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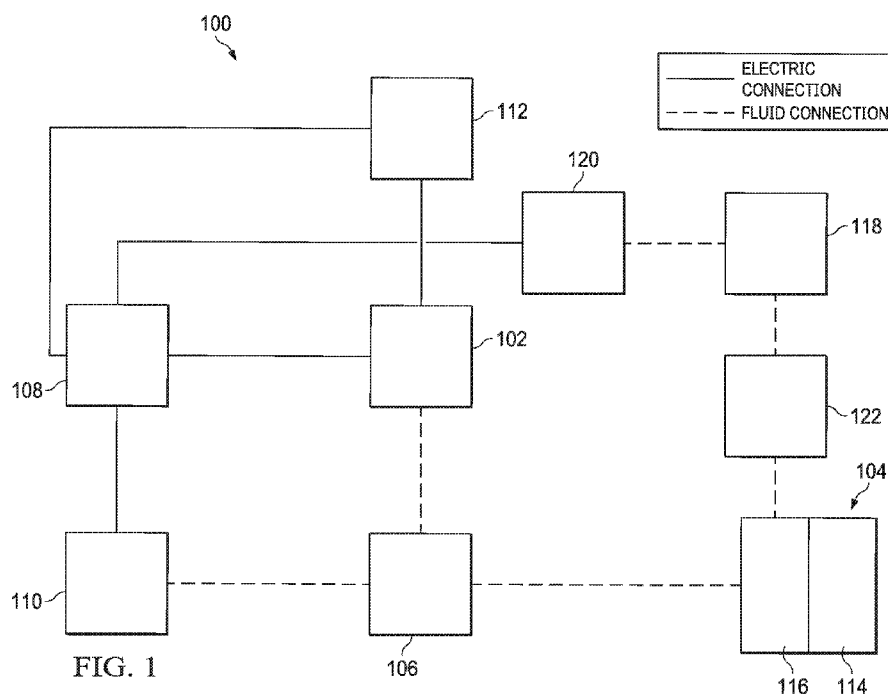
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(54) Title: TISSUE INTERFACE WITH FOLD-RETAINING FASTENER



(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. In some embodiments, one or more fasteners on a surface of the tissue interface may be configured to retain the tissue interface in a folded configuration. In some embodiments, each fastener may include two fastener elements. Fastener elements may be configured to only bond to each other in some embodiments.

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TISSUE INTERFACE WITH FOLD-RETAINING FASTENER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Provisional Application No. 62/884,564, 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 dressing tissue interface may include one or more retainers or fasteners on at least one exterior surface, which may be configured to retain the dressing in a folded configuration. For example, the dressing tissue interface may be folded as part of the shaping process to better fill a wound, and the one or more fasteners may help hold the folded shape at least for the amount of time it takes to place and/or cover the tissue interface. In some embodiments, the one or more fasteners may comprise adhesive patches. For example, the adhesive may comprise low tack acrylic, polyurethanes, or silicones. In some embodiments, the adhesives may comprise double-sided film, transfer adhesives, or hot melt pads. In some embodiments, the fasteners may be perforated, for example to match underlying fluid restrictions.

[0009] In some embodiments, each fastener may comprise two fastener elements. It may be desirable in some embodiments to prevent the fasteners from inadvertently sticking to other surfaces, such as the wound surface. Some embodiments are configured so that fastener elements only bond to each other. For example, the fastener elements may comprise cold seal adhesive. In other embodiments, the fastener elements may comprise hook-and-loop features. In some embodiments, a

plurality of fasteners or fastener elements may be located on a common surface of the dressing tissue interface, for example spaced to allow one or more fold configurations for the dressing tissue interface.

[0010] More generally, some embodiments may relate to dressings for treating a tissue site with negative pressure, and the dressing embodiments may comprise: a tissue interface having a first surface and a second surface; a plurality of fluid valves in at least the first surface; and at least one fastener attached to the second surface and configured to retain a first portion of the second surface to a second portion of the second surface. In some embodiments, the fastener may comprise an adhesive. For example, the fastener may comprise one or more of the following: an acrylic adhesive, a polyurethane adhesive, a silicone adhesive, a film having an adhesive on a first side and on a second side, a cold-seal adhesive, an adhesive that is soluble in liquid, and an adhesive having a tack of about 0.8 – 7 N/25mm. In some embodiments, each fastener may comprise two fastener elements, and each fastener element may comprise the cold-seal adhesive. In some embodiments, the fastener may comprise a plurality of flexible hooks attached to the first portion and a plurality of flexible loops attached to the second portion. The tissue interface may comprise a plurality of separable sections in some embodiments. For example, the first portion may comprise at least one separable section (e.g. a first separable section), and the second portion may comprise at least one different separable section (e.g. a second separable section). In some embodiments, the tissue interface may comprise: a spacer manifold; a first film layer adjacent to the spacer manifold and forming the first surface of the tissue interface; and a second film layer adjacent to the spacer manifold and forming the second surface of the tissue interface. A plurality of bonds between the first film layer and the second film layer may define the plurality of separable sections in some embodiments.

[0011] Other exemplary embodiments may relate to a dressing comprising: a manifold comprising a first surface and a second surface opposite the first surface; a first layer adjacent to the first surface and a second layer adjacent to the second surface, the first layer and the second layer each comprising a polymer film; a plurality of fluid restrictions in the polymer film adjacent to at least the first surface; a plurality of bonds between the first layer and the second layer, the plurality of bonds defining manifold sections; and at least one fastener attached to the second layer and configured to retain a first portion of the second layer to a second portion of the second layer. In some embodiments, the plurality of bonds may form seams between the manifold sections. For example, the seams may bound each manifold section about a perimeter. In some embodiments, the seams may define separable sections, each comprising one of the manifold sections. In some embodiments, the seams may be configured to allow separation of the separable sections without exposing the manifold sections.

[0012] In some embodiments, the dressing may be foldable. For example, the dressing may be sufficiently flexible to allow the first portion of the second layer to contact the second portion of the second layer when folded. In some embodiments, the seams may be more flexible than the manifold sections, which may allow easy folding of the dressing along the seams. In some embodiments, each

fastener may comprise a first fastener element and a second fastener element. For example, the first fastener element and the second fastener element may both be attached to a common outer surface, for example the outer surface of the second layer. In some embodiments having multiple fasteners, each of the first fastener elements may be configured to couple to one of the second fastener elements, and/or each of the second fastener elements may be configured to couple to one of the plurality of first fastener elements. In some embodiments, the first fastener element may be attached to the first portion and the second fastener element may be attached to the second portion. For example, the first fastener element may be attached to a first separable section and the second fastener element may be attached to a second separable section.

[0013] In some embodiments, the separable sections may form rows, and each row of separable sections may comprise at least one fastener. For example in embodiments in which each fastener comprises a first fastener element and a second fastener element, each row of separable sections may comprise at least one fastener element. In some embodiments, the first and second fastener elements may be configured to jointly retain the dressing in a folded configuration when coupled. For example, the first and second fastener elements may be configured to jointly retain one portion of the second layer to another portion of the second layer. In some embodiments, the plurality of first and second fastener elements may be configured to allow the dressing to be retained in a plurality of different folded configurations. For example, the retained fold configuration of the dressing may depend on which fastener elements are coupled together. In some embodiments, the first fastener elements may be configured to only couple to the second fastener elements. For example, the first and second fastener elements may each comprise a cold-seal adhesive (e.g. the same cold-seal adhesive). In another example, each of the first fastener elements may comprise a plurality of flexible hooks, and each of the second fastener elements may comprise a plurality of flexible loops. The first and second fastener elements may be configured to not bond to a tissue site in some embodiments.

[0014] In some embodiments, each fastener may comprise perforations, and at least some of the perforations may be aligned with at least some of the plurality of fluid restrictions. For example in embodiments in which each fastener comprises a first fastener element and a second fastener element, each fastener element may comprise perforations, and at least some of the perforations may be aligned with at least some of the plurality of fluid restrictions. In some embodiments, the fastener may comprises an adhesive that is soluble in liquid. In some embodiments, each fastener may comprises a first color, and the second surface may comprise a second color. In some embodiments, each first fastener element may comprise a first color, each second fastener element may comprise a second color, and the second layer may comprise a third color.

[0015] A method of treating a tissue site with negative pressure is also described herein, and the method embodiments may comprise the steps of: folding a manifold having a first surface and a second surface to dispose a first portion of the second surface to a second portion of the second surface;

coupling the first portion to the second portion with a fastener to retain the manifold in a folded configuration; applying the manifold to the tissue site; applying a cover over the tissue site to fluidly isolate the manifold from the ambient environment; and applying a therapeutic level of negative pressure to the manifold through the cover. In some embodiments, the fastener may be attached to the first portion. In some embodiments, the fastener may comprise a first fastener element attached to the first portion and a second fastener element attached to the second portion, and coupling the first portion to the second portion may comprise coupling the first fastener element to the second fastener element. Some method embodiments may further comprise excising one or more separable sections of the manifold based upon at least one of a size and shape of the tissue site, wherein excising separable sections does not expose any foam of the manifold. Some method embodiments may further comprise stacking excised separable sections, and retaining the stacked separable sections by coupling a first fastener element to a second fastener element. In some embodiments, the fastener may comprise an adhesive that is soluble in liquid, and the method may further comprise applying liquid to release the fastener.

[0016] A method of forming a tissue interface is also described herein, and the method embodiments 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 a first fastener element on a first separable section and a second fastener element on a second separable section. In some embodiments, the first fastener element may be configured to couple to the second fastener element, the first fastener element and the second fastener element may both be attached to a common outer surface of the same polymer film layer, and the first fastener element and the second fastener element may be configured to jointly retain the tissue interface in a folded configuration.

[0017] In some embodiments, forming a first fastener element on a first separable section and a second fastener element on a second separable section may comprise: providing the first fastener element and the second fastener element; and attaching the first fastener element to the first separable section and attaching the second fastener element to the second separable section. In some embodiments, providing the first fastener element and the second fastener element may comprise selecting a first fastener element configured to only bond to the second fastener element, and/or selecting a second fastener element configured to only bond to the first fastener element. For example, the first fastener element and the second fastener element may each comprise a cold-seal adhesive. In another example, the first fastener element may comprise flexible hooks and the second fastener element may comprise flexible loops. In some embodiments, forming a first fastener element on a first separable section and a second fastener element on a second separable section may comprise integrally forming the flexible hooks and the flexible loops when forming the common surface. In some embodiments, the method may further comprise aligning at least some perforations of the first fastener element and

second fastener element with fluid restrictions of the common surface. In some embodiments, the perforations in the first fastener element and in the second fastener element may be formed after attachment to the common surface. For example, the perforations in the first fastener element and the second fastener element may be formed simultaneously with formation of the fluid restrictions in the underlying polymer film layer, resulting in alignment.

[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 9A is an isometric view of yet another tissue interface embodiment of the dressing of Figure 2, illustrating a first surface;

[0028] Figure 9B is another isometric view of the tissue interface embodiment of Figure 9A, illustrating a second surface with an exemplary fastener;

[0029] Figure 9C is a side view of the tissue interface embodiment of Figure 9A, illustrating the fastener retaining a fold;

[0030] Figure 10A is an isometric view of still another tissue interface embodiment of the dressing of Figure 2, illustrating two exemplary fastener elements;

[0031] Figure 10B is a side view of the tissue interface embodiment of Figure 10A, illustrating the fastener elements jointly retaining a fold;

[0032] Figure 11 is a top view of another exemplary tissue interface embodiment of the dressing of Figure 2, illustrating two exemplary fastener elements located on different separable sections;

[0033] Figure 12 is a schematic cross-sectional view of the tissue interface of Figure 11, illustrating exemplary perforations in the fastener elements;

[0034] Figure 13 is a plan view of an exemplary tissue interface of Figure 2 having a plurality of rows of separable sections; and

[0035] Figure 14 is an isometric view of the tissue interface of Figure 13 in an exemplary folded configuration and retained by a plurality of exemplary fastener elements.

