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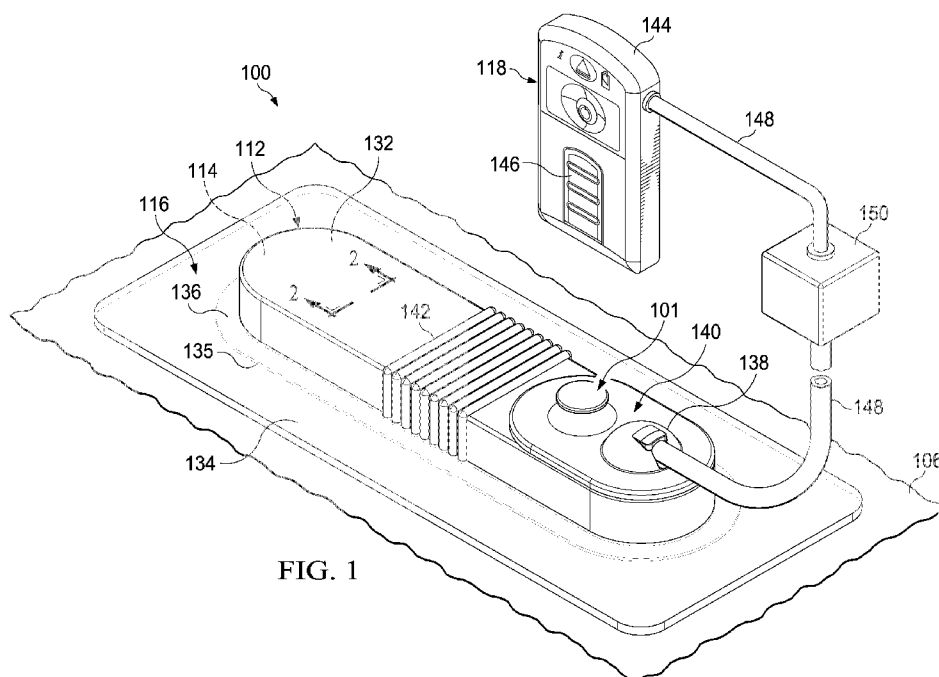


FIG. 1

(57) Abstract: In some examples, an auxiliary port assembly may be configured to be coupled to a cover for providing a sealed space at a tissue site. The auxiliary port assembly may include an access portal and an adhesive. The access portal may include an exterior side and a mounting side opposite the exterior side. The mounting side may be configured to face the cover. The access portal may be configurable between an open state and a closed state, and may provide a passage through the cover in the open state. The adhesive may be configured to couple the mounting side of the access portal to the cover. Other systems, dressings, apparatuses, and methods are disclosed.

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SYSTEM FOR TREATING A TISSUE SITE

CROSS-REFERENCE TO RELATED APPLICATIONS

5 **[0001]** This application claims the benefit of priority to U.S. Provisional Application No. 62/878,120, filed on July 24, 2019, which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

10 **[0002]** This disclosure relates generally to medical treatment systems and, more particularly, but not by way of limitation, to absorbent dressings, systems, and methods for treating a tissue site with reduced pressure.

BACKGROUND

15 **[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 have proven particularly advantageous for treating wounds. Regardless of the etiology of a wound, whether trauma, surgery, or another cause, proper care of a 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
20 “negative-pressure wound therapy,” “reduced-pressure therapy,” “vacuum therapy,” and “vacuum-assisted closure,” 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.

25 **[0004]** While the clinical benefits of negative-pressure therapy are widely known, the cost and complexity of negative-pressure therapy can be a limiting factor in its application, and the development and operation of negative-pressure systems, components, and processes continues to present significant challenges to manufacturers, healthcare providers, and patients.

SUMMARY

30 **[0005]** Shortcomings with certain aspects of tissue treatment dressings, systems, and methods are addressed as shown and described in a variety of illustrative, non-limiting example embodiments herein.

[0006] In some example embodiments, a system for treating a tissue site may include a dressing assembly, an access portal, and a reduced-pressure source. The dressing assembly may

include a dressing bolster, a comfort layer, a first sealing member, a second sealing member, and a sealing ring. The dressing bolster may include a first side and a second side, and the comfort layer may be coupled to the second side of the dressing bolster. The first sealing member may cover the first side of the dressing bolster. The second sealing member may cover a portion of the second side of the dressing bolster and extend outward from the dressing bolster. A portion of the first sealing member may be coupled to the second sealing member. The sealing ring may be positioned at the second side of the dressing bolster. The first sealing member, the second sealing member, and the sealing ring may be configured to provide a sealed space at the tissue site. The access portal may be configurable between an open state and a closed state. The access portal may provide a passage into the sealed space in the open state and a fluid seal in the closed state. The reduced-pressure source may be configured to be coupled in fluid communication with the sealed space.

[0007] In some example embodiments, a system for treating a tissue site may include a dressing assembly, a sealing member, an access portal, and a reduced-pressure source. The dressing assembly may include a dressing bolster and a gasket member. The dressing bolster may include a first side and an opposing second side. The second side of the dressing bolster may be configured to be positioned in fluid communication with the tissue site. The gasket member may be coupled at the second side of the dressing bolster. The sealing member may be configured to cover the dressing assembly and to create a sealed space between the dressing assembly and the tissue site. The access portal may be configurable between an open state and a closed state such that the access portal is configured to provide a passage through the sealing member in the open state and a fluid seal in the closed state. The reduced-pressure source may be configured to be coupled in fluid communication with the dressing bolster through the sealing member.

[0008] In some example embodiments, a dressing assembly for treating a tissue site may include a dressing bolster, a tissue interface, a sealing member, and an auxiliary port. The dressing bolster may comprise a porous foam and may include a first side and an opposing second side. The tissue interface may be coupled to the second side of the contoured bolster and may be configured to be positioned proximate to and in fluid communication with the tissue site. The sealing member may be configured to cover the dressing assembly and to create a sealed space between the dressing assembly and the tissue site. The auxiliary port assembly may be configured to be coupled to an exterior surface of the sealing member, and may include an access portal configurable between an open state and a closed state. The access portal may be configured to provide a passage through the sealing member in the open state and a fluid seal in the closed state.

[0009] In some example embodiments, an auxiliary port assembly may be configured to be coupled to a cover for providing a sealed space at a tissue site. The auxiliary port assembly may include an access portal and an adhesive. The access portal may include an exterior side and a mounting side opposite the exterior side. The mounting side may be configured to face the cover. The access portal may be configurable between an open state and a closed state, and may provide a

passage through the cover in the open state. The adhesive may be configured to couple the mounting side of the access portal to the cover.

[0010] In some example embodiments, a method for treating a tissue site may include positioning a monitoring device at the tissue site and providing a dressing assembly. The dressing assembly may include a dressing bolster and a cover for creating a sealed space over the dressing bolster at the tissue site. Further, the method may include coupling an auxiliary port assembly to the cover. The auxiliary port assembly may include an access portal configurable between an open state and a closed state. The access portal may provide a passage through the cover in the open state. Further, the method may include guiding an external portion of the monitoring device through the dressing assembly and the access portal with the access portal in the open state. Further, the method may include securing the dressing assembly at the tissue site and over an internal portion of the monitoring device. Further, the method may include positioning the access portal in the closed state to form a seal around the internal portion of the monitoring device.

[0011] Other features and advantages of the illustrative example embodiments will become apparent with reference to the drawings and detailed description that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIGURE 1 is a perspective view of an illustrative example embodiment of a system for treating a tissue site;

[0013] FIGURE 2 is a cross-section of a portion of an illustrative example embodiment of a dressing assembly depicted in FIGURE 1, taken along line 2-2;

[0014] FIGURE 3 is a perspective view of an illustrative example embodiment of a portion of a treatment system for treating a tissue site;

[0015] FIGURE 4 is a cross-section of an illustrative example embodiment of a dressing assembly depicted in FIGURE 3, taken along line 4-4;

[0016] FIGURE 5 is an exploded, perspective view of the example dressing assembly of FIGURE 4 in a state prior to assembly or deployment at a tissue site;

[0017] FIGURES 6A-6C are perspective views, with a portion shown in cross-section, of a portion of an illustrative example embodiment of a treatment system being deployed over a linear wound;

[0018] FIGURE 7A is a perspective view of an illustrative example embodiment of an auxiliary port assembly suitable for use with the systems and dressings according to this disclosure;

[0019] FIGURE 7B is a perspective view of an illustrative example embodiment of an access portal, shown in FIGURE 7A, and positioned in an open state;

[0020] FIGURE 8A is a perspective view of the dressing assembly of FIGURE 1 being fitted with the illustrative auxiliary port assembly of FIGURE 7A and an optional sealing patch, shown in exploded view;

5 [0021] FIGURE 8B is a perspective view of the dressing assembly of FIGURE 1 fitted with the illustrative auxiliary port assembly of FIGURE 7A and an optional sealing patch, shown in assembled view;

[0022] FIGURE 9 is a perspective view of the dressing assembly of FIGURE 1 fitted with an illustrative auxiliary port assembly through a side portion of the dressing assembly;

10 [0023] FIGURE 10A is a perspective view of the dressing assembly of FIGURE 1 fitted with an another illustrative example embodiment of an auxiliary port assembly or access portal, shown in an open state;

[0024] FIGURE 10B is a side view of the illustrative example embodiment of FIGURE 10A, depicting the illustrative auxiliary port assembly or access portal in a closed state;

15 [0025] FIGURE 11A is a perspective view of the dressing assembly of FIGURE 1 fitted with an another illustrative example embodiment of an auxiliary port assembly or access portal; and

[0026] FIGURE 11B is a side view of the illustrative example embodiment of FIGURE 11A.

DETAILED DESCRIPTION OF EXAMPLE EMBODIMENTS

20 [0027] The following description of example embodiments enables a person skilled in the art to make and use the subject matter set forth in the appended claims. Certain details already known in the art may be omitted. Further, the following detailed description is illustrative and non-limiting.

[0028] Referring primarily to FIGURES 1 and 2, presented is an illustrative, non-limiting example embodiment of a treatment system 100 for treating a tissue site 102, such as an incision 104. The incision 104 is shown extending through or involving epidermis 106, dermis 108, and subcutaneous tissue 110. The treatment system 100 may also be used with other tissue sites, and may
25 be utilized with or without reduced pressure as described herein.

[0029] In some embodiments, the treatment system 100 may include a dressing assembly 112 having a dressing bolster 114, which may be referred to as a manifold member 114. In addition, some embodiments of the treatment system 100 may include a sealing member 116 and a reduced-pressure subsystem 118. Some embodiments of the treatment system 100 may also include a reduced-
30 pressure indicator 101. While the treatment system 100 is shown in the context of a reduced-pressure dressing over an incision 104, the treatment system 100 may be used on other tissue sites, including open wounds. Further, features may be optionally added to or omitted from the treatment system 100 to suit different therapeutic applications, scenarios, or preferences, and thus, features described herein are not to be considered essential unless explicitly stated.

[0030] In some embodiments, the dressing bolster 114 may include a first side 120 and a second side 122 positioned opposite or facing opposite to the first side 120. The first side 120 of the dressing bolster 114 may be configured to face outward from or away from the tissue site 102, and the second side 122 of the dressing bolster 114 may be configured to face inward or toward the tissue site 102 and in fluid communication with the tissue site 102. The second side 122 of the dressing bolster 114 may also be referred to as a second, inward-facing side 122.

[0031] The dressing bolster 114 may be formed from any bolster material or manifold material that provides a vacuum space, or treatment space. Reduced pressure applied to the dressing bolster 114 may enhance the permeability of the dressing bolster 114. For example, the dressing bolster 114 may be formed from a porous and permeable foam or foam-like material, a member formed with pathways, a graft, a gauze, or any combination thereof. In some embodiments, the dressing bolster 114 may be a reticulated, open-cell polyurethane or polyether foam that may be fluid permeable. One example of a suitable foam material may be a GRANUFOAM™ material available from Kinetic Concepts, Inc. (KCI) of San Antonio, Texas.

[0032] The term “manifold” as used herein may refer to a substance or structure that may assist in applying reduced pressure to, delivering fluids to, or removing fluids from a tissue site. A manifold may include a plurality of flow channels or pathways. The plurality of flow channels may be interconnected to improve distribution of fluids provided to and removed from an area of tissue around the manifold. Examples of manifolds may include, without limitation, devices that have structural elements arranged to form flow channels, cellular foam, such as open-cell foam, porous tissue collections, and liquids, gels, and foams that include or cure to include flow channels.

[0033] The reticulated pores of the GRANUFOAM™ material may be helpful in carrying out the manifold function, but as stated above, other materials may be utilized. A material with a higher or lower density than the GRANUFOAM™ material may be desirable in some embodiments. This material may have, for example, a smaller pore size than the GRANUFOAM™ material. Among the many possible materials, the following may be used without limitation: GRANUFOAM™ material, FXI technical foam, gauze, a flexible channel-containing member, a graft, and other similar materials. In some embodiments, ionic silver may be added to the material, such as, for example, by a micro bonding process. Other substances, such as antimicrobial agents, may also be added to the material.

[0034] In some embodiments, a comfort layer 124 may be coupled, for example, by a heat bond 130 or other suitable technique to the second, inward-facing side 122 of the dressing bolster 114. The comfort layer 124 may include a first side 126 and a second side 128 positioned opposite or facing opposite to the first side 126. The first side 126 of the comfort layer 124 may be configured to face outward from or away from the tissue site 102, and the second side 128 of the comfort layer 124 may be configured to face inward or toward the tissue site 102. The first side 126 of the comfort layer 124 may be coupled to the second side 122 of the dressing bolster 114. Herein, the comfort layer 124

may also be referred to as an interfacial layer, a tissue interface layer, or tissue contact layer. Further, the second side 128 of the comfort layer 124 may also be referred to as a second, inward-facing side 128.

[0035] The comfort layer 124 may enhance patient comfort when the dressing bolster 114 is adjacent to or in contact with the epidermis 106 of a patient. The comfort layer 124 may be any material that helps prevent skin irritation and discomfort while allowing fluid transmission through the comfort layer 124. As non-limiting examples, the comfort layer 124 may include or be formed of a woven material, an elastic material, a polyester knit textile substrate, a non-woven material, or a fenestrated film. As another non-limiting example, an INTERDRY™ textile material available from Milliken Chemical, a division of Milliken & Company, Inc. of Spartanburg, South Carolina, may be utilized. In some embodiments, the comfort layer 124 may include antimicrobial substances, such as silver.

