, one or more of the fluid bridges 905 may provide a fluid path that pneumatically links adjacent interface sections 205. In some embodiments, one or more of the fluid bridges 905 may allow fluid communication between manifold sections 420, for example by spanning the seams 210 between the adjacent manifold sections 420. In some embodiments, each of the fluid bridges 905 may have a width ranging from about 1-5 millimeters and a thickness ranging from about 1-5 millimeters. For example, each of the fluid bridges 905 may have a width of about 2 millimeters and a thickness of about 1.5 millimeters or a width of about 2 millimeters and a thickness of about 2 millimeters.

[0089] As shown in Figure 9, each of the interface sections 205 may be in fluid communication with at least two adjacent interface sections 205 via fluid bridges 905. In some embodiments, at least two fluid bridges 905 may span each seam 210 between adjacent interface sections 205. In some embodiments, each seam 210 between adjacent interface sections 205 may comprise a perforation line 910 configured to designate a location for separation of the interface sections 205 and/or to ease separation of the interface sections 205. For example, the perforation lines 910 may simplify cutting apart the interface sections 205 in some embodiments, or may allow tearing apart the interface sections 205. In some embodiments, each perforation line 910 may be located approximately along the longitudinal centerline of the seams 210 between adjacent interface sections 205, and/or there may be a perforation line for each seam 210 between adjacent interface sections 205.

[0090] In some embodiments, the fluid bridges 905 may each comprise felted foam. In some embodiments, the plurality of bonds that form the seams 210 may comprise welds between the first layer and the second layer. In some embodiments, the fluid bridges 905 may be disposed between welds

forming the seams 210. In some embodiments, the one or more fluid bridges 905 may be formed by gaps in the welds forming the seams 210. For example, the fluid bridges 905 may be formed by portions of the seams 210 that are not welded. In some embodiments, the fluid bridges 905 may be formed by portions of the seams 210 that are not fully welded. For example, the fluid bridges 905 may be formed by portions of the seams 210 that are partially welded. In some embodiments, the welds or partial welds may compress the spacer manifold at the seams 210.

[0091] Figure 10 is a schematic cross-section view of the tissue interface 114 of Figure 9, illustrating additional details that may be associated with some embodiments. As shown in Figure 10, each manifold section 420 may span the corresponding interface section 205 between the bounds of the seams 210 defining the manifold section 420. For example, the manifold section 420 may comprise foam, and the foam of the manifold section 420 may fill an interior space of the interface section 205 between the seams 210 defining the manifold section 420. In some embodiments, the manifold sections 215 may comprise unfelted foam. The seam 210 between adjacent interface sections 205 may be formed by bonding the first layer 405 to the second layer 410. In some embodiments, a portion of the spacer manifold 415 may also be part of the weld between the first layer 405 and the second layer 410. For example, the welded seams 210 may comprise felted foam with firmness greater than 10, and often greater than 20 or 30 in some embodiments. The seam 210 bounding an exterior edge of the manifold section 420 may bond the first layer 405 to the second layer 410 in some embodiments.

[0092] Figure 11 is another schematic cross-section view of the tissue interface 114 of Figure 9, illustrating additional details that may be associated with some embodiments. As shown in Figure 11, the fluid bridge 905 may span the seam 210 to pneumatically connect two of the interface sections 205. For example, adjacent interface sections 205 may not be entirely sealed across the side edges by the seams 210, but may have some pneumatic connection via the fluid bridges 905. In some embodiments in which the spacer manifold 415 comprises foam, the fluid bridges 905 may comprise portions of the spacer manifold 415 that are compressed or felted. For example, during welding to form the seams, portions of the seams may only be partially welded in a way that forms fluid bridges 905 comprising portions of the spacer manifold 415 that are felted (e.g. with a firmness less than that of the weld). In some embodiments, partial welding may occur when heat is applied to a compressed portion of the tissue interface 114, bonding the first layer 405 to the second layer 410 and felting the spacer manifold 415 therebetween. For example, the first layer 405 may be bonded to the second layer 410 indirectly by fusing to the spacer manifold 415 within the fluid bridges 905. In some embodiments, fluid bridges 905 may provide fluid flow channels between adjacent interface sections 205 across the seams which allow increased fluid flow between adjacent interface sections 205 over that provided by the seams. For example, the fluid bridge 905 may comprise felted foam between portions of the first layer 405 and the second layer 410, and the felted foam may pneumatically connect the adjacent interface sections 205 across the seam being spanned by the fluid bridge 905.

[0093] The thickness of the fluid bridge 905 may be less than that of the manifold sections 420. For example, compressing or felting portions of the spacer manifold 415 to form the fluid bridges 905 may result in a smaller thickness than that of the manifold sections 420. In some embodiments, the manifold sections 420 may comprise foam having a first density, and the fluid bridges 905 may comprise foam having a second density that is greater than the first density. For example, the fluid bridges 905 may comprise the same type of foam as the manifold sections 420, except that the foam of the fluid bridges 905 may be felted. In some embodiments, the fluid bridges 905 may have a felted foam firmness ranging from 2 to 10, from 2 to 5, from 2 to 3, from 3 to 5, from 3 to 10, from 5 to 7, or from 5 to 10 (for example, about 5). The process of felting the spacer manifold 415 in the fluid bridges 905 may alter certain properties. For example, compressing the spacer manifold 415 can reduce the size of the pores in the foam, reduce the thickness of the foam, reduce the risk of tissue in-growth, and/or reduce the fluid flow therethrough. In some embodiments, the manifold section 420 may be substantially uncompressed. In some embodiments, the entire spacer manifold 415 may be compressed or felted, for example with the manifold sections 420 and the fluid bridges 905 comprising felted foam.

[0094] Figure 12 is yet another schematic cross-section view of the tissue interface of Figure 9, illustrating additional details that may be associated with some embodiments. As shown in Figure 12, at least two fluid bridges 905 may extend from each interface section 205. The thickness T3 of each fluid bridge 905 may be less than the thickness T1 of the interface sections 205 and greater than the thickness T4 of the seam 210. For example, the thickness of the fluid bridges 905 may be about 1 millimeter to 5 millimeters (e.g. about 1.5 to 2 millimeters); the thickness of the interface sections 205 may be about 8 to 12 millimeters (e.g. about 10 millimeters); and the thickness of the seams 210 may be about 0.24 to 1 millimeter (e.g. less than about 0.5 millimeters). In some embodiments, the width W2 of the fluid bridges may be about 1 to 5 millimeters (e.g. about 1.5 to 2 millimeters). In some embodiments, the cross-sectional area of the fluid bridges 905 may be significantly less than the cross-sectional area of the related side of the interface section 205.

[0095] In some embodiments, separating an interface section 205 may expose only a small cross-section of the spacer manifold 415. For example, if the spacer manifold 415 comprises porous foam, upon separation of the interface sections 205, relatively small amounts of foam forming the one or more fluid bridges 905 may be exposed. In some embodiments, the interface sections 205 may be sealed about the perimeter by the seams 210 except for the fluid bridges 905. In some embodiments having a plurality of fluid bridges 905 between adjacent interface sections 205, the fluid bridges 905 may be evenly spaced along the seam 210 separating the adjacent interface sections 205. For example, Figure 12 illustrates two such evenly spaced fluid bridges 905. In some embodiments, before separation, the fluid bridges 905 may provide a fluid conduit between adjacent interface sections 205, while being configured to minimize risk of in-growth after separation. For example, after separation, exposure of the spacer manifold 415 may be limited to only a small portion within the fluid bridges

905, which may be compressed or felted material that is less conducive to tissue in-growth. In some embodiments, the seam 210 may bisect the thickness T1 of the interface sections, for example with the seam 210 extending approximately across the midpoint of the thickness T1 of the interface section 205. In some embodiments, the thickness T3 of the fluid bridges 905 may be centered on the seam 210 (e.g. about half of the thickness T3 of the fluid bridges 905 above the seam 210 and about half of the thickness T3 of the fluid bridges 905 below the seam 210, as shown in Figure 12).