DESCRIPTION OF EXAMPLE EMBODIMENTS

[0036] 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.

[0037] 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.

[0038] 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.

[0039] 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.

[0040] 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.

[0041] 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.

[0042] 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.

[0043] 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.

[0044] 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.

[0045] 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).

[0046] 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.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] 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.

[0051] 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.

[0052] 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.

[0053] 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.

[0054] 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, 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.

[0055] 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 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.

[0056] 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 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.

[0057] 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.

[0058] 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.

- 5 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.
- 10 Other example embodiments of an attachment device may include a double-sided tape, paste, hydrocolloid, hydrogel, silicone gel, or organogel.

- [0059]** 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
- 15 for some prescriptions include hypochlorite-based solutions, silver nitrate (0.5%), sulfur-based solutions, biguanides, cationic solutions, and isotonic solutions.

- [0060]** 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 may be placed over
- 20 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.

- 25 **[0061]** 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,
- 30 for example.

- [0062]** 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
- 35 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.

[0063] 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.

[0064] 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.

[0065] For example, some embodiments of the fluid restrictions 220 may comprise or consist essentially of one or more slits, slots or combinations of slits and slots. In 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.

[0066] 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.

[0067] 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.

5 **[0068]** 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
10 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
15 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 may have a
20 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.

[0069] 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
25 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 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
30 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 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.

35 **[0070]** 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 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 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 millimeters over a centimeter.

[0071] 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, 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.

[0072] 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.

[0073] 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.

[0074] 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.

[0075] 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/or 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 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.

5 **[0076]** Each of the manifold sections 420 in Figure 4 has a length L1, 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 D1 of about 5 mm to about 15 mm. For example, a distance D1 of about 10 mm may be particularly advantageous for some
10 embodiments.

[0077] 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.

[0078] In some embodiments, the tissue interface 114 has a thickness T1 ranging from about
15 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 T1 of about 8 mm. The thickness T1 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).

20 **[0079]** 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.

[0080] 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.

25 **[0081]** 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
30 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
35 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.

[0082] 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.

[0083] 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).

[0084] 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 a 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.

[0085] 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.

[0086] 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.

[0087] 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.

[0088] 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.

[0089] 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.

[0090] In some embodiments, the tissue interface 114 may be configured to be foldable. Some embodiments may comprise one or more fasteners, which may be configured to retain the tissue interface 114 in one or more folded configurations. The following examples may be illustrative of a foldable tissue interface 114 having one or more retaining fasteners.

[0091] Figure 9A is an isometric view of another example of the tissue interface 114, illustrating additional details that may be associated with some embodiments. In Figure 9A, the tissue interface 114 may comprise the manifold 905. In some embodiments, a barrier may be integral to the manifold 905. For example, an integral barrier may be formed by a skin or thin film, which may be integrally formed with the manifold 905 and form a first surface 910 of the manifold 905. In some embodiments, the first surface 910 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 the manifold (e.g. as shown in Figure 4). The barrier may substantially reduce or prevent the flow of fluid in and/or out of the tissue interface 114 and the growth of tissue into the tissue interface 114. In some embodiments, the barrier may be substantially impermeable to liquid. In Figure 9A, the fluid restrictions 220 may be located in at least the first surface 910, for example passing through the barrier to be in fluid communication with the remainder of the manifold 905. In some embodiments, the fluid restrictions 220 may be fluid valves. In some embodiments, the fluid valves may be coextensive with at least the first surface 910.

[0092] Figure 9B is another isometric view of the tissue interface 114 of Figure 9A, illustrating additional details that may be associated with some embodiments. As shown in Figure 9B, the tissue interface 114 may comprise one or more fasteners 915 located on the second surface 920 of the tissue interface 114. Although not shown here, some embodiments may comprise a barrier and/or fluid restrictions 220 on the second surface 920. In the embodiment shown in Figure 9B, the second surface 920 may be part of the manifold 905. The fastener 915 shown in Figure 9B may be configured to retain a first portion 925 of the second surface 920 to a second portion 930 of the second surface 920. For example, the fastener 915 may be located on and/or attached to the first portion 925 of the second side 920 of the tissue interface 114, and may be configured to couple to the second portion 930 of the second surface 920, for example upon contact when the tissue interface 114 is folded. Thus, the fastener 915 may be configured to retain the tissue interface 114 in a folded configuration. In some embodiments, the tissue interface 114 may be sufficiently foldable and/or flexible to allow the tissue interface 114 to be folded into a configuration in which the first portion 925 is in proximity to the second portion 930.

[0093] Figure 9C is a side view of the tissue interface 114 of Figure 9A when folded, illustrating additional details that may be associated with some embodiments. In Figure 9C, the tissue interface 114 has been folded, bringing the first portion 925 of the second surface 920 into proximity with the second portion 930 of the second surface 920 of the tissue interface 114. The fastener 915 may be attached to the first portion 925 and may couple to the second portion 930, retaining the tissue interface 114 in the folded configuration. For example, the fastener 915 may retain the folded configuration by retaining the first portion 925 of the second surface 920 to the second portion 930 of the second surface 920. The fastener 915 may be configured to retain the fold at least long enough to place and/or cover the tissue interface 114 with respect to a tissue site.

[0094] The locations of the first portion 925 and the second portion 930 in Figure 9C are merely exemplary. In some embodiments, the second portion 930 and/or the first portion 925 may be located at various locations on the tissue interface 114. In some embodiments, the second portion 930 may represent any location on the second surface 920 to which the fastener 915 may couple. In some embodiments, the first portion 925 may represent any location on the second surface 920 to which the fastener 915 may be mounted. While Figure 9C illustrates only one fastener 915 on the second surface 920, other embodiments may comprise a plurality of fasteners 915. In some embodiments, a plurality of fasteners 915 may be positioned on the second surface, for example at locations which may allow a plurality of retained folded configurations for the tissue interface 114. Some embodiments may also comprise one or more fasteners 915 on the first surface 920 of the tissue interface 114.

[0095] In some embodiments, the fastener 915 may comprise an adhesive. For example, the fastener 915 may comprise one or more of the following: an acrylic adhesive, a polyurethane adhesive, a silicone adhesive, a film having an adhesive on a first side and on a second side, a cold-seal adhesive, an adhesive that is soluble in liquid, and an adhesive having a tack of about 0.8 – 7 N/25mm. In some

embodiments, the fastener 915 may comprise one color, and the second surface 920 may comprise another color. Typically, the two colors may be chosen so that the one or more fasteners 915 may stand out from the background surface.

[0096] Figure 10A is an isometric view of another example of the tissue interface 114, illustrating additional details that may be associated with some embodiments. Figure 10A is similar to the tissue interface 114 of Figure 9B, but illustrates that in some embodiments each fastener may comprise two fastener elements: a first fastener element 1005 and a second fastener element 1010. As shown in Figure 10A, the tissue interface 114 may comprise a first fastener element 1005 and a second fastener element 1010 located on the second surface 920 of the tissue interface 114. For example, the first fastener element 1005 may be located on and attached to the first portion 925 of the second surface 920 of the tissue interface 114, and the second fastener element 1010 may be located on and attached to the second portion 930 of the second surface 920 of the tissue interface 114. The first fastener element 1005 may be configured to be coupled to the second fastener element 1010, and the second fastener element 1010 may be configured to be coupled to the first fastener element 1005. Jointly, the first fastener element 1005 and the second fastener element 1010 may be configured to retain the tissue interface 114 in a folded configuration (e.g. when the first fastener element 1005 and the second fastener element 1010 are coupled). For example, the first fastener element 1005 and the second fastener element 1010 may be configured to jointly (e.g. when coupled) retain the first portion 925 of the second surface 920 of the tissue interface 114 in proximity to the second portion 930 of the second surface 920 of the tissue interface 114.

[0097] Figure 10B is a side view of the tissue interface 114 of Figure 10A, illustrating additional details that may be associated with some embodiments. Figure 10B illustrates the tissue interface 114 in an exemplary folded configuration. The first fastener element 1005 and the second fastener element 1010 are shown coupled together in Figure 10B to retain the tissue interface 114 in an exemplary folded configuration. For example, in the folded configuration shown in Figure 10B, the first portion 925 of the second surface 920 of the tissue interface 114 may be retained in proximity to the second portion 930 of the second surface 920 of the tissue interface 114.

[0098] In some embodiments, the tissue interface 114 may comprise a plurality of first fastener elements 1005 and/or a plurality of second fastener elements 1010. In some embodiments, each of the first plurality of fastener elements 1005 may be configured to couple to any one of the plurality of second fastener elements 1010, and/or each of the second plurality of fastener elements 1010 may be configured to couple to any one of the plurality of first fastener elements 1005. Each pairing of first fastener element 1005 and second fastener element 1010 may be configured to jointly retain the tissue interface 114 in folded configuration when coupled. For example, each pairing may jointly retain one portion of the second surface 920 to another portion of the second surface 920. In some embodiments, the plurality of first fastener elements 1005 and the plurality of second fastener elements 1010 may be

positioned on the second surface 920, for example at locations which may allow a plurality of retained folded configurations for the tissue interface 114. Some embodiments may also comprise one or more first fastener elements 1005 and one or more second fastener elements 1010 on the first surface of the tissue interface 114.

5 **[0099]** In some embodiments, the one or more first fastener element 1005 may be configured to only attach to the one or more second fastener element 1010. In some embodiments, the tissue interface may comprise a plurality of first fastener elements 1005 and a plurality of second fastener elements 1010. In some embodiments, each of the first plurality of fastener elements 1005 may be configured to only couple to any one of the plurality of second fastener elements 1010, and/or each of
10 the second plurality of fastener elements 1010 may be configured to only couple to any one of the plurality of first fastener elements 1005. For example, the one or more first fastener elements 1005 may comprise a plurality of flexible hooks, and the one or more second fastener elements 1010 may comprise a plurality of flexible loops (e.g. jointly forming a hook-and-loop fastener similar to VELCRO fasteners). In another example, the one or more first fastener elements 1005 and the one or more second
15 fastener elements 1010 may each comprise a cold-seal adhesive. For example, the one or more first fastener elements 1005 and the one or more second fastener elements 1010 may all comprise the same cold-seal adhesive, so that the fastener elements may be configured to only bond to each other. If all fastener elements comprise the same cold-seal adhesive, then any fastener element may couple to any other fastener element. In some embodiments, the fastener elements may be configured to not
20 substantially bond to the tissue site. For example, the cold-seal adhesive may not bond to the tissue site or to other portions of the dressing. The cold-seal adhesive may comprise dry-to-the-touch films which only bond to each other, do not require heat to bond, and/or may be referred to as self-seal adhesives or cohesives. Examples of the cold-seal adhesive may be supplied by Bostik or Dow (e.g. COSEAL adhesive).