[0036] In some embodiments, the dressing bolster 114 may include a plurality of flexibility notches or recesses, analogous to notches 218 shown in FIGURE 4, for example, that may be lateral cuts in the dressing bolster 114 on the first side 120. The dressing bolster 114 may additionally or alternatively include one or more longitudinal cuts or notches, which may intersect the lateral cuts or notches. The flexibility notches may enhance the flexibility of the dressing bolster 114. The enhanced flexibility may be particularly useful when the dressing assembly 112 is applied over a joint or other area of movement on a patient. The flexibility notches may also take various shapes without limitation, such as, for example, hexagons, slits, or squares.

[0037] In some embodiments, the dressing bolster 114 may include lateral edges (not shown) that are orthogonal relative to the second, inward-facing side 122 of the dressing bolster 114. The lateral edges of the dressing bolster 114 may be analogous to lateral edges 205 of dressing bolster 204 depicted in FIGURE 4. The lateral edges of the dressing bolster 114 may also have a beveled edge or angled edge. The angled or beveled edge may help distribute shear stress between the dressing bolster 114 and the epidermis 106 of a patient. The lateral edges of the dressing bolster 114 may substantially correspond to lateral edges (not shown) of the comfort layer 124.

[0038] The sealing member 116 may provide a fluid seal over the dressing bolster 114 and a portion of the epidermis 106 of the patient. As such, the sealing member 116 may be formed from any material that allows for a fluid seal. Herein, the terms “fluid seal,” or “seal,” may be a seal adequate to maintain reduced pressure at a desired site given the particular reduced-pressure source or subsystem involved. The sealing member 116 may be sealed against the epidermis 106, or against a gasket or drape, by a sealing apparatus, such as, for example, a pressure-sensitive adhesive.

[0039] The sealing apparatus may take numerous forms, such as an adhesive sealing tape, drape tape, or strip; double-sided drape tape; pressure-sensitive adhesive; paste; hydrocolloid; hydrogel; or other suitable sealing device. If a tape is used, the tape may be formed of the same material as the sealing member 116 with a pre-applied, pressure-sensitive adhesive. The pressure-

sensitive adhesive may be applied on a side of the sealing member 116 adapted to face the epidermis 106, such as an inward-facing side of the sealing member 116. The pressure-sensitive adhesive may provide a fluid seal between the sealing member 116 and the epidermis, and may be utilized in combination with a gasket or drape against the epidermis 106. Before the sealing member 116 is secured to the epidermis 106, removable strips or release liners that cover the pressure-sensitive adhesive may be removed.

[0040] In some embodiments, the sealing member 116 may be an elastomeric material configured to provide a fluid seal. "Elastomeric" may refer to a material having the properties of an elastomer, such as a polymeric material that has rubber-like properties. Some elastomers may have ultimate elongations greater than 100% and a significant amount of resilience. The resilience of a material may refer to the ability of the material to recover from an elastic deformation. Examples of elastomers may include, without limitation, natural rubbers, polyisoprene, styrene butadiene rubber, chloroprene rubber, polybutadiene, nitrile rubber, butyl rubber, ethylene propylene rubber, ethylene propylene diene monomer, chlorosulfonated polyethylene, polysulfide rubber, polyurethane, EVA film, co-polyester, and silicones. Further, sealing member materials may include a silicone drape, a TEGADERM™ drape available from 3M, an acrylic drape, such as one available from Avery Dennison, or an incise drape.

[0041] In some embodiments, the sealing member 116 may be comprised of a material including a high moisture vapor transmission rate (MVTR). The use of a high MVTR material for the sealing member 116 may permit moisture vapor to pass through the sealing member 116, external to the dressing assembly 112, while maintaining the fluid seal described herein.

[0042] In some embodiments, the sealing member 116 may include a first sealing member portion 132 and a second sealing member portion 134. The first sealing member portion 132 may extend over or cover the first side 120 of the dressing bolster 114. The sealing member 116 may extend further to form a sealing member flange, or sealing member extension 136, which has a first side (not shown) and a second, inward-facing side (not shown). The second, inward-facing side of the sealing member extension 136 may be adapted to face the epidermis 106. An aperture (not shown) may be formed on a portion of the sealing member 116 to allow fluid communication with a reduced pressure interface, such as a conduit interface 138, which may be part of a reduced-pressure assembly 140. The aperture on the sealing member 116 may be analogous to aperture 234 depicted in FIGURE 3.

[0043] The second, inward-facing side of the sealing member extension 136 may be placed on a first side (not shown) of the second sealing member portion 134, and coupled, such as by an adhesive, a bond 135, a weld (e.g., ultrasonic or RF welding), or by cements. The first side of the second sealing member portion 134 may face away or outward from the epidermis 106. In some example embodiments, the second sealing member portion 134 may be positioned on and extend outward from the second side 122 of the dressing bolster 114 and be coupled to a portion of the first

sealing member 132 as described. Further, in some examples, the first sealing member portion 132 and the second sealing member portion 134 may be integrally formed with one another. Further, the first sealing member portion 132 may include a plurality of bellows 142, folds, or stretch zones. The bellows 142 may provide additional drape material when needed to respond to stretching or other movement. For example, if the dressing assembly 112 is used on a joint, when the joint is flexed, the bellows 142 may provide additional drape material to facilitate such movement.

[0044] Prior to application, one or more release members (not shown) may be releasably coupled to the first side of the second sealing member portion 134. The release members may be analogous to release members 242 depicted in FIGURE 5, and may provide stiffness to assist with, for example, deployment of the dressing assembly 112. The release members may be, for example, casting paper or a film held on the first side of the second sealing member portion 134. Each release member may have a release agent disposed on a side of the release member configured to contact a component of the dressing assembly 112, such as the second sealing member portion 134, or other components described herein. In some embodiments, the release agent may be a silicone coating and may have a release factor between about 5 grams per centimeter to about 15 grams per centimeter. In some embodiments, the release factor may be between about 2 grams per centimeter to about 6 grams per centimeter. The release agent may facilitate removal of the release member by hand and without damaging or deforming the dressing assembly 112.

[0045] Release members suitable for use with the embodiments described herein may be, for example and without limitation, polyester release members specified as FRA 301(T-36) and FRA 396-T13, available from Fox River Associates, LLC of Geneva, Illinois. The polyester release members may be a polyethylene terephthalate (PET) release member as described herein. In some embodiments, the release members may have a film thickness between about 30 microns to about 70 microns. In some embodiments, the film thickness may be between about 47 microns to about 53 microns. Further, the release members may have a tensile break strength in a machine direction between about 9 kilograms per square millimeter to about 15 kilograms per square millimeter. In a transverse direction, or direction transverse to the machine direction, the release members may have a tensile break strength between about 15 kilograms per square millimeter to about 23 kilograms per square millimeter. The elongation at break of the release members in both the machine direction and the transverse direction may be between about 40 percent to about 140 percent. The release members may have a shrinkage in the machine direction between about 0.0 percent to about 2.5 percent, and a shrinkage in the transverse direction between about 0.0 percent to about 1.2 percent.

[0046] The reduced-pressure subsystem 118 may include a reduced-pressure source 144. In some example embodiments, the reduced-pressure source 144 may provide reduced pressure as a part of the treatment system 100. Further, in some examples, the reduced-pressure source 144 may be configured to be coupled in fluid communication with the dressing assembly 112. For example, the

reduced-pressure source 144 may be fluidly coupled to the conduit interface 138 by a delivery conduit 148.

[0047] As used herein, the term “reduced pressure” may refer to a pressure less than the ambient pressure at a tissue site being subjected to treatment, such as the tissue site 102. The reduced pressure may be less than the atmospheric pressure. The reduced pressure may also be less than a hydrostatic pressure at a tissue site. Unless otherwise indicated, quantitative values of pressure stated herein are gauge pressures.

[0048] The reduced pressure delivered to the dressing bolster 114 may be constant or varied, patterned or random, and may be delivered continuously or intermittently. Although the terms “vacuum” and “negative pressure” may be used to describe the pressure applied to a tissue site, the actual pressure applied to the tissue site may be more than the pressure normally associated with a complete vacuum. Consistent with the use herein, unless otherwise indicated, an increase in reduced pressure or vacuum pressure may refer to a relative reduction in absolute pressure.

[0049] Continuing with FIGURE 1, the reduced-pressure source 144 is shown as having a reservoir region 146, or canister region. An interposed membrane filter (not shown), such as hydrophobic or oleophobic filter, may be interspersed between the reduced-pressure delivery conduit 148 and the reduced-pressure source 144. One or more devices, such as a representative device 150, may be fluidly coupled to the reduced-pressure delivery conduit 148. The representative device 150 may be, for example, another fluid reservoir, a collection member to hold exudates and other fluids removed, a pressure-feedback device, a volume detection system, a blood detection system, an infection detection system, a flow monitoring system, or a temperature monitoring system. Multiple representative devices 150 may be included. One or more of the representative devices 150 may be formed integrally with the reduced-pressure source 144.

[0050] The reduced-pressure source 144 may be any device for supplying a reduced pressure, such as a vacuum pump, wall suction, or other source. While the amount and nature of reduced pressure applied to a tissue site may vary according to the application, the reduced pressure may be, for example, between about -5 mm Hg (-667 Pa) to about -500 mm Hg (-66.7 kPa). In some embodiments, the reduced pressure may be between about -75 mm Hg (-9.9 kPa) to about -300 mm Hg (-39.9 kPa).

[0051] The reduced pressure interface or conduit interface 138 may be coupled in fluid communication with a sealed space at the tissue site 102, and the reduced-pressure source 144 may be configured to be coupled in fluid communication with the sealed space through the interface 138. The reduced pressure developed by the reduced-pressure source 144 may be delivered through the delivery conduit 148 to the conduit interface 138. The conduit interface 138 may allow the reduced pressure to be delivered through the sealing member 116 to the dressing bolster 114. In some embodiments, the conduit interface 138 may provide fluid communication external to the sealing member 116 without the application of reduced pressure.

[0052] The reduced-pressure indicator 101 may be configured to indicate that a reduced pressure of at least of certain threshold level is being delivered to the tissue site 102. The reduced-pressure indicator 101 may be a separate unit fluidly coupled to the sealing member 116 such that reduced pressure from within the sealed space of the sealing member 116 reaches the reduced-pressure indicator 101. In some embodiments, as shown in FIGURE 1, the reduced-pressure indicator 101 may be associated with the conduit interface 138 as a part of the reduced-pressure assembly 140. When adequate reduced pressure is present, the reduced-pressure indicator 101 may be configured to assume a collapsed position. When inadequate reduced pressure is present, the reduced-pressure indicator 101 may be configured to assume a non-collapsed position.

[0053] Referring primarily to FIGURE 2, the dressing assembly 112 may include a gasket member 117. The gasket member 117 may also be referred to interchangeably as an interface seal or sealing ring 117. For example, features or characteristics of the gasket member 117 may apply to the sealing ring 117, and features or characteristics of the sealing ring 117 may apply to the gasket member 117. The gasket member 117 and the sealing ring 117 may be configured in any suitable shape to enhance or otherwise provide a fluid seal around the tissue site 102, such as the incision 104. For example, the epidermis 106 may have recesses, cracks, wrinkles, or other discontinuities on a surface of the epidermis 106 that may cause leaks. Moreover, folds, buckles, wrinkles, or other discontinuities may form in the sealing member 116 and cause leaks. The gasket member 117 and the sealing ring 117 may help seal any such skin or sealing member discontinuities around the tissue site 102.

[0054] The gasket member 117 or the sealing ring 117 may be adapted to be positioned between the dressing assembly 112 and the epidermis 106 and/or the tissue site 102. In some examples, the gasket member 117 may be positioned on, coupled to, or directly coupled to the second side 122 of the dressing bolster 114 or the second side 128 of the comfort layer 124. The gasket member 117 or the sealing ring 117 may be formed, as an illustrative example, by applying or bonding a sealing material around a perimeter or circumference of a portion of the dressing assembly 112. Although the sealing material of the gasket member 117 or the sealing ring 117 may be configured in the shape of a ring in some embodiments, other shapes are suitable, and may include, without limitation, circles, squares, rectangles, discontinuous shapes, continuous shapes, irregular shapes, linear shapes, other shapes or portions that overlap one another, or combinations thereof. The sealing material may include hydrocolloids, hydrogels, silicone polymers (both crosslinked and uncrosslinked gels), and natural gums (xanthan, guar, cellulose). The sealing material may include other soft polymer gels, such as, for example, those based on polyurethanes, polyolefin gels, and acrylics.

[0055] In some embodiments, the gasket member 117 or the sealing ring 117 may be deployed by hand or extruded from an applicator, such as a syringe, to form a ring or other shape prior to application of the dressing assembly 112 to the tissue site 102. Sealing materials suitable for

application by extrusion may include, without limitation, water soluble gums such as xanthan, guar, or cellulose, and thick greases, such as silicones. In another embodiment, the sealing ring 117 may be bonded in any suitable manner, such as, for example, by a heat bond, to the second, inward facing side 128 of the comfort layer 124 during manufacture of the dressing assembly 112. In at least this manner, the sealing ring 117 may be adapted to be positioned between the comfort layer 124 and the epidermis 106 and/or the tissue site 102.

[0056] In some embodiments, the gasket member 117 or the sealing ring 117 may include an absorbent. For example, the sealing ring 117 may be a hydrocolloid comprising an absorbent, such as carboxy methyl cellulose (CMC). The absorbent may permit the sealing ring 117 to absorb fluid from the tissue site 102 in addition to enhancing the fluid seal around the tissue site 102. The sealing ring 117 including the absorbent may enhance the ability of the dressing assembly 112 to manage and direct fluid away from the tissue site 102 for keeping the tissue site 102 dry. For example, the dressing bolster 114 may have a thickness between the first side 120 and the second, inward-facing side 122 of the dressing bolster 114. The thickness of the dressing bolster 114 may define at least a portion of a thickness of the dressing assembly 112. The sealing ring 117 may be adapted to be positioned between the dressing assembly 112 and the tissue site 102, as described above, and around or surrounding a circumference of the tissue site 102. Relative to the dressing assembly 112, the sealing ring 117 or the gasket member 117 may be positioned, for example, around, on, or at the lateral edges of the dressing bolster 114 and/or the comfort layer 124. Further, the sealing ring 117 or the gasket member 117 may extend beyond a lateral edge of the dressing bolster 114 and the comfort layer 124. Further, the sealing ring 117 may be positioned around or surrounding a circumference of the dressing bolster 114 and/or the comfort layer 124. Further, the sealing ring 117 may be positioned around at least a portion of the dressing bolster 114 or the comfort layer 124 that is configured to be positioned directly against or in direct contact with the tissue site 102. At least a portion of the dressing bolster 114 and/or the comfort layer 124 may be exposed and configured to be positioned directly against the tissue site 102 when the sealing ring 117 is positioned on the dressing assembly 112. Further, in such embodiments, the sealing ring 117 may surround the exposed portion of the dressing bolster 114 and/or the comfort layer 124.