[0096] In some embodiments, the barrier providing fluid control and/or preventing or reducing growth of tissue into the tissue interface may be integral to the manifold. For example, at least a first surface of the manifold may comprise an integral barrier, which may be a skin or thin film which may be integrally formed with the foam of the manifold. In some embodiments, the barrier may be substantially impermeable to liquid. In some embodiments, the barrier may be a skin formed of felted foam. In other embodiments, the barrier may comprise one or more separate film layers which may be attached to one or more surface of the manifold (e.g. as shown in Figure 10). In some embodiments, the fluid restrictions may be located in at least the first surface of the tissue interface, for example passing through the integral barrier to be in fluid communication with the remainder of the manifold. In some embodiments, the fluid restrictions may be fluid valves. In some embodiments, the fluid valves may be coextensive with at least the first surface. The fluid bridges in some embodiments may provide fluid connection between interface sections, for example through the barrier and/or the seams.

[0097] Figure 13 is a chart relating to an example of the tissue interface without fluid bridges between interface sections, illustrating additional details that may be associated with some embodiments. Figure 13 illustrates an exemplary pressure drop that may occur during usage of a particular exemplary tissue interface embodiment. In Figure 13, the Trac line illustrates the initial negative pressure applied from the source (e.g. to the exterior surface of the tissue interface), while the Instil line illustrates the pressure at the surface of the tissue interface located farthest away from the introduction of negative pressure (e.g. in proximity to the tissue site). By comparing the two lines, the pressure drop (e.g. the difference between the Trac and Instil lines) due to the tissue interface can be seen.

[0098] Figure 14 is a chart relating to another example of the tissue interface with two (e.g. dual) 2 millimeter by 2 millimeter fluid bridges (e.g. with felted foam firmness of about 5) between adjacent interface sections, illustrating additional details that may be associated with some embodiments. Figure 14 illustrates an exemplary pressure drop that may occur during usage of this particular exemplary tissue interface embodiment, which for example may have all the same basic configurations as the tissue interface in Figure 13 except for the additional presence of the fluid bridges. In Figure 14, the Trac line illustrates the initial negative pressure applied from the source (e.g. to the exterior surface of the tissue interface), while the Instil line illustrates the pressure at the surface of the tissue interface located farthest away from the introduction of negative pressure (e.g. in proximity to

the tissue site). A comparison of Figure 14 with respect to Figure 13 may illustrate via experimental data that the fluid bridges may significantly reduce pressure drop during usage of the tissue interface. So in considering the data in the figures, the example of Figure 14 (e.g. with bridges) allows more of the provided negative pressure to be applied to the tissue site. This comparison may highlight the improved manifolding offered by tissue interface embodiments having fluid bridges spanning seams between interface sections.

[0099] Some embodiments may be directed to a method of forming a tissue interface for a dressing, and the methods may comprise the steps of: providing a manifold, a first polymer film layer, and a second polymer film layer; positioning the manifold between the first polymer film layer and the second polymer film layer; bonding the first polymer film layer to the second polymer film layer to form seams defining separable sections of the manifold; and forming one or more fluid bridges through each seam between adjacent separable sections. In some embodiments, bonding the first polymer film layer to the second polymer film layer may comprise welding the first polymer film layer to the second polymer film layer. In some embodiments, the manifold may comprise foam, and the fluid bridges may be formed by felting portions of the foam within the seams. In some embodiments, forming the fluid bridges may occur during bonding to form the seams. For example, felting may occur as part of the seam formation process. In some embodiments, the fluid bridges may be formed by partially welding the first polymer film layer to the second polymer film layer, with the manifold between the first polymer film layer and the second polymer film layer. The partial weld may felt foam to form the fluid bridges during the seam formation process. In some embodiments, forming the one or more fluid bridges may comprise leaving gaps in the welds of the seams.

[00100] In some embodiments, forming the one or more fluid bridges may be part of and/or occur at the time of bonding the first polymer film layer to the second polymer film layer to form seams defining separable sections of the manifold. For example, forming the one or more fluid bridges may comprise configuring a bonding tool to define the fluid bridges when forming the seams, and then the remainder of formation of the fluid bridges may occur simultaneous with the formation of the seams. Alternatively, forming the one or more fluid bridges may comprise forming a plurality of holes in the seams that are cratered spaced, for example at about 3 to 4 millimeter pitches. The plurality of holes may allow for vertical pressure communication and/or better lateral communication of pressure within the tissue interface. For example, the holes may act as islands for pressure manifolding. In some embodiments, the plurality of holes may be formed using a perforation tool.

[00101] In some embodiments, the method may further comprise perforating some of the seams to form perforation lines between adjacent separable sections. For example, perforation lines may be formed along the longitudinal centerline of the seams between adjacent separable sections. Some method embodiments may further comprise forming a plurality of fluid restrictions in the first polymer film layer and/or the second polymer film layer. In some embodiments, each separable section

may be bounded by the seams, the portion of the manifold between the seams may form a plurality of manifold sections, and the fluid restrictions may be coextensive with the manifold sections. In some embodiments, forming the plurality of fluid restrictions may occur after bonding the first polymer film layer to the second polymer film layer.

5 **[00102]** In some embodiments, a method for treating a tissue site may include excising separable sections of a dressing tissue interface based upon at least one of a size and shape of the tissue site being treated. In some embodiments, excising separable sections may not expose any manifold section within the dressing, for example due to bounding seams about the manifold section. In some
10 embodiments, excising separable sections may not expose unfelted foam of the manifold. For example, if the tissue interface comprises fluid bridges spanning the seams between separable sections, then excising separable sections may only expose felted foam within the fluid bridges and/or may not expose unfelted foam of the manifold sections. In some embodiments, excising separable sections may comprise cutting or tearing a seam or seal between the separable sections. For example, excising may
15 occur along a perforation line within the seam. In some embodiments, the perforation line may be located in proximity to the centerline of the seam. The method may also include applying the dressing to fill and/or cover the tissue site, and sealing the dressing to epidermis adjacent to the tissue site. In some embodiments, applying the dressing may comprise applying only a single layer of tissue interface to the tissue site, while providing effective manifolding. In other embodiments, applying the dressing may comprise stacking two or more layers of tissue interface and/or folding a tissue interface to form
20 two or more layers at the tissue site. The method may further include fluidly coupling the dressing to a negative-pressure source, and applying negative pressure from the negative-pressure source to the dressing.

[00103] The systems, apparatuses, and methods described herein may provide significant advantages. For example, in some embodiments, the seams 210 may be wide enough to allow the
25 interface sections 205 to be cut apart or otherwise separated so as to obtain a tissue interface 114 having a desired size and shape. For example, tissue interface 114 can be sized and shaped to fill deep and/or irregular wounds by separating the interface sections 205. Moreover, some embodiments of the tissue interface 114 may be separated without increasing risk of tissue growth into the tissue interface 114, which can allow the dressing to be worn for about 3 to about 10 days (e.g., about 7 days).

30 **[00104]** In some embodiments, the tissue interface 114 may be configured to minimize pressure drops across the manifold sections 215, to ensure that manifolding is not unduly compromised by the seams 210 between the manifold sections 215. For example, the configuration may enable the tissue interface 114 to be effectively used over a larger area and/or in deeper wounds, and may be particularly helpful if the tissue interface 114 needs to be used as a single layer over a large area. In
35 some embodiments, the tissue interface may be configured to increase pneumatic connection between manifold sections (e.g. across the seams). In some embodiments, the tissue interface 114 may be

configured to minimize risk of tissue in-growth, for example if the tissue interface is left in place within a wound for extended periods. For example, separating one or more interface sections 205 while shaping and/or sizing the tissue interface 114 may occur without exposing material that can increase the risk of tissue in-growth, may expose only a small cross-section of the material, and/or may expose only low-risk material. In particular, the tissue interface 114 configuration of some embodiments may minimize or prevent in-growth if an edge of a separated interface section 205 is placed in contact with tissue.

[00105] 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. 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 115, or both may be separated from other components for manufacture or sale. In other example configurations, the tissue interface 114 may also be manufactured, configured, assembled, or sold independently of other components.