25 **[00100]** In some embodiments, the one or more first fastener elements 1005 and/or the one or more second fastener elements 1010 may comprise an adhesive that is soluble in liquid. For example, application of water or other irrigation or instillation fluid may be sufficient to release the retaining fastener. In some embodiments, the one of more first fastener elements 1005 may comprise a first color, and the one or more second fastener elements 1010 may comprise a second color. In some
30 embodiments, the second surface 920 may comprise a third color. So in some embodiments, the first fastener elements 1005 may be a different color than the second fastener elements 1010, and/or both the first fastener elements 1005 and the second fastener elements 1010 may differ in color from the second surface 920 on which they are located.

[00101] Figures 11 is a plan view of another example of the tissue interface 114,
35 illustrating additional details that may be associated with some embodiments. The tissue interface 114 shown in Figure 11 is similar to that in Figure 3, but further comprises one or more first fastener

elements 1005 and one or more second fastener elements 1010. In some embodiments, the first fastener element 1005 and the second fastener element 1010 may be similar to those in Figure 10A. In some embodiments, each of the one or more first fastener element 1005 may be attached to an interface section 205, and each of the one or more second fastener element 1005 may be attached to a different interface section 205. For example, the first fastener element 1005 of Figure 11 may be attached to a first of a plurality of interface sections 205, and the second fastener element 1010 may be attached to a second of the plurality of interface sections 205. In some embodiments, both the first fastener element 1005 and the second fastener element 1010 may be attached to a common surface of the tissue interface 114. In some embodiments, the seams 210 may be substantially more flexible than the interface sections 205, allowing easy folding of the tissue interface 114 along one or more seams 210 to place the tissue interface 114 into one or more folded configurations. The first fastener element 1005 and the second fastener element 1010 may be located on the tissue interface 114 to interact when the tissue interface 114 is folded to retain the tissue interface 114 in folded configuration. For example, the first fastener element 1005 and the second fastener element 1010 may be located on adjacent interface sections and spaced with respect to the seam 210 between the interface sections 205 so that the first fastener element 1005 and the second fastener element 1010 may couple when the tissue interface 114 is folded at the seam 210 between the adjacent interface sections 205. In some embodiments, the first fastener element 1005 and the second fastener element 1010 may each be centered on the interface section 205 to which they are attached.

[00102] Figure 12 is a schematic cross-section view of the tissue interface 114 of Figure 11, illustrating additional details that may be associated with some embodiments. In the embodiment of Figure 12, the tissue interface 114 comprises manifold sections 420 sandwiched between the first layer 405 and the second layer 410. In some embodiments, the manifold sections 420 may be subdivided portions of a spacer manifold. The first layer 405 may be bonded to the second layer 410 to form seams 210 defining the manifold sections 420. In some embodiments, both the first layer 405 and the second layer 410 may provide fluid control, may act as a tissue barrier, and may comprise fluid restrictions 220. In some embodiments, the fluid restrictions 220 may be coextensive with the first layer 405 and/or the second layer 410. In some embodiments, the fluid restrictions may be coextensive with the manifold sections 420.

[00103] As shown in Figure 12, the first fastener element 1005 and the second fastener element 1010 may be attached to a common surface of the tissue interface 114. For example, the first fastener element 1005 and the second fastener element 1010 may both be attached to the exterior of the first layer 405, opposite the manifold sections 420. For example, the first fastener element 1005 may be attached to one of the interface sections 205 and the second fastener element 1010 may be attached to another interface section 205, and both the first fastener element 1005 and the second fastener element 1010 may be attached to the first layer 405.

[00104] In some embodiments, each of the one or more first fastener elements 1005 and each of the one or more second fastener elements 1010 may comprise perforations 1205. For example, in Figure 12 the perforations 1205 in the first fastener element 1005 and in the second fastener elements 1010 may align with at least some of the fluid restrictions 220 in the first layer 405. In some
5 embodiments, the perforations 1205 may align with all underlying fluid restrictions 220. For example, the perforations 1205 and the fluid restrictions 220 might be formed simultaneously, after the one or more first fastener elements 1005 and the one or more second fastener elements 1010 are attached to the first layer 405. In some embodiments, one or more fastener or fastener element may be located on each surface of the tissue interface 114. For example, one or more fastener or fastener element may be
10 attached to the first layer 405, and one or more fastener or fastener element may be attached to the second layer 410. In some embodiments, one or more first fastener element 1005 and one or more second fastener element 1010 may be attached or mounted to the first layer 405, the second layer 410, or both.

[00105] Figure 13 is a plan view of another example of the tissue interface 114,
15 illustrating additional details that may be associated with some embodiments. The embodiment shown in Figure 13 may be similar to that of Figure 11, but may comprise additional interface sections 205. In some embodiments, the tissue interface 114 may comprise a plurality of rows 1305 of interface sections 205. For example, the tissue interface 114 in Figure 13 comprises five rows, with each row 1305 having three interface sections 205. In some embodiments, each row 1305 may comprise at least
20 one fastener or fastener element. For example, in Figure 13 each row 1305 may comprise either a first fastener element 1005 or a second fastener element 1010. In Figure 13, the fastener elements are located on the interface section 205 in the middle of each row 1305, and adjacent rows 1305 alternate between first fastener elements 1005 and second fastener elements 1010. In some embodiments, the first fastener elements 1005 and the second fastener elements 1010 may be identical. For example, all fastener
25 elements may be formed of the same cold-seal adhesive. Other locations of fastener elements are possible depending on the fold configurations desired for the tissue interface 114. In some embodiments, each interface section 205 may comprise a fastener or fastener element on at least one surface. In some embodiments, each interface section 205 may have no more than one fastener or fastener element on each surface. In some embodiments, one or more fastener or two or more fastener
30 elements may be located on each surface of the tissue interface 114.

[00106] Figure 14 is an isometric view of the tissue interface 114 of Figure 13 in an exemplary folded configuration, illustrating additional details that may be associated with some embodiments. In Figure 14, the rows 1305 of interface sections 205 are folded accordion-style (e.g. a plurality of accordion folds), and the fastener elements are coupled and retain the folded configuration.
35 For example, fastener elements on at least one pair of adjacent rows 1305 of interface sections 205 may be coupled to retain an accordion fold. In Figure 14, fastener elements on at least two pairs of adjacent

rows 1305 of interface sections 205 may be coupled to retain a plurality of accordion folds. In some embodiments, the plurality of first fastener elements 1005 and the plurality of second fastener elements 1010 may be configured to allow the tissue interface 114 to be retained in a plurality of different folded configurations. In some embodiments, the fasteners or fastener elements may be configured to retain a plurality of folds of the tissue interface 114. In some embodiments, the fasteners or fastener elements may be configured to retain an accordion fold between each row 1305 of separable sections of the tissue interface 114 or between at least some of the rows 1305.

[00107] Some embodiments may be directed to a method of treating a tissue site with negative pressure, and the methods may comprise the steps of: folding a manifold having a first surface and a second surface to dispose a first portion of the second surface to a second portion of the second surface; coupling the first portion to the second portion with a fastener to retain the manifold in a folded configuration; applying the manifold to the tissue site; applying a cover over the tissue site to fluidly isolate the manifold from the ambient environment; and applying a therapeutic level of negative pressure to the manifold through the cover. In some embodiments, the fastener may be attached to the first portion. In some embodiments, the fastener may comprise a first fastener element attached to the first portion and a second fastener element attached to the second portion, and coupling the first portion to the second portion may comprise coupling the first fastener element to the second fastener element. The coupling may be a removable coupling in some embodiments.

[00108] Some method embodiments may further comprise excising one or more separable sections of the manifold based upon at least one of a size and shape of the tissue site. In some embodiments, excising separable sections may not expose any foam of the manifold. For example, excising separable sections may comprise cutting or tearing along a seam, with at least a portion of the seam remaining to prevent exposure of the foam of the manifold. In some embodiments, excising may occur between separable sections, for example along a perforation line within the seam. Some method embodiments may further comprise stacking one or more excised separable sections onto the second surface, and retaining the stacked separable sections by coupling a first fastener element to a second fastener element. For example, a fastener element on an excised separable section may be coupled to a fastener element on the second surface of the tissue interface (e.g. with the remaining separable sections). In some embodiments, two or more excised separable sections may be stacked and/or coupled together with fasteners. The fastener or fastener elements of some embodiments may comprise an adhesive that is soluble in liquid, and the method may further comprise applying liquid to release the fastener. For example, the manifold may be released from its folded configuration after being applied to the tissue site, so that the manifold may spring out to better fill or contact the wound cavity. Any of these method embodiments may relate to or make use of any of the apparatus or system embodiments described herein.

[00109] Some embodiments may be directed to a method of forming a tissue interface for a dressing for treating a tissue site with negative pressure, 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 a first fastener element on a first separable section and a second fastener element on a second separable section. In some embodiments, the first fastener element may be configured to couple to the second fastener element. In some embodiments, the first fastener element and the second fastener element may both be attached to a common outer surface of the same polymer film layer. For example, both may be attached to either the first polymer film layer or to the second polymer film layer. In some embodiments, the first fastener element and the second fastener element may be configured to jointly retain (e.g. when coupled) the tissue interface in a folded configuration. For example, the first fastener element and the second fastener element may be configured to retain a first portion of the common surface to a second portion of the common surface, when coupled.

[00110] 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. Some embodiments further comprise perforating the seams to form perforation lines between adjacent separable sections. Some embodiments further comprise forming a plurality of fluid restrictions in the first polymer film layer and/or in 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, the step of forming the plurality of fluid restrictions may occur after bonding the first polymer film layer to the second polymer film layer.

[00111] In some embodiments, forming a first fastener element on a first separable section and a second fastener element on a second separable section may comprise: providing the first fastener element and the second fastener element; and attaching the first fastener element to the first separable section and attaching the second fastener element to the second separable section. The step of providing the first fastener element and the second fastener element may comprise selecting a first fastener element configured to only bond to the second fastener element, and selecting a second fastener element configured to only bond to the first fastener element. For example, the first fastener element and the second fastener element may each comprise the same cold-seal adhesive. In an alternate example, the first fastener element may comprise flexible hooks and the second fastener element may comprise flexible loops. In some embodiments, forming a first fastener element on a first separable section and a second fastener element on a second separable section may comprise integrally forming the flexible hooks and the flexible loops when forming the common surface, such that the hooks and loops are integral parts of the common surface.

[00112] In some embodiments, the first fastener element and the second fastener element may each comprise perforations. Some embodiments may comprise forming the perforations. Some method embodiments may further comprise aligning at least some of the perforations of the first fastener element and the second fastener element with at least some of the underlying fluid restrictions of the common surface. In some embodiments, all of the perforations may align with underlying fluid restrictions. In some embodiments, the perforations in the first fastener element and in the second fastener element may be formed after attachment of the first fastener element and the second fastener element to the common surface. For example, the perforations in the first fastener element and in the second fastener element may be formed simultaneously with formation of the fluid restrictions in the underlying common polymer film layer. Any of these method embodiments may relate to any of the apparatus or system embodiments described herein.

[00113] 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 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).

