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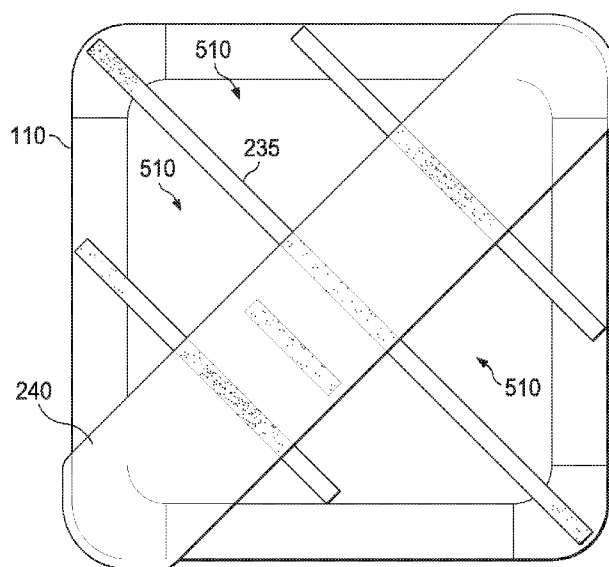


FIG. 5

(57) Abstract: Systems, apparatuses, and methods for providing negative pressure and/or instillation to a tissue site are disclosed. Illustrative embodiments may include an apparatus or system comprising a dressing for treating a tissue site with negative pressure. For example, the dressing may comprise or consist essentially of a fluid-management layer, a vapor-transfer surface, and a thermochromic material on the vapor-transfer surface or in the vapor-transfer surface and configured to change color in response to fluid movement through the dressing. Methods of manufacturing and using the dressing are also disclosed.



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## **NEGATIVE PRESSURE WOUND THERAPY SYSTEMS AND METHODS TO INDICATE TOTAL FLUID HANDLING**

### **RELATED APPLICATIONS**

**[0001]** The present application claims priority to U.S. Provisional Patent Application No. 62/730,300, entitled “Negative Pressure Wound Therapy Systems and Methods to Indicate Total Fluid Handling,” filed September 12, 2018, which is incorporated herein by reference for all purposes.

### **TECHNICAL FIELD**

**[0002]** The invention set forth in the appended claims relates generally to tissue treatment systems and more particularly, but without limitation, to evaporative dressings for use with negative-pressure treatment and methods of using the dressings for 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, an apparatus for treating tissue with negative pressure may comprise a dressing associated with a fluid-handling indicator to indicate fluid movement through parts of the dressing. The apparatus may be beneficial for various modes of treatment and for various types of tissue sites to make sure the dressing is used in such a way that the conditions of the dressing are ideally suited to the function of the dressing. More generally, a dressing may be provided for treating tissue with negative pressure and managing fluid. The dressing may comprise or consist essentially of a fluid-management layer, a vapor-transfer surface covering the fluid-management layer, and a fluid-handling indicator.

[0008] For example, the fluid-handling indicator may comprise a thermochromic material on the vapor-transfer surface or in the vapor-transfer surface. In certain embodiments, the thermochromic material is configured to change color in response to fluid evaporation through the vapor-transfer surface that is adjacent to an ambient environment or fluid entry into the fluid-management layer adjacent to a tissue site. In some embodiments, the thermochromic material may comprise a thermochromic ink print, a thermochromic self-adhesive label, or a plurality of thermochromic materials, at least one of the plurality of thermochromic materials configured to change color within a first temperature range different from a second temperature range of at least one other of the plurality of thermochromic materials.

[0009] In further embodiments, the dressing may comprise a blocking layer adjacent to an area of the vapor-transfer surface, wherein the blocking layer is configured to block or reduce fluid evaporation of the area. For example, the blocking layer may comprise a material with a moisture-vapor transmission rate less than a moisture-vapor transmission rate of the vapor-transfer surface.

[0010] The vapor-transfer surface may comprise or consist essentially of a polymer film in some examples. In some embodiments, the vapor-transfer surface may comprise a first area configured to allow evaporation of the fluid from the first area, and a second area configured to allow less evaporation of the fluid from the second area than the first area. In

some embodiments, the fluid-handling indicator is configured to change color in response to evaporation of the fluid across the first area and second area of the polymer film. The first and second areas may have similar or same sizes, or the first area is larger than the second area. In further embodiments, the polymer film may be configured to allow movement of the fluid from the absorbent to the polymer film and evaporation of the fluid through the polymer film into an ambient environment. The polymer film may be hydrophilic. For example, the polymer film may have a moisture-vapor transmission rate of between about 1,000 to about 14,000 g/m<sup>2</sup>/day, particularly a moisture-vapor transmission rate of about 12,000 g/m<sup>2</sup>/day, measured using an upright cup technique according to ASTM E96/E96M Upright Cup Method at 38°C and 10% relative humidity (RH). In further embodiments, the polymer film may be a polyurethane film. In some embodiments, the polymer film may have a thickness of between about 15 microns and about 100 microns, or a thickness of between about 10 microns and about 50 microns.

**[0011]** The dressing may comprise a fluid-management layer. In some embodiments, the fluid-management layer may comprise an absorbent. In some embodiments, the fluid-management layer may be a manifold. For example, the fluid-management layer can be configured to transfer fluid from a tissue site and store the fluid within the absorbent. The dressing may further comprise an adhesive configured to couple a portion of the vapor-transfer surface to a tissue site, and the thermochromic material may be configured to cover the portion of the polymer film. In further embodiments, the fluid-management layer may be coupled to the vapor-transfer surface. For example, the fluid-management layer may comprise an absorbent, the vapor-transfer surface may comprise a polymer film, and the absorbent can be coupled to the polymer film. In still further embodiments, the dressing can be configured to be fluidly coupled to a negative pressure source, a fluid source, or both.

**[0012]** Alternatively, other example embodiments may comprise a dressing for managing fluid, and the dressing may comprise: an absorbent; a polymer film covering the absorbent; and a thermochromic material in the polymer film. The thermochromic material can be configured to change color in response to fluid evaporation through the polymer film, in response to fluid entry into the absorbent, or both. In further embodiments, a dressing may comprise a vapor-transfer surface or a cover layer and a fluid-handling indicator configured to change color in response to fluid evaporation through the vapor-transfer surface or cover layer.

**[0013]** In some embodiments, a method of monitoring fluid movement in a dressing is also described herein, wherein some example embodiments include positioning a dressing

adjacent to a tissue site; reading color change of the thermochroic material; and monitoring fluid movement in the dressing indicated by the color change.

**[0014]** In further embodiments, the dressing may comprise an absorbent, a polymer film covering the absorbent, and a thermochromic material adjacent to the polymer film, the thermochromic material configured to change color in response to fluid evaporation through the polymer film or fluid entry into the absorbent.

**[0015]** In certain embodiments, a method of manufacturing a dressing is also described herein, wherein some example embodiments include providing an absorbent; disposing a polymer film on the absorbent; and covering the polymer film with a thermochromic material on the polymer film, the thermochromic material configured to change color in response to fluid evaporation from the through the polymer film or fluid entry into the absorbent.

**[0016]** An alternative method of manufacturing a dressing is also described herein, wherein some example embodiments include providing an absorbent; providing a polymer film comprising a thermochromic material in the polymer film, the thermochromic material configured to change color in response to fluid evaporation from the through the polymer film or fluid entry into the absorbent; and disposing the polymer film on the absorbent.

**[0017]** 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

[0018] Figure 1 is a functional block diagram of an example embodiment of a therapy system that can provide tissue treatment in accordance with example embodiments of this specification;

[0019] Figure 2 is a schematic view of an example of a dressing that may be associated with some embodiments of the therapy system of Figure 1;

[0020] Figure 3 is a schematic section of the dressing of Figure 2, illustrating additional details that may be associated with some embodiments;

[0021] Figure 4 is an assembly view of an example of the dressing of Figure 2, illustrating additional details that may be associated with some embodiments;

[0022] Figure 5 is a top view of another example configuration of a dressing, illustrating additional details that may be associated with some embodiments;

[0023] Figure 6 illustrates an example of the dressing of Figure 5 applied to a limb of a patient, illustrating additional details that may be associated with some embodiments;

[0024] Figure 7 is a perspective view of the dressing of Figure 5, illustrating additional details that may be associated with some embodiments;

[0025] Figure 8 illustrates a thermal image taken by a forward-looking infrared (FLIR) camera of the dressing of Figure 5, illustrating additional details that may be associated with some example embodiments;

[0026] Figure 9 illustrates a thermal image taken by a forward-looking infrared (FLIR) camera of the dressing of Figure 5, illustrating additional details that may be associated with some example embodiments;

[0027] Figure 10 illustrates an example of another example configuration of a dressing applied to a limb of a patient, illustrating additional details that may be associated with some embodiments;

[0028] Figure 11 illustrates a thermal image taken by a forward-looking infrared (FLIR) camera of the dressing of Figure 10, illustrating additional details that may be associated with some example embodiments;

[0029] Figure 12 illustrates a thermal image taken by a forward-looking infrared (FLIR) camera of the dressing of Figure 10, illustrating additional details that may be associated with some example embodiments;

[0030] Figure 13 is a top view of another example configuration of a dressing, illustrating additional details that may be associated with some embodiments;

**[0031]** Figure 14 is a perspective view of the dressing of Figure 13 applied to a limb of a patient, illustrating additional details that may be associated with some embodiments; and

**[0032]** Figure 15 illustrates a thermal image taken by a forward-looking infrared (FLIR) camera of the dressing of Figure 13, illustrating additional details that may be associated with some example embodiments.

## DESCRIPTION OF EXAMPLE EMBODIMENTS

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

[0034] The example embodiments may also be described herein with reference to spatial relationships between various elements or to the spatial orientation of various elements depicted in the attached drawings. In general, such relationships or orientation assume a frame of reference consistent with or relative to a patient in a position to receive treatment. However, as should be recognized by those skilled in the art, this frame of reference is merely a descriptive expedient rather than a strict prescription.

[0035] Figure 1 is a simplified functional block diagram of an example embodiment of a therapy system 100 that can provide negative-pressure therapy with instillation of topical treatment solutions to a tissue site in accordance with this specification.

[0036] The term “tissue site” in this context broadly refers to a wound, defect, or other treatment target located on or within tissue, including but not limited to, a bone tissue, an adipose tissue, a muscle tissue, a neural tissue, a dermal tissue, a vascular tissue, a connective tissue, a cartilage, tendons, or ligaments. A wound may include chronic, acute, traumatic, subacute, and dehiscent wounds, flaps, and grafts, for example. The term “tissue site” may also refer to areas of any tissue that are not necessarily wounded or defective, but are instead areas in which it may be desirable to add or promote the growth of additional tissue. For example, negative pressure may be applied to a tissue site to grow additional tissue that may be harvested and transplanted.

[0037] The therapy system 100 may include a source or supply of negative pressure, such as a negative-pressure source 105, a dressing 110, a fluid container, such as a container 115, and a regulator or controller, such as a controller 120, for example. Additionally, the therapy system 100 may include sensors to measure operating parameters and provide feedback signals to the controller 120 indicative of the operating parameters. As illustrated in Figure 1, for example, the therapy system 100 may include a first sensor 125, a second sensor 130, or both, coupled to the controller 120. As illustrated in the example of Figure 1, the dressing 110 may comprise or consist essentially of one or more dressing layers, such as a tissue interface 135, a vapor-transfer surface 140, or both in some embodiments. A fluid

bridge 145 may fluidly couple the dressing 110 to other components, such as the negative-pressure source 105.

**[0038]** The therapy system 100 may also include a source of instillation solution, such as saline, for example. For example, a solution source 155 may be fluidly coupled to the dressing 110, as illustrated in the example embodiment of Figure 1. The solution source 155 may be fluidly coupled to a positive-pressure source such as the positive-pressure source 150, a negative-pressure source such as the negative-pressure source 105, or both in some embodiments. A regulator, such as an instillation regulator 160, may also be fluidly coupled to the solution source 155 and the dressing 110 to ensure proper dosage of instillation solution to a tissue site. For example, the instillation regulator 160 may comprise a piston that can be pneumatically actuated by the negative-pressure source 105 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 120 may be coupled to the negative-pressure source 105, the positive-pressure source 150, or both, to control dosage of instillation solution to a tissue site. In some embodiments, the instillation regulator 160 may also be fluidly coupled to the negative-pressure source 105 through the dressing 110, as illustrated in the example of Figure 1.

**[0039]** Some components of the therapy system 100 may be housed within or used in conjunction with other components, such as sensors, processing units, alarm indicators, memory, databases, software, display devices, or user interfaces that further facilitate therapy. For example, in some embodiments, the negative-pressure source 105 may be combined with the solution source 155, the controller 120 and other components into a therapy unit.

**[0040]** In general, components of the therapy system 100 may be coupled directly or indirectly. For example, the negative-pressure source 105 may be directly coupled to the container 115, and may be indirectly coupled to the dressing 110 through the container 115. 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 105 may be electrically coupled to the controller 120. The negative-pressure source may be fluidly coupled to one or more distribution components, which provide a fluid path to a tissue site. In some embodiments, components may also be coupled by virtue of physical proximity, being integral to a single structure, or being formed from the same piece of material. For example, the tissue interface 135 and the vapor-transfer surface 140 may be discrete layers disposed adjacent to each other, and may be joined together or coupled in some embodiments.

**[0041]** A distribution component is preferably detachable, and may be disposable, reusable, or recyclable. The dressing 110 and the container 115 are illustrative of distribution components. A fluid conductor is another illustrative example of a distribution component. A "fluid conductor," in this context, broadly includes a tube, pipe, hose, conduit, or other structure with one or more lumina or open pathways adapted to convey a fluid between two ends. Typically, a tube is an elongated, cylindrical structure with some flexibility, but the geometry and rigidity may vary. Moreover, some fluid conductors may be molded into or otherwise integrally combined with other components. Distribution components may also include or comprise interfaces or fluid ports to facilitate coupling and de-coupling other components, including sensors and data communication devices. In some embodiments, for example, a dressing interface may facilitate coupling a fluid conductor to the dressing 110. For example, such a dressing interface may be a SENSAT.R.A.C™ Pad available from Kinetic Concepts, Inc. of San Antonio, Texas.