[00106] 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

What is claimed is:

1. A dressing for treating a tissue site with negative pressure, the dressing comprising:
 - 5 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 adjacent to at least the first surface;
a plurality of bonds between the first layer and the second layer, the plurality of bonds
10 forming seams defining separable sections of the manifold; and
one or more fluid bridges through at least some of the seams.
2. The dressing of claim 1, wherein:
 - the plurality of bonds form a seal between adjacent separable sections of the manifold; and
the one or more fluid bridges are configured to provide fluid communication through the
15 seal.
3. The dressing of claim 1, wherein:
 - the plurality of bonds form a seal between adjacent separable sections of the manifold; and
the one or more fluid bridges are configured to provide fluid communication across the
seams.
- 20 4. The dressing of claims 1, wherein the one or more fluid bridges are configured to provide
substantially more fluid communication between adjacent separable sections than provided by the
seams.
5. The dressing of claims 1-4, wherein:
 - 25 the plurality of bonds comprises welds between the first layer and the second layer; and
the one or more fluid bridges are disposed between welds.
6. The dressing of claims 1-4, wherein:
 - the plurality of bonds comprises welds between the first layer and the second layer; and
the one or more fluid bridges are formed by portions of the seam that are partially welded.
- 30 7. The dressing of claims 1-4, wherein:
 - the plurality of bonds comprises welds between the first layer and the second layer; and
the one or more fluid bridges are formed by portions of the seam that are not welded.

8. The dressing of claims 5-7, wherein the one or more fluid bridges are formed by gaps in the welds.
9. The dressing of claims 5-8, wherein the welds locally compress the manifold at the seams.
10. The dressing of claims 1-9, wherein:
 - 5 the manifold comprises foam; and
 - the one or more fluid bridges comprise portions of the manifold that are felted.
11. The dressing of claim 10, wherein the one or more fluid bridges have a felted foam firmness ranging from 2 to 10.
12. The dressing of claims 1-11, wherein the one or more fluid bridges each have a width ranging
10 from about 1-5 millimeters and a thickness ranging from about 1-5 millimeters.
13. The dressing of claims 1-11, wherein the one or more fluid bridges each have a width of about 2 millimeters and a thickness of about 1.5 millimeters.
14. The dressing of claims 1-13, wherein the seams each have a width ranging from about 2-5 millimeters.
- 15 15. The dressing of claims 1-13, wherein the seams each have a width of about 5 millimeters.
16. The dressing of claims 1-15, wherein the first layer and the second layer each comprise polyurethane film.
17. The dressing of claims 1-16, wherein the first layer and the second layer each have a thickness of about 75 micron.
- 20 18. The dressing of claims 1-17, wherein the fluid restrictions are located in both the first layer and the second layer.
19. The dressing of claims 5-18, wherein the welds between the first layer and the second layer comprise portions of the manifold between the first layer and the second layer at the seams.
20. The dressing of claims 1-19, wherein:
 - 25 each separable section is bounded by the seams; and
 - the portion of the manifold between the seams forms a plurality of manifold sections.
21. The dressing of claims 1-20, wherein the seams are configured to allow separation of the separable sections without exposing the manifold sections.

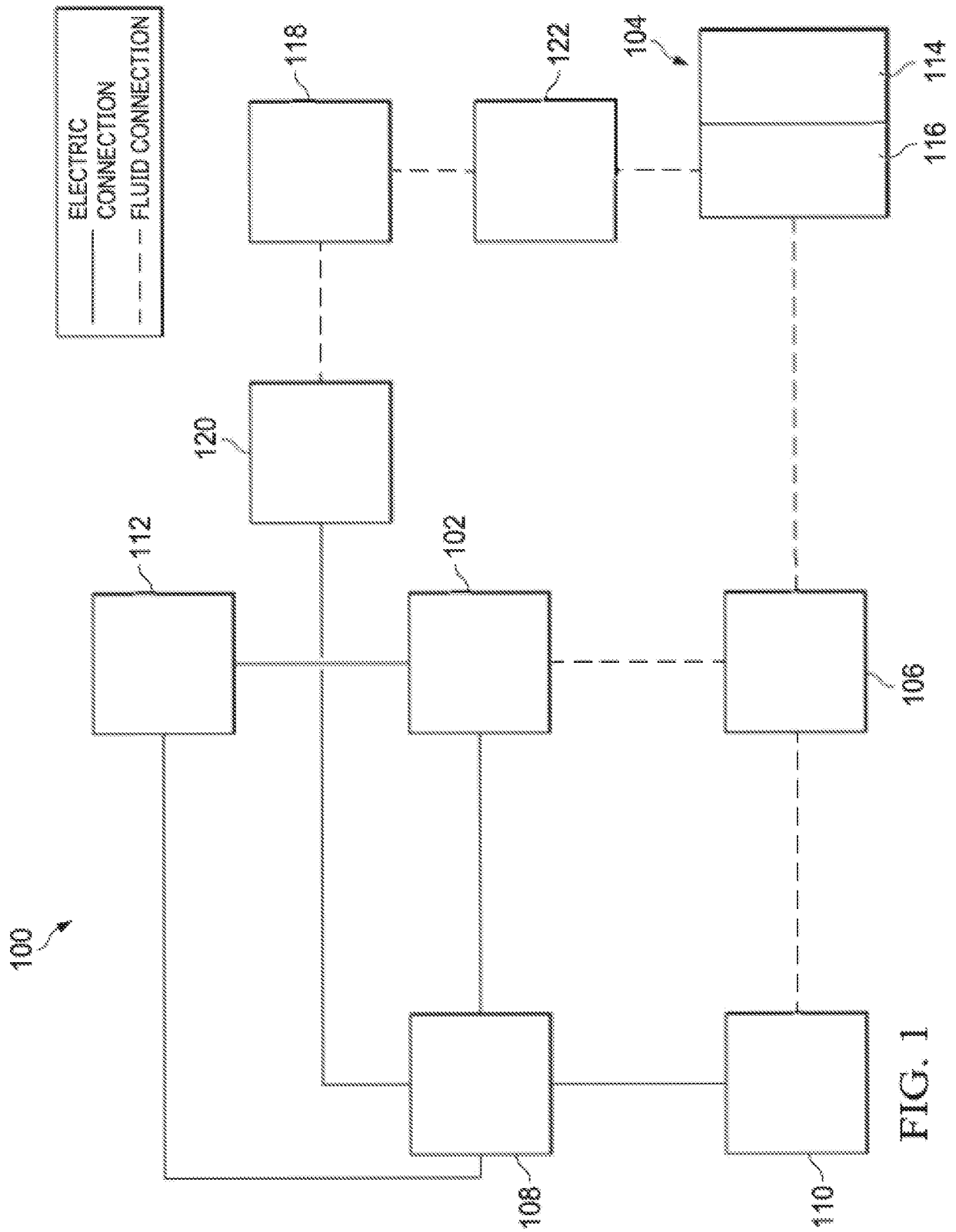
22. The dressing of claims 1-21, wherein the seam thickness is about 1mm or less, and wherein the manifold section thickness is about 10 millimeters.
23. The dressing of claims 1-22, wherein the manifold section thickness is not less than 5 millimeters.
24. The dressing of claims 1-23, wherein:
- 5 the manifold comprises foam; and
- the one or more fluid bridges each comprise felted foam.
25. The dressing of claims 1-24, wherein each separable section is in fluid communication with at least two other adjacent separable sections via fluid bridges.
26. The dressing of claims 1-25, wherein at least two fluid bridges span each seam between adjacent
- 10 separable sections.
27. The dressing of claims 1-26, wherein each seam between adjacent separable sections comprises a perforation line located approximately along a centerline of the seam between the adjacent separable sections.
28. The dressing of claims 1-27, wherein the polymer film is hydrophobic.
- 15 29. The dressing of claims 1-28, wherein the polymer film is a polyethylene film.
30. The dressing of claims 1-29, wherein the plurality of fluid restrictions comprise a plurality of slots, each of the slots having a length less than 4 millimeters.
31. The dressing of claims 1-30, wherein the plurality of fluid restrictions comprise a plurality of slots, each of the slots having a width less than 2 millimeters.
- 20 32. The dressing of claim 31, wherein the width is less than 1 millimeter.
33. The dressing of claims 30-32, wherein the length is less than 3 millimeters.
34. The dressing of claims 30-33, wherein the width is at least 0.5 millimeters.
35. The dressing of claims 30-34, wherein the length is at least 2 millimeters.
- 25 36. The dressing of claims 1-35, wherein the plurality of fluid restrictions are coextensive with the polymer film.
37. The dressing of claims 20-35, wherein the plurality of fluid restrictions are coextensive with the manifold sections.