[00114] In some embodiments, the tissue interface 114 may be configured to be retained in one or more folded configurations. This may allow for easier and/or better sizing and shaping of the tissue interface to match the size and/or shape of the wound cavity, for example. Also, retaining the tissue interface 114 in a folded configuration during application to a wound cavity may help to ensure that the tissue interface 114 stays in place in the wound cavity. For example, the tissue interface 114 may be retained in a folded configuration without beginning to unfold in a way that might push the tissue interface out of the wound cavity while the cover 116 of the dressing 104 is being applied. One or more fasteners may allow the tissue interface 114 to retain its folded shape. Some embodiments may configure the fastener elements to only couple or bond to each other. For example, the fastener elements may not bond to the tissue site, reducing potential damage to the tissue site upon removal of the tissue interface 114. Some embodiments may also use color to improve ease of use of the fasteners, for example allowing the fasteners to be easily discerned against the background of the tissue interface surface and/or allowing a user to quickly identify which fastener elements are configured to couple together. Some embodiments may use liquid soluble adhesive for the one or more fasteners, which may allow the retained fold to be released after the tissue interface 114 and cover 116 have been applied so that the tissue interface 114 may spring outward to better fill the wound cavity.

[00115] 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 110, the container 115, or both may be separated from other components for manufacture or sale. In other example configurations, the controller 130 may also be manufactured, configured, assembled, or sold independently of other components.

[00116] 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:

- 5 1. A dressing for treating a tissue site with negative pressure, the dressing comprising:
a tissue interface having a first surface and a second surface;
a plurality of fluid valves in at least the first surface; and
at least one fastener attached to the second surface and configured to retain a first
portion of the second surface to a second portion of the second surface.
- 10 2. The dressing of claim 1, wherein the fastener comprises an adhesive.
3. The dressing of claim 1, wherein the fastener comprises a cold-seal adhesive.
- 15 4. The dressing of claim 3, wherein each fastener comprises two fastener elements, and each
fastener element comprises the cold-seal adhesive.
5. The dressing of claim 1, wherein the fastener comprises an adhesive that is soluble in liquid.
- 20 6. The dressing of claim 1, wherein the fastener comprises an adhesive having a tack of about 0.8
– 7 N/25mm.
7. The dressing of claim 1, wherein the fastener comprises an acrylic adhesive.
- 25 8. The dressing of claim 1, wherein the fastener comprises a polyurethane adhesive.
9. The dressing of claim 1, wherein the fastener comprises a silicone adhesive.
10. The dressing of claim 1, wherein the fastener comprises a film having an adhesive on a first
30 side and on a second side.
11. The dressing of claim 1, wherein the fastener comprises a first color and the second surface
comprises a second color.
- 35 12. The dressing of claim 1, wherein the fastener comprises a plurality of flexible hooks attached
to the first portion and a plurality of flexible loops attached to the second portion.

13. The dressing of claim 1, wherein the tissue interface comprises a plurality of separable sections.

14. The dressing of claim 1, wherein the first portion comprises at least one separable section, and the second portion comprises at least one different separable section.

5

15. The dressing of claim 1, wherein the tissue interface comprises:

a spacer manifold;

a first film layer adjacent to the spacer manifold and forming the first surface of the tissue interface; and

10 a second film layer adjacent to the spacer manifold and forming the second surface of the tissue interface.

16. The dressing of claim 1, wherein the tissue interface comprises:

a spacer manifold;

15 a first film layer adjacent to the spacer manifold and forming the first surface of the tissue interface;

a second film layer adjacent to the spacer manifold and forming the second surface of the tissue interface; and

20 a plurality of bonds between the first film layer and the second film layer, the plurality of bonds defining a plurality of separable sections.

17. A dressing for treating a tissue site with negative pressure, the dressing comprising:

a manifold comprising a first surface and a second surface opposite the first surface;

a first layer adjacent to the first surface and a second layer adjacent to the second surface, the first layer and the second layer each comprising a polymer film;

25 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 defining manifold sections; and

at least one fastener attached to the second layer and configured to retain a first portion of the second layer to a second portion of the second layer.

30

18. The dressing of claim 17, wherein the plurality of bonds form seams between the manifold sections.

19. The dressing of claim 18, wherein the seams bound each manifold section about a perimeter.

35

20. The dressing of claims 17-19, wherein the plurality of bonds form a seal between adjacent manifold sections.

21. The dressing of claims 17-20, wherein the seams define separable sections, each comprising one of the manifold sections.
- 5 22. The dressing of claim 21, wherein the seams are configured to allow separation of the separable sections without exposing the manifold sections.
23. The dressing of claims 17-22, wherein the dressing is foldable.
- 10 24. The dressing of claims 18-23, wherein the seams are more flexible than the manifold sections.
25. The dressing of claims 17-24, wherein the plurality of fluid restrictions are coextensive with the polymer film.
- 15 26. The dressing of claims 17-24, wherein the plurality of fluid restrictions are coextensive with the manifold sections.
27. The dressing of claims 17-26, wherein:
 each fastener comprises a first fastener element and a second fastener element; and
 20 the first fastener element is configured to couple to the second fastener element.
28. The dressing of claims 17-26, wherein:
 the at least one fastener comprises a plurality of fasteners, with each fastener
 comprising a first fastener element and a second fastener element;
 25 each of the first fastener elements is configured to couple to one of the plurality of
 second fastener elements; and
 each of the second fastener elements is configured to couple to one of the plurality of
 first fastener elements.
- 30 29. The dressing of claims 27-28, wherein the first fastener element is attached to the first portion and the second fastener element is attached to the second portion.
30. The dressing of claims 27-29, wherein the first fastener element is attached to a first separable section and the second fastener element is attached to a second separable section.
- 35 31. The dressing of claims 27-30, wherein the first fastener elements are configured to only couple to the second fastener elements.

32. The dressing of claims 27-31, wherein the first and second fastener elements are configured to not bond to the tissue site.

33. The dressing of claims 27-32, wherein only one fastener element is attached to any one of the separable sections.

34. The dressing of claims 21-33, wherein the separable sections form rows, and each row of separable sections comprises at least one fastener.

35. The dressing of claims 27-33, wherein the separable sections form rows, and each row of separable sections comprises at least one fastener element.

36. The dressing of claims 27-33, wherein one of the fastener elements is attached to each separable section.

37. The dressing of claims 17-33, wherein one of the fasteners is attached to each separable section.

38. The dressing of claims 27-37, wherein each pair of first and second fastener elements are configured to jointly retain the dressing in a folded configuration when coupled.

39. The dressing of claims 27-38, wherein each pair of first and second fastener elements are configured to jointly retain one portion of the second layer to another portion of the second layer.

40. The dressing of claims 27-39, wherein the plurality of first and second fastener elements are configured to allow the dressing to be retained in a plurality of different folded configurations, depending on which fastener elements are coupled together.

41. The dressing of claims 27-40, wherein the first and second fastener elements each comprise a cold-seal adhesive.

42. The dressing of claims 27-40, wherein each of the first fastener elements comprises a plurality of flexible hooks, and each of the second fastener elements comprises a plurality of flexible loops.

43. The dressing of claims 17-42, wherein:

each fastener comprises perforations;

the plurality of fluid restrictions are located in both the first and second polymer layers;

and

at least some of the perforations are aligned with at least some of the plurality of fluid restrictions.

44. The dressing of claim 27-42, wherein:

each fastener element comprises perforations;

the plurality of fluid restrictions are located in both the first and second polymer layers;

and

at least some of the perforations are aligned with at least some of the plurality of fluid restrictions.

45. The dressing of claims 17-44, wherein the fastener comprises an adhesive that is soluble in liquid.

46. The dressing of claims 27-44, wherein each fastener element comprises an adhesive that is soluble in liquid.

47. The dressing of claims 17-46, wherein each fastener comprises a first color, and the second surface comprises a second color.

48. The dressing of claims 27-46, wherein each first fastener element comprises a first color, and each second fastener element comprises a second color.

49. The dressing of claims 48, wherein the second layer comprises a third color.

50. A system for treating a tissue site with negative pressure, the system comprising:
the dressing of any preceding claim; and
a source of negative pressure configured to be fluidly coupled to the dressing.

51. The system of claim 50, further comprising a cover.

52. A method of treating a tissue site with negative pressure, the method comprising:
folding a manifold having a first surface and a second surface to dispose a first portion of the second surface to a second portion of the second surface;
coupling the first portion to the second portion with a fastener to retain the manifold in a folded configuration;
applying the manifold to the tissue site; and
applying a cover over the tissue site to fluidly isolate the manifold from the ambient

environment; and

applying a therapeutic level of negative pressure to the manifold through the cover.

53. The method of claim 52, wherein the fastener is attached to the first portion.

54. The method of claim 52, wherein:

the fastener comprises a first fastener element attached to the first portion and a second fastener element attached to the second portion; and

coupling the first portion to the second portion comprises coupling the first fastener element to the second fastener element.

55. The method of claim 54, wherein coupling the first fastener element to the second fastener element comprises removably coupling the first fastener element to the second fastener element.

56. The method of claims 52-55, further comprising excising one or more separable sections of the manifold based upon at least one of a size and shape of the tissue site, wherein excising separable sections does not expose any foam of the manifold.

57. The method of claim 56, wherein excising separable sections comprises cutting or tearing along a seam.

58. The method of claims 56-57, further comprising stacking excised separable sections, and retaining the stacked separable sections by coupling a first fastener element to a second fastener element.

59. The method of claims 52-58, wherein the fastener comprises an adhesive that is soluble in liquid, the method further comprising applying liquid to release the fastener.

60. A method of forming a tissue interface for a dressing for treating a tissue site with negative 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 defining separable sections of the manifold; and

forming a first fastener element on a first separable section and a second fastener element on a second separable section;

wherein:

the first fastener element is configured to couple to the second fastener element;

the first fastener element and the second fastener element are both attached to a common outer surface of the same polymer film layer; and

the first fastener element and the second fastener element are configured to jointly retain the tissue interface in a folded configuration.

61. The method of claim 60, 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.

62. The method of claims 60-61, further comprising perforating the seams to form perforation lines between adjacent separable sections.

63. The method of claims 60-62, further comprising forming a plurality of fluid restrictions in the first polymer film layer.

64. The method of claims 60-63, further comprising forming a plurality of fluid restrictions in the second polymer film layer.

65. The method of claims 63-64, 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.

66. The method of claims 63-65, wherein forming the plurality of fluid restrictions occurs after bonding the first polymer film layer to the second polymer film layer.

67. The method of claims 60-66, wherein forming a first fastener element on a first separable section and a second fastener element on a second separable section comprises:
providing the first fastener element and the second fastener element; and
attaching the first fastener element to the first separable section and attaching the second fastener element to the second separable section.

68. The method of claim 67, wherein providing the first fastener element and the second fastener element comprises selecting a first fastener element configured to only bond to the second fastener element, and selecting a second fastener element configured to only bond to the first fastener element.

5 69. The method of claims 60-68, wherein the first fastener element and the second fastener element each comprise the same cold-seal adhesive.

70. The method of claims 60-68, wherein the first fastener element comprises flexible hooks and the second fastener element comprises flexible loops.