[0057] The absorbent in the sealing ring 117 may wick or draw fluid in a lateral direction within the dressing assembly 112, normal to the thickness of the dressing bolster 114, and toward the lateral edges of the dressing bolster 114 for absorption in the sealing ring 117. Thus, fluid from the tissue site 102 may be wicked or otherwise drawn in a lateral direction along the surface of the tissue site 102 toward the lateral edges of the dressing bolster 114 and into the sealing ring 117. Further, fluid from the tissue site 102 may also flow through the thickness of the dressing assembly 112 and the dressing bolster 114 at least by operation of the manifold material comprising the dressing bolster 114, described above.

[0058] Referring now primarily to FIGURES 3-5, depicted is a portion of an illustrative embodiment of a treatment system 200 suitable for treating, for example, a linear wound, area wound, a graft, or other wound. FIGURES 3-5 depict the treatment system 200 in a pre-deployment state. The treatment system 200 may include a dressing assembly 202, and the dressing assembly 202 may include a dressing bolster 204. The dressing bolster 204 has a first side 206 and a second, inward-facing side 208. The dressing bolster 204 may be formed from any suitable bolster material, or manifold material, as previously referenced in connection with the dressing bolster 114. A comfort layer 210, which has a first side 212 and a second, inward-facing side 214, may be coupled, such as, for example, by a heat bond 216 or other suitable technique to the second, inward-facing side 208 of the dressing bolster 204.

[0059] The comfort layer 210 may be any material that helps prevent skin irritation and discomfort while allowing fluid transmission through the comfort layer 210. Suitable materials for the comfort layer 210 have been mentioned in connection with the comfort layer 124 of FIGURES 1-2. In some embodiments, the comfort layer 210 may include antimicrobial substances, such as silver. Further, in some embodiments, the comfort layer 210 may be made as a breathable, dry layer.

[0060] In some illustrative embodiments, the dressing bolster 204 may include a plurality of flexibility notches 218. The flexibility notches 218 may extend partially through or completely through the dressing bolster 204. The flexibility notches 218 may be lateral notches, or lateral cuts, in the dressing bolster 204. The flexibility notches 218 may also be one or more longitudinal notches, longitudinal cuts, or other cuts. The cuts may be made using a saw, a notched blade, a hot knife, or other device. The flexibility notches 218 may enhance the flexibility of the dressing bolster 204. The enhanced flexibility may be particularly useful when the dressing assembly 202 is applied over a joint or other area of movement on a patient. For example, if the dressing bolster 204 is used on a knee, the dressing bolster 204 may need to flex or extend as much as 100 % or more. The flexibility notches 218 may provide such flexibility.

[0061] The dressing bolster 204 may have lateral edges 205 that are orthogonal with respect to the second, inward-facing side 208 of the dressing bolster 204. The lateral edges 205 may also have a shape, such as, for example, a beveled, angled, or rounded shape. The lateral edges 205, when angled, may be between about 10 degrees to about 90 degrees with respect to the second, inward-facing side 208 of the dressing bolster 204. The shaped lateral edges 205 may reduce shear stress between an epidermis of a patient and the dressing bolster 204. Other dimensions, steps, and processes may be used.

[0062] In some illustrative embodiments, the dressing bolster 204 may be manufactured from a foam block of GRANUFOAM™ material. The GRANUFOAM™ material may be, for example, a foam block having the dimensions of 1.21 meters x 1.8 meters x 0.5 meters. The foam block may be cut to have a 19 millimeter height, and a saw may be used to form lateral grooves, such as the flexibility notches 218, in the foam block. A dry layer, such as the comfort layer 210, may be

laminated or otherwise attached to the second, inward facing side 208 of the dressing bolster 204. The foam block may be cut, for example, utilizing a die cutter to form a plurality of individual dressing bolsters 204.

[0063] A sealing subsystem 222 may provide a fluid seal over the dressing assembly 202 and at least a portion of an epidermis of a patient. The sealing subsystem 222 may include a sealing member 224. The sealing member 224 may be formed with an upper drape portion or first sealing member portion 226 and a lower drape portion or second sealing member portion 228. The first sealing member portion 226 may extend over or cover the first side 206 of the dressing bolster 204 to form a drape flange, or drape extension 230. The drape extension 230 has a first side 232 and a second, inward-facing side 233. The second, inward-facing side 233 of the drape extension 230 may be adapted to face a tissue site of a patient as described above. An aperture 234 may be formed on the first sealing member portion 226. The aperture 234 may provide fluid communication with a conduit interface (not shown). The conduit interface may be analogous to the conduit interface 138 in FIGURE 1.

[0064] The second sealing member portion 228 may have a first side 236 and a second, inward-facing side 237 adapted to face a tissue site as described above. The second, inward-facing side 233 of the drape extension 230 may be placed on the first side 236 of the second sealing member portion 228, and may be coupled to the first side 236 by an attachment device 238. The attachment device 238 may be, for example, an adhesive, a bond, a weld (e.g., ultrasonic or RF weld), cements, stitching, staples, or other coupling device. The second sealing member portion 228 may include an attachment apparatus on the second, inward-facing side 237 as described below. The second sealing member portion 228 may also include a treatment area aperture 240, depicted in FIGURE 5, that may be adapted to permit fluid communication through the second sealing member portion 228 and, for example, between a tissue site and the dressing bolster 204. The treatment area aperture 240 may also provide an opening for at least a portion of the dressing bolster 204, or the comfort layer 210, to be positioned directly against an epidermis and/or a tissue site of a patient.

[0065] The first sealing member portion 226 may include a plurality of folds 220 or bellows to facilitate movement as described above. The folds 220 may allow the first sealing member portion 226 to expand. For example, if the dressing assembly 202 is used on a joint, when the joint is flexed, additional drape material from the folds 220 may be released to facilitate movement of the first sealing member portion 226. The folds 220 may also be formed as ridges having the cross-sectional shape of an accordion that provides additional drape material when flattened or stretched, for example.

[0066] One or more release members 242 may be releasably coupled to the first side 236 of the second sealing member portion 228, such as, for example, with an adhesive (not shown) applied on at least a portion of the first side 236. Four of the release members 242 are shown in the illustrative embodiment of FIGURE 3. The release members 242 may provide stiffness to the second

sealing member portion 228, and may cover the adhesive or other attachment apparatus to provide a grasping surface during deployment of the dressing assembly 202. The release members 242 may be casting paper or a film held on the first side 236 of the second sealing member portion 228.

[0067] The first side 236 of the second sealing member portion 228 may include an adhesive 244 adapted to retain the second side 208 of the dressing bolster 204 against the second sealing member portion 228 during assembly and usage. A center release member 246 may cover and protect the adhesive 244 prior to assembly. The release members 242 that may provide stiffness to the sealing member 224 during deployment may be positioned outboard of the adhesive 244 on the first side 236 of the second sealing member portion 228.

[0068] The dressing assembly 202 may include a sealing ring 248. Analogous to the sealing ring 117, the sealing ring 248 may help seal any wrinkles or discontinuities in the epidermis or drape that might otherwise cause leaks. Also analogous to the sealing ring 117, the sealing ring 248 may also be referred to interchangeably as an interface seal or a gasket member 248. For example, features or characteristics of the gasket member 248 may apply to the sealing ring 248, and features or characteristics of the sealing ring 248 may apply to the gasket member 248. Further, the previously described features of the sealing ring 117 or the gasket member 117 associated with the dressing assembly 112 may apply by analogy to the sealing ring 248 or the gasket member 248 associated with the dressing assembly 202.

[0069] The sealing ring 248 or the gasket member 248 may be, for example, positioned to cover a portion of the second, inward-facing side 237 of the second sealing member portion 228. The sealing ring 248 or the gasket member 248 may be coupled directly to the dressing assembly 202, or coupled with an optional sealing-ring attachment device 249, such as an acrylic adhesive, cement, or other coupling device. In other embodiments, the sealing ring 248 or the gasket member 248 may be coupled to the second inward-facing side 208 of the dressing bolster 204, and/or to an adjacent layer, such as the comfort layer 210.

[0070] The sealing ring 248 or the gasket member 248 may straddle an edge of the dressing bolster 204, or otherwise extend beyond an edge of the dressing bolster 204, as depicted in FIGURE 4. In some embodiments, the sealing ring 248 or the gasket member 248 may be coupled to a portion of the sealing member 224, such as the first sealing member 226 and/or the second sealing member 228. In some embodiments, the dressing bolster 204 may entirely overlap the sealing ring 248 or the gasket member 248 as suggested in FIGURE 11. While reference is made to a "ring," discrete members, including linear members, may make up the sealing ring 248 or the gasket member 248.

[0071] The sealing ring 248 may comprise a sealing material, such as, for example, any of the sealing materials previously described in connection with the sealing ring 117, or other material that provides initial tack between the dressing assembly 202 and an epidermis of a patient. Further, the sealing ring 248 may have a durometer, such as a material softness or hardness, between about 20 Shore 00 to about 90 Shore OO. In some embodiments, the durometer of the sealing ring 248 may be

between about 70 Shore 00 to about 80 Shore 00. The sealing ring 248 may have a modulus of elasticity that falls between the modulus of elasticity of the second sealing member portion 228 and the modulus of elasticity of a tissue site and/or epidermis of a patient. As shown in FIGURE 4, the sealing ring 248 may have a thickness 250 and a width 252. The thickness 250 of the sealing ring 248 may be between about 0.3 millimeters to about 2.5 millimeters. In some embodiments, the thickness 250 may be between about 0.7 millimeters to about 1.25 millimeters. The width 252 of the sealing ring 248 may be between about 10 millimeters to about 30 millimeters. Other dimensions are possible. In some illustrative embodiments, the thickness 250 may be about 0.7 millimeters and the width 252 may be about 20 millimeters. Further, in some embodiments, the width 252 of the sealing ring 248 may extend beyond an edge of the dressing bolster 204 by about 10 millimeters and overlap the dressing bolster 204 by about 10 millimeters.

[0072] In some embodiments, the second sealing member portion 228 may have a thickness 229 between about 0.178 millimeters to about 0.254 millimeters, or about 7 mils to about 10 mils. The ratio of the sealing ring thickness 250 to the sealing member thickness 229 may be between about 2.75 to about 7.03.

[0073] The sealing ring 248 may include fenestrations or apertures. In some embodiments, the sealing ring 248 may comprise a patterned sealing material on the second, inward-facing side 214 of the comfort layer 210, or on the second, inward-facing side 208 of the dressing bolster 204. The pattern may be, for example, spaced islands, crossing lines of sealing material, or any other suitable pattern.

[0074] The sealing ring 248 may function as a two-sided gasket that may provide a seal between the dressing assembly 202 and a tissue site and/or epidermis of a patient. For example, the sealing ring 248 may provide a seal between the dressing bolster 204, the comfort layer 210, or the second sealing member portion 228 and a tissue site and/or epidermis of a patient. The sealing ring 248 may absorb perspiration or other fluids from a tissue site. Further, the sealing ring 248 may help distribute shear forces created, for example, by the application of reduced pressure at the interface of the dressing bolster 204 and a tissue site and/or epidermis of a patient.

[0075] As shown in FIGURE 4, a portion of the second, inward-facing side 237 of the second sealing member portion 228 may be covered with a sealing apparatus or device 254, such as an adhesive. With reference to FIGURES 4 and 5, when in the pre-deployment state, the sealing device 254 may be covered by a bottom release member 256 and side release members 258.

[0076] The bottom release member 256 may cover and protect, for example, the sealing device 254 and the sealing ring 248. The side release members 258 may also cover and protect the sealing device 254. Similar to the release members 242, the side release members 258 may provide a grasping surface for a user to facilitate deployment of the dressing assembly 202. The release members 242, the bottom release member 256, and /or the side release members 258 may be comprised of a polar semi-crystalline polymer, such as, for example, polyethylene terephthalate

(PET). Use of a polar semi-crystalline polymer for the release members 242, the bottom release member 256, and /or the side release members 258 may substantially preclude wrinkling or other deformation of the dressing assembly 202. Any deformation of the release members 242, the bottom release member 256, and/or the side release members 258 may cause wrinkling or deformation of a component of the dressing assembly 202. The polar semi-crystalline polymer is highly orientated and resistant to softening, swelling, or other deformation that may occur when brought into contact with components of the dressing assembly 202, or when subjected to temperature or environmental variations, or sterilization. Thus, for example, when the polar semi-crystalline polymer is used in combination with the hydrocolloid described above for the sealing ring 248, the polar semi-crystalline polymer may not deform when in contact with the compounding ingredients of the hydrocolloid. In some embodiments, the release members 242, the bottom release member 256, and/or the side release members 258 may be configured to resist deformation when exposed to temperature variations between about 40 degrees Celsius to about 60 degrees Celsius, and gamma sterilization doses between about 25kGy to about 45 kGy.

[0077] Continuing with FIGURES 3-5, according to an illustrative embodiment of operation, the bottom release member 256 may be removed to expose the sealing device 254 on the second, inward-facing side 237 of the second sealing member portion 228. Removal of the bottom release member 256 may also expose a second, inward-facing surface 247 of the sealing ring 248. The sealing device 254 and/or the second, inward-facing surface 247 of the sealing ring 248 may be placed against a portion of an epidermis of a patient and around a tissue site that may include a linear wound as described above. The side release members 258 may be removed after applying the second sealing member portion 228. Similarly, the release members 242 on the first side 236 of the second sealing member portion 228 may be removed after applying the second sealing member portion 228. A conduit interface may be coupled to the aperture 234 in the first sealing member portion 226, and reduced pressure may be delivered to the dressing assembly 202.

[0078] Regarding the manufacture of the systems and components described above, in applying and coupling a sealing member to a dressing bolster, a press may be utilized to remove any wrinkles in the sealing member. Further, the medical bolster material of the shaped dressing assembly may be cut using a die cutter, or by hand with a router.

[0079] Referring now primarily to FIGURES 6A-6C, presented is another illustrative embodiment of a portion of a treatment system 300. FIGURES 6A-6C depict the treatment system 300 assembled in stages at a tissue site, such as a linear wound 306. In FIGURE 6A, a closure device 302, such as, for example, stitches 304, close the linear wound 306. Other closure devices 302, such as epoxy or staples may be utilized to close the linear wound 306. The linear wound 306 may include a portion through an epidermis 308, dermis 310, and subcutaneous tissue 312 of a patient.