**[0042]** A negative-pressure supply, such as the negative-pressure source 105, may be a reservoir of air at a negative pressure, or may be a manual or electrically-powered device, such as a vacuum pump, a suction pump, a wall suction port available at many healthcare facilities, or a micro-pump, for example. "Negative pressure" generally refers to a pressure less than a local ambient pressure, such as the ambient pressure in a local environment external to a sealed therapeutic environment. In many cases, the local ambient pressure may also be the atmospheric pressure at which a tissue site is located. Alternatively, the pressure may be less than a hydrostatic pressure associated with tissue at the tissue site. Unless otherwise indicated, values of pressure stated herein are gauge pressures. References to increases in negative pressure typically refer to a decrease in absolute pressure, while decreases in negative pressure typically refer to an increase in absolute pressure. While the amount and nature of negative pressure applied to a tissue site may vary according to therapeutic requirements, the pressure is generally a low vacuum, also commonly referred to as a rough vacuum, between -5 mm Hg (-667 Pa) and -500 mm Hg (-66.7 kPa). Common therapeutic ranges are between -50 mm Hg (-9.9 kPa) and -300 mm Hg (-39.9 kPa).

**[0043]** The container 115 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 used 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. Some examples of the therapy system 100 may include more than

one container. Additionally or alternatively, the container 115 may be integrated or combined with the negative-pressure source 105 into a single unit in some embodiments.

**[0044]** A controller, such as the controller 120, may be a microprocessor or computer programmed to operate one or more components of the therapy system 100, such as the negative-pressure source 105. In some embodiments, for example, the controller 120 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 105, the pressure generated by the negative-pressure source 105, or the pressure distributed to the tissue interface 135, for example. In some embodiments, the controller 120 is particularly configured to receive one or more input signals, such as a feedback signal, and programmed to modify one or more operating parameters based on the input signals.

**[0045]** Sensors, such as the first sensor 125 and the second sensor 130, 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 first sensor 125 and the second sensor 130 may be configured to measure one or more operating parameters of the therapy system 100. In some embodiments, the first sensor 125 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 first sensor 125 may be a piezo-resistive strain gauge. The second sensor 130 may optionally measure operating parameters of the negative-pressure source 105, such as the voltage or current, in some embodiments. Preferably, the signals from the first sensor 125 and the second sensor 130 are suitable as an input signal to the controller 120, 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 120. Typically, the signal is an electrical signal, but may be represented in other forms, such as an optical signal.

**[0046]** The tissue interface 135 can be adapted to or configured to be adjacent to a tissue site. If the tissue site is a wound, for example, the tissue interface 135 may partially or completely fill the wound, or may be placed over the wound. The tissue interface 135 may take many forms and have more than one layer in some embodiments. The tissue interface 135 may also have many sizes, shapes, or thicknesses depending on a variety of factors, such as the type of treatment being implemented or the nature and size of a tissue site. For

example, the size and shape of the tissue interface 135 may be adapted to the contours of deep and irregular shaped tissue sites.

**[0047]** In some embodiments, the tissue interface 135 may comprise a means to transfer fluid. For example, the tissue interface 135 may comprise or consist essentially of a fluid transfer member, such as a manifold member, a wicking member, or some combination of manifold and wicking members. A manifold member in this context generally includes material, substances, or structures that provide pathways adapted to collect or distribute fluid across a tissue site under pressure. A wicking member generally includes material, substances, or structures that can move liquid by capillary action. In some illustrative embodiments, the pathways of a manifold or wicking member may be interconnected to improve distribution or collection of fluids across a tissue site.

**[0048]** In some illustrative embodiments, a manifold may be a porous material having interconnected cells. For example, open-cell foam generally includes pores, edges, and/or walls adapted to form interconnected fluid channels. Liquids, gels, and other foams may also include or be cured to include apertures and fluid pathways. In some embodiments, a manifold may additionally or alternatively comprise projections that form interconnected fluid pathways. For example, a manifold may be molded to provide surface projections that define interconnected fluid pathways.

**[0049]** Some textiles may also be suitable as a fluid transfer member. For example, woven and non-woven textiles are generally porous, making them suitable as a manifold in some embodiments. Some textiles may additionally or alternatively be configured to transfer fluid through wicking action. In general, a textile includes any cohesive network of natural or synthetic fibers. For example, fibers may be woven, knitted, knotted, pressed together, or otherwise bonded to form a textile. Sheets or webs of fibers that are bonded together by entangling fibers mechanically, thermally, or chemically are generally classified as a non-woven textile. More broadly, though, a non-woven textile may include any sheet or layer of fibers which are neither woven nor knitted, such as felt, for example.

**[0050]** In some embodiments, a fluid transfer member may be a composite textile having a hydrophobicity that varies from a first side to a second side. For example, the hydrophobicity may increase from an acquisition surface to a distribution surface. In some examples, a fluid transfer member may be a non-woven textile having an acquisition surface that is hydrophilic and a distribution surface that is hydrophobic. In some embodiments, a fluid distribution surface may include hydrophobic fibers oriented substantially within a plane of the surface. A fluid acquisition surface may include hydrophilic fibers oriented

substantially normal to a plane of the surface. More specifically, in some example embodiments, a fluid transfer member may comprise or consist essentially of a dual-layer non-woven textile, such as a through-air bonded web of dry polyester and hydrophilic, profiled polyester and bi-component fibers. Suitable products may include the DRYWEB TDL2 acquisition and distribution layer from LIBELTEX, or the SLIMCORE TL4 acquisition and distribution layer from LIBELTEX, for example.

**[0051]** The vapor-transfer surface 140 may have a high moisture-vapor transmission rate (MVTR) in some applications. For example, the MVTR may be in a range of about 1,000 grams per square meter per twenty-four hours to 14,000 grams per square meter per twenty-four hours in some embodiments, or about 12,000 grams per square meter per twenty-four hours, measured using an upright cup technique according to ASTM E96/E96M Upright Cup Method at 38°C and 10% relative humidity (RH).

**[0052]** In some example embodiments, the vapor-transfer surface 140 may be part of a cover layer, such as a polymer drape. The vapor-transfer surface 140 may comprise a hydrophilic polyurethane film. Such a drape may have a thickness in a range between 10 microns to 50 microns, or in a range between 15 microns and 100 microns. For permeable materials, the permeability may be low enough that a desired negative pressure may be maintained. The cover layer 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; 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); co-polyester; and polyether block polyimide copolymers. Such materials are commercially available as, for example, Tegaderm® drape, commercially available from 3M Company, Minneapolis Minnesota; polyurethane (PU) drape, commercially available from Avery Dennison Corporation, Pasadena, California; polyether block polyamide copolymer (PEBAX), for example, from Arkema S.A., Colombes, France; and Inspire 2301 and Inspire 2327 polyurethane films, commercially available from Expopak Advanced Coatings, Wrexham, United Kingdom.

**[0053]** An attachment device may be used to attach the vapor-transfer surface 140 to an attachment surface, such as undamaged epidermis, a gasket, or another cover. The attachment device may take many forms. For example, the attachment device may be a medically-acceptable, pressure-sensitive adhesive configured to bond the vapor-transfer

surface 140 to epidermis around a tissue site, such as a tunnel wound or a fistula. In some embodiments, for example, some or all of the vapor-transfer surface 140 may be coated with an adhesive, such as an acrylic adhesive, which may have a coating weight between 25-65 grams per square meter (g.s.m.). Thicker adhesives, or combinations of adhesives, may be applied in some embodiments to improve the seal and reduce leaks. Other example embodiments of an attachment device may include a double-sided tape, paste, hydrocolloid, hydrogel, silicone gel, or organogel.

**[0054]** In certain embodiments, the vapor-transfer surface 140 may be pattern printed with an adhesive to allow the overall dressing structure to achieve a structural integrity while allowing for increase diffusion and MVTR. In other embodiments, there may be no attachment or adhesive over the area of evaporation on the vapor-transfer surface 140 as this may reduce the MVTR. The dressing 110 of this construction may be held together with a hot-melt use-able fiber or any other attachment devices that do not effect of the MVTR of the vapor-transfer surface 140 significantly.

**[0055]** The solution source 155 may also be representative of a container, canister, pouch, bag, or other storage component, which can provide a solution for instillation therapy. Compositions of solutions may vary according to a prescribed therapy, but examples of solutions that may be suitable for some prescriptions include hypochlorite-based solutions, silver nitrate (0.5%), sulfur-based solutions, biguanides, cationic solutions, and isotonic solutions.

**[0056]** Figure 2 is a schematic view of an example of a bridge dressing 200. As shown in the example of Figure 2, the bridge dressing 200 may be an assembly of the dressing 110 and the fluid bridge 145. Figure 2 illustrates additional details that may be associated with some examples of the dressing 110 and the fluid bridge 145. For example, the tissue interface 135 of Figure 2 comprises a contact layer 205 and a fluid-management layer 210. The fluid bridge 145 may be elongated, having a length that is substantially greater than its width. For example, the fluid bridge 145 may have an aspect ratio of about 6:1 to about 12:1. A width of about two inches and a length of about 12 to 24 inches may be suitable for some embodiments. A first end of the fluid bridge 145 may be fluidly coupled to the fluid-management layer 210. A fluid interface 215 may be disposed on the second end of the fluid bridge 145. A fluid conductor 220 with a connector 225 may optionally be connected to the fluid interface 215 in some examples.

**[0057]** The vapor-transfer surface 140 may be disposed between the tissue interface 135 and an ambient environment. In some embodiments, the vapor-transfer surface 140 may

provide a fluid-handling indicator 235 that allows for the detection and indication of the fluid movement from a wound dressing where the dressing structure is optimized for diffusion and total fluid handling. The fluid-handling indicator 235 may be used to indicate fluid movement entering or evaporating from certain layers of the dressing 110, such as the vapor-transfer surface 140. The fluid-handling indicator 235 may be used to indicate fluid movement based on a temperature change between a first area that comprises the fluid-handling indicator 235 and a second area comprising a blocking layer 240 adjacent to the vapor-transfer surface 140. The second area may be an area that has less evaporation than that of the first area and may serve as a negative control. The fluid-handling indicator 235 may indicate a temperature difference between the first area and the second area, and may not be needed to indicate a specific temperature. The fluid-handling indicator 235 may include one or more thermochromic inks. Thermochromic inks may include LCD inks or any other inks that target a specific temperature or temperature ranges, such as an array of inks to cover a range of possible temperatures.

**[0058]** In some embodiments, the vapor-transfer surface 140 may be covered with the fluid-handling indicator 235. In further embodiments, the fluid-handling indicator 235 may be printed in a pattern which covers sections of the tissue interface 135, including foam or absorbent pad areas, island adhesive areas outside the foam or absorbent pad areas, or both. In certain embodiments, such as a borderless dressing, certain areas of the vapor-transfer surface 140 may be blocked from evaporation by a blocking layer 240, such as a low MVTR film or tape, prior to or after printing to provide a control of the indication by the fluid-handling indicator 235. For example, the low MVTR may be less than about 1,000 grams or less than about 250 grams per square meter per twenty-four hours, measured using an upright cup technique according to ASTM E96/E96M Upright Cup Method at 38°C and 10% relative humidity (RH). In certain embodiments, the blocking layer 240 may only cover a small area of the vapor-transfer surface 140 so that it will not impact total fluid handling significantly.

**[0059]** The fluid-handling indicator 235 may comprise a printed ink in certain embodiments. In particular embodiments, a printed material may be pad printed or screen printed to the vapor-transfer surface 140 before or after assembly, although it may be optional in some embodiments to apply after assembly. The printed material may be protected by a thin coat of varnish, drape or a protective coating. The printed material may be only protected in the area of the fluid-handling indicator 235 so that MVTR in the area of the fluid-handling indicator 235 is not reduced. In further embodiments, the fluid-handling indicator 235 may be a self-adhesive label-like structure which is bonded to the vapor-

transfer surface 140. The fluid-handling indicator 235 may be designed to indicate a temperature change of at least 5 degrees C, such as from 20 to 25 degrees C, from 25 to 30 degrees C, or from 30 to 35 degrees. In some embodiments, this change may be an increase of the temperature. In other embodiments, this change may be a decrease of the temperature.

**[0060]** In certain embodiments, negative pressure distributed from the negative-pressure source 105 may assist with the performance of the dressing 110 and this fluid-handling indicator 235. In particular embodiments, negative pressure can provide a better thermal connection of the fluid-handling indicator 235 to the structures of the dressing 110, which retain the fluids, increasing evaporation and fluid distribution.

**[0061]** The use of the fluid-handling indicator 235 may help identify evaporation of fluids from the vapor-transfer surface 140 or, alternatively or additionally, movement of fluids into the dressing 110. The use of negative pressure may compress the dressing 110, and the compression may allow the structure to rapidly adjust to a temperature. A combination of various types of the fluid-handling indicators 235, such as thermochromic crystals and inks, may allow detection of areas that change color in response to a drop in temperature from ambient (e.g., 35 degrees) indicating evaporation, and may also allow detection of areas that change color in response to increases in temperature from ambient, which could allow the user to see where the fluid is entering the dressing 110 and the temperatures of that fluid. In some embodiments, the dressing 110 may be further determined as being full if at this point it is indicated that all areas of the dressing are evaporating.

**[0062]** Figure 3 is a schematic section of the bridge dressing 200 of Figure 2, taken along line 3-3, illustrating additional details that may be associated with some embodiments. In some embodiments, the fluid-handling indicator 235 may be a thermochromic material, such as thermochromic crystals, ink or dyes, printed on the vapor-transfer surface 140. In the example configuration of Figure 3, the contact layer 205 has apertures 305, and the fluid-management layer 210 is disposed between the vapor-transfer surface 140 and the contact layer 205. The fluid-management layer 210 can separate the vapor-transfer surface 140 and the contact layer 205, and may comprise or consist essentially of one or more fluid transfer members. In some embodiments, the fluid-management layer 210 may comprise or consist essentially of a fluid transfer layer having a fluid acquisition surface and a fluid distribution surface, such as a dual-layer non-woven textile from LIBELTEX.

**[0063]** The fluid bridge 145 may comprise an enclosure, such as an envelope 310, which can define a fluid channel 315. The envelope 310 may be made from a material that is

impermeable to liquid, and may comprise at least one vapor-transfer surface 320 that is permeable to vapor. A fluid transfer bridge 325 may be disposed within the envelope 310, adjacent to the vapor-transfer surface 320. The fluid transfer bridge 325 may be elongated, having a length that is substantially longer than its thickness and width. In some embodiments the fluid transfer bridge 325 may substantially fill the fluid channel 315 and structurally support the envelope 310. A first end of the fluid transfer bridge 325 may be fluidly coupled to the fluid-management layer 210 through a first transfer channel 330. A second end of the fluid transfer bridge 325 may be fluidly coupled to a fluid interface, such as the fluid interface 215, through a second transfer channel 335. The fluid transfer bridge 325 preferably has a low profile. A thickness of 15 millimeters or less may be suitable for some configurations.