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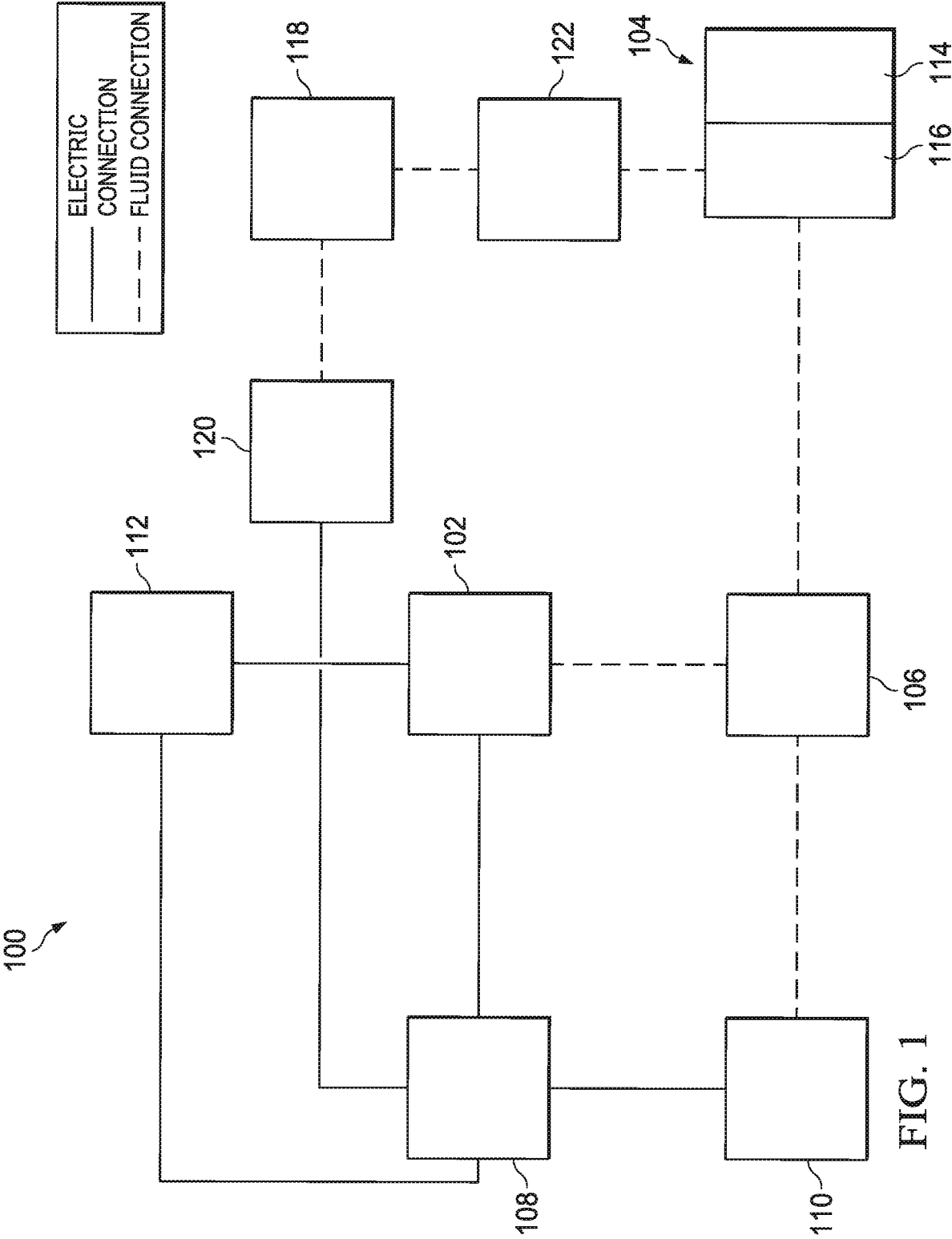
71. The method of claim 70, wherein forming a first fastener element on a first separable section and a second fastener element on a second separable section comprises integrally forming the flexible hooks and the flexible loops when forming the common surface.

15 72. The method of claims 63-71, wherein the first fastener element and the second fastener element each comprise perforations, the method further comprising aligning at least some of the perforations of the first fastener element and second fastener element with at least some of the fluid restrictions of the common surface.

20 73. The method of claim 72, wherein the perforations in the first fastener element and in the second fastener element are formed after attachment to the common surface.

74. The method of claims 52-73, using or relating to the dressing of claims 1-49.

25 75. The systems, apparatuses, and methods substantially as described above.



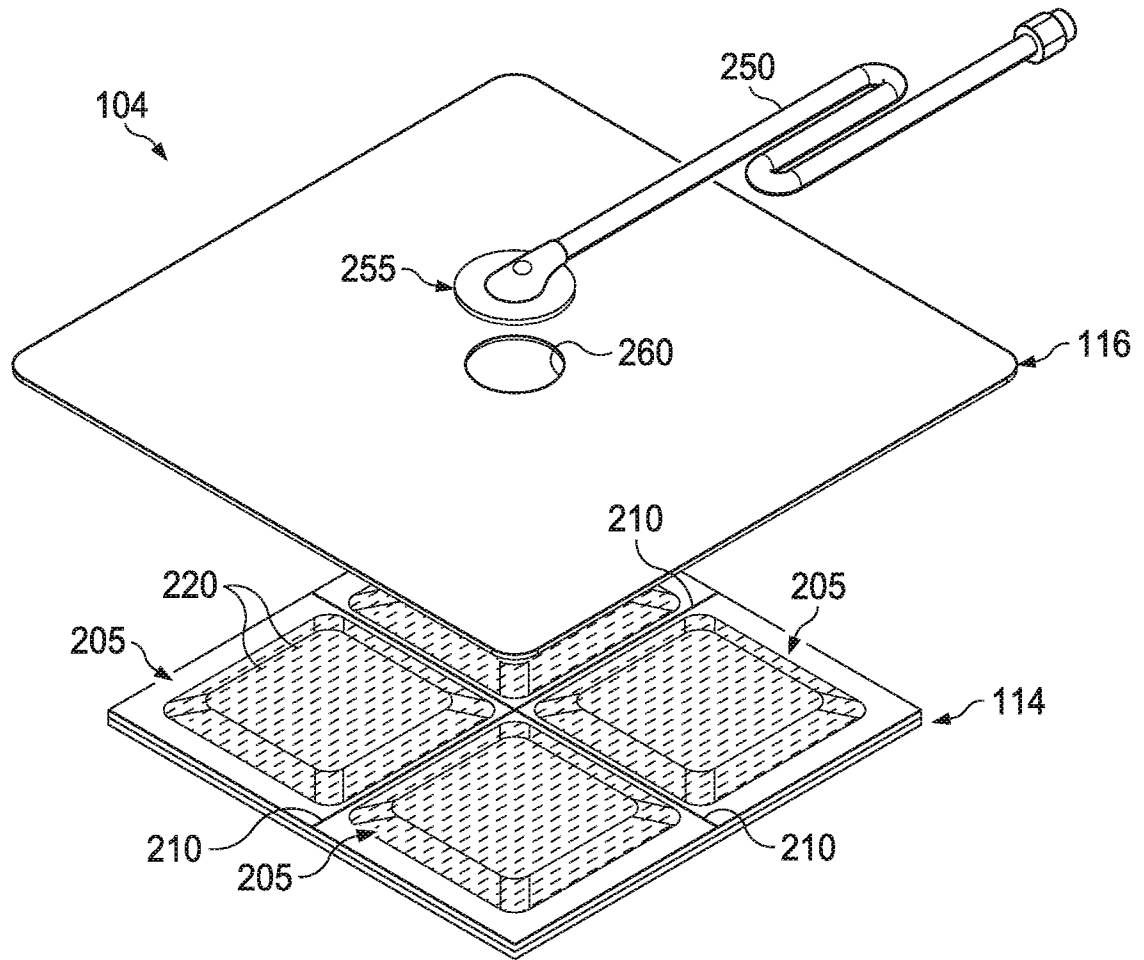


FIG. 2

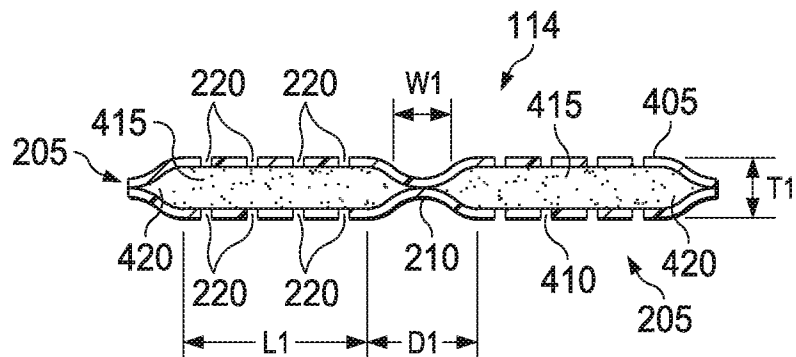
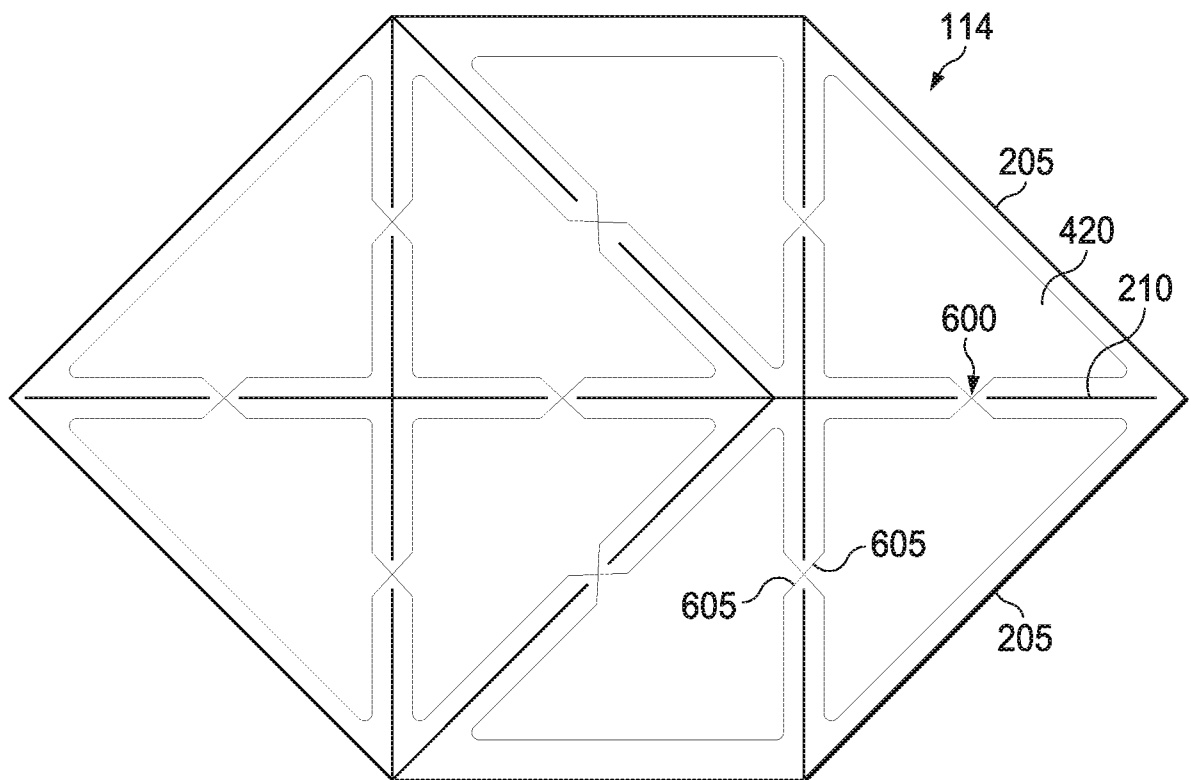
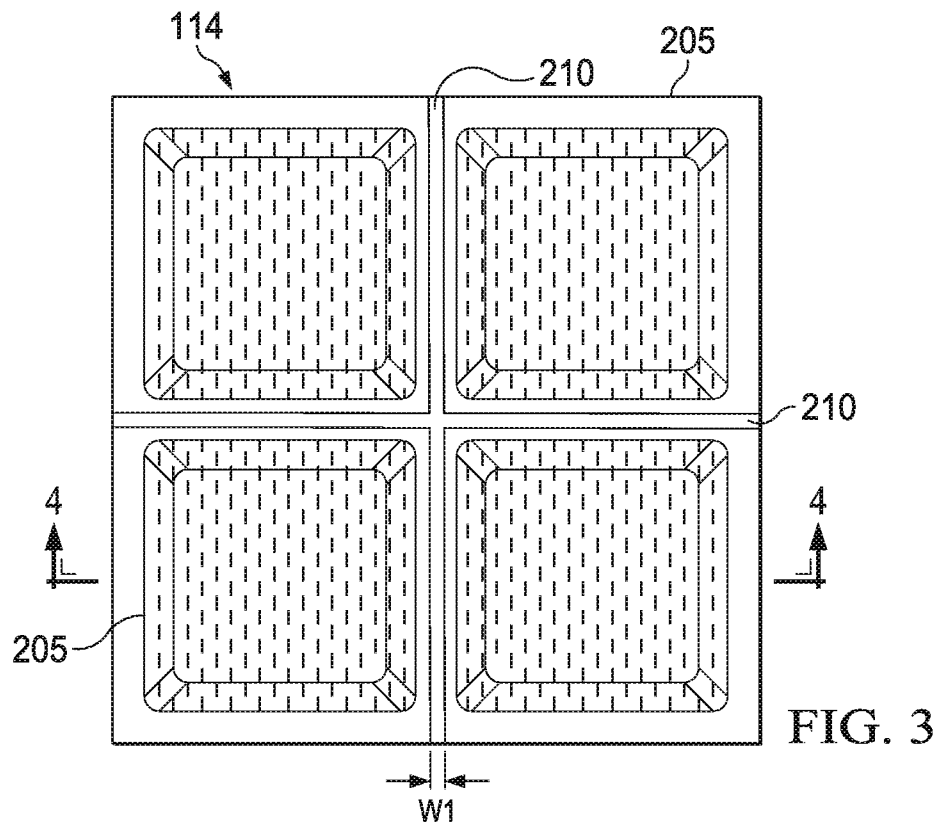