38. The dressing of claim 1-37, wherein the plurality of fluid restrictions are distributed across the polymer film in a uniform pattern.
39. The dressing of claims 1-38, wherein the first layer is coextensive with the second layer.
40. The dressing of claims 1-39, wherein each of the separable sections comprises the same size and
5 shape.
41. The dressing of claims 10-40, wherein the foam of the manifold comprises open-cell foam.
42. The dressing of claims 10-41, wherein the foam of the manifold is hydrophobic.
43. The dressing of claims 10-42, wherein the foam of the manifold comprises polyurethane foam.
44. The dressing of claims 1-43, wherein the one or more fluid bridges each comprise a plurality of
10 holes in the seam that are crater spaced at about 3 to about 4 millimeter pitches.
45. The dressing of claims 1-44, further comprising a separate drape.
46. The dressing of claims 1-45, further comprising a separate port configured to facilitate coupling a fluid conductor to the dressing.
47. A method of forming a tissue interface for a dressing for treating a tissue site with negative
15 pressure, the method comprising the steps of:
 providing a manifold, a first polymer film layer, and a second polymer film layer;
 positioning the manifold between the first polymer film layer and the second polymer film
 layer;
 bonding the first polymer film layer to the second polymer film layer to form seams
20 defining separable sections of the manifold; and
 forming one or more fluid bridges through each seam between adjacent separable
 sections.
48. The method of claim 47, wherein bonding the first polymer film layer to the second polymer film layer comprises welding the first polymer film layer to the second polymer film layer.
- 25 49. The method of claims 47-48, wherein:
 the manifold comprises foam; and
 the fluid bridges are formed by felting portions of the foam within the seams.

50. The method of claims 47-49, wherein the fluid bridges are formed by partially welding the first polymer film layer to the second polymer film layer with the manifold between the first polymer film layer and the second polymer film layer.
51. The method of claims 47-50, wherein forming the one or more fluid bridges comprises leaving
5 gaps in the welds of the seams.
52. The method of claims 47-51, wherein forming the one or more fluid bridges comprises configuring a bonding tool to define the fluid bridges when forming the seams.
53. The method of claims 47-51, wherein forming the one or more fluid bridges comprises forming a plurality of holes in the seams that are crater spaced at about 3 to about 4 millimeter pitches.
- 10 54. The method of claims 47-53, further comprising perforating the seams to form perforation lines between adjacent separable sections.
55. The method of claims 47-54, further comprising forming a plurality of fluid restrictions in the first polymer film layer.
56. The method of claim 55, further comprising forming a plurality of fluid restrictions in the second
15 polymer film layer.
57. The method of claims 55-56, wherein:
each separable section is bounded by the seams;
the portion of the manifold between the seams forms a plurality of manifold sections; and
the fluid restrictions are coextensive with the manifold sections.
- 20 58. The method of claims 55-57, wherein forming the plurality of fluid restrictions occurs after bonding the first polymer film layer to the second polymer film layer.
59. A method for treating a tissue site using a dressing having a manifold, the method comprising the steps of:
excising separable sections of the dressing based upon at least one of a size and shape of
25 the tissue site, wherein excising separable sections does not expose unfelted foam of the manifold;
applying the dressing to fill or cover the tissue site;
sealing the dressing to epidermis adjacent to the tissue site;
fluidly coupling the dressing to a negative-pressure source; and
30 applying negative pressure from the negative-pressure source to the dressing.

60. The method of claim 59, wherein excising separable sections comprises cutting or tearing a seam between the separable sections along a perforation line within the seam.
61. The method of claims 59-60, wherein sealing the dressing comprises applying a separate cover over the manifold.
- 5 62. The method of claims 59-61, wherein fluidly coupling the dressing comprises applying a separate port to the dressing and fluidly coupling the port to the negative-pressure source, wherein the applied port provides fluid communication between the negative-pressure source and the manifold.
63. The method of claims 59-62, further comprising delivering instillation solution to the dressing.
- 10 64. The method of claims 47-63, using or relating to the dressing embodiments of claims 1-46.
65. 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 plurality of fluid valves adjacent to at least the first surface;
a plurality of bonds between the first surface and the second surface, the plurality of bonds
15 forming seams defining separable sections of the manifold; and
one or more fluid bridges through at least some of the seams.
66. The dressing of claim 65, wherein:
the plurality of bonds form a seal between adjacent separable sections of the manifold; and
the one or more fluid bridges are configured to provide fluid communication through the
20 seal.
67. The dressing of claim 65, wherein:
the plurality of bonds form a seal between adjacent separable sections of the manifold; and
the one or more fluid bridges are configured to provide fluid communication across the
seams.
- 25 68. The dressing of claims 65-67, wherein the plurality of bonds comprise welds between the first surface and the second surface; and the one or more fluid bridges are formed by portions of the seam that are only partially welded.
69. The dressing of claims 65-68, wherein:
the manifold comprises foam; and
30 the one or more fluid bridges comprise portions of the manifold that are felted.

70. The dressing of claim 69, wherein the one or more fluid bridges have a felted foam firmness ranging from 2 to 5.
71. The dressing of claim 65-70, wherein the manifold further comprises an integral barrier on at least the first surface.
- 5 72. The dressing of claims 65-70, further comprising 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, the fluid valves being located in the polymer film, and the plurality of bonds joining the first layer and the second layer.
- 10 73. The dressing of claim 72, wherein the manifold comprises a spacer manifold disposed between the first layer and the second layer.
74. The systems, apparatuses, and methods substantially as described above.