**[0064]** The fluid transfer bridge 325 may comprise or consist essentially of one or more fluid transfer members, which may include one or more manifold members, wicking members, or some combination of manifold and wicking members. In Figure 3, for example, the fluid transfer bridge 325 comprises a first wicking layer 340 and a second wicking layer 345. At least one fluid transfer layer may be disposed adjacent to the vapor-transfer surface 320 in some embodiments, and may be oriented to maximize adjacent surface area. For example, in Figure 3 the second wicking layer 345 is disposed adjacent to the vapor-transfer surface 320. In some embodiments, the fluid transfer bridge 325 may comprise an intermediate fluid transfer member, such as a fluid-management layer 350. For example, the fluid-management layer 350 may be a hydrophilic wicking member or manifold member. The fluid-management layer 350 may be adapted to distribute negative pressure between the first transfer channel 330 and the second transfer channel 335, and may also be adapted to transfer liquid between the first wicking layer 340 and the second wicking layer 345. In some embodiments, the first wicking layer 340 and the second wicking layer 345 can also be considered be to separate fluid-management layers.

**[0065]** The thickness of fluid transfer layers in the fluid transfer bridge 325 may vary according to needs of a prescribed therapy. For example, each of the first wicking layer 340 and the second wicking layer 345 may have a thickness in a range of about 1 millimeter to about 4 millimeters. A thickness in a range of about 5 millimeters to 10 millimeters may be suitable for some embodiments of the fluid-management layer 350, and a thickness of about 6 millimeters may be preferable. The thickness of the fluid-management layer 350 may be decreased to relieve stress on other layers in some embodiments. The thickness of the fluid-management layer 350 can also affect the conformability of the fluid transfer bridge 325.

[0066] In some embodiments, at least a portion of the first wicking layer 340 may be in direct contact with at least a portion of the second wicking layer 345. In some embodiments, at least a portion of the first wicking layer 340 may be spaced apart or separated from the second wicking layer 345 by the fluid-management layer 350.

[0067] One or more of the fluid transfer layers of the fluid transfer bridge 325 may have a fluid acquisition surface and a fluid distribution surface. For example, the first wicking layer 340 may have a fluid acquisition surface oriented toward the first transfer channel 330, and the second wicking layer 345 may have a fluid distribution surface oriented toward the vapor-transfer surface 320.

[0068] Figure 4 is an assembly view of an example of the bridge dressing 200, illustrating additional details that may be associated with some embodiments. In some embodiments, the fluid-handling indicator 235 may comprise a thermochromic material and may be placed on the vapor-transfer surface 140. In further embodiments, a blocking layer 240 may be diagonally placed on the vapor-transfer surface 140 and may be on top of the fluid-handling indicator 235 in some areas.

[0069] As illustrated in the example of Figure 4, some embodiments of the contact layer 205 may be perforated. In some embodiments, the contact layer 205 may comprise or consist essentially of a soft, pliable material suitable for providing a fluid seal around a tissue site, and may have a substantially flat surface. For example, the contact layer 205 may comprise, without limitation, a silicone gel, a soft silicone, hydrocolloid, hydrogel, polyurethane gel, polyolefin gel, hydrogenated styrenic copolymer gel, a foamed gel, a soft closed cell foam such as polyurethanes and polyolefins coated with an adhesive, polyurethane, polyolefin, or hydrogenated styrenic copolymers. In some embodiments, the contact layer 205 may have a thickness between about 200 microns ( $\mu\text{m}$ ) and about 1000 microns ( $\mu\text{m}$ ). In some embodiments, the contact layer 205 may have a hardness between about 5 Shore OO and about 80 Shore OO. In some embodiments, the contact layer 205 may be a hydrophobic-coated material. For example, the contact layer 205 may be formed by coating a spaced material, such as woven, non-woven, molded, or extruded mesh, with a hydrophobic material. The hydrophobic material for the coating may be a soft silicone, for example.

[0070] In further embodiments, the fluid-management layer 210 may comprise or consist essentially of one or more fluid transfer members, such as a third wicking layer 405 and a fourth wicking layer 410. In some examples, the third wicking layer 405 and the fourth wicking layer 410 may be disposed between the vapor-transfer surface 140 and the contact

layer 205 in a stacked relationship as shown in Figure 4. In some examples, two or more fluid transfer layers may be laminated. For example, an adhesive or thermal weld can bond or otherwise secure the third wicking layer 405 and the fourth wicking layer 410 to each other without adversely affecting fluid transfer. In some embodiments, the third wicking layer 405 may have a fluid acquisition surface oriented toward the contact layer 205, and the fourth wicking layer 410 may have a fluid distribution surface oriented toward the vapor-transfer surface 140. LIBELTEX TDL2 having a weight of 80 gsm or similar materials may be suitable for use as or in the third wicking layer 405, the fourth wicking layer 410, or both.

[0071] In some examples, the third wicking layer 405 may have a wider base and a higher density relative to the fourth wicking layer 410. The third wicking layer 405 may have a surface area that is greater than a surface area of the fourth wicking layer 410. The third wicking layer 405 may be thicker than the fourth wicking layer 410 in some examples. For example, the third wicking layer 405 may have a thickness of about 50 millimeters, and the fourth wicking layer 410 may have a thickness of about 20 millimeters. The third wicking layer 405 may include a profile configured to spread fluid out over an entire surface of the third wicking layer 405 to increase evaporation. The fourth wicking layer 410 may be used to pull fluid away from the third wicking layer 405. In some embodiments, the fourth wicking layer 410 may alternatively or additionally include a profile like the profile of the third wicking layer 405 to spread fluid out over an entire surface of the fourth wicking layer 410. The profile of the fourth wicking layer 410 may also be used to increase evaporation.

[0072] In some embodiments, the fluid-management layer 210 may include a film between two adjacent fluid transfer layers. For example, a film may be disposed between the third wicking layer 405 and the fourth wicking layer 410. The film may include one or more of the same properties as the vapor-transfer surface 140.

[0073] In the example of Figure 4, the dressing 110 may further include an attachment device, such as an adhesive 420. The adhesive 420 may be, for example, a medically-acceptable, pressure-sensitive adhesive that extends about a periphery, a portion, or the entire vapor-transfer surface 140. In some embodiments, for example, the adhesive 420 may be an acrylic adhesive having a coating weight between 25-65 grams per square meter (g.s.m.). Thicker adhesives, or combinations of adhesives, may be applied in some embodiments to improve the seal and reduce leaks. In some embodiments, the adhesive 420 may be continuous or discontinuous layer. Discontinuities in the adhesive 420 may be provided by apertures or holes (not shown) in the adhesive 420. The apertures or holes in the adhesive 420 may be formed after application of the adhesive 420 or by coating the adhesive

420 in patterns on a carrier layer, such as, for example, a side of the vapor-transfer surface 140. Apertures or holes in the adhesive 420 may also be sized to enhance the moisture-vapor transfer rate of the vapor-transfer surface 140 in some example embodiments.

**[0074]** In some embodiments, a release liner (not shown) may be attached to or positioned adjacent to the contact layer to protect the adhesive 420 prior to use. The release liner may also provide stiffness to assist with, for example, deployment of the dressing 110. The release liner may be, for example, a casting paper, a film, or polyethylene. Further, in some embodiments, the release liner may be a polyester material such as polyethylene terephthalate (PET), or similar polar semi-crystalline polymer. The use of a polar semi-crystalline polymer for the release liner may substantially preclude wrinkling or other deformation of the dressing 110. For example, the polar semi-crystalline polymer may be highly orientated and resistant to softening, swelling, or other deformation that may occur when brought into contact with components of the dressing 110, or when subjected to temperature or environmental variations, or sterilization. In some embodiments, the release liner may have a surface texture that may be imprinted on an adjacent layer, such as the contact layer 205. Further, a release agent may be disposed on a side of the release liner that is adjacent to the contact layer 205. For example, the release agent may be a silicone coating and may have a release factor suitable to facilitate removal of the release liner by hand and without damaging or deforming the dressing 110. In some embodiments, the release agent may be a fluorocarbon or a fluorosilicone, for example. In other embodiments, the release liner may be uncoated or otherwise used without a release agent.

**[0075]** As illustrated in the example of Figure 4, the fluid bridge 145 may include a base layer 425 and a top layer 430. Each of the base layer 425 and the top layer 430 may comprise or consist essentially of a material that is substantially impermeable to liquid. The base layer 425 may include a second aperture 435, which may be disposed at one end of the base layer 425 and aligned with the first aperture 415 to form a fluid interface between the dressing 110 and the fluid bridge 145. In some embodiments, for example, the first aperture 415 and the second aperture 435 may be assembled to form the first transfer channel 330 of Figure 3. A first adhesive ring 440 may optionally be disposed around the first aperture 415, the second aperture 435, or both in some embodiments. The top layer 430 may include a third aperture 445, which may be disposed at an end opposite the second aperture 435. In some embodiments, the third aperture 445 may be aligned with an aperture (not shown) in the fluid interface 215 to form the second transfer channel 335 of Figure 3. A second adhesive ring 450 may optionally be disposed around the third aperture 445 in some embodiments.

[0076] The base layer 425, the top layer 430, or both may comprise or consist essentially of materials similar to the vapor-transfer surface 140. For example, the base layer 425, the top layer 430, or both may comprise or consist essentially of a vapor-transfer film. In some embodiments, suitable materials may include a film that is permeable to vapor and substantially impermeable to liquid, and may have an MVTR in a range of about 250 grams per square meter per 24 hours and about 5000 grams per square meter per 24 hours. For example, the base layer 425, the top layer 430, or both, may comprise or consist essentially of a film having an MVTR of about 2600 grams per square meter per 24 hours. Further, in some embodiments, suitable materials may be breathable. Additional examples of suitable materials may include, without limitation, a polyurethane (PU) drape or film such as SCAPA BIOFLEX 130 polyurethane film; films formed from polymers, such as polyester and co-polyester; polyamide; polyamide/block polyether; acrylics; vinyl esters; polyvinyl alcohol copolymers; and INSPIRE 2305 polyurethane drape. High-MVTR films may be advantageous for evaporation of condensate, which may occur around the entire exterior surface of the fluid bridge 145. In this manner, capacity, fluid handling, and evaporative properties of the fluid bridge 145 may be enhanced or improved due at least to increased surface area and air movement provided around all sides and portions of the exterior surface of the fluid bridge 145.

[0077] In some examples, one or more of the fluid transfer layers of the fluid transfer bridge 325 may comprise a non-woven material or structure such as, without limitation, a polyester, co-polyester, polyolefin, cellulosic fiber, and combinations or blends of these materials. In the example of Figure 4, the first wicking layer 340, the second wicking layer 345, or both may comprise or consist essentially of a wicking textile, such as LIBELTEX TDL2 having a weight of 80 grams per square meter or similar materials. The fluid transfer layers of the fluid transfer bridge 325 preferably have a density in a range of 0.2-0.5 grams per cubic centimeter. For example, in some embodiments, the first wicking layer 340 and the second wicking layer 345 may be a textile having a density of about 0.4 grams per cubic centimeter.

[0078] In some embodiments, the fluid-management layer 350 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 25% compression load deflection of the fluid-

management layer 350 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 fluid-management layer 350 may be at least 10 pounds per square inch. The fluid-management layer 350 may have a tear strength of at least 2.5 pounds per inch. In some embodiments, the fluid-management layer 350 may comprise or consist essentially of foam polyols such as polyester or polyether, isocyanate such as toluene diisocyanate, and polymerization modifiers such as amines and tin compounds. In some examples, the fluid-management layer 350 may be reticulated polyurethane ether foam having a density of about 0.2 grams per cubic centimeter.

**[0079]** In some embodiments, an attachment device may be disposed on an interior surface of the base layer 425, the top layer 430, or both, to secure the fluid transfer bridge 325. In some embodiments, an attachment device may be disposed between the base layer 425 and the fluid transfer bridge 325. For example, an adhesive 455 may be coated on the interior surface of the base layer 425 to adhere the first wicking layer 340 to the base layer 425. To maximize evaporation performance of the top layer 430, there may be no adhesive between the top layer 430 and the fluid transfer bridge 325 in some embodiments.

**[0080]** In the example of Figure 4, the first wicking layer 340, the fluid-management layer 350, and the second wicking layer 345 are stacked between the base layer 425 and the top layer 430. In some embodiments, the base layer 425 and the top layer 430 may be coupled together to form the envelope 310 of Figure 3. For example, the edges of the base layer 425 and the top layer 430 may be welded together to enclose the first wicking layer 340, the fluid-management layer 350, and the second wicking layer 345.

**[0081]** Figure 4 also illustrates one example of the fluid interface 215 and the fluid conductor 220. As shown in the example of Figure 4, the fluid conductor 220 may be a flexible tube, which can be fluidly coupled on one end to the fluid interface 215. The fluid interface 215 may be an elbow connector, as shown in the example of Figure 4, which can be placed over the third aperture 445 to provide a fluid path between the fluid conductor 220 and the fluid transfer bridge 325. The fluid interface 215 may comprise or consist essentially of a soft, medical-grade polymer or other pliable material. Examples of suitable materials include polyurethane, polyethylene, polyvinyl chloride (PVC), fluorosilicone, or ethylene-propylene. In some illustrative, non-limiting embodiments, the fluid interface 215 may be molded from DEHP-free PVC. The fluid interface 215 may be formed in any suitable manner such as by molding, casting, machining, or extruding.

**[0082]** In some embodiments, the fluid interface 215 may be formed of a material having absorbent properties, evaporative properties, or both. The material may be vapor permeable and liquid impermeable, which can permit vapor to be absorbed into and evaporated from the material through permeation while inhibiting permeation of liquids. The absorbent material may be, for example, a hydrophilic polymer such as hydrophilic polyurethane.

**[0083]** Various components of the bridge dressing 200 may be assembled before application. In some embodiments, one or more layers of the dressing 110 may coextensive. For example, the contact layer 205 may be coextensive with the vapor-transfer surface 140, as illustrated in the example of Figure 4. In some embodiments, the dressing 110 may be provided as a single, composite dressing. The vapor-transfer surface 140 may be coupled to the contact layer 205 to enclose the fluid-management layer 210 in some embodiments. For example, the vapor-transfer surface 140 may be adhered to a periphery of the contact layer 205 around the fluid-management layer 210. In further embodiments, the contact layer 205 may be coupled to the vapor-transfer surface 140 to enclose the fluid-management layer 210, wherein the contact layer 205 is configured to face a tissue site. In some embodiments, the vapor-transfer surface 140 may additionally include a fluid interface such as a first aperture 415, which may be centrally disposed over the fluid-management layer 210. Additionally or alternatively, the fluid bridge 145 may be provided as a composite structure, and may be provided attached or unattached to the dressing 110.

**[0084]** In use, the release liner (if included) may be removed to expose the contact layer 205, which may be placed within, over, on, or otherwise proximate to a tissue site. The contact layer 205 may be sufficiently tacky to hold the dressing 110 in position, while also allowing the dressing 110 to be removed or re-positioned without trauma to a tissue site.