FIG. 4



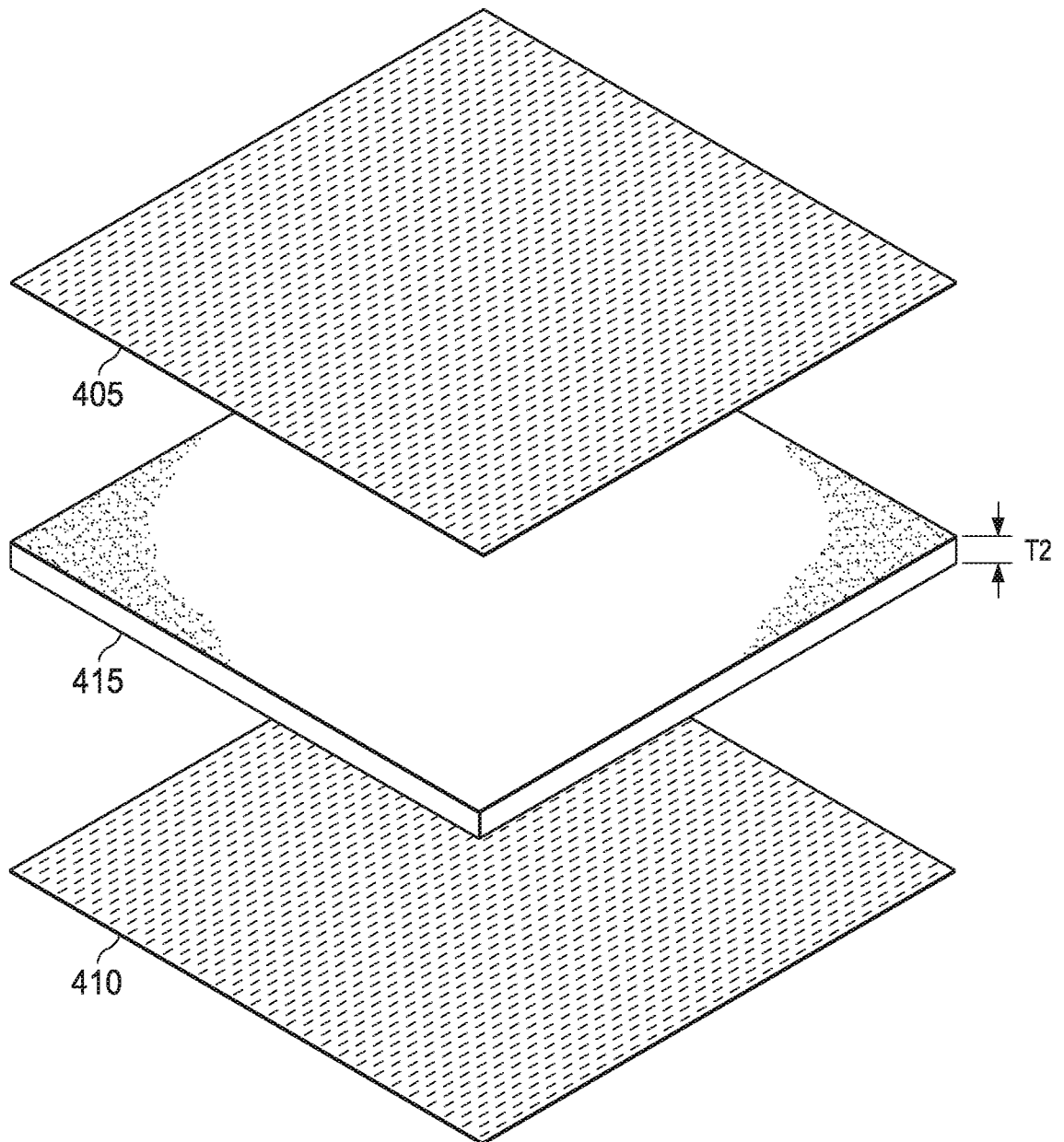


FIG. 5

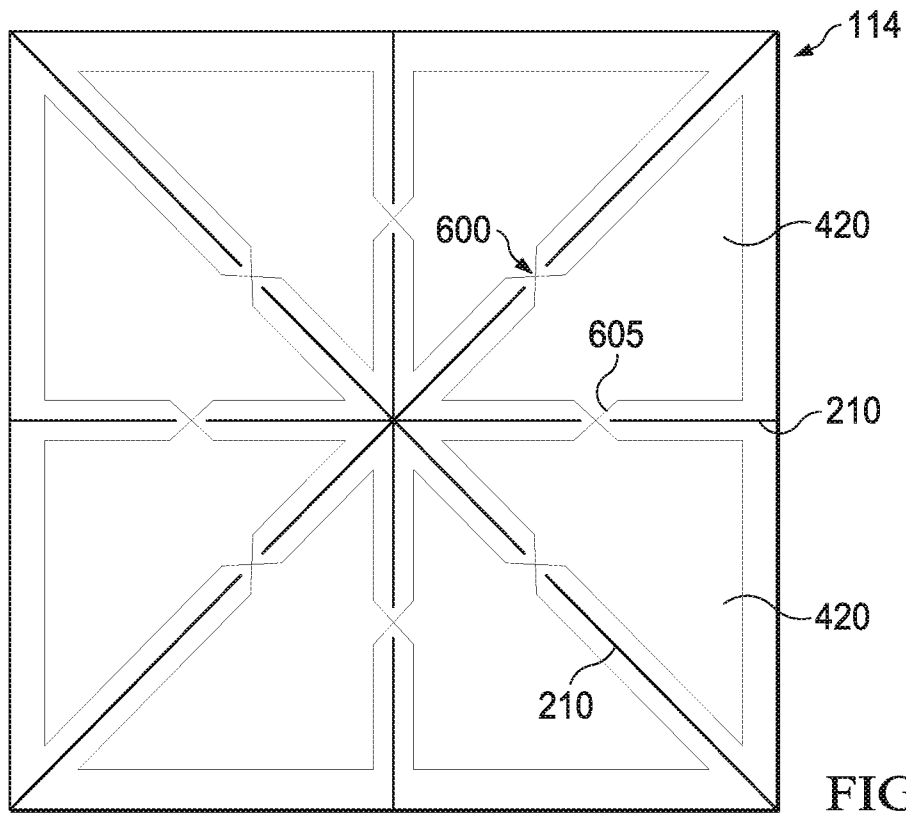


FIG. 7

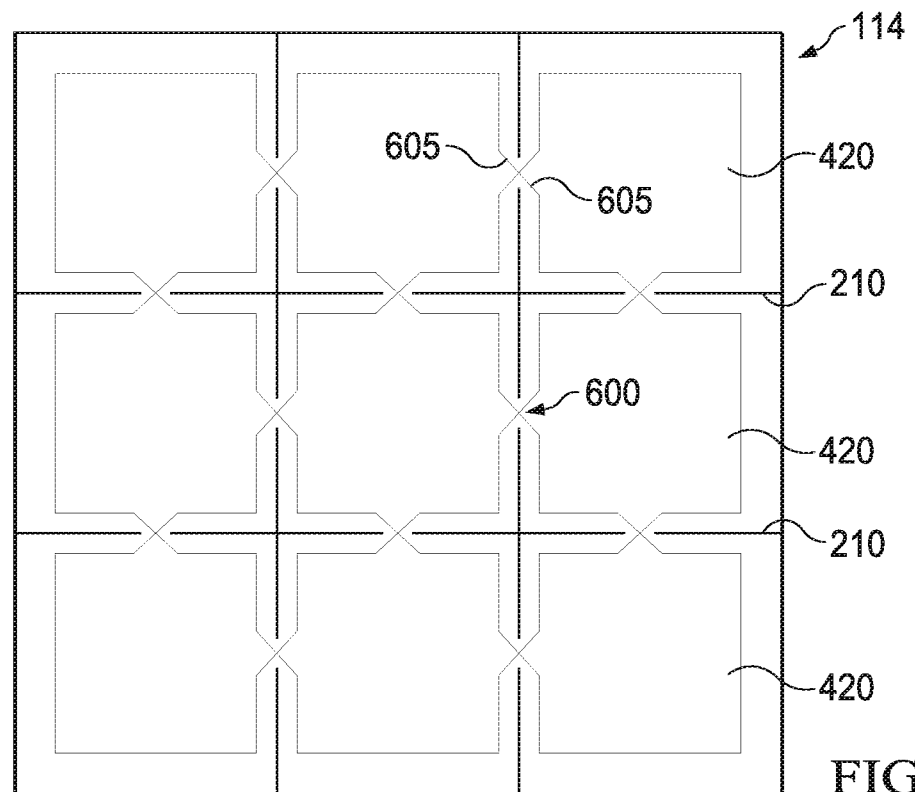
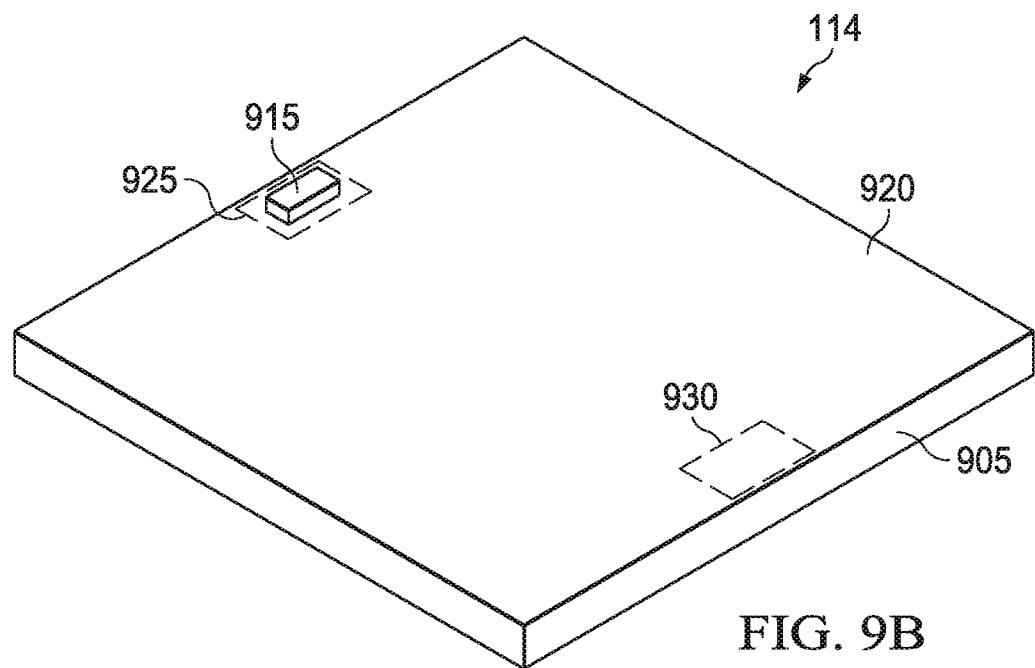