[0080] Referring now to FIGURE 6B, after the linear wound 306 is closed or prepared as described above, a dressing assembly 314 may be disposed proximate to the linear wound 306. The

5 dressing assembly 314 may include a dressing bolster 316. The dressing bolster 316 may be formed from the bolster or manifold materials previously mentioned. The dressing bolster 316 may include a plurality of lateral notches 318 and one or more longitudinal notches 320. The dressing bolster 316 has a first side 322 and a second, inward-facing side 324. The first side 322 may include an adhesive layer 323. The adhesive layer 323 may help secure a sealing member 340 thereto, as shown in
FIGURE 6C.

10 [0081] The dressing assembly 314 may include a comfort layer 326. The second, inward-facing side 324 of the dressing bolster 316 may be covered with the comfort layer 326. The comfort layer 326 has first side 328 and a second, inward-facing side 330. The first side 328 of the comfort layer 326 may be coupled by an attachment device 332, such as, for example, a heat bond, adhesive, weld, or other attachment device, to the second, inward-facing side 324 of the dressing bolster 316.

15 [0082] The dressing assembly 314 may include a sealing ring 334. The sealing ring 334 may be coupled, at least in part, to the second, inward-facing side 330 of the comfort layer 326. The sealing ring 334 may be analogous to the sealing ring 117 of FIGURE 2 and the sealing ring 248 of FIGURES 3-5. Further, the sealing ring 334 may be referred to interchangeably as a gasket member 334 analogous to the gasket member 117 and the gasket member 248.

20 [0083] The sealing ring 334 may comprise any of the sealing materials previously described in connection with the sealing ring 117 and the sealing ring 248. The sealing ring 334 may adhere directly to the comfort layer 326, or may be coupled with a sealing-ring attachment device 336 to the comfort layer 326. The sealing-ring attachment device 336 may be, for example, acrylic adhesive, cement, or other suitable attachment device. The sealing ring 334 and/or the sealing ring attachment device 336 may be co-extensive with the comfort layer 326, or may extend beyond a lateral edge of the comfort layer 326 and the dressing bolster 316.

25 [0084] Prior to application, a second, inward-facing surface 338 of the sealing ring 334 may be covered by a release member or release liner (not shown). When the release liner is removed, the sealing ring 334 may be centered about the linear wound 306 for deployment. A release member or release liner (not shown) may also temporarily cover a portion of the sealing ring 334 and/or sealing ring attachment device 336 to provide a grasping surface during deployment of the dressing assembly 314. The release liner or release member covering, for example, the sealing ring 334, the sealing ring attachment device 336, and/or other components of the dressing assembly 314 may be analogous to the release members 242, 256, and 258 of FIGURES 3-5. For example, the release members may be positioned on the dressing assembly 314 analogous to the release members 242, 256, and 258. Further, the release members on the dressing assembly 314 may be comprised of any of the materials previously described for the release members 242, 256, and 258, such as, for example, a polar semi-crystalline polymer or polyethylene terephthalate (PET). As described above, use of a polar semi-crystalline polymer such as PET as a release member on the dressing assembly 314 may substantially

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preclude deformation of the dressing assembly 314. In another embodiment, the sealing ring 334 may be separately applied around the linear wound 306 before the dressing bolster 316 is applied thereto.

[0085] Referring now to FIGURE 6C, a sealing member 340 may be disposed over the dressing assembly 314 and a portion of the epidermis 308 to form a sealed space 342 between the dressing assembly 314 and the linear wound 306. Analogous to the aperture 234 in FIGURE 3, an aperture (not shown) may be formed or preformed in the sealing member 340. A conduit interface (not shown), analogous to conduit interface 138 described above, may be coupled to the sealing member 340 to provide fluid communication with the sealed space 342 through the aperture. Further, a reduced-pressure source (not shown), analogous to the reduced-pressure source 144 in FIGURE 1, may be coupled to the conduit interface 138 to provide reduced pressure to the sealed space 342 to treat the linear wound 306. A delivery conduit (not shown), analogous to the delivery conduit 148 in FIGURE 1, may be utilized for coupling the reduced pressure source to the conduit interface. Reduced pressure may be applied to the tissue site, such as the linear wound 306, and fluid may be extracted from the tissue site and into the dressing assembly 314. The fluid from the tissue site may be absorbed into the sealing ring 334. The fluid from the tissue site may be wicked or otherwise communicated in a lateral direction within the dressing assembly 314 toward the sealing ring 334.

[0086] Referring to FIGURES 7A-8B, in some example embodiments, the systems or the dressing assemblies according to this disclosure may include an auxiliary port assembly 404, which may include or may be an access portal 406. The auxiliary port assembly 404 or the access portal 406 may be provided, for example, as part of the system 100, 200, 300, part of the dressing assembly 112, 202, 314, or as a separate component for use with another system, assembly, or dressing as desired. However, as a non-limiting, illustrative example, FIGURES 8A-8B depict the auxiliary port assembly 404 and the access portal 406 associated with the treatment system 100 and the dressing assembly 112.

[0087] The auxiliary port assembly 404 or the access portal 406 may provide a variety of benefits, such as, for example, the ability to monitor, inspect, scope, or drain at least a portion of the tissue site 102 without removing the dressing assembly 112 from the tissue site 102. In some examples, an accessory component 405 may be used or deployed with the treatment system 100 or the dressing assembly 112. The accessory component 405 may include an internal portion 407 in communication with an external portion 409. The internal portion 407 may include, without limitation, a sensor, camera, scope, or drain configured to be positioned in the sealed space at the tissue site 102 or between the tissue site 102 and a portion of the dressing assembly 112. The external portion 409 may include, without limitation, wires, leads, or tubes configured to be routed, guided, or disposed through the auxiliary port assembly 404 or the access portal 406 to an exterior of the dressing assembly 112. In some examples, the accessory component 405 may include or may be, without limitation, a monitoring device, a drain, an oxygen sensor, or a perfusion sensor, such as a ViOptix perfusion sensor. Accordingly, the auxiliary port assembly 404 or the access portal 406 may

allow a caregiver to, for example, monitor healing progression, oxygenation, and blood flow at a tissue site while a dressing, such as the dressing assembly 112, remains positioned at the tissue site.

[0088] In some examples, the auxiliary port assembly 404 or the access portal 406 may be configured to be coupled to an exterior surface of a cover or sealing member, such as the sealing member 116, 224, 340, which may provide a sealed space, such as the sealed space 342, at the tissue site 102. As a non-limiting, illustrative example, FIGURES 8A-8B depict the sealing member 116, but the auxiliary port assembly 404 or the access portal 406 may be associated with the sealing member 224, 340 or other sealing members or covers by analogy. The auxiliary port assembly 404 or the access portal 406 may include an exterior side 408 and a mounting side 410 opposite the exterior side 408. The mounting side 410 may be configured to face the cover or the sealing member 116. An attachment device, such as an adhesive 412, may be configured to couple the mounting side 410 to the cover or the sealing member 116. In some examples, the attachment device may be, for example, an acrylic adhesive, hydrocolloid, cement, weld, heat bond, or other device.

[0089] The access portal 406 may be configurable between an open state 414, shown in FIGURE 7B, and a closed state 416, shown in FIGURE 7A. The access portal 406 may provide an opening or passage 418 through the cover or the sealing member 116 in the open state 414 and a fluid seal in the closed state 416. The opening or passage 418 through the cover or the sealing member 116 may provide access to the sealed space when the cover or the sealing member 116 is positioned at the tissue site 102.

[0090] In some examples, the access portal 406 may include or may be formed of a penetrable membrane 420. The penetrable membrane 420 may include an optional perforation 422 that may be tearable or severable and configured to be collapsed or sealed in the closed state 416 and torn, severed, or separated in the open state 414. In some examples, the penetrable membrane 420 may be configured or formed of a material configured to self-heal or sealingly deform or conform around a penetrating device, such as a wire, sensor lead, or tube extending through the penetrable membrane 420. The penetrable membrane 420 may include or may be formed of a variety of self-healing materials, elastomeric materials, or polymers, such as, without limitation, silicone, a thermoplastic elastomer, a thermos-plastic elastomer gel, hydrocolloid, similar or analogous materials as those described herein for the gasket member 117, 248, 334, or sleeves, sheets, or discs formed from any of these materials or combinations thereof.

[0091] In some examples, the auxiliary port assembly 404 or the access portal 406 may include a release liner 424. The release liner 424 may be coupled to the attachment device or the adhesive 412 on the mounting side 410 of the access portal 406. The attachment device or the adhesive 412 may be positioned between the mounting side 410 and the release liner 424. The release liner 424 may be configured to be removed prior to coupling the auxiliary port assembly 404 or the access portal 406 to the cover or the sealing member 116. The release liner 424 may include or may be formed of similar or analogous materials as described herein for the release members 242.

[0092] Referring to FIGURES 8A-8B, in some examples, an optional sealing patch 428 may be included in or used with the auxiliary port assembly 404 or the access portal 406. The sealing patch 428 may be, for example, a liquid impermeable material configured to cover at least a portion of the exterior side 408 of the access portal 406. In some examples, the sealing patch 428 may include or may be formed of, without limitation, a sealing film, drape, adhesive film, or an adhesive-backed polyurethane film.

[0093] Referring to FIGURES 8A-9, the auxiliary port assembly 404 or the access portal 406 may be used or deployed in any suitable location through the cover or the sealing member 116, such as, without limitation, through a top portion of the sealing member 116, shown in FIGURES 8A-8B, or a side portion of the sealing member 116, shown in FIGURE 9.

[0094] Referring to FIGURES 10A-10B, in some examples, the access portal 406 may be an access portal 406b. The access portal 406b may include a housing 430, a housing opening 432 disposed through the housing 430, and a removable closure device 434, such as a cap or plug. The removable closure device 434 may be configured to seal the housing opening 432 when the access portal 406b is in the closed state 416, shown in FIGURE 10B, and to be removed from the housing opening 432 in the open state 414, shown in FIGURE 10A. In some examples, the housing 430 may include a threaded connection 436 and the removable closure device 434 may include a cap 438 configured to seal the housing opening 432 in the access portal 406b when engaged with the threaded connection 436.

[0095] Referring to FIGURES 11A-11B, in some examples, the access portal 406 may be an access portal 406c positioned on or formed as part of a reduced pressure interface, such as the conduit interface 138, or the reduced-pressure assembly 140. In some examples, the access portal 406c may be coupled to the conduit interface 138 or the reduced-pressure assembly 140 by an attachment device, such as the adhesive 412, positioned at the mounting side 410 of the access portal 406c as shown in FIGURES 11A-11B. In other examples, the access portal 406c may be formed integrally or molded as part of the conduit interface 138 or the reduced-pressure assembly 140.

[0096] In some example embodiments, a method for treating the tissue site 102 may include positioning the accessory component 405, such as the monitoring device, at the tissue site 102 and providing a dressing assembly, such as the dressing assembly 112. The dressing assembly 112 may include the dressing bolster 114 and the cover, such as the sealing member 116, for creating a sealed space over the dressing bolster 114 at the tissue site 102. Further, the method may include coupling an auxiliary port assembly 404 to the cover or the sealing member 116. The auxiliary port assembly 404 may include the access portal 406, which may be configurable between the open state 414 and the closed state 416. The access portal 406 may provide the passage 418 through the cover or the sealing member 116 in the open state 414. Further, the method may include guiding the external portion 409 of the accessory component 405 or the monitoring device through the dressing assembly 112 and the access portal 406 with the access portal 406 in the open state 414. Further, the method may include

securing the dressing assembly 112 at the tissue site 102 and over the internal portion 407 of the accessory component 405 or the monitoring device. Further, the method may include positioning the access portal 406 in the closed state 416 to form a seal around the internal portion 407 of the accessory component 405 or monitoring device.

5 **[0097]** In some examples, the accessory component 405 may be pushed through the dressing assembly 112 and the access portal 406 with a fixture (not shown) that may include a needle and attachment cord or guide wire secured to the external portion 409 of the accessory component 405. In such embodiments, penetrating, severing, or puncturing the access portal 406 with the fixture or a portion of the fixture may position the access portal 406 in the open state 414 and create the passage
10 418. The self-healing or elastomeric properties of the access portal 406 may position the access portal 406 in the closed state 416 around or into sealing engagement with the external portion 409 of the accessory component 405. Accordingly, the closed state 416 may also be referred to as a sealed state, which may not be entirely closed, but provide a fluid seal, if required. Additional sealing capability may be provided by the optional sealing patch 428, which may cover gaps, seams, or holes in the
15 access portal 406.

[0098] The appended claims set forth novel and inventive aspects of the subject matter in this disclosure. While shown in several 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. Features may be emphasized in some example embodiments
20 while being omitted in others, but a person of skill in the art will appreciate that features described in the context of one example embodiment may be readily applicable to other example embodiments. Further, certain features, elements, or aspects may be omitted from this disclosure 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 herein may also be combined or replaced by
25 different or alternative features serving the same, equivalent, or similar purpose without departing from the scope of the invention defined by 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. Further, the benefits and advantages described herein may relate to
30 one embodiment or several embodiments. Even further, the steps of the methods described herein may be carried out in any suitable order, or simultaneously, where appropriate.

We claim:

1. A system for treating a tissue site, comprising:

a dressing assembly, comprising:

a dressing bolster having a first side and a second side,

a comfort layer coupled to the second side of the dressing bolster,

a first sealing member covering the first side of the dressing bolster,

a second sealing member covering a portion of the second side of the dressing bolster and extending outward from the dressing bolster, wherein a portion of the first sealing member is coupled to the second sealing member, and

a sealing ring positioned at the second side of the dressing bolster, wherein the first sealing member, the second sealing member, and the sealing ring are configured to provide a sealed space at the tissue site;

an access portal configurable between an open state and a closed state, wherein the access portal provides a passage into the sealed space in the open state and a fluid seal in the closed state; and

a reduced-pressure source configured to be coupled in fluid communication with the sealed space.

2. The system of claim 1, wherein the dressing bolster is comprised of a reticulated open-cell foam.

3. The system of claim 1, wherein the sealing ring is positioned around a circumference of the dressing bolster.

4. The system of claim 1, wherein at least a portion of the comfort layer is exposed and configured to be positioned directly against the tissue site, the sealing ring being configured to surround the tissue site and the portion of the comfort layer that is exposed.

5. The system of claim 1, wherein the comfort layer is selected from the group consisting of a woven material, a non-woven material, a polyester knit material, and a fenestrated film.