**[0085]** Figure 5 is a top view of another example configuration of the dressing 110, illustrating additional details that may be associated with some embodiments. As shown in the example of Figure 5, the fluid-handling indicator 235 may be in the form of thermochromic LCD strips and printed on a surface of the dressing 110, particularly its evaporative areas 510. The thermochromic LCD strips may be able to have a color change in response to a temperature change, e.g., in a range of between 20 to 25°C. Also, the blocking layer 240, such as a barrier adhesive tape that is able to prevent evaporation, may be used. The blocking layer 240 may be diagonally placed on a surface of the dressing 110 and may cover a portion of the fluid-handling indicator 235. When the dressing 110 is hydrated to its absorption capacity, for example, about 30 ml, the fluid-handling indicator 235 may be

monitored for its baseline color (e.g., black) in areas covered by a blocking layer 240 or its color change in evaporative areas 510 not covered by the blocking layer 240.

[0086] Figure 6 illustrates an example of the dressing of Figure 5 applied to a limb of a patient, illustrating additional details that may be associated with some embodiments. In the example embodiment of Figure 6, the dressing 110 may be placed on skin of a patient. Some areas of the dressing 110 may adjust to the temperature of the skin where the water in these areas of the dressing 110 starts to conduct the heat and evaporates from the dressing 110. In some embodiments, the fluid-handling indicator 235 turns colors (e.g., from black to green; not shown) in response to the evaporation in areas not covered by the blocking layer 240.

[0087] Figure 7 is a perspective view of the dressing of Figure 5, illustrating additional details that may be associated with some embodiments. In the example embodiment of Figure 7, the dressing 110 may be applied to a silicone test plate. The dressing 110 starts to evaporate at ambient temperature (e.g., 22-23°C) through the unblocked areas 705, *i.e.*, areas that are not blocked by a blocking layer 240. The fluid-handling indicator 235 may be in the form of thermochromic strips, which may have a color (e.g., green; not shown) in blocked areas 710 and edge of dressing to indicate higher temperature (not evaporating). The fluid-handling indicator 235 may change color (e.g., become darker) in unblocked strip area 715 where the temperature is lower in response to evaporation.

[0088] Figure 8 illustrates a thermal image taken by a forward-looking infrared (FLIR) camera of the dressing of Figure 7 applied to a silicone test plate, illustrating additional details that may be associated with some example embodiments. In the example embodiment of Figure 8, the temperature 22.7°C is indicated by a color (e.g., pink; not shown) on the area 810, which is blocked by the blocking layer 240, such as a barrier tape.

[0089] Figure 9 illustrates a thermal image taken by a forward-looking infrared (FLIR) camera of the dressing of Figure 7 applied to a silicone test plate, illustrating additional details that may be associated with some example embodiments. In the example embodiment of Figure 9, the temperature 20.5°C is indicated by a color (e.g., purple; not shown) on the area 910, which is not blocked by the blocking layer 240, such as a barrier tape. The area 910 is therefore permitting evaporation, which lowers the temperature by 2.2°C due to evaporation.

[0090] Figure 10 is a perspective view of another example configuration of the dressing 110, illustrating additional details that may be associated with some embodiments.

In the example embodiment of Figure 10, the dressing 110 is applied to a test subject to show evaporation. The dressing 110 may include a 20-25°C indicator 1005 and a 25-30°C indicator 1010. The 20-25°C indicator 1005 or 25-30°C indicator 1010 may be in the form of a thermochroic strip. The 25-30°C indicator 1010 may be indicated by a color (e.g., green; not shown) in an area 1015 where no evaporation is taking place (evaporation blocked by a blocking layer 240) but may turn to a different color (e.g., red; not shown) in an area 1020 where evaporation is occurring.

**[0091]** Figure 11 illustrates a thermal image taken by a forward-looking infrared (FLIR) camera of the dressing 110 of Figure 10 applied to a test subject, illustrating additional details that may be associated with some example embodiments. In the example embodiment of Figure 11, the dressing 110 is applied to a test subject. The temperature 30.5°C is indicated by a color (e.g., pink; not shown) on the area 1100, which is blocked by the blocking layer 240, such as a barrier tape.

**[0092]** Figure 12 illustrates a thermal image taken by a forward-looking infrared (FLIR) camera of the dressing 110 of Figure 10 applied to a test subject, illustrating additional details that may be associated with some example embodiments. In the example embodiment of Figure 12, the temperature 28.9°C is indicated by a color (e.g., purple; not shown) on the area 1200, which is not blocked by the blocking layer 240, such as a barrier tape. The area 1200 is therefore permitting evaporation, which lowers the temperature by 2.2°C due to evaporation.

**[0093]** Figure 13 is a top view of another example configuration of the dressing 110, illustrating additional details that may be associated with some embodiments. In the example embodiment of Figure 13, the fluid-handling indicator 235 may be in the form of two thermochromic indicator strips that form a cross on the dressing 110. The blocking layer 240 may be a square barrier adhesive placed in the center of the dressing 110.

**[0094]** Figure 14 is a perspective view of the dressing of Figure 13 applied to a limb of a patient, illustrating additional details that may be associated with some embodiments. In the example embodiment of Figure 14, the dressing 110 is applied to a test subject. The dressing 110 may have a fluid-handling indicator 235, which is a 25-30°C indicator. The 25-30°C indicator 235 may be in the form of a thermochroic strip. The 25-30°C indicator 235 may be indicated by a color (e.g., green; not shown) under the blocking layer 240 where no evaporation is taking place, but may turn to a different color (e.g., red; not shown) in an area 1415 where evaporation is occurring.

[0095] Figure 15 illustrates a thermal image taken by a forward-looking infrared (FLIR) camera of the dressing of Figure 14 applied to a test subject, illustrating additional details that may be associated with some example embodiments. The temperature 27.6°C is indicated by a color (e.g., orange; not shown) on the area 1510, which is not blocked by the blocking layer 240, such as a barrier tape.

[0096] In some embodiments, the fluid-handling indicator 235 may be additionally or alternatively associated with other parts of the dressing 110 or the fluid bridge 145. For example the fluid-handling indicator 235 may be used to indicate fluid movement entering or evaporating from certain layers of the fluid bridge 145, such as the vapor-transfer surface 320.

[0097] Additionally or alternatively, the fluid-handling indicator may be thermochromic crystals, inks, or dyes mixed with a drape adhesive, which may be completely coating a polymer film or pattern coated on the film to provide thermal data over the areas of the film during manufacturing of the film. This may be used as a drape cover for a dressing.

[0098] Additionally or alternatively, the film may be further integrated as a layer or part of a layer on a dressing, which may use the evaporation of the dressing structure to increase fluid capacity. A fluid-handling indicator may be used to provide indication with forced-air evaporation function in systems where motors or blowers are used over a conduit to achieve evaporation. The thermochromic crystals may be mixed with the polymer (e.g., polyurethane (PU) or other) prior to extrusion of the tube-set such that some of the tube conduits are manufactured to not only evaporate but to also show the temperature change.

[0099] Additionally or alternatively, a fluid-handling indicator may be combined with a display, such as symbols or texts, when at optional and functional evaporation conditions. The blocked areas may show a symbol demonstrating that the dressing is in the operating temperature range and then an “evaporation” symbol may be shown over the dressing in the areas it evaporates within.

[00100] In further embodiments, there may be provided an optional test sticker that can be applied to products and dressings that claim high total fluid handling through evaporation to provide support or not to their claims. Such a configuration may include a pre-assembled test strip with integrated blocking section and integrated labeling.

[00101] The fluid-handling indicator, such as thermochromic dye, crystals, or pigments, may also be combined with an absorbent compound. Additionally or alternatively, the fluid-handling indicator may be mixed with the absorbent compound to provide a method

for users to understand if the fluid has started to absorb and also if these absorbed areas are evaporating later.

**[00102]** The systems, apparatuses, and methods described herein may provide significant advantages. For example, the fluid-handling indicator 235 may allow a user and caregiver to see a measurable effect of total fluid handling and support the correct function of a dressing product. The fluid-handling indicator 235 may also facilitate wearing a dressing to maintain the dressing in such a way that the full benefits of evaporation and total fluid handling are achieved. The fluid-handling indicator 235 may allow the user to make sure that the conditions, cover, temperature and other parameters are ideally suited to the function of the dressing. Additionally or alternatively, some embodiments of the fluid-handling indicator 235 may also allow the patient and caregiver to determine the fill status of the dressing, and when empty in the ideal conditions there will be no evaporation due to there being no fluid present. In some embodiments, the fluid-handling indicator 235 may be used to estimate the amount of fluid evaporated, for example, the change in temperature over a given area will be related to the amount of liquid lost. Also, the fluid-handling indicator 235 may be used to identify areas that have elevated temperature, which may indicate areas where fluid is entering the dressing. Some embodiments of the fluid-handling indicator 235 may help with placement of a dressing after a change and also may help identify areas of low temperature, which may assist with locating necrotic tissues.

**[00103]** 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 eliminated or separated from other components for manufacture or sale. In other example configurations, the controller 120 may also be manufactured, configured, assembled, or sold independently of other components.

**[00104]** The appended claims set forth novel and inventive aspects of the subject matter described above, but the claims may also encompass additional subject matter not specifically recited in detail. For example, certain features, elements, or aspects may be omitted from the claims if not necessary to distinguish the novel and inventive features from

what is already known to a person having ordinary skill in the art. Features, elements, and aspects described in the context of some embodiments may also be omitted, combined, or replaced by alternative features serving the same, equivalent, or similar purpose without departing from the scope of the invention defined by the appended claims.

## CLAIMS

What is claimed is:

1. A dressing for managing fluid, the dressing comprising:
  - a fluid-management layer;
  - a vapor-transfer surface covering the fluid-management layer; and
  - a fluid-handling indicator on the vapor-transfer surface, the fluid-handling indicator configured to change color in response to fluid evaporation through the vapor-transfer surface or fluid entry into the fluid-management layer.
2. The dressing of claim 1, wherein the fluid-management layer comprises a manifold.
3. The dressing of claim 1 or 2, wherein the vapor-transfer surface comprises a polymer film.
4. The dressing of any of claims 1-3, wherein the fluid-handling indicator comprises a thermochromic material.
5. The dressing of any of claims 1-4, wherein the fluid-handling indicator comprises a thermochromic ink.
6. The dressing of any of claims 1-5, wherein the fluid-handling indicator comprises a thermochromic label adhered to the vapor-transfer surface.
7. The dressing of any of claims 1-6, wherein the fluid-handling indicator comprises a plurality of thermochromic materials, at least one of the plurality of thermochromic materials configured to change color within a temperature range different from that of at least one other of the plurality of thermochromic materials.
8. The dressing of any of claims 1-7, further comprising a blocking layer adjacent to an area of the vapor-transfer surface, wherein the blocking layer is configured to block or reduce fluid evaporation of the area of the vapor-transfer surface.
9. The dressing of claim 8, wherein the blocking layer comprises a material with a moisture-vapor transmission rate less than that of the vapor-transfer surface.

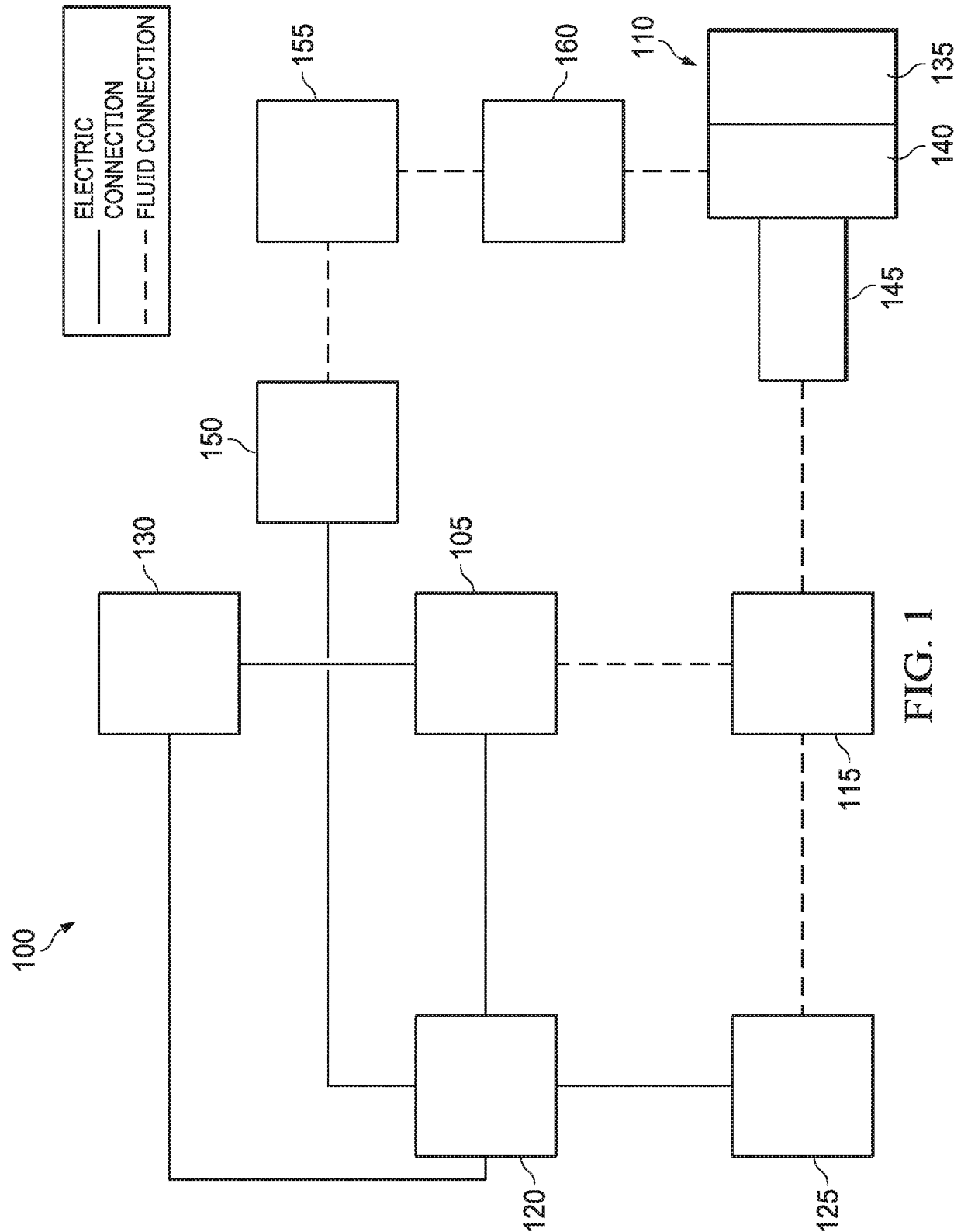
10. The dressing of any of claims 1-9, wherein the vapor-transfer surface comprises:
  - a first area configured to allow evaporation of the fluid from the first area, and
  - a second area configured to allow less evaporation of the fluid from the second area than the first area.
11. The dressing of claim 10, wherein the fluid-handling indicator is configured to change color in response to evaporation of the fluid across the first area and second area of the polymer film.
12. The dressing of claim 10, wherein the first area is larger than the second area.
13. The dressing of any of claims 1-12, wherein the vapor-transfer surface is configured to allow movement of the fluid from the fluid-management layer to the vapor-transfer surface and evaporation of the fluid through the vapor-transfer surface into an ambient environment.
14. The dressing of any of claims 1-13, wherein the vapor-transfer surface is hydrophilic.
15. The dressing of any of claims 1-14, wherein the vapor-transfer surface has a moisture-vapor transmission rate of between about 1,000 to about 14,000 g/m<sup>2</sup>/day.
16. The dressing of any of claims 1-14, wherein the vapor-transfer surface has a moisture-vapor transmission rate of about 12,000 g/m<sup>2</sup>/day.
17. The dressing of any of claims 1-16, wherein the vapor-transfer surface is a polyurethane film.
18. The dressing of any of claims 1-17, wherein the vapor-transfer surface has a thickness of between about 15 microns and about 100 microns.
19. The dressing of any of claims 1-17, wherein the vapor-transfer surface has a thickness of between about 10 microns and about 50 microns.
20. The dressing of any of claims 1-19, wherein the fluid-management layer comprise an absorbent.
21. The dressing of claim 20, wherein the absorbent is configured to transfer fluid from a tissue site and store the fluid within the absorbent.