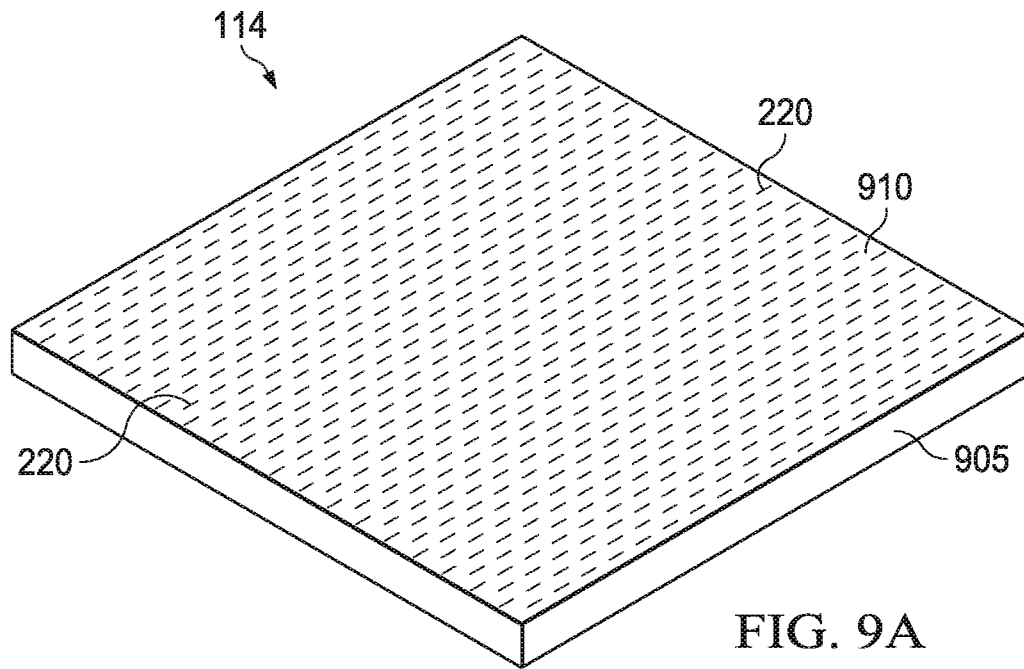


FIG. 8



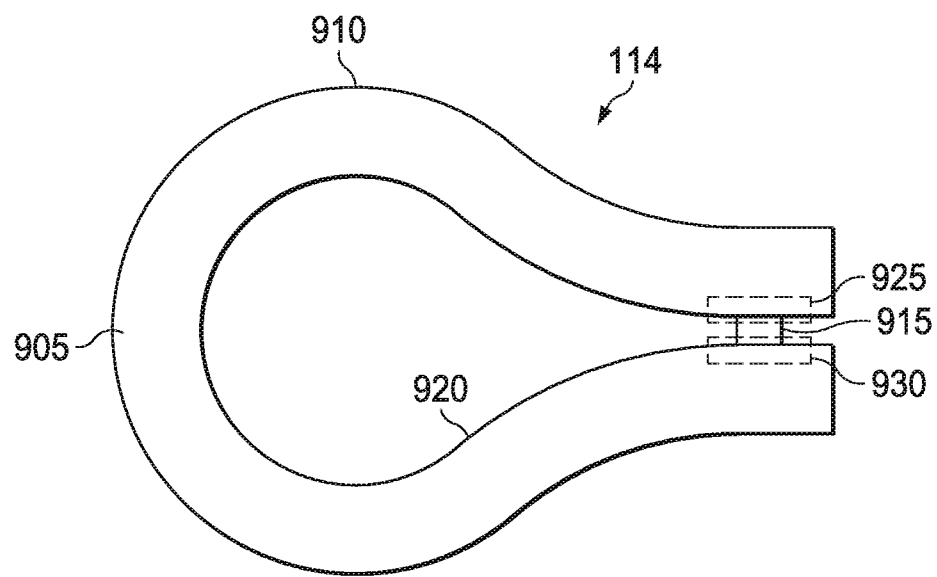
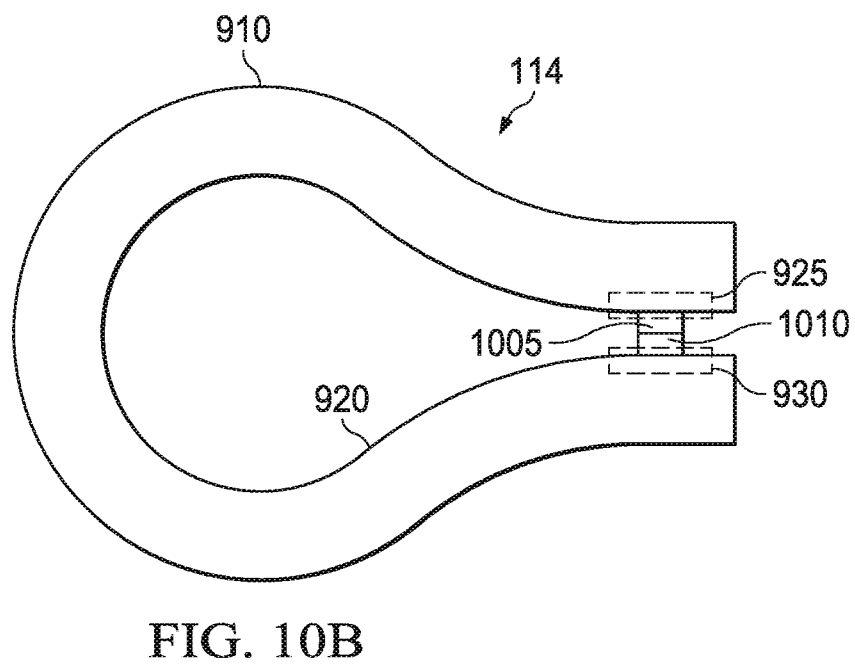
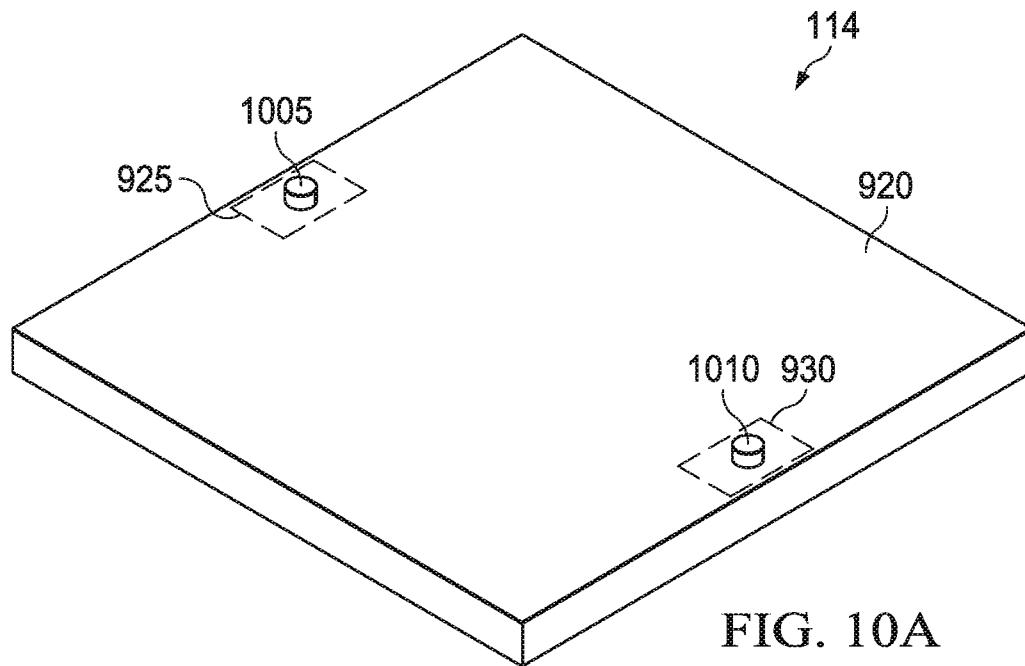