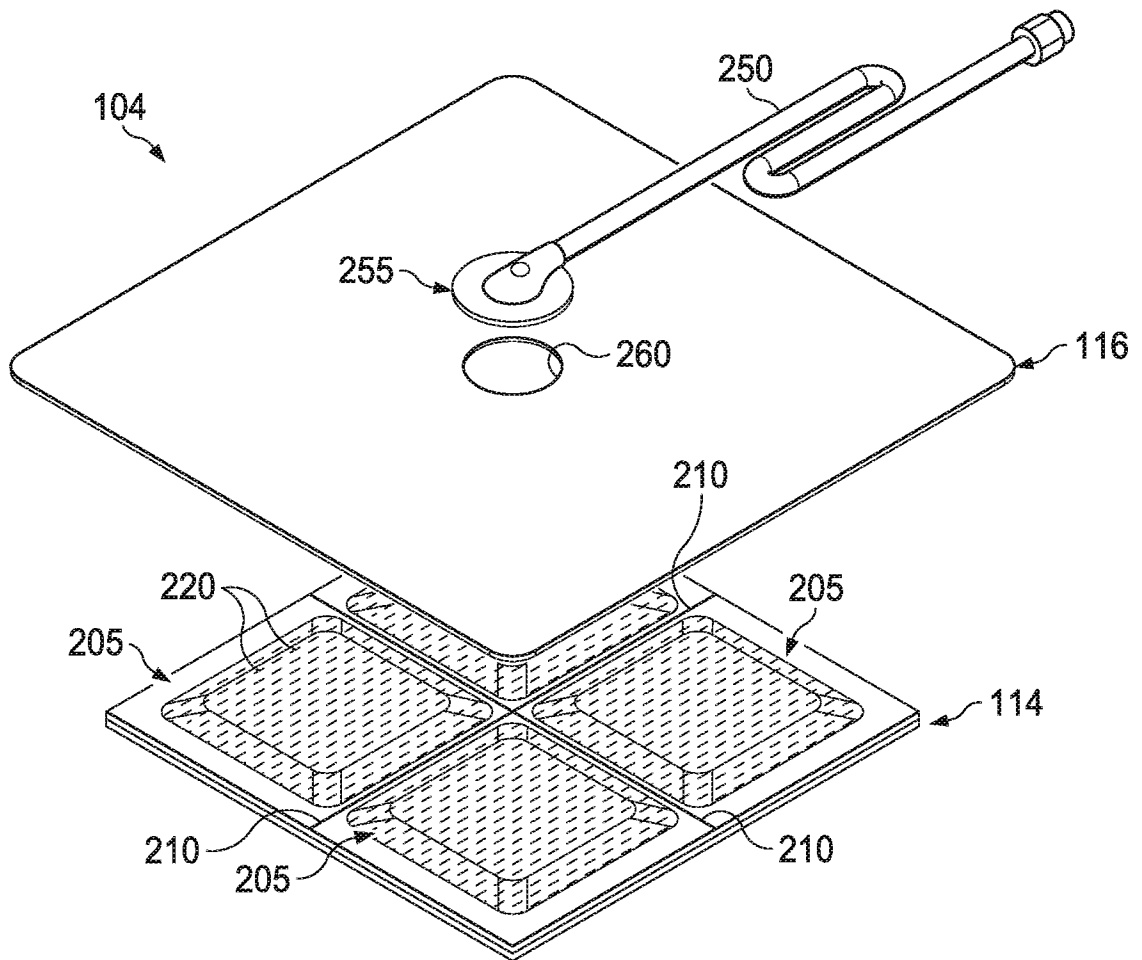


FIG. 2

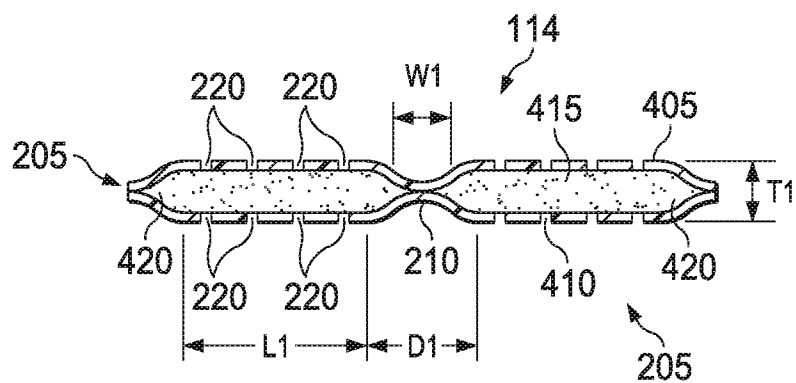
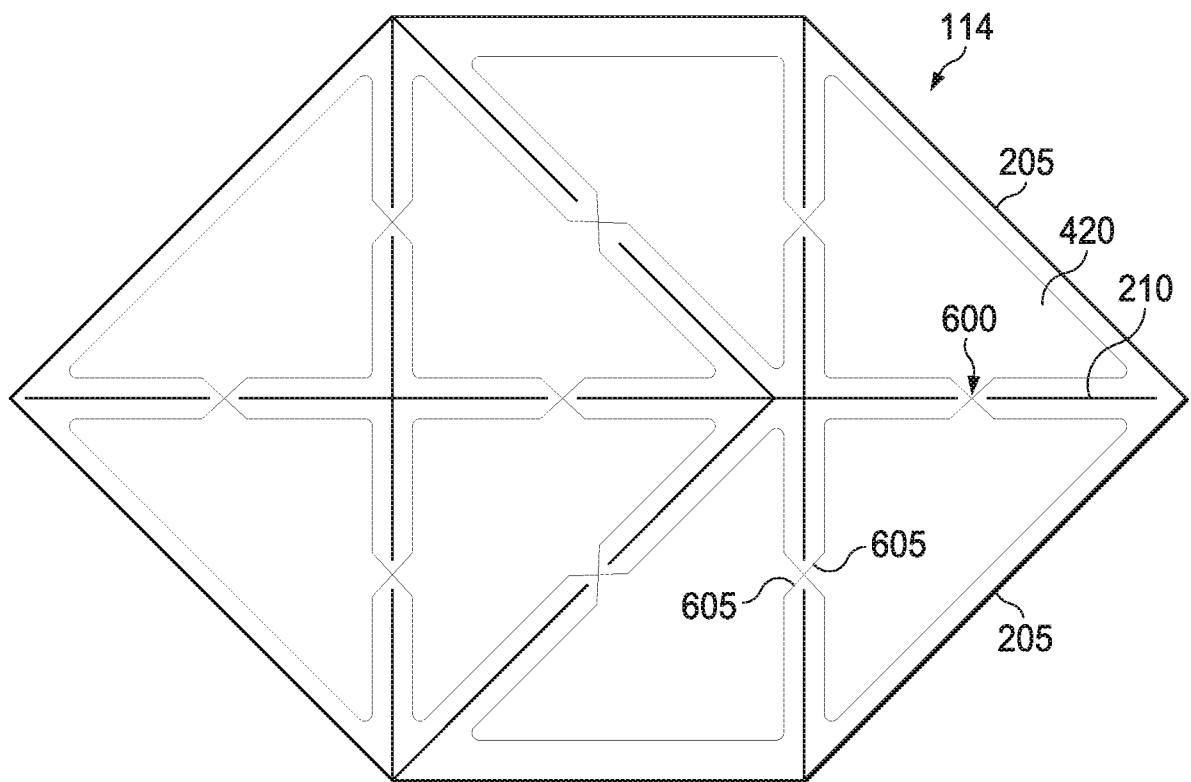
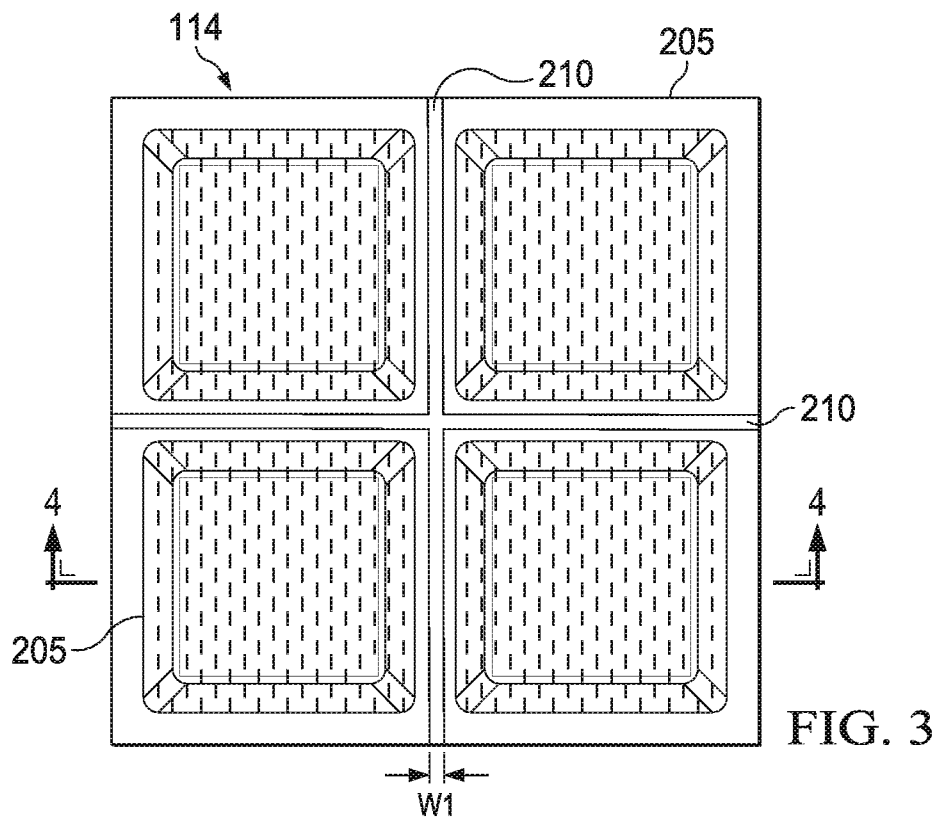