22. The dressing of any of claims 1-21, wherein the fluid-management layer comprises foam.
23. The dressing of any of claims 1-22, further comprising an adhesive configured to couple a portion of the vapor-transfer surface to a tissue site.
24. The dressing of claim 23, wherein the fluid-handling indicator is configured to cover the portion of the polymer film.
25. The dressing of any of claims 1-24, wherein the fluid-management layer is coupled to the vapor-transfer surface.
26. The dressing of claim 25, wherein the fluid-management layer is coupled to the vapor-transfer surface through a fiber.
27. The dressing of any of claims 1-26, wherein the dressing is configured to be fluidly coupled to a negative pressure source.
28. The dressing of any of claims 1-27, wherein the dressing is configured to be fluidly coupled to a fluid source.
29. The dressing of any of claims 1-28, wherein the vapor-transfer surface comprises the fluid-handling indicator or a second fluid-handling indicator.

30. A dressing comprising:
- a cover layer; and
  - a fluid-handling indicator configured to change color in response to fluid evaporation through the cover layer.
31. The dressing of claim 30, wherein the fluid-handling indicator comprises a thermochromic material.
32. The dressing of claim 30 or 31, wherein the fluid-handling indicator comprises a thermochromic ink.
33. The dressing of any of claims 30-32, wherein the fluid-handling indicator comprises a thermochromic label adhered to the cover layer.
34. The dressing of any of claims 30-33, wherein the fluid-handling indicator comprises a plurality of thermochromic materials, at least one of the plurality of thermochromic materials configured to change color within a temperature range different from that of at least one other of the plurality of thermochromic materials.
35. The dressing of any of claims 30-34, wherein the cover layer comprises a polymer film.
36. The dressing of any of claims 30-35, wherein the cover layer comprises:
- a first area configured to allow evaporation of the fluid from the first area, and
  - a second area configured to allow less evaporation of the fluid from the second area than the first area.
37. The dressing of any of claims 30-36, wherein the cover layer is hydrophilic.
38. The dressing of any of claims 30-37, wherein the cover layer has a moisture-vapor transmission rate of between about 1,000 to about 14,000 g/m<sup>2</sup>/day.
39. The dressing of any of claims 30-37, wherein the cover layer has a moisture-vapor transmission rate of about 12,000 g/m<sup>2</sup>/day.
40. The dressing of any of claims 30-39, wherein the cover layer is a polyurethane film.
41. The dressing of any of claims 30-40, wherein the cover layer has a thickness of between about 15 microns and about 100 microns.

42. The dressing of any of claims 30-40, wherein the cover layer has a thickness of between about 10 microns and about 50 microns.
43. A dressing for managing fluid, the dressing comprising:
- an absorbent;
  - a polymer film covering the absorbent; and
  - a thermochromic material in the polymer film and configured to change color in response to fluid evaporation through the polymer film or fluid entry into the absorbent.
44. A method of monitoring fluid movement in a dressing, comprising:
- positioning a dressing adjacent to a tissue site, wherein the dressing comprises:
    - an absorbent,
    - a polymer film covering the absorbent, and
    - a thermochromic material adjacent to the polymer film, the thermochromic material configured to change color in response to fluid evaporation through the polymer film or fluid entry into the absorbent;
  - reading color change of the thermochromic material; and
  - monitoring fluid movement in the dressing indicated by the color change.
45. A method of manufacturing a dressing, the method comprising:
- providing an absorbent;
  - disposing a polymer film on the absorbent; and
  - covering the polymer film with a thermochromic material on the polymer film, the thermochromic material configured to change color in response to fluid evaporation from the through the polymer film or fluid entry into the absorbent.

46. A method of manufacturing a dressing, the method comprising:
- providing an absorbent;
  - providing a polymer film comprising a thermochromic material in the polymer film, the thermochromic material configured to change color in response to fluid evaporation from the through the polymer film or fluid entry into the absorbent; and
  - disposing the polymer film on the absorbent.
47. The systems, apparatuses, and methods substantially as described herein.



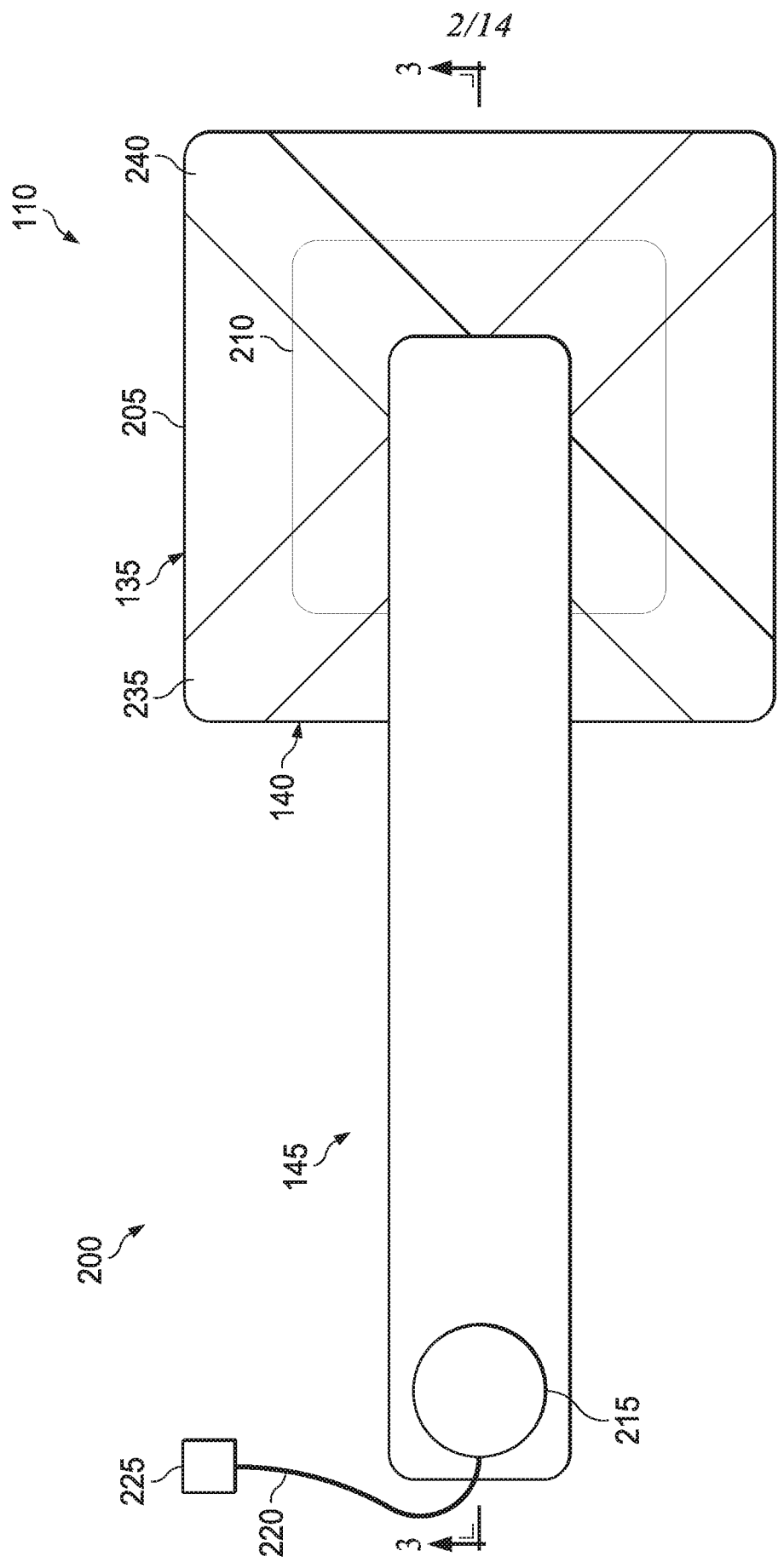
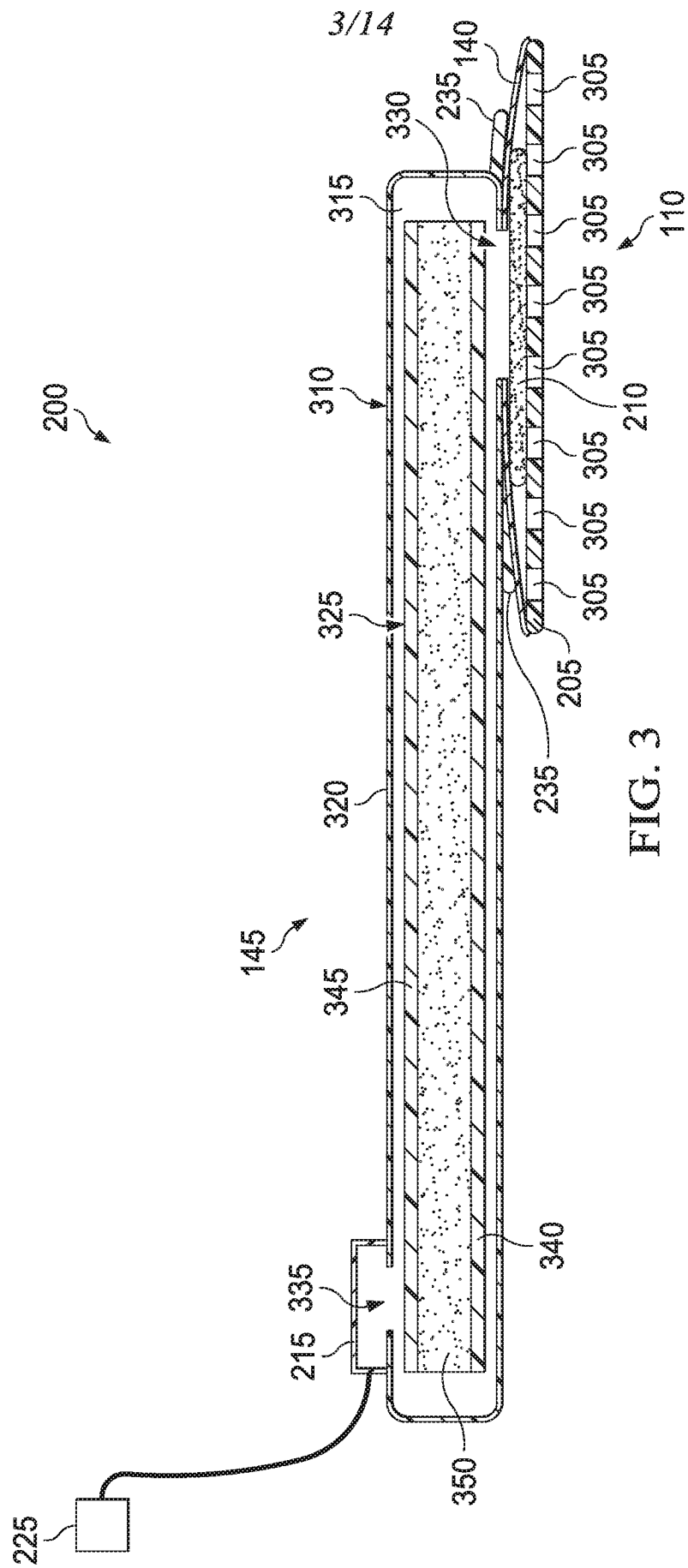
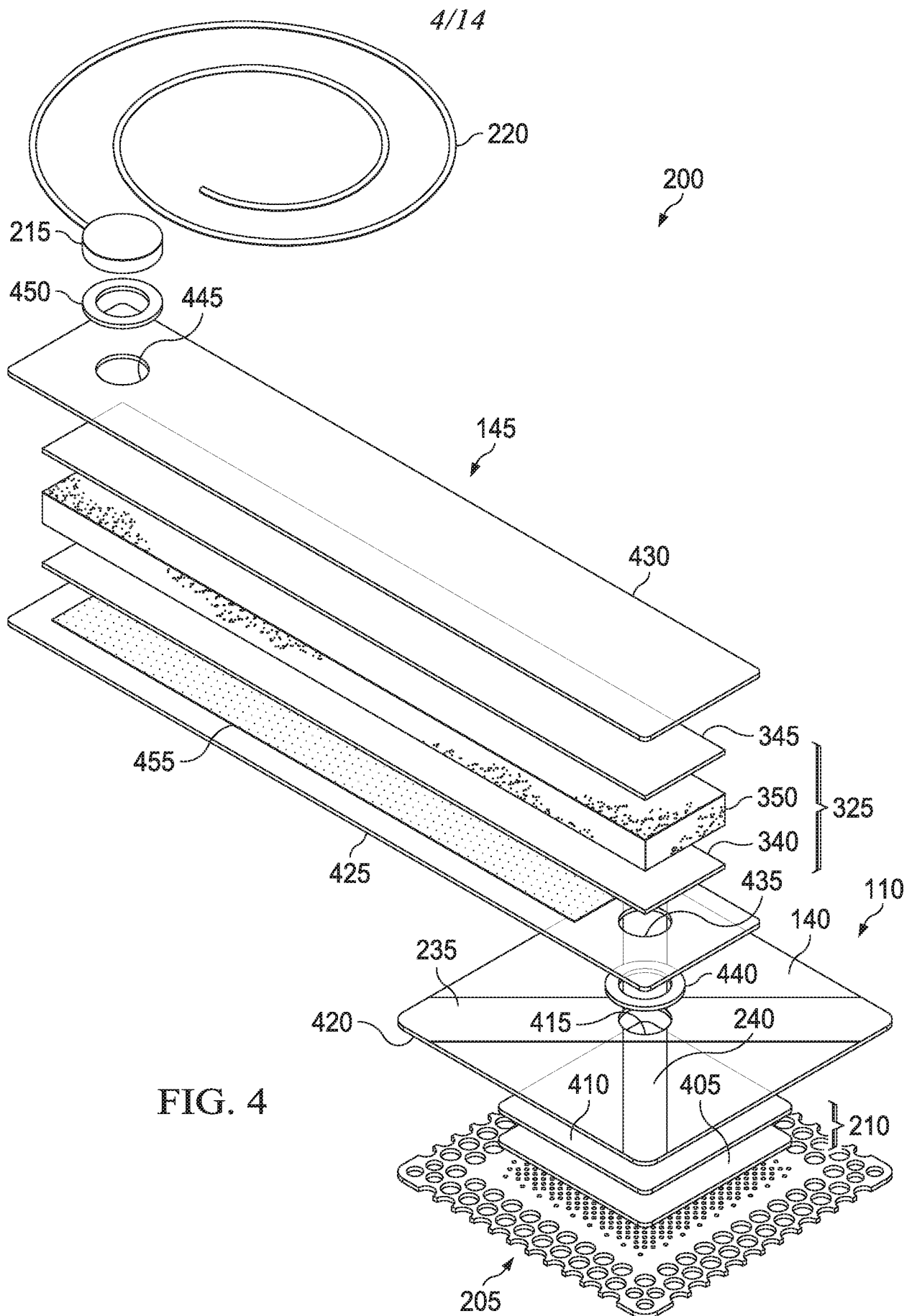