FIG. 9C



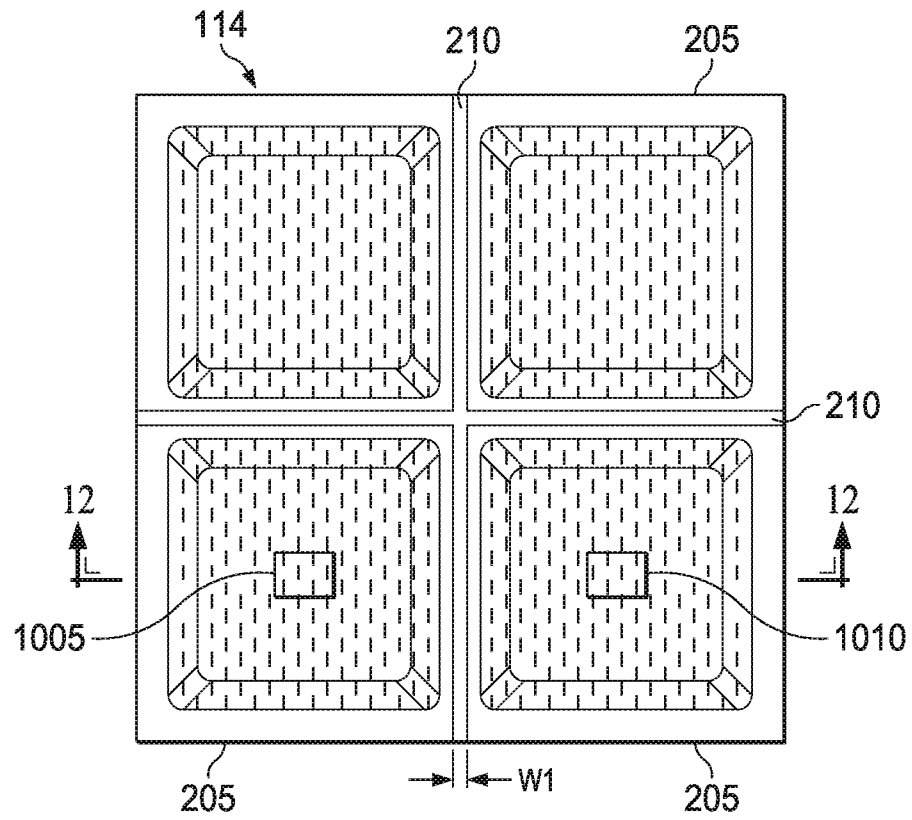


FIG. 11

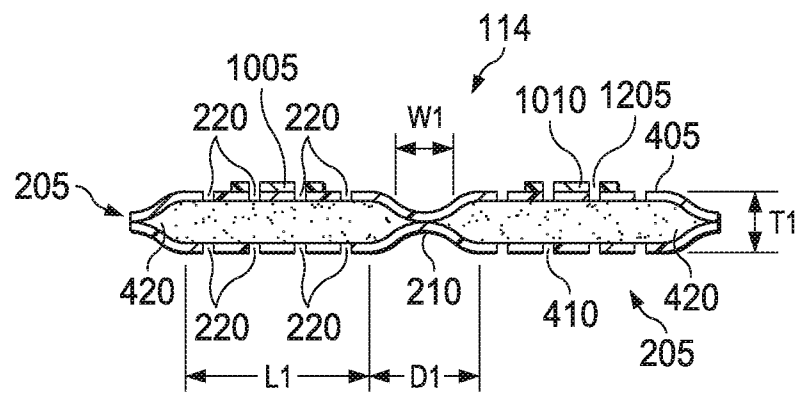


FIG. 12

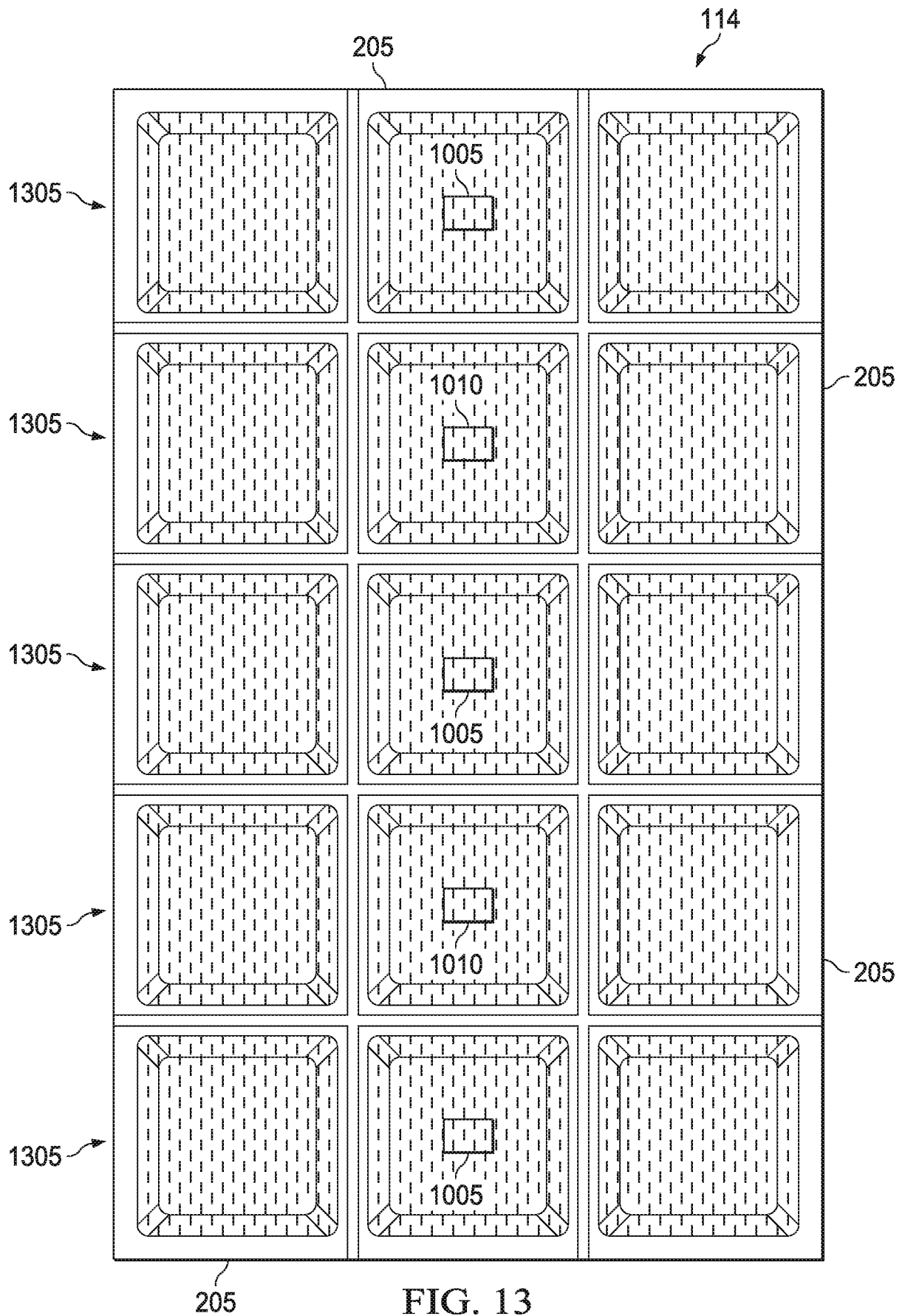


FIG. 13

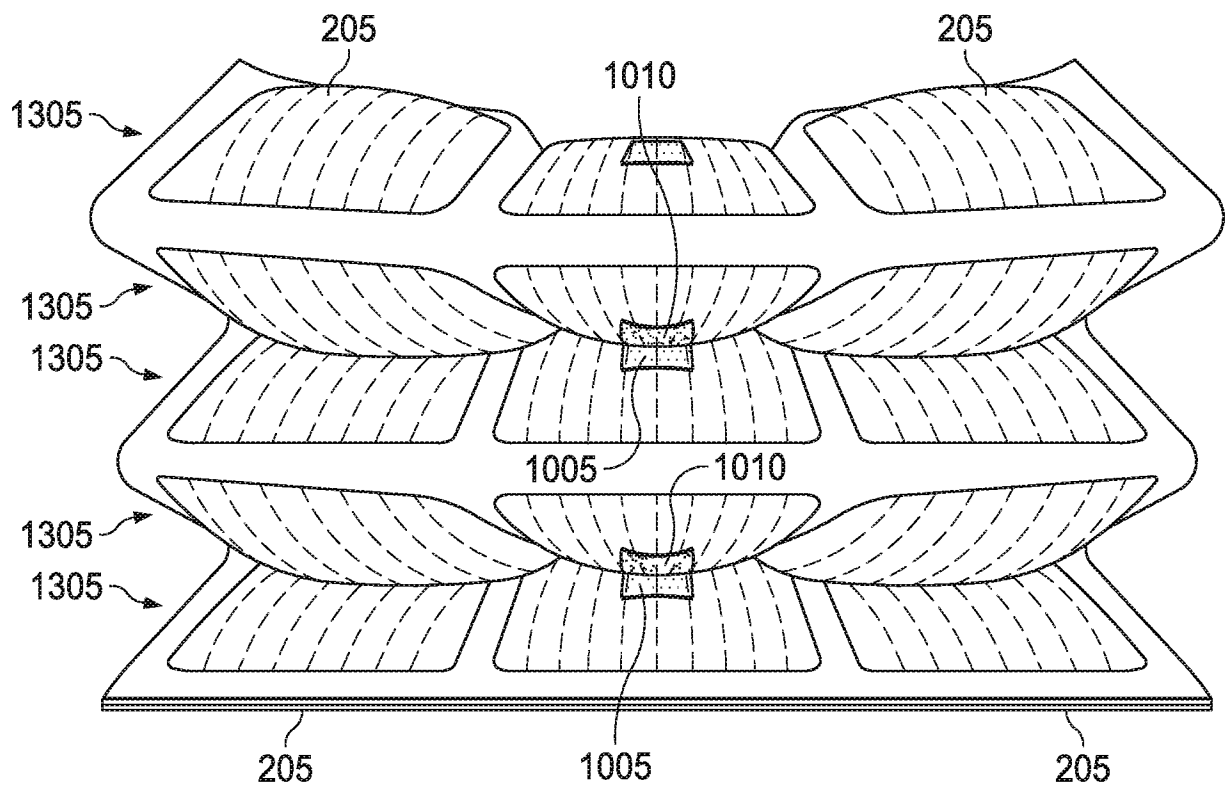


FIG. 14

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2020/057333

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) paragraphs [0002], [0007] - [0009], [0064] - [0070] claims 1-71; figures 1-14 -----	1-51, 60-73
A	US 2018/353337 A1 (LOCKE CHRISTOPHER BRIAN [GB]) 13 December 2018 (2018-12-13) claims 1-34 -----	1-51, 60-73
A	US 2007/185426 A1 (AMBROSIO ARCHEL [US] ET AL) 9 August 2007 (2007-08-09) paragraph [0052]; figure 3 -----	1-51, 60-73



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"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

13 October 2020

Date of mailing of the international search report

21/10/2020

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Beins, Ulrika

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2020/057333

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.: 52-59, 74, 75
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/IB2020/057333

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2018226650	A1	13-12-2018	AU 2018281102 A1 19-12-2019
			CA 3065379 A1 13-12-2018
			CN 110799222 A 14-02-2020
			EP 3634519 A1 15-04-2020
			JP 2020523079 A 06-08-2020
			US 2019231600 A1 01-08-2019
			WO 2018226650 A1 13-12-2018

US 2018353337	A1	13-12-2018	AU 2018281120 A1 02-01-2020
			AU 2018281333 A1 31-10-2019
			BR 112019025029 A2 23-06-2020
			CA 3061327 A1 13-12-2018
			CA 3066065 A1 13-12-2018
			CN 110691573 A 14-01-2020
			CN 110799157 A 14-02-2020
			CN 111295209 A 16-06-2020
			EP 3634332 A1 15-04-2020
			EP 3634339 A1 15-04-2020
			EP 3634520 A1 15-04-2020
			JP 2020523073 A 06-08-2020
			JP 2020523083 A 06-08-2020
			KR 20200016932 A 17-02-2020
			US 2018353337 A1 13-12-2018
			US 2018353342 A1 13-12-2018
			US 2019231601 A1 01-08-2019
			WO 2018226630 A1 13-12-2018
			WO 2018226744 A1 13-12-2018
			WO 2018226746 A1 13-12-2018

US 2007185426	A1	09-08-2007	AU 2008209626 A1 31-07-2008
			CA 2674024 A1 31-07-2008
			CN 101588836 A 25-11-2009
			CN 103120610 A 29-05-2013
			EP 2121110 A2 25-11-2009
			EP 2767305 A1 20-08-2014
			EP 3127577 A1 08-02-2017
			EP 3372207 A1 12-09-2018
			EP 3563816 A1 06-11-2019
			JP 4777462 B2 21-09-2011
			JP 2010516387 A 20-05-2010
			KR 20090122206 A 26-11-2009
			RU 2009122936 A 27-02-2011
			TW 200845948 A 01-12-2008
			US 2007185426 A1 09-08-2007
			US 2010249688 A1 30-09-2010
			WO 2008091521 A2 31-07-2008
			ZA 200904095 B 28-04-2010