6. The system of claim 1, wherein the sealing ring is coupled to at least a portion of the comfort layer.

7. The system of claim 1, wherein the sealing ring is coupled to at least a portion of the second sealing member.

8. The system of claim 1, wherein the sealing ring extends beyond a lateral edge of the dressing bolster and a lateral edge of the comfort layer.

9. The system of claim 1, further comprising a reduced pressure interface coupled in fluid communication with the sealed space, wherein the reduced-pressure source is configured to be coupled in fluid communication with the sealed space through the reduced pressure interface.
10. The system of claim 9, wherein the access portal is coupled to the reduced pressure interface.
- 5 11. The system of claim 1, wherein the access portal comprises a penetrable membrane.
12. The system of claim 11, wherein the penetrable membrane comprises a tearable perforation configured to be sealed in the closed state and torn in the open state.
13. The system of claim 11, wherein the penetrable membrane comprises a silicone sleeve.
14. The system of claim 11, wherein the penetrable membrane comprises a thermo-plastic elastomer.
- 10 15. The system of claim 1, wherein the access portal comprises a housing, an opening disposed through the housing, and a removable plug, wherein the removable plug is configured to seal the opening when the access portal is in the closed state and to be removed from the opening in the open state.
- 15 16. The system of claim 15, wherein the housing includes a threaded connection and the removable plug includes a cap configured to seal the opening in the access portal when engaged with the threaded connection.
17. The system of claim 1, wherein the access portal includes an exterior side and a mounting side opposite the exterior side, the mounting side configured to be coupled to the first sealing member.
- 20 18. The system of claim 17, the system further comprising an adhesive configured to couple the mounting side of the access portal to the first sealing member, and wherein the adhesive comprises a hydrocolloid.
19. The system of claim 17, further comprising a sealing patch, wherein the sealing patch comprises a liquid impermeable material configured to cover at least a portion of the exterior side of the access portal.
- 25 20. The system of claim 19, wherein the sealing patch comprises an adhesive film.
21. A system for treating a tissue site, comprising:
a dressing assembly, comprising:

a dressing bolster including a first side and an opposing second side, the second side configured to be positioned in fluid communication with the tissue site, and

a gasket member coupled at the second side of the dressing bolster;

5 a sealing member configured to cover the dressing assembly and to create a sealed space between the dressing assembly and the tissue site;

an access portal configurable between an open state and a closed state, wherein the access portal is configured to provide a passage through the sealing member in the open state and a fluid seal in the closed state; and

10 a reduced-pressure source configured to be coupled in fluid communication with the dressing bolster through the sealing member.

22. The system of claim 21, wherein the second side of the dressing bolster is configured to face the tissue site.

15 23. The system of claim 21, further comprising a tissue interface layer including a first side and a second side, wherein the first side of the tissue interface layer is coupled to the second side of the dressing bolster, and wherein the gasket member is coupled to the second side of the tissue interface layer.

24. The system of claim 21, further comprising a tissue interface coupled to the second side of the dressing bolster and configured to be positioned in contact with the tissue site.

20 25. The system of claim 23 or 24, wherein the tissue interface is selected from the group consisting of a woven material, a non-woven material, a polyester knit material, and a fenestrated film.

26. The system of claim 21, wherein the gasket member comprises a hydrocolloid.

25 27. The system of claim 21, wherein the gasket member is positioned around a circumference of the dressing bolster and configured to surround the tissue site.

28. The system of claim 21, further comprising a reduced pressure interface configured to be coupled in fluid communication with the sealed space, wherein the reduced-pressure source is configured to be coupled in fluid communication with the sealed space through the reduced pressure interface.

30 29. The system of claim 28, wherein the access portal is coupled to the reduced pressure interface.

30. The system of claim 21, wherein the access portal comprises a penetrable membrane.
31. The system of claim 30, wherein the penetrable membrane comprises a tearable perforation configured to be sealed in the closed state and torn in the open state.
32. The system of claim 30, wherein the penetrable membrane comprises a silicone sleeve.
- 5 33. The system of claim 30, wherein the penetrable membrane comprises a thermo-plastic elastomer.
34. The system of claim 21, wherein the access portal comprises a housing, an opening disposed through the housing, and a removable plug, wherein the removable plug is configured to seal the opening when the access portal is in the closed state and to be removed from the opening in
10 the open state.
35. The system of claim 34, wherein the housing includes a threaded connection and the removable plug includes a cap configured to seal the opening in the access portal when engaged with the threaded connection.
36. The system of claim 21, wherein the access portal includes an exterior side and a mounting
15 side opposite the exterior side, the mounting side configured to be coupled to the sealing member.
37. The system of claim 36, the system further comprising an adhesive configured to couple the mounting side of the access portal to the sealing member, and wherein the adhesive comprises a hydrocolloid.
- 20 38. The system of claim 36, further comprising a sealing patch, wherein the sealing patch comprises a liquid impermeable material configured to cover at least a portion of the exterior side of the access portal.
39. The system of claim 38, wherein the sealing patch comprises an adhesive film.
40. A dressing assembly for treating a tissue site, comprising:
25 a dressing bolster comprising a porous foam and including a first side and an opposing second side;
a tissue interface coupled to the second side of the dressing bolster and configured to be positioned proximate to and in fluid communication with the tissue site;
a sealing member configured to cover the dressing assembly and to create a sealed space
30 between the dressing assembly and the tissue site; and

an auxiliary port assembly configured to be coupled to an exterior surface of the sealing member and including an access portal configurable between an open state and a closed state, wherein the access portal is configured to provide a passage through the sealing member in the open state and a fluid seal in the closed state.

- 5 41. The dressing assembly of claim 40, wherein the second side of the dressing bolster is configured to face the tissue site.
42. The dressing assembly of claim 40, wherein the tissue interface is configured to contact the tissue site.
- 10 43. The dressing assembly of claim 40, wherein the tissue interface is selected from the group consisting of a woven material, a non-woven material, a polyester knit material, and a fenestrated film.
44. The dressing assembly of claim 40, further comprising a gasket member coupled at the second side of the dressing bolster.
45. The dressing assembly of claim 44, wherein the gasket member comprises a hydrocolloid.
- 15 46. The dressing assembly of claim 44, wherein the gasket member is positioned around a circumference of the dressing bolster and configured to surround the tissue site.
47. The dressing assembly of claim 40, further comprising a reduced pressure interface coupled at the first side of the dressing bolster in fluid communication with the porous foam through the sealing member, and wherein the reduced pressure interface is configured to be fluidly coupled
- 20 to a reduced-pressure source.
48. The dressing assembly of claim 40, further comprising a reduced pressure interface configured to be coupled in fluid communication with the sealed space and to provide fluid communication between the sealed space and a reduced-pressure source.
49. The dressing assembly of claim 48, wherein the access portal is coupled to the reduced
- 25 pressure interface.
50. The dressing assembly of claim 40, wherein the access portal comprises a penetrable membrane.
51. The dressing assembly of claim 50, wherein the penetrable membrane comprises a tearable perforation configured to be sealed in the closed state and torn in the open state.

52. The dressing assembly of claim 50, wherein the penetrable membrane comprises a silicone sleeve.

53. The dressing assembly of claim 50, wherein the penetrable membrane comprises a thermo-plastic elastomer.

5 54. The dressing assembly of claim 40, wherein the access portal comprises a housing, an opening disposed through the housing, and a removable plug, wherein the removable plug is configured to seal the opening when the access portal is in the closed state and to be removed from the opening in the open state.

10 55. The dressing assembly of claim 54, wherein the housing includes a threaded connection and the removable plug includes a cap configured to seal the opening in the access portal when engaged with the threaded connection.

56. The dressing assembly of claim 40, wherein the access portal includes an exterior side and a mounting side opposite the exterior side, the mounting side configured to be coupled to the sealing member.

15 57. The dressing assembly of claim 56, further comprising an adhesive configured to couple the mounting side of the access portal to the sealing member, and wherein the adhesive comprises a hydrocolloid.

20 58. The dressing assembly of claim 56, further comprising a sealing patch, wherein the sealing patch comprises a liquid impermeable material configured to cover at least a portion of the exterior side of the access portal.

59. The dressing assembly of claim 58, wherein the sealing patch comprises an adhesive film.

60. An auxiliary port assembly configured to be coupled to a cover for providing a sealed space at a tissue site, the auxiliary port assembly comprising:

25 an access portal including an exterior side and a mounting side opposite the exterior side,
 the mounting side configured to face the cover, wherein the access portal is
 configurable between an open state and a closed state, and wherein the access
 portal provides a passage through the cover in the open state; and
 an adhesive configured to couple the mounting side of the access portal to the cover.

30 61. The auxiliary port assembly of claim 60, wherein the access portal provides a fluid seal in the closed state.

62. The auxiliary port assembly of claim 60, further comprising a release liner coupled to the adhesive on the mounting side of the access portal, wherein the adhesive is positioned between the mounting side and the release liner, and wherein the release liner is configured to be removed prior to coupling the auxiliary port assembly to the cover.

5 63. The auxiliary port assembly of claim 60, wherein the passage through the cover provides access to the sealed space when the cover is positioned at the tissue site.

64. The auxiliary port assembly of claim 60, wherein the adhesive comprises a hydrocolloid.

65. The auxiliary port assembly of claim 60, further comprising a sealing patch, wherein the sealing patch comprises a liquid impermeable material configured to cover at least a portion of
10 the exterior side of the access portal.

66. The auxiliary port assembly of claim 65, wherein the sealing patch comprises an adhesive film.

67. The auxiliary port assembly of claim 65, wherein the sealing patch comprises an adhesive-backed polyurethane film.

15 68. The auxiliary port assembly of claim 60, wherein the access portal comprises a penetrable membrane.

69. The auxiliary port assembly of claim 68, wherein the penetrable membrane comprises a tearable perforation configured to be sealed in the closed state and torn in the open state.

20 70. The auxiliary port assembly of claim 68, wherein the penetrable membrane comprises a silicone sleeve.

71. The auxiliary port assembly of claim 68, wherein the penetrable membrane comprises a thermo-plastic elastomer.

72. The auxiliary port assembly of claim 60, wherein the access portal comprises a housing, an opening disposed through the housing, and a removable plug, wherein the removable plug is
25 configured to seal the opening when the access portal is in the closed state and to be removed from the opening in the open state.

73. The auxiliary port assembly of claim 72, wherein the housing includes a threaded connection and the removable plug includes a cap configured to seal the opening in the access portal when engaged with the threaded connection.

74. A method for treating a tissue site, comprising:

positioning a monitoring device at the tissue site;

providing a dressing assembly, comprising:

a dressing bolster, and

a cover for creating a sealed space over the dressing bolster at the tissue site;

coupling an auxiliary port assembly to the cover, the auxiliary port assembly including an

access portal configurable between an open state and a closed state, wherein the

access portal provides a passage through the cover in the open state;

guiding an external portion of the monitoring device through the dressing assembly and

the access portal with the access portal in the open state;

securing the dressing assembly at the tissue site and over an internal portion of the

monitoring device;

positioning the access portal in the closed state to form a seal around the internal portion

of the monitoring device.