FIG. 4



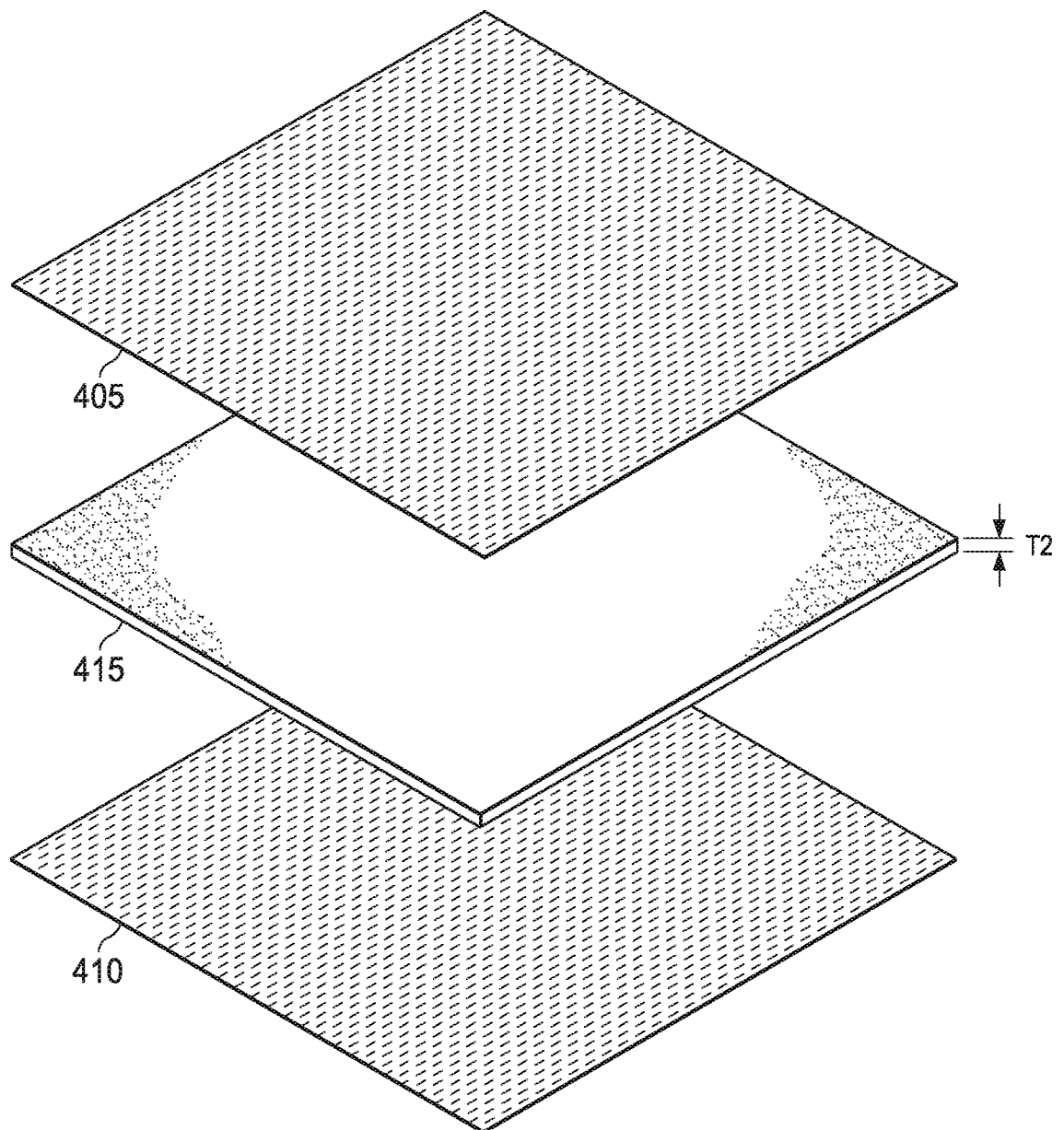
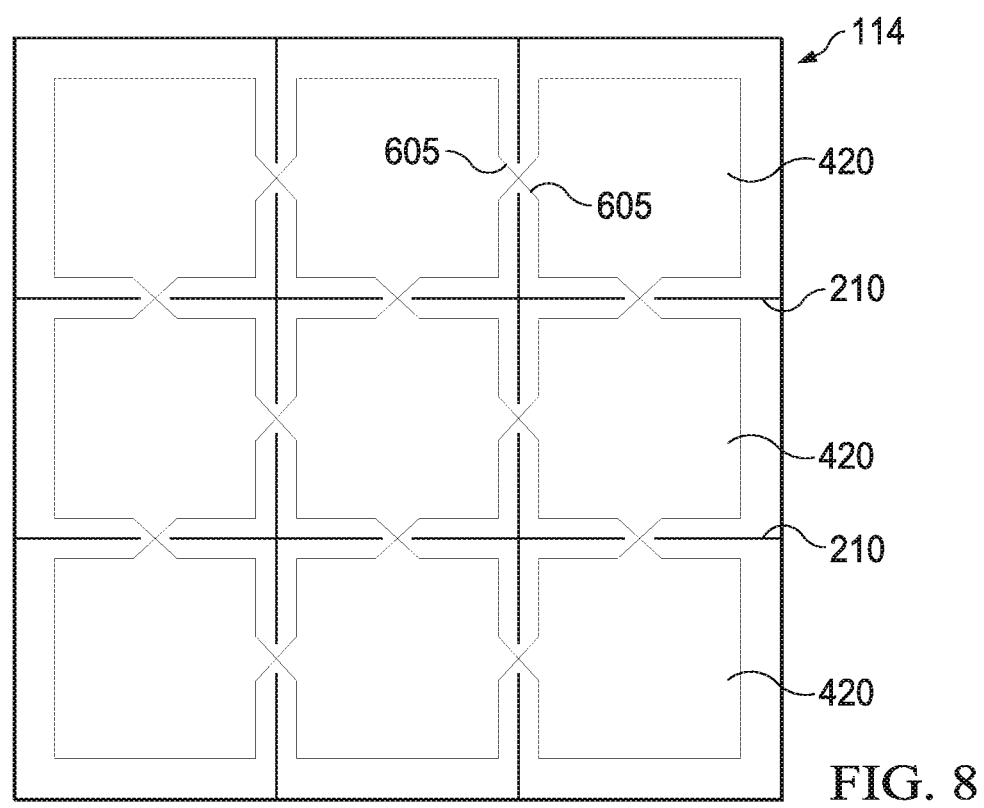
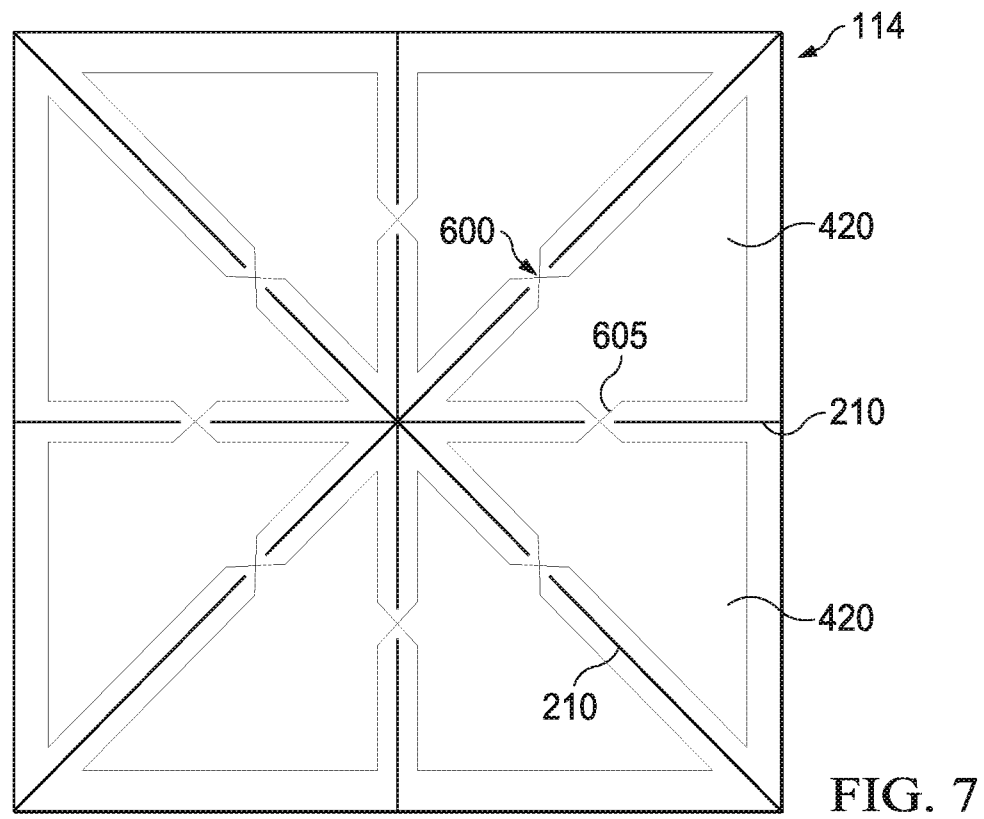