FIG. 2





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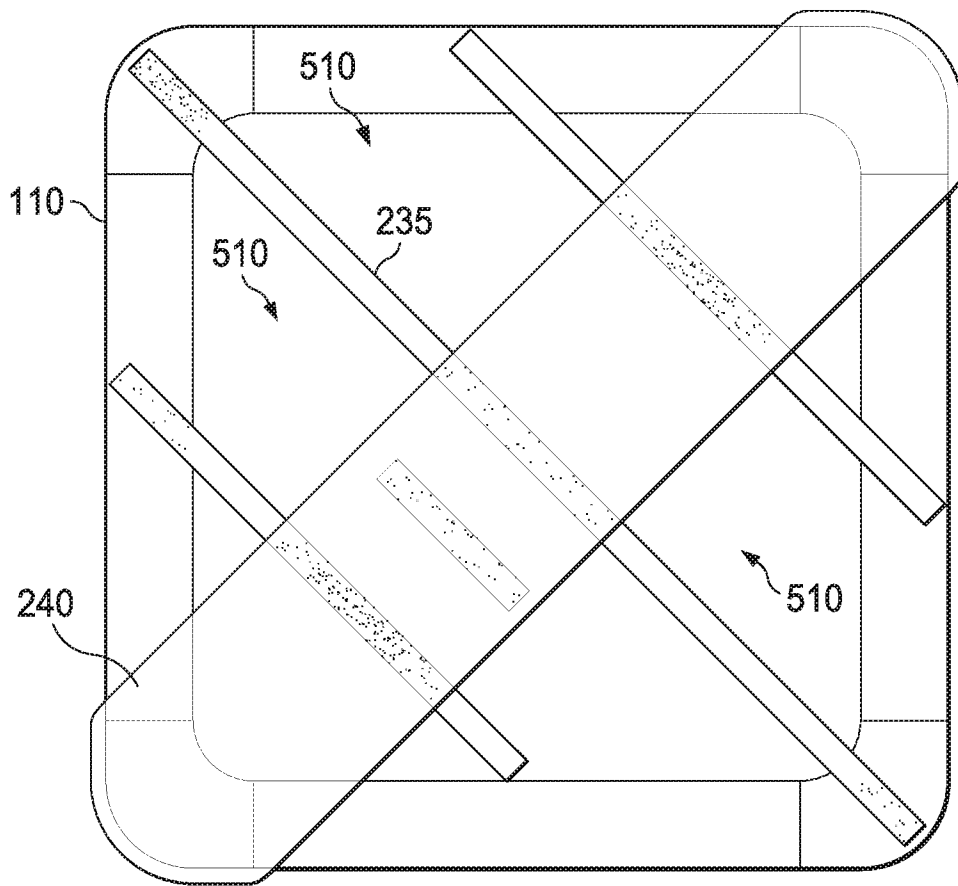


FIG. 5

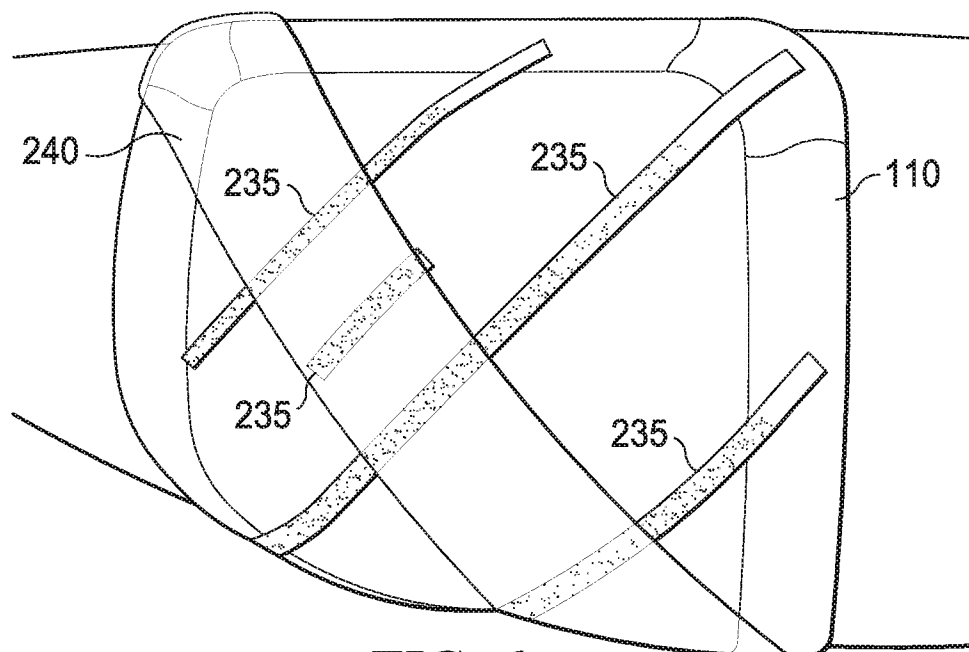


FIG. 6

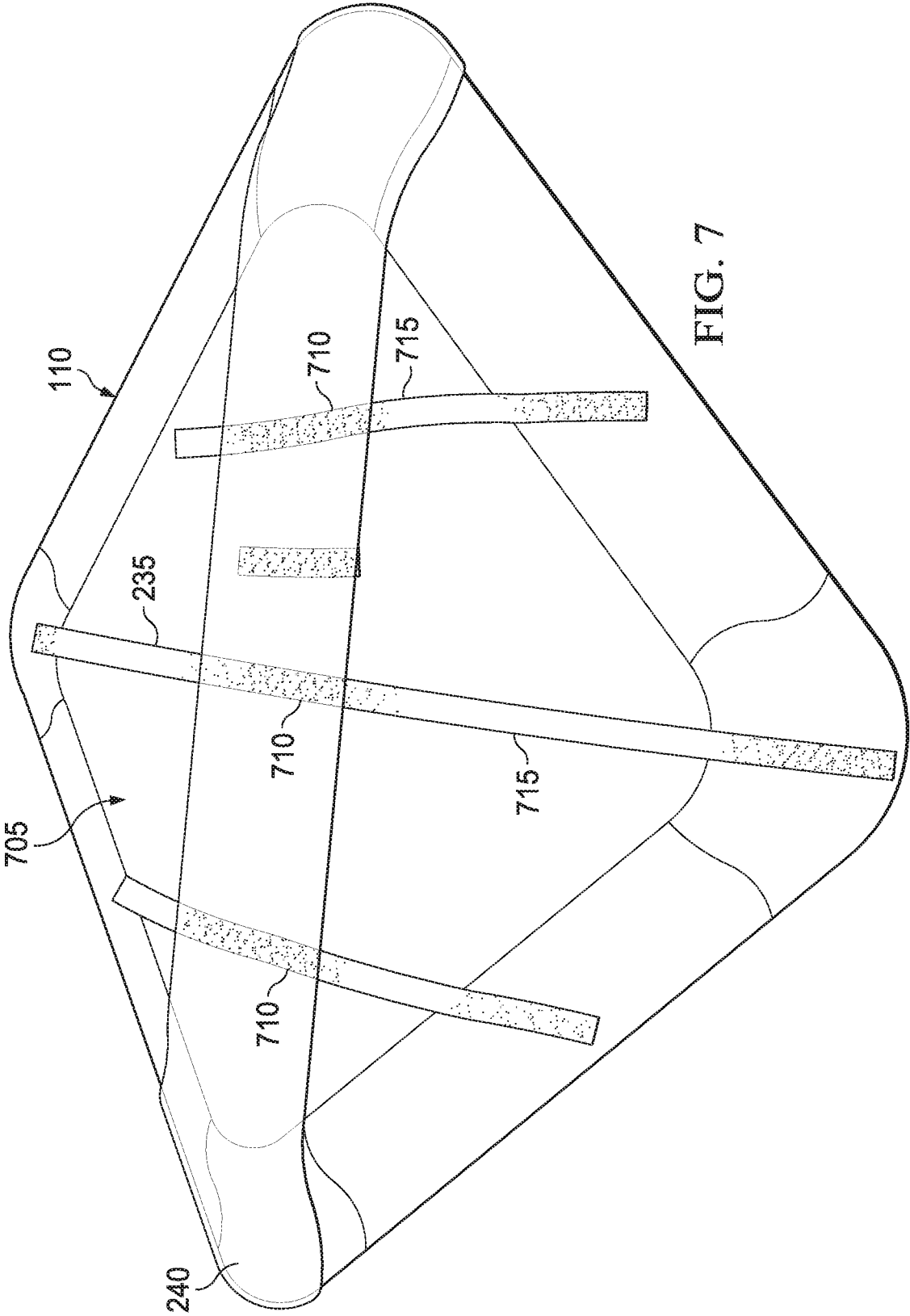
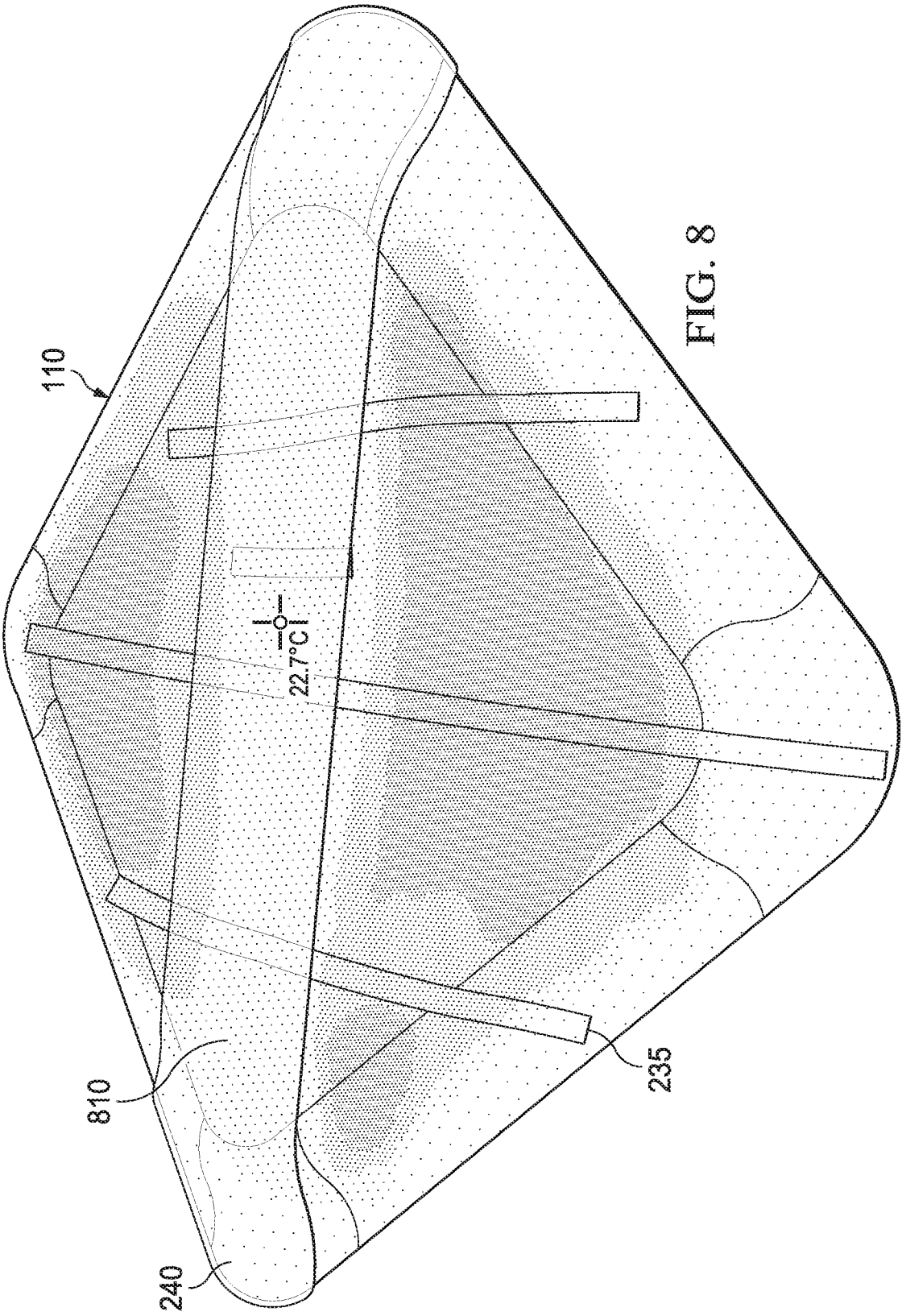
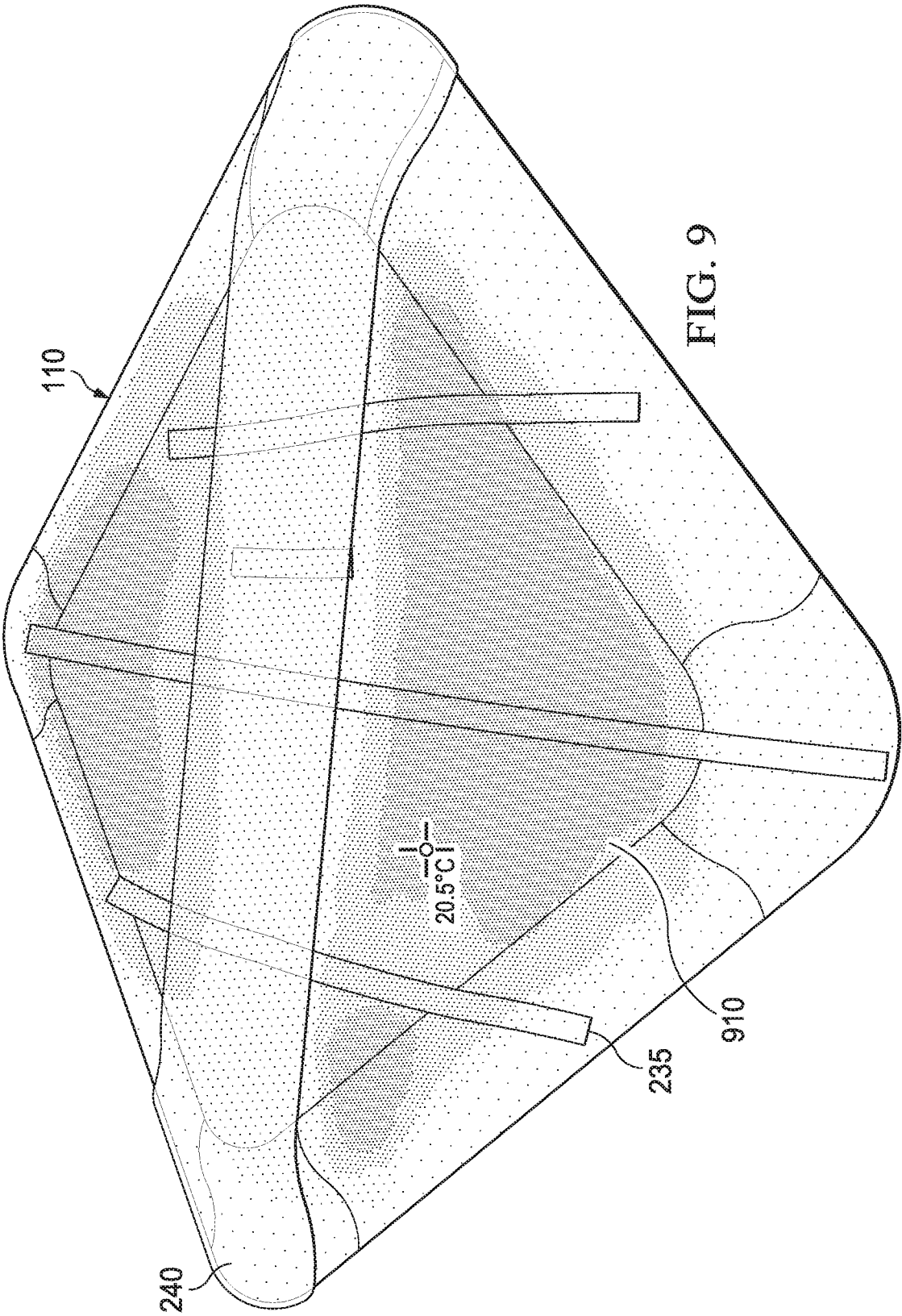
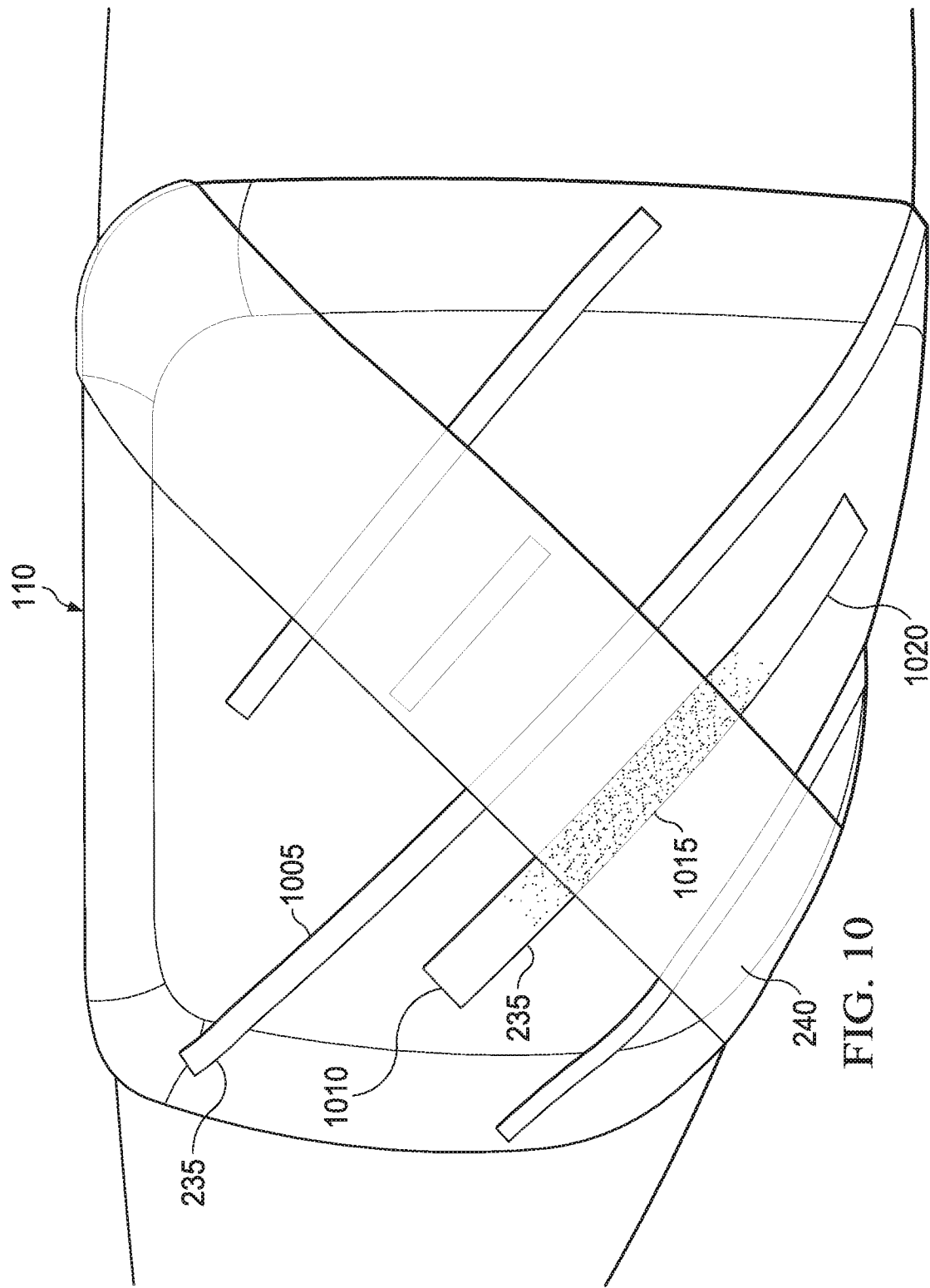