75. The apparatus, dressings, systems, and methods as shown and described herein.

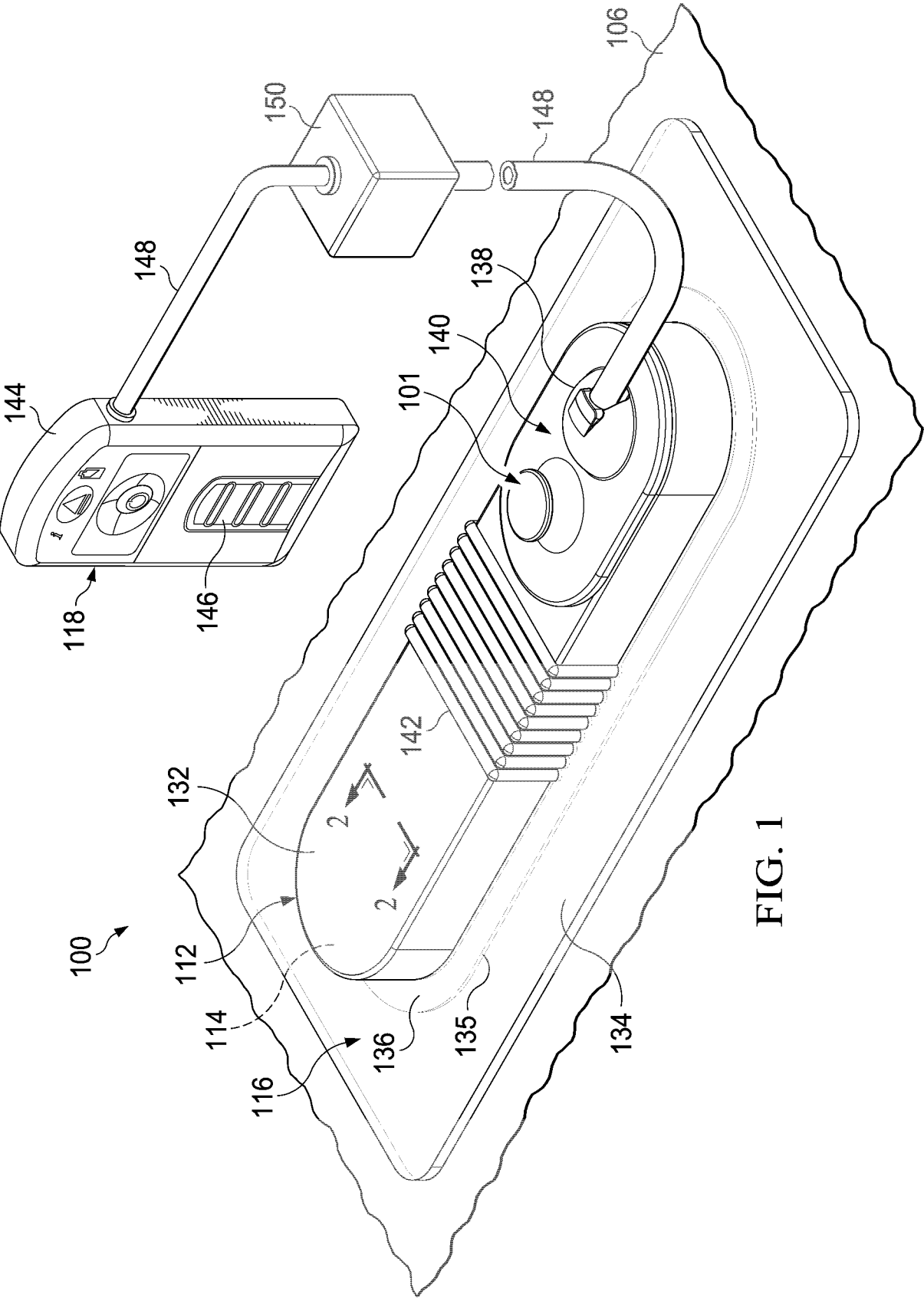


FIG. 1

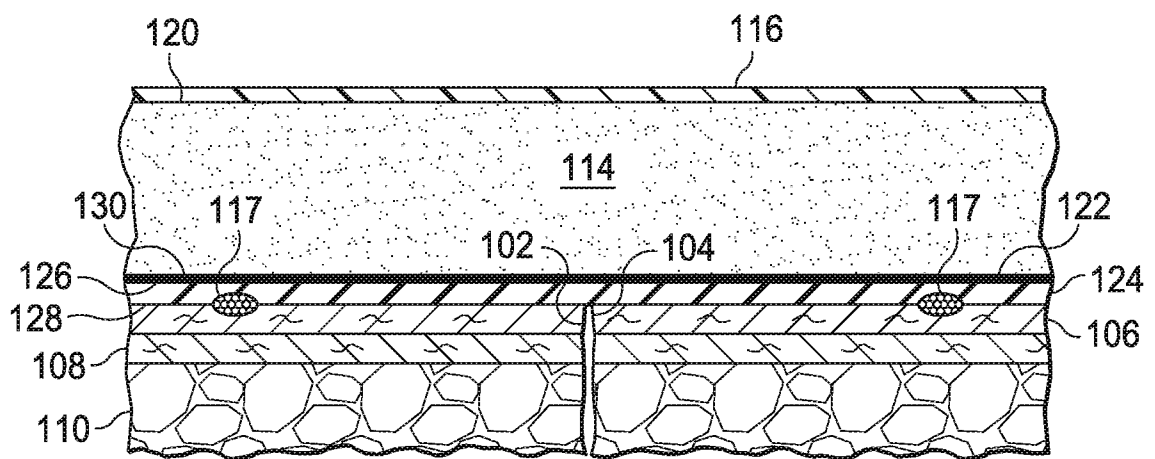


FIG. 2

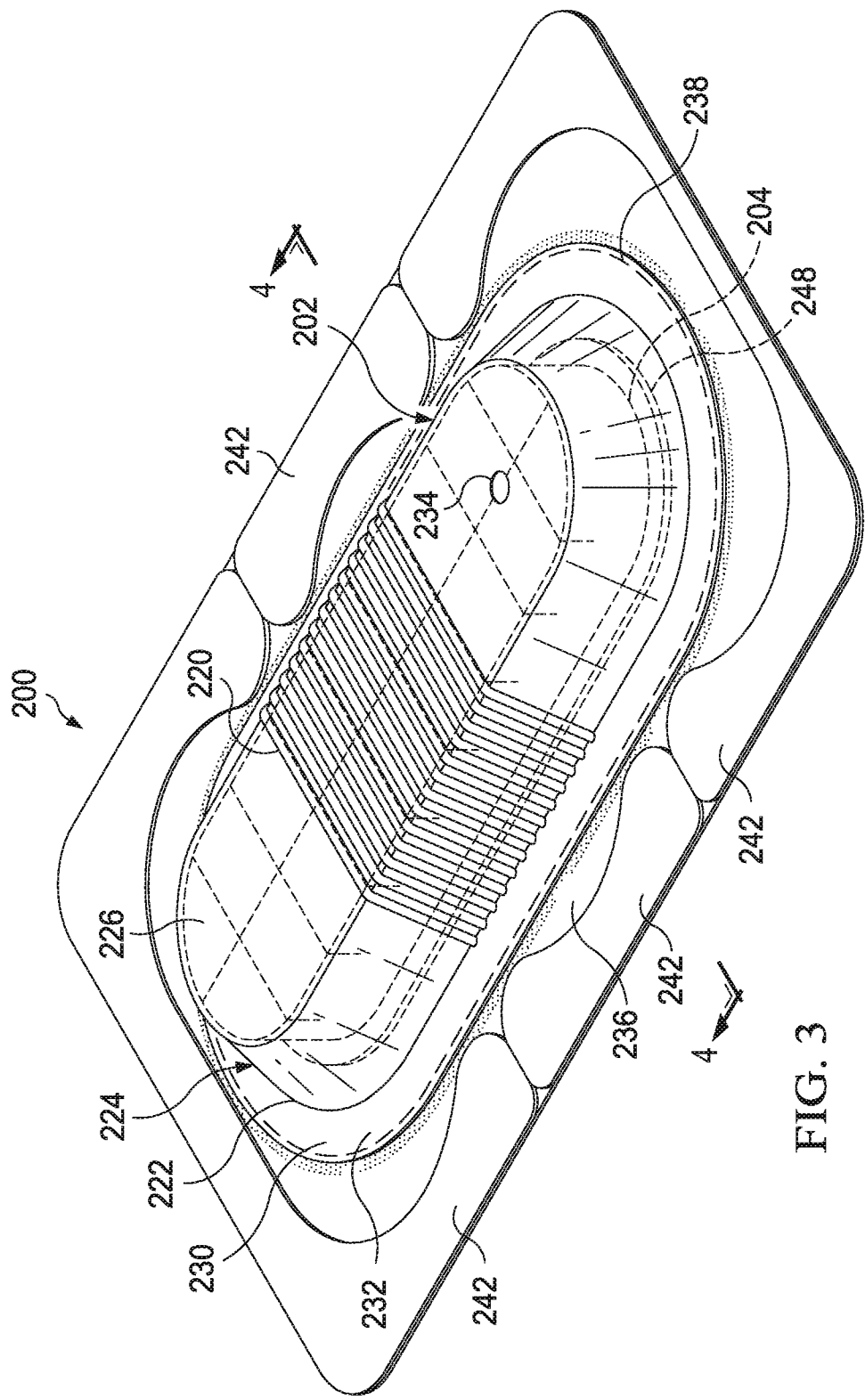


FIG. 3

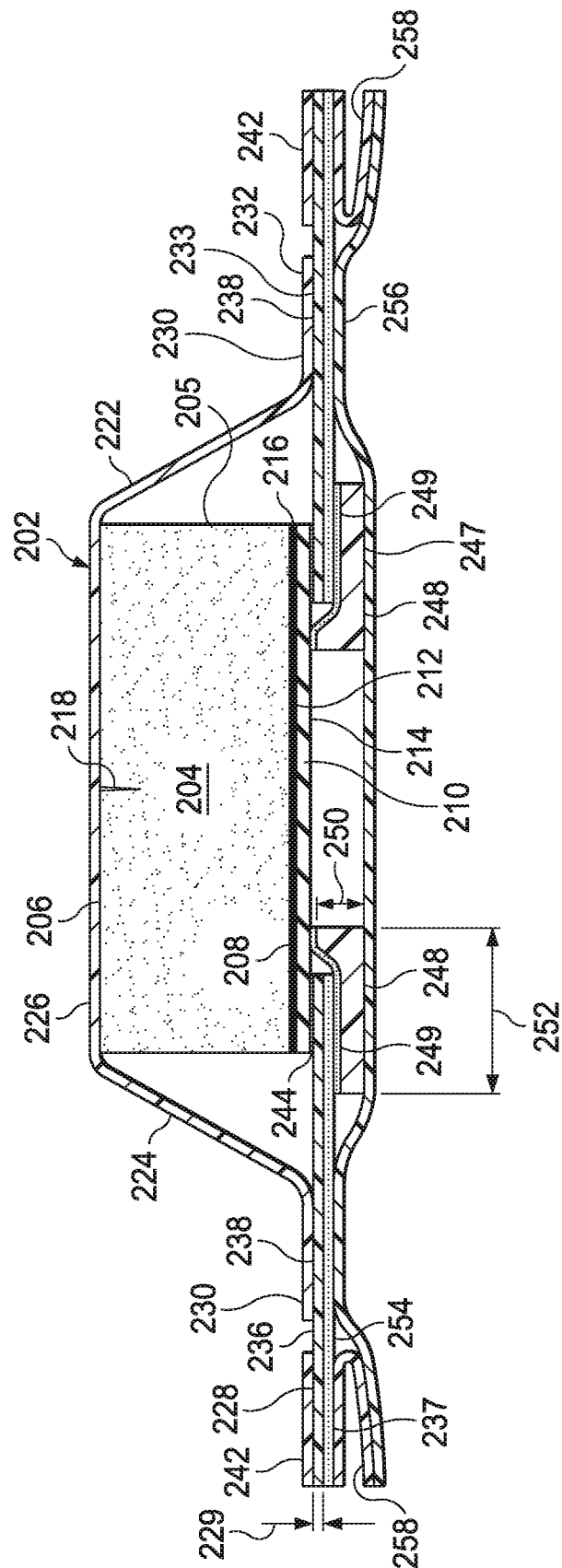


FIG. 4

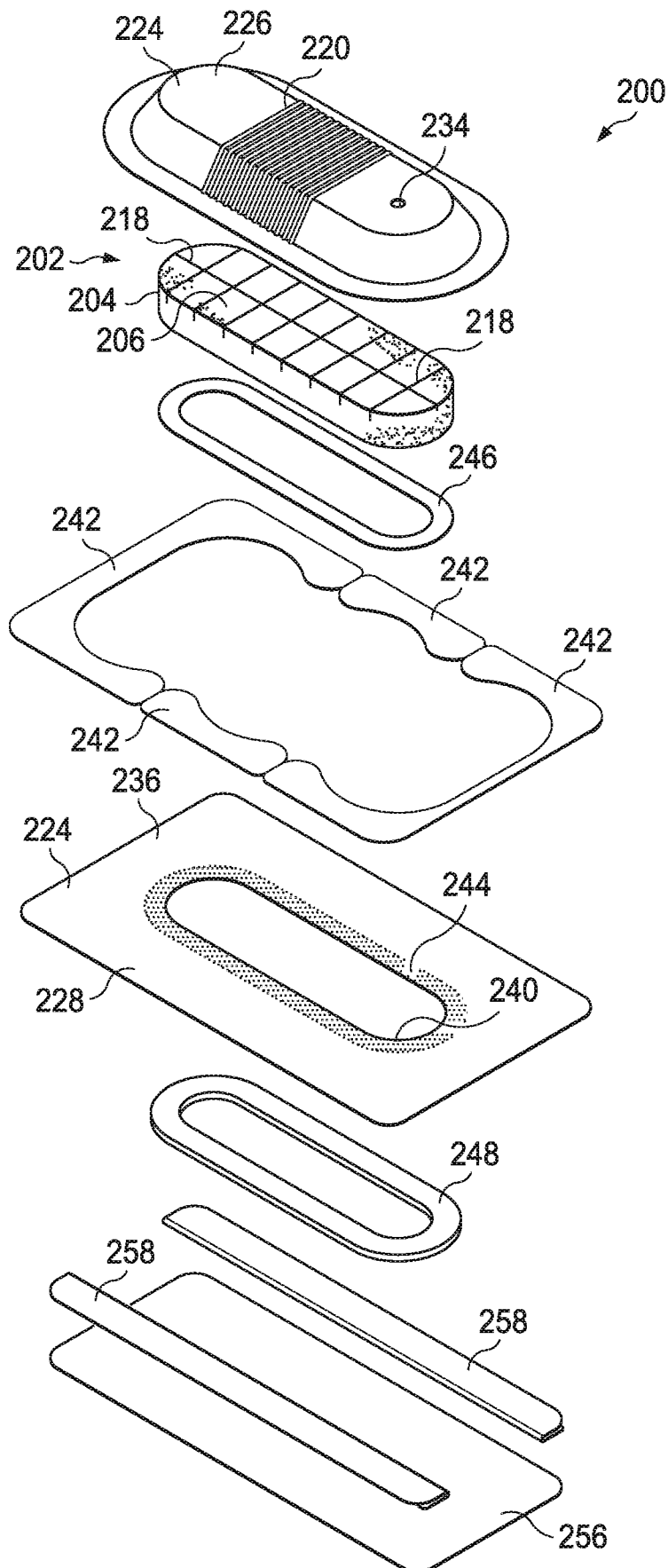
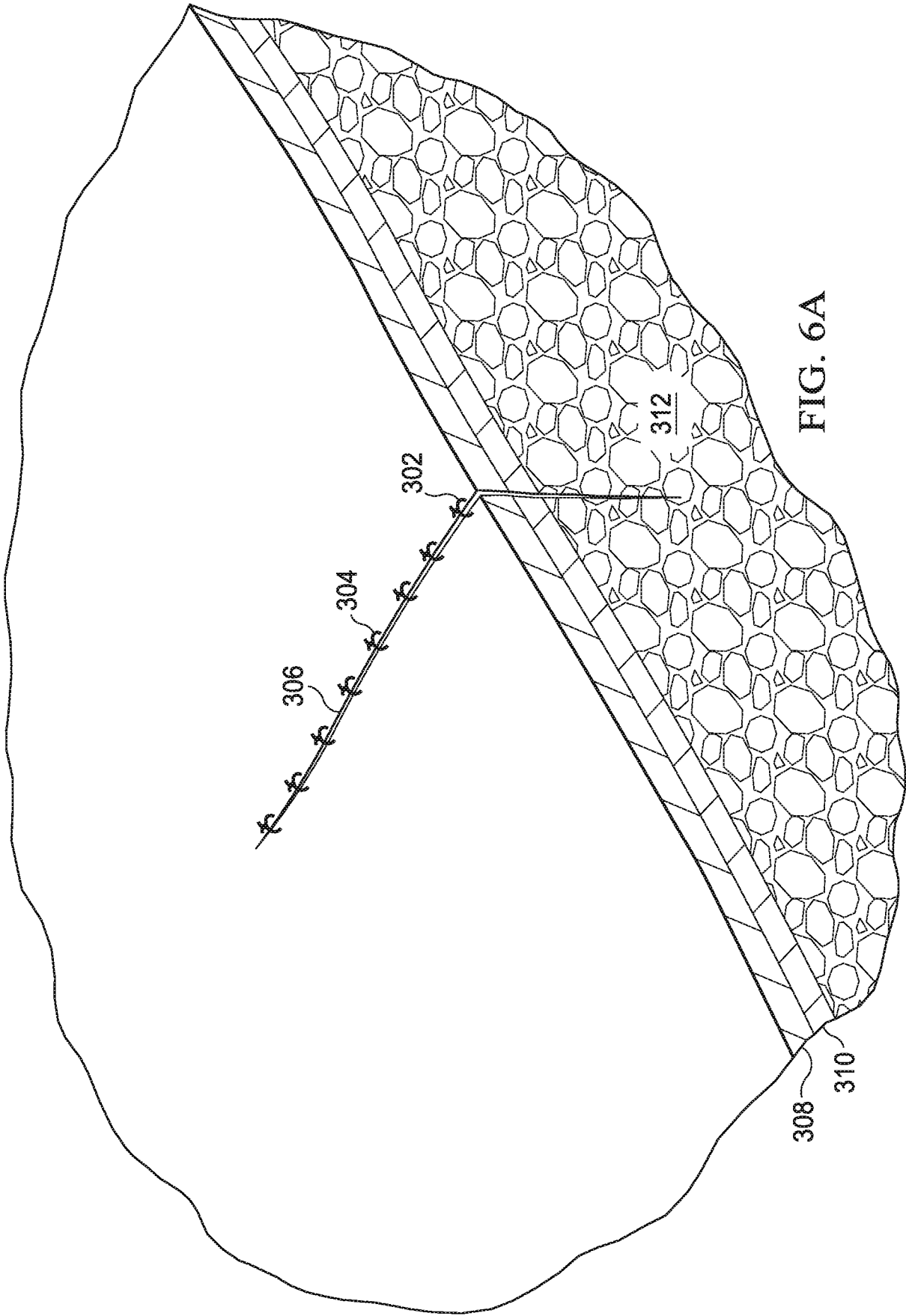
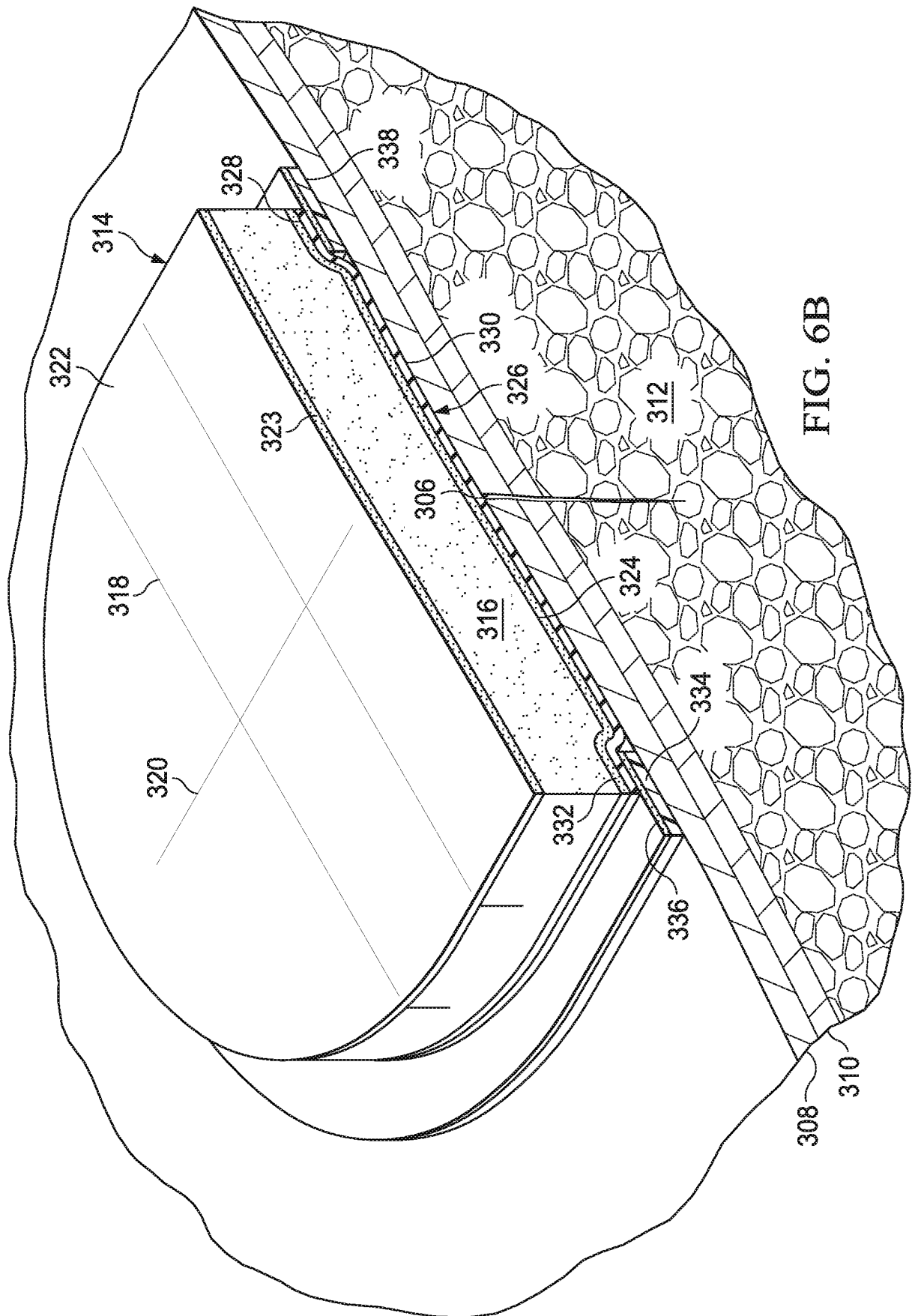