FIG. 5



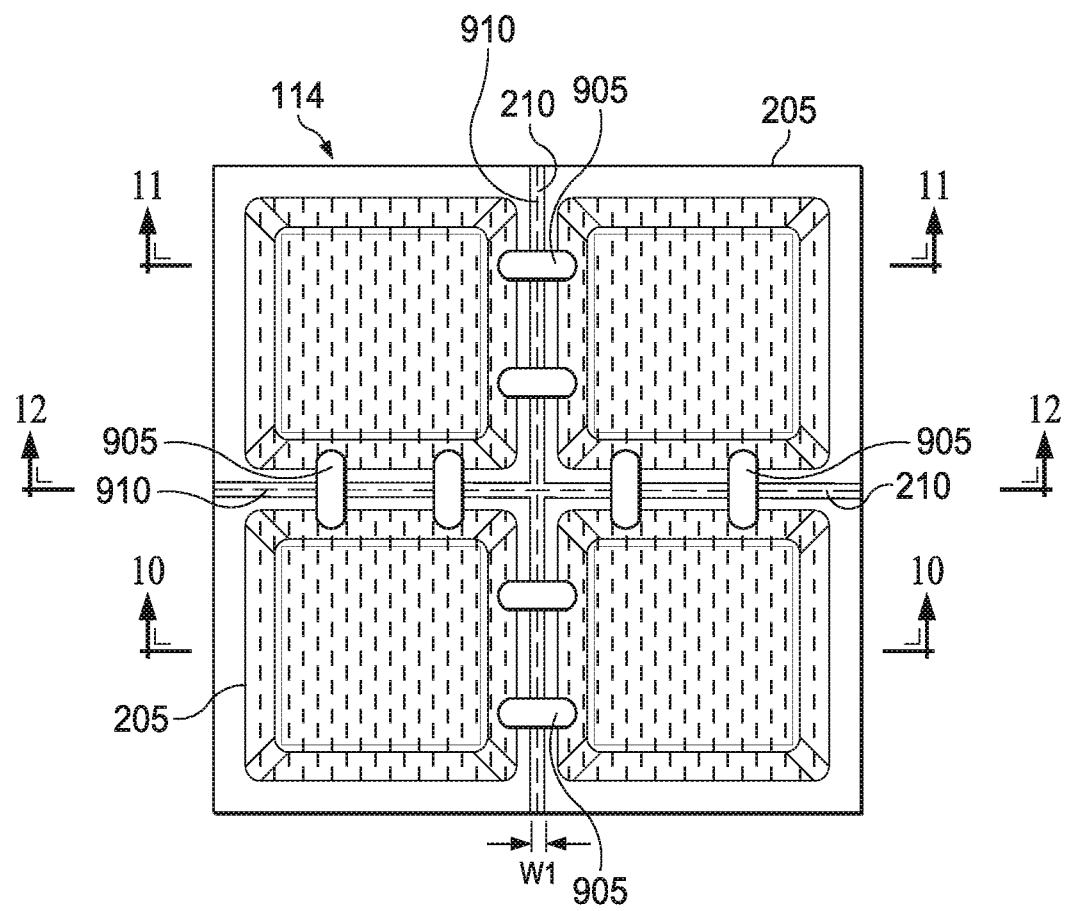


FIG. 9

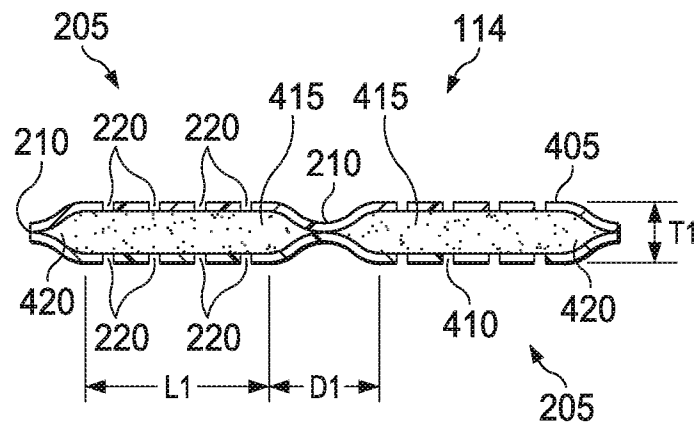


FIG. 10

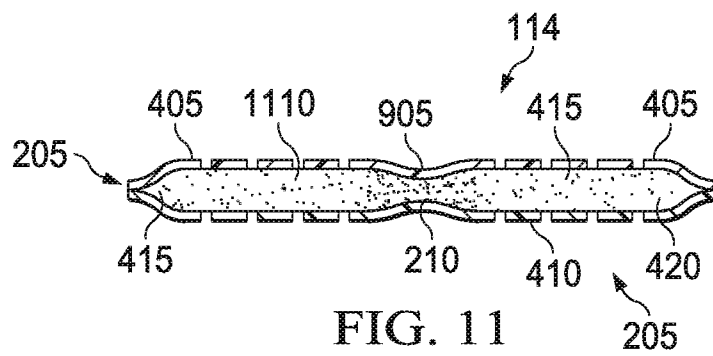


FIG. 11

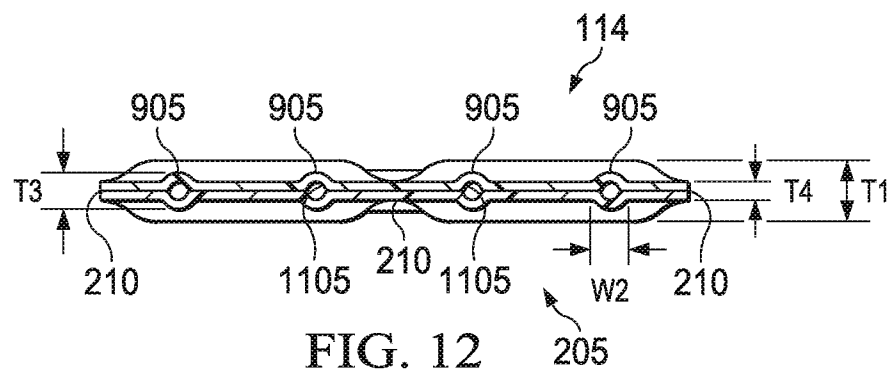


FIG. 12

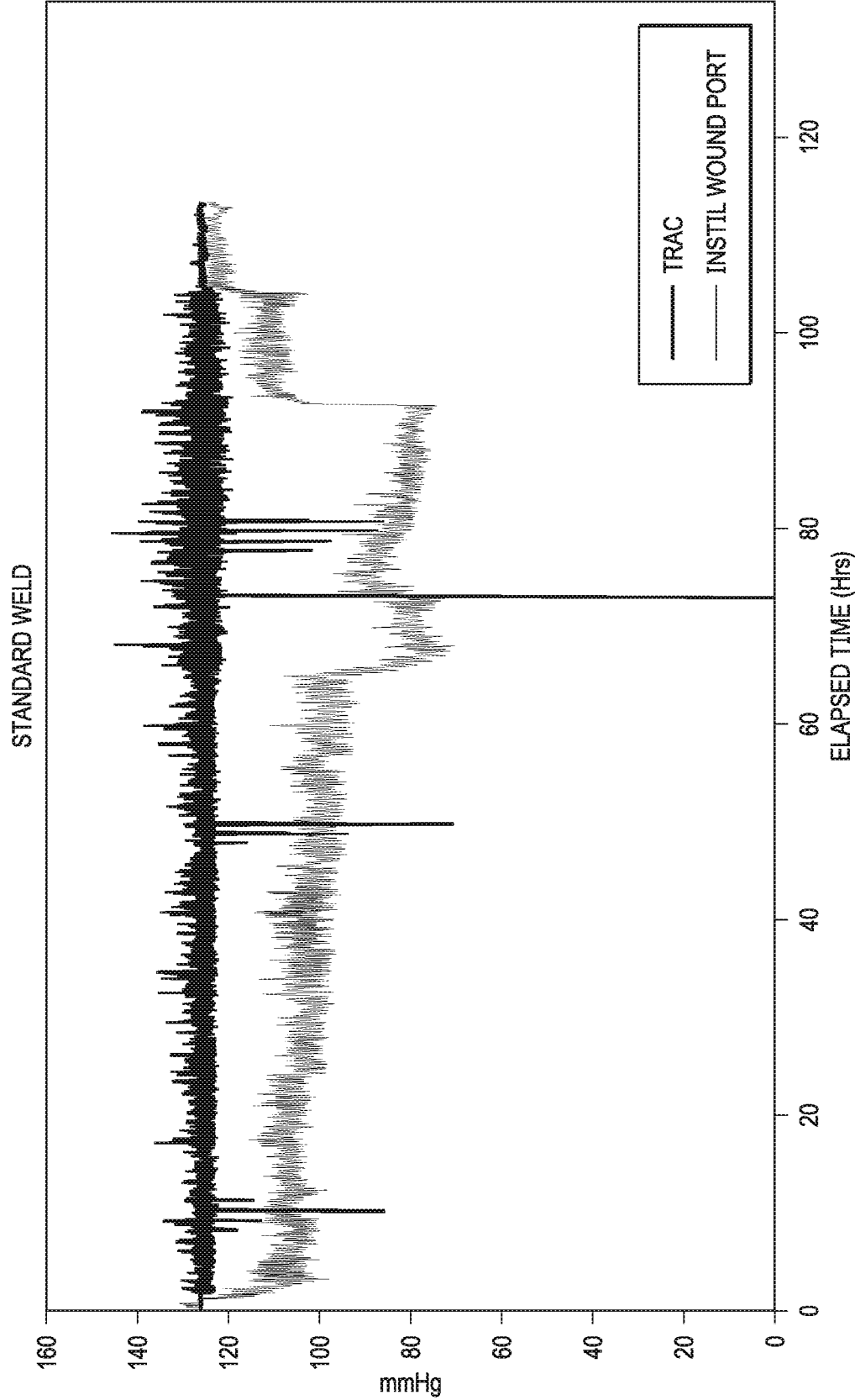


FIG. 13

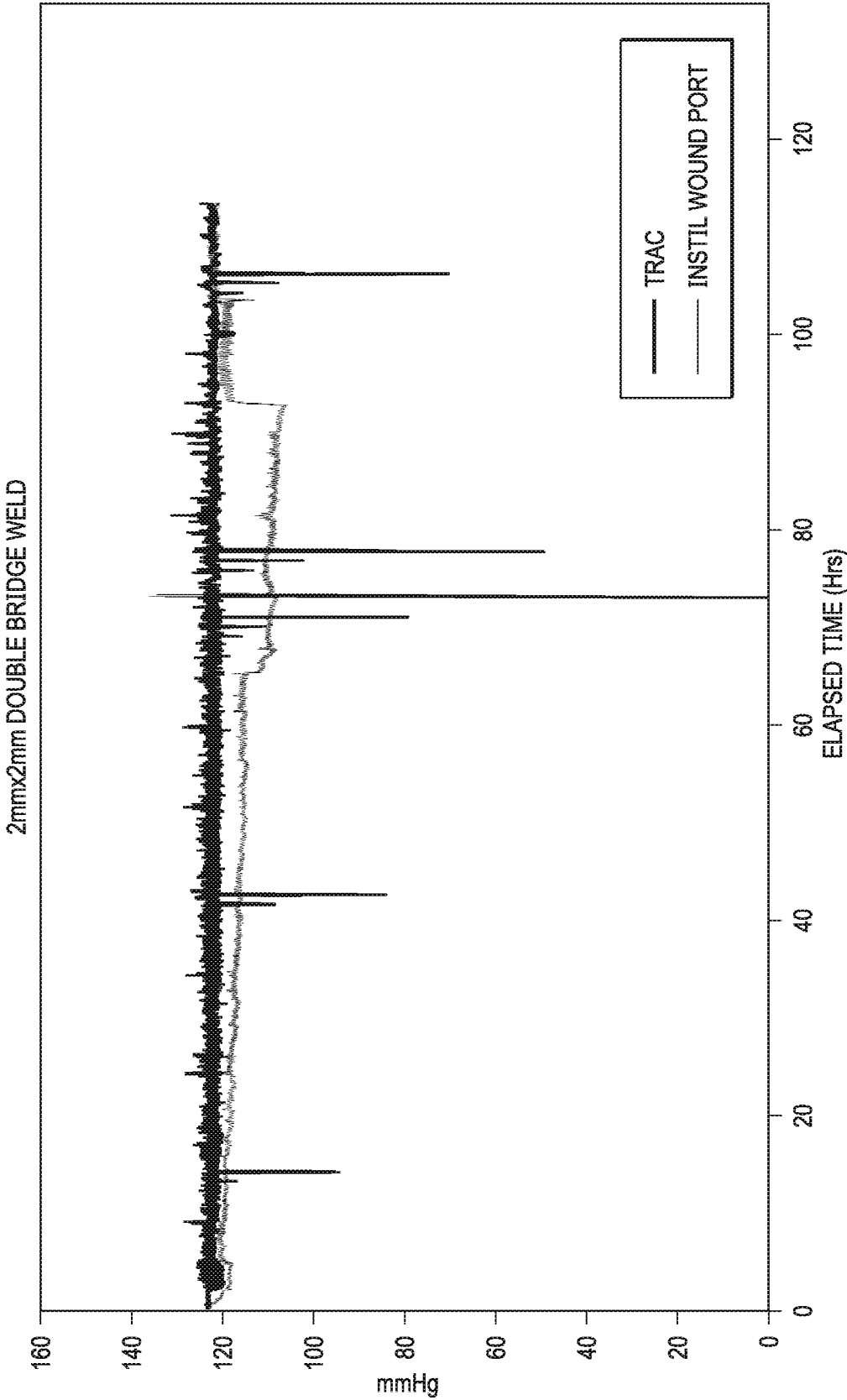


FIG. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2020/057337

A. CLASSIFICATION OF SUBJECT MATTER INV. A61F13/00 A61F13/02 A61M1/00 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61F A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2018/226650 A1 (KCI LICENSING INC [US]) 13 December 2018 (2018-12-13) claims 1-71; figures 1-14 paragraphs [0002], [0007], [0008], [0009], [0064] - [0070] -----	1-58, 65-73
A	WO 2018/094061 A1 (KCI LICENSING INC [US]) 24 May 2018 (2018-05-24) claims 1-48 -----	1-58, 65-73
A	US 2018/214315 A1 (MERCER DAVID RICHARD [US] ET AL) 2 August 2018 (2018-08-02) paragraphs [0066] - [0068]; figure 3 -----	1-58, 65-73
<input style="width: 20px; height: 20px; margin-right: 5px;" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" style="width: 20px; height: 20px; margin-right: 5px;" type="checkbox"/> See patent family annex.		
* Special categories of cited documents :		
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family	
Date of the actual completion of the international search 16 October 2020	Date of mailing of the international search report 26/10/2020	
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Beins, Ulrika	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2020/057337

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

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

1. ☒ Claims Nos.: 59-64, 74
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2020/057337

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