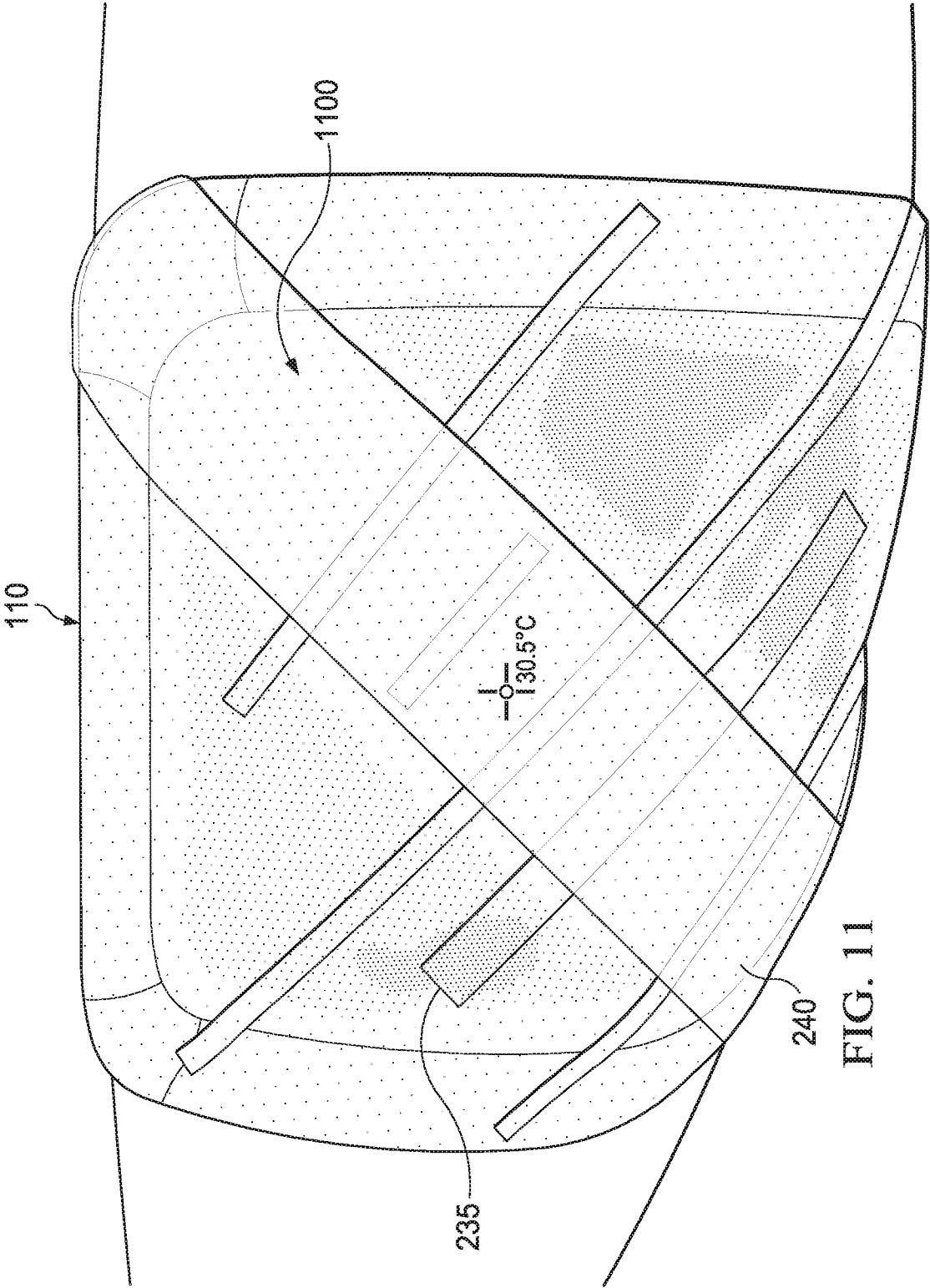
FIG. 7

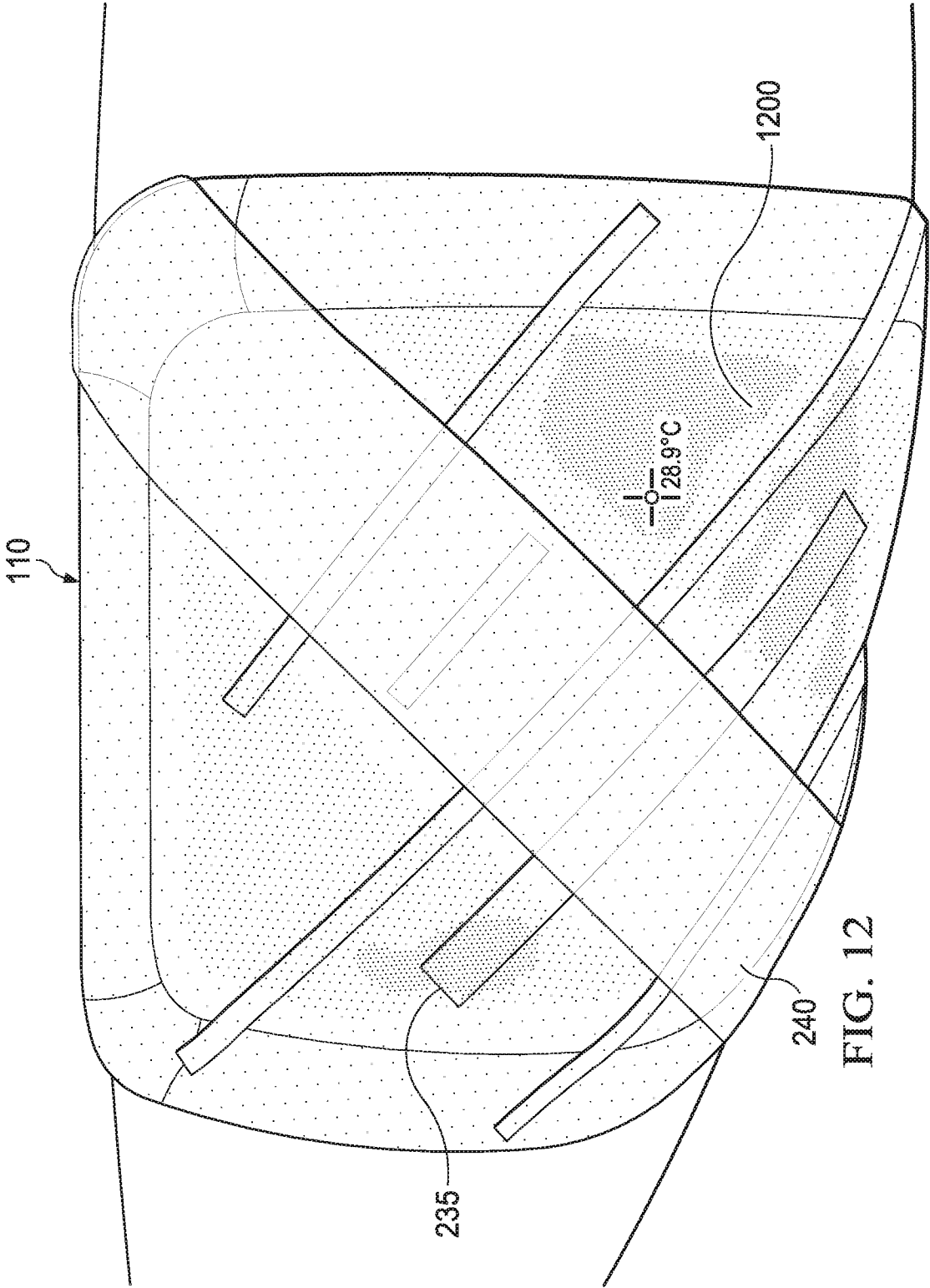






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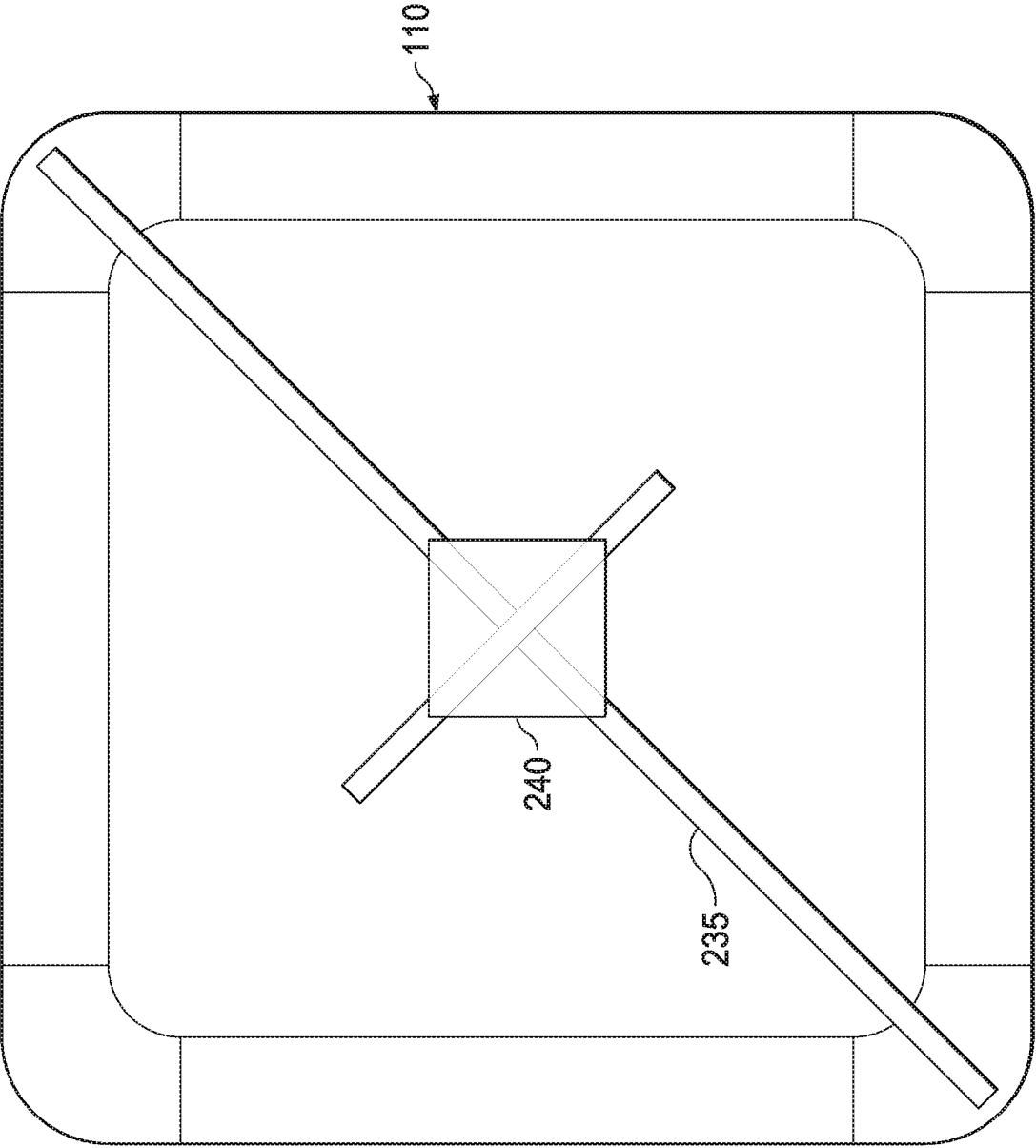


FIG. 13

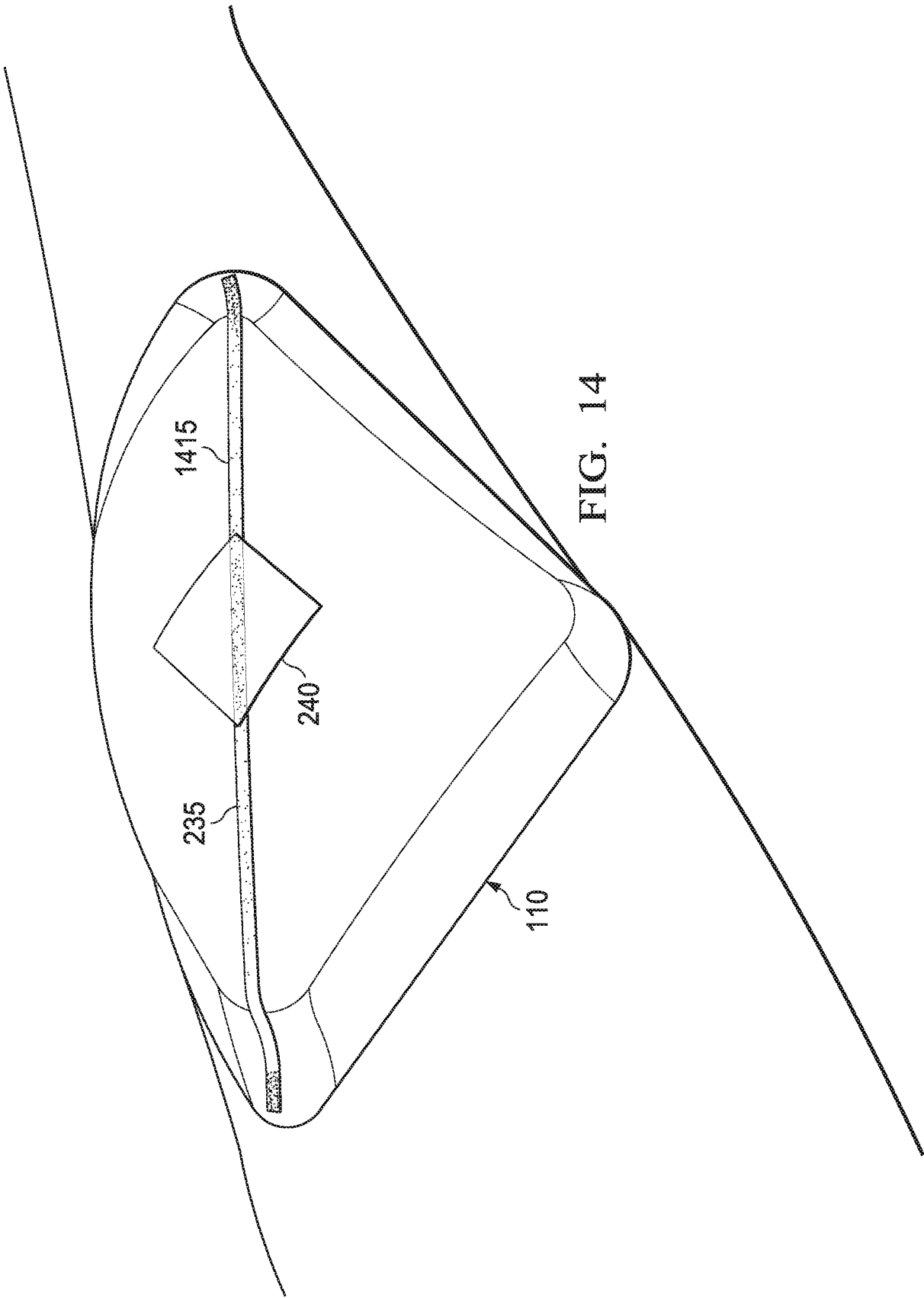
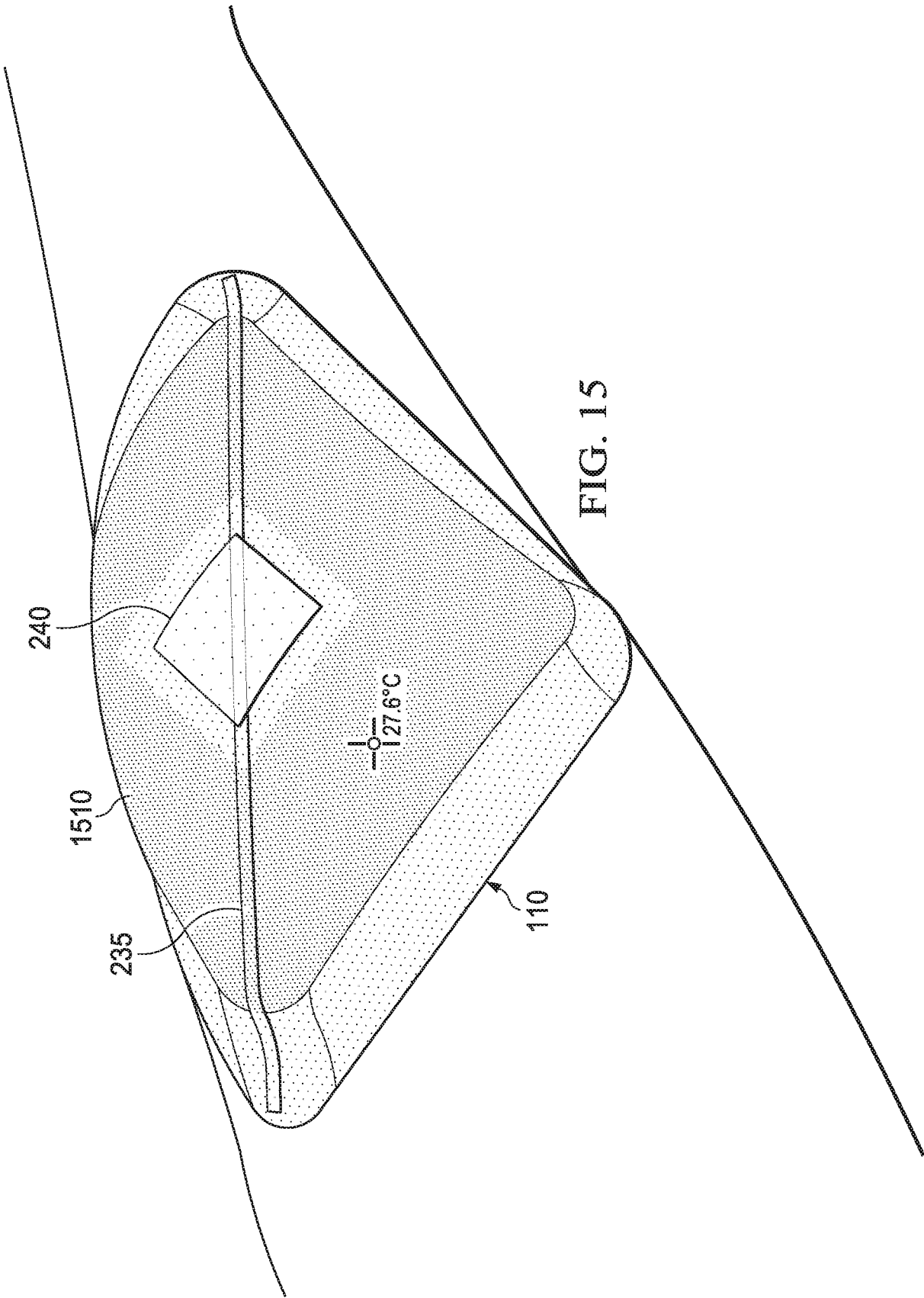


FIG. 14



# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2019/050513

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61F13/00 A61F13/02 A61B5/00  
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 A61B

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)

EP0-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                                                     | Relevant to claim No.                      |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| X         | US 2016/067102 A1 (COTTON STEPHEN [GB])<br>10 March 2016 (2016-03-10)<br><br>paragraphs [0018], [0020], [0028],<br>[0033], [0035]; claims 1,3<br>----- | 1-6,<br>8-15,<br>17-33,<br>35-38,<br>40-47 |
| A         | GB 2 531 612 A (OLIVIA NILE SOBEK [GB])<br>27 April 2016 (2016-04-27)<br>abstract<br>-----                                                             | 1-47                                       |
| A         | US 2010/268112 A1 (SHORT DAN C [US] ET AL)<br>21 October 2010 (2010-10-21)<br>abstract; figures<br>-----<br>-/--                                       | 1-47                                       |



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

8 November 2019

Date of mailing of the international search report

22/11/2019

Name and mailing address of the ISA/

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Authorized officer

Elsässer, Ralf

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2019/050513

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                            | Relevant to claim No. |
|-----------|---------------------------------------------------------------------------------------------------------------|-----------------------|
| A         | US 2009/204100 A1 (VAN PIETERSON LIESBETH [NL] ET AL) 13 August 2009 (2009-08-13)<br>abstract                 | 1-47                  |