FIG. 5





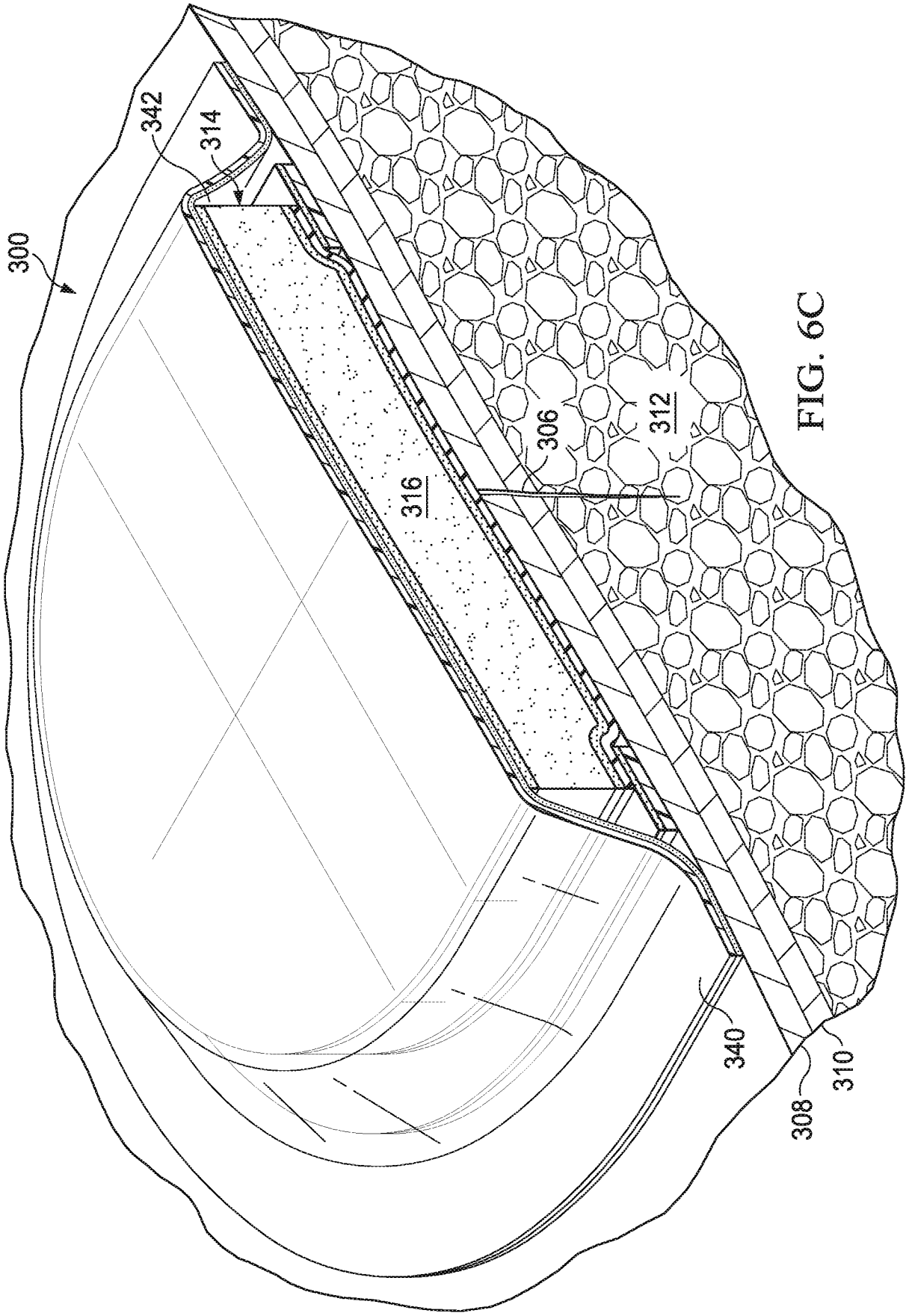


FIG. 6C

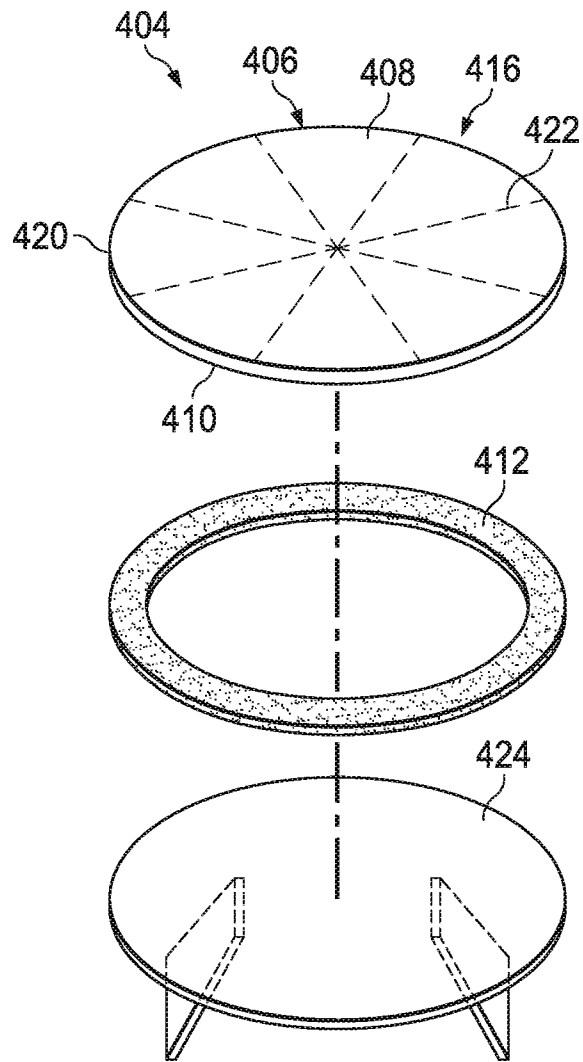


FIG. 7A

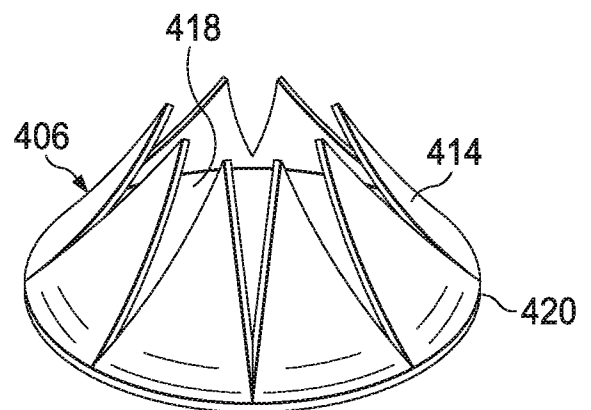
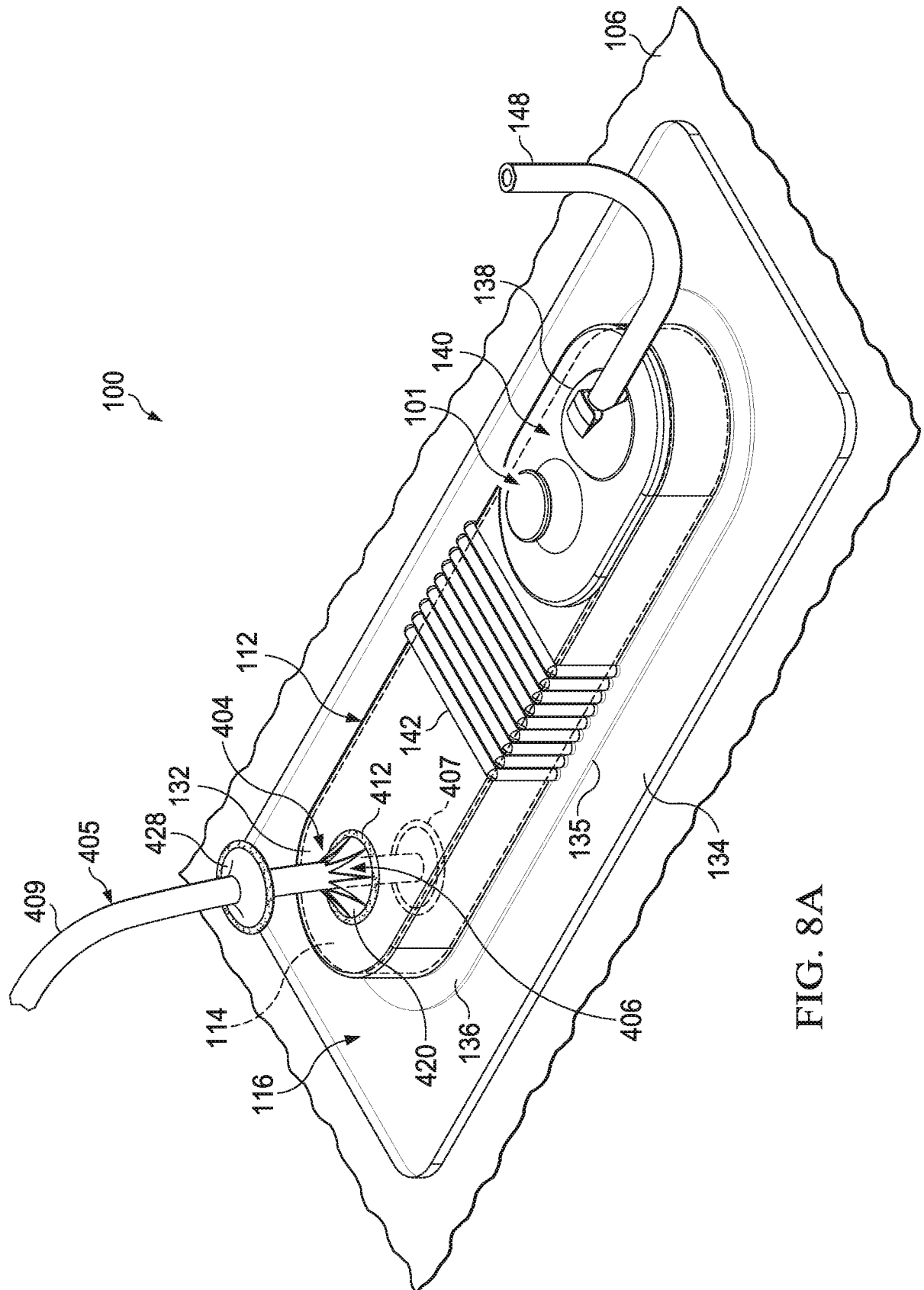


FIG. 7B



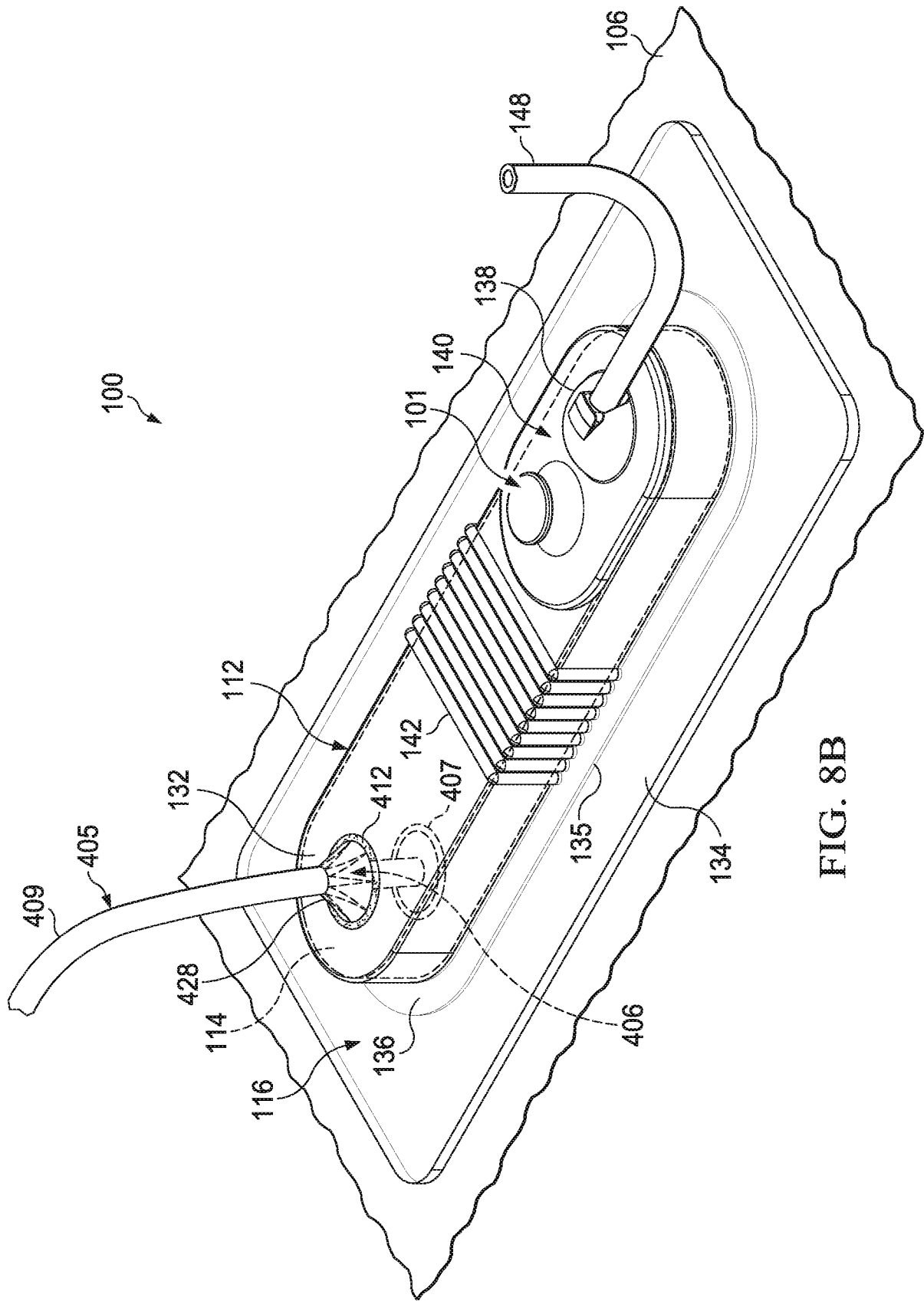


FIG. 8B

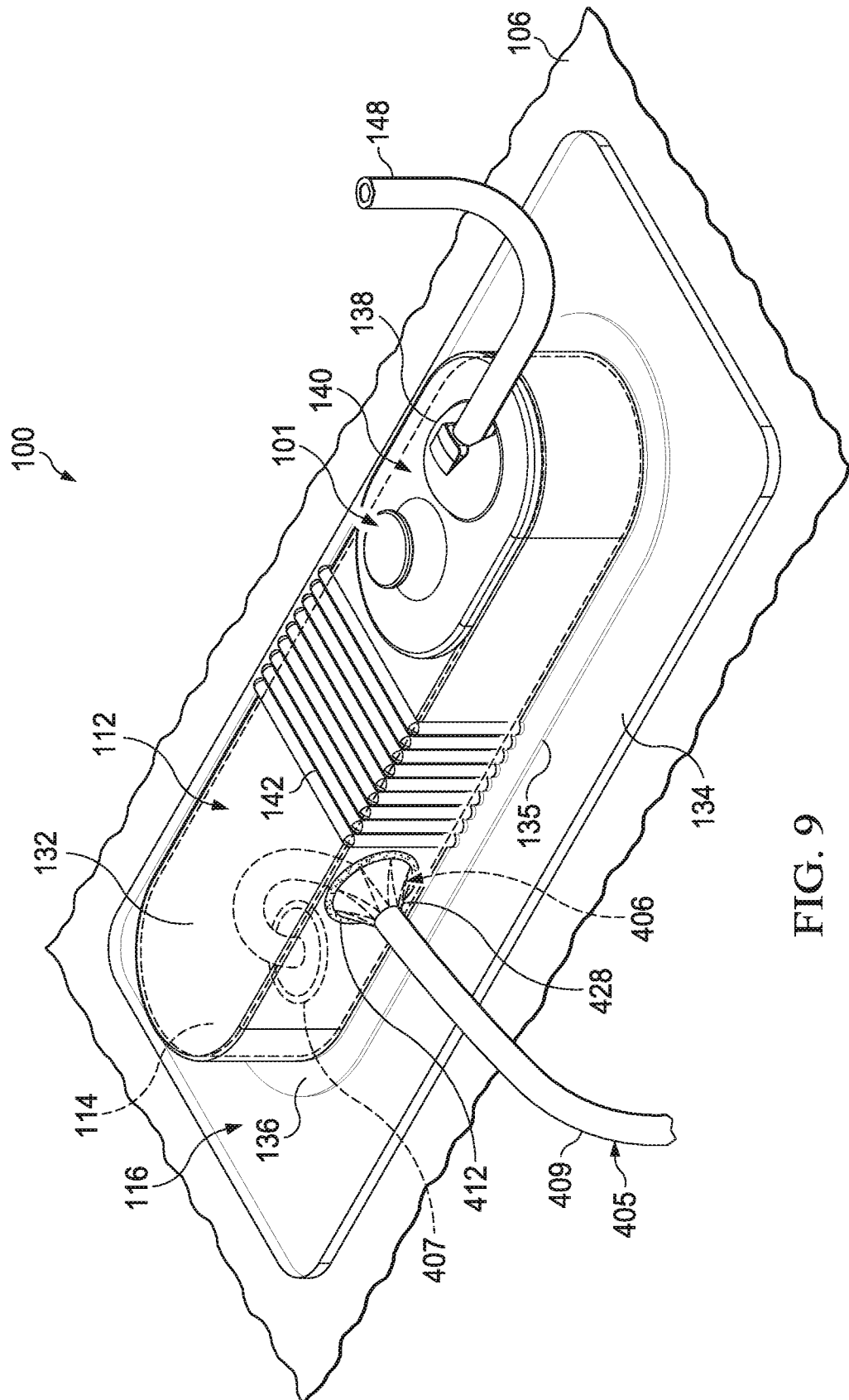


FIG. 9

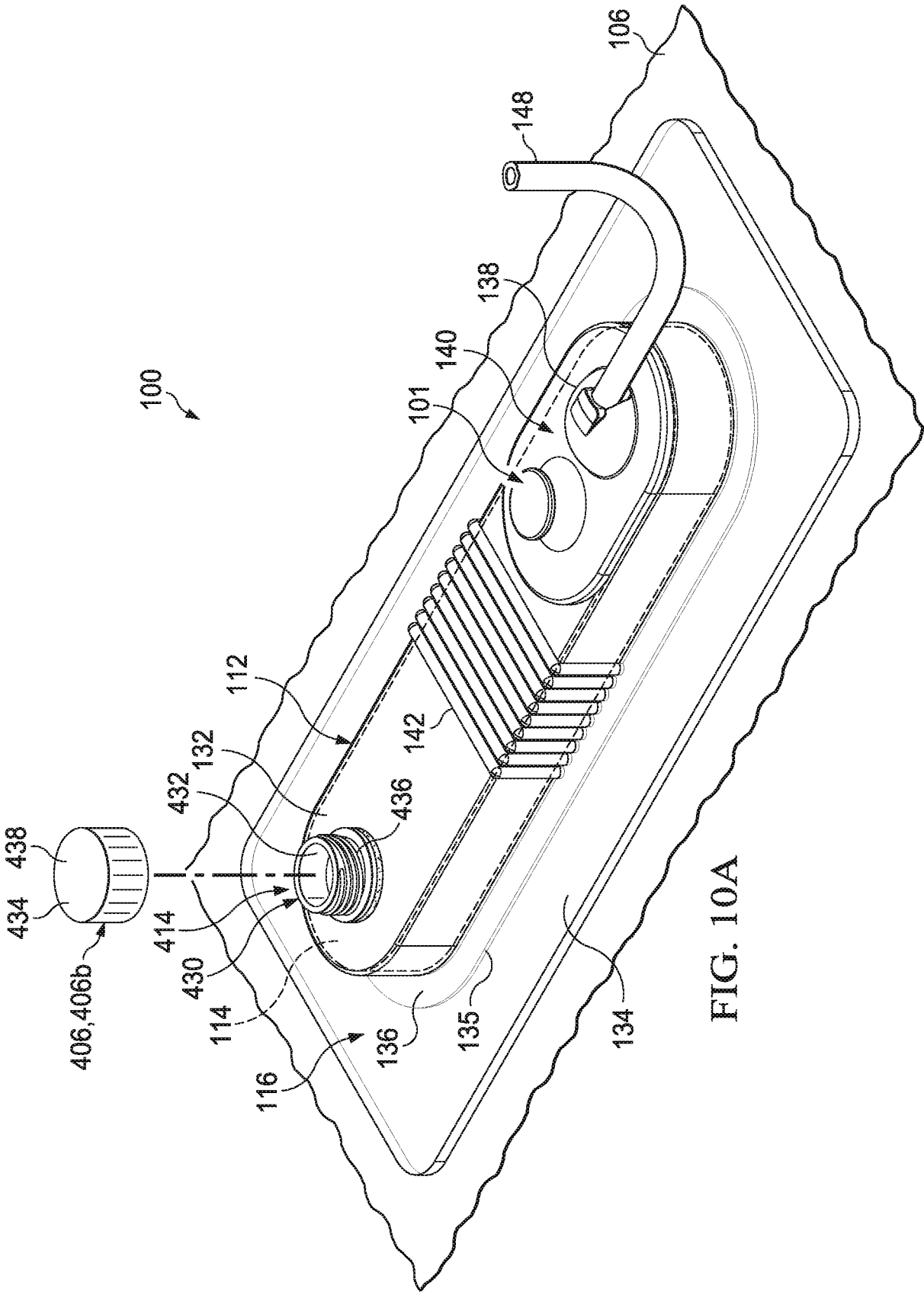


FIG. 10A

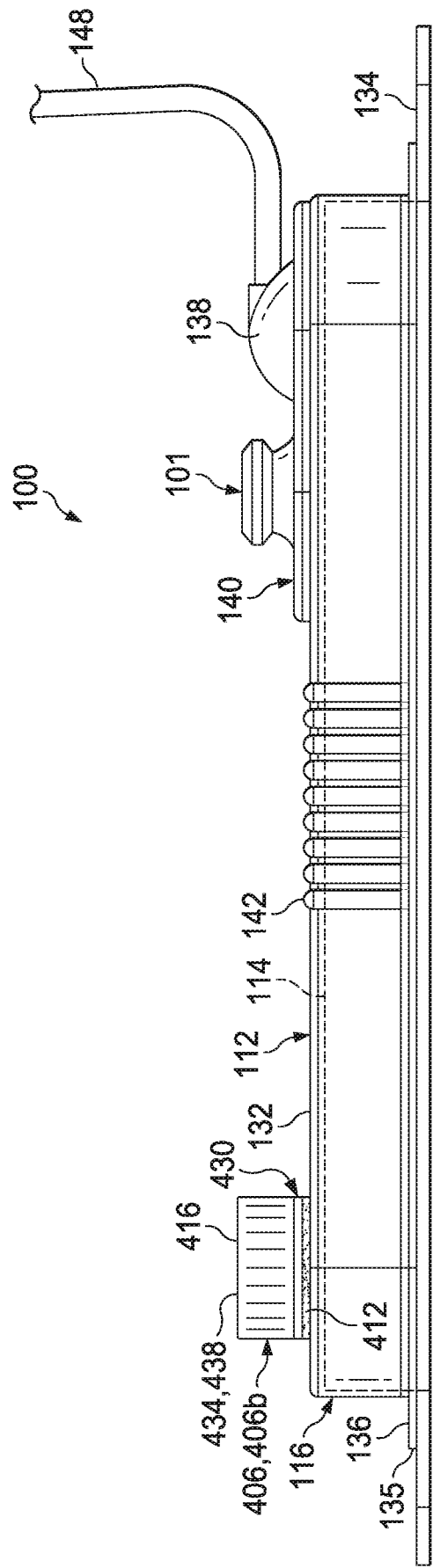