| A         | -----<br>US 8 349 358 B1 (MCBRIDE EMILY VANN [US])<br>8 January 2013 (2013-01-08)<br>claims; figures<br>----- | 1-47                  |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2019/050513

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s)                                                                                                                         | Publication<br>date                                                                                          |
|-------------------------------------------|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| US 2016067102 A1                          | 10-03-2016          | CA 2911278 A1<br>CN 105101920 A<br>EP 2988713 A1<br>GB 2516340 A<br>US 2016067102 A1<br>WO 2014174291 A1                                           | 30-10-2014<br>25-11-2015<br>02-03-2016<br>21-01-2015<br>10-03-2016<br>30-10-2014                             |
| GB 2531612 A                              | 27-04-2016          | NONE                                                                                                                                               |                                                                                                              |
| US 2010268112 A1                          | 21-10-2010          | US 2010268112 A1<br>WO 2010123986 A1                                                                                                               | 21-10-2010<br>28-10-2010                                                                                     |
| US 2009204100 A1                          | 13-08-2009          | BR PI0712706 A2<br>CN 101466300 A<br>EP 2032018 A1<br>JP 2009539536 A<br>RU 2008152369 A<br>TW 200806252 A<br>US 2009204100 A1<br>WO 2007144795 A1 | 03-07-2012<br>24-06-2009<br>11-03-2009<br>19-11-2009<br>20-07-2010<br>01-02-2008<br>13-08-2009<br>21-12-2007 |
| US 8349358 B1                             | 08-01-2013          | NONE                                                                                                                                               |                                                                                                              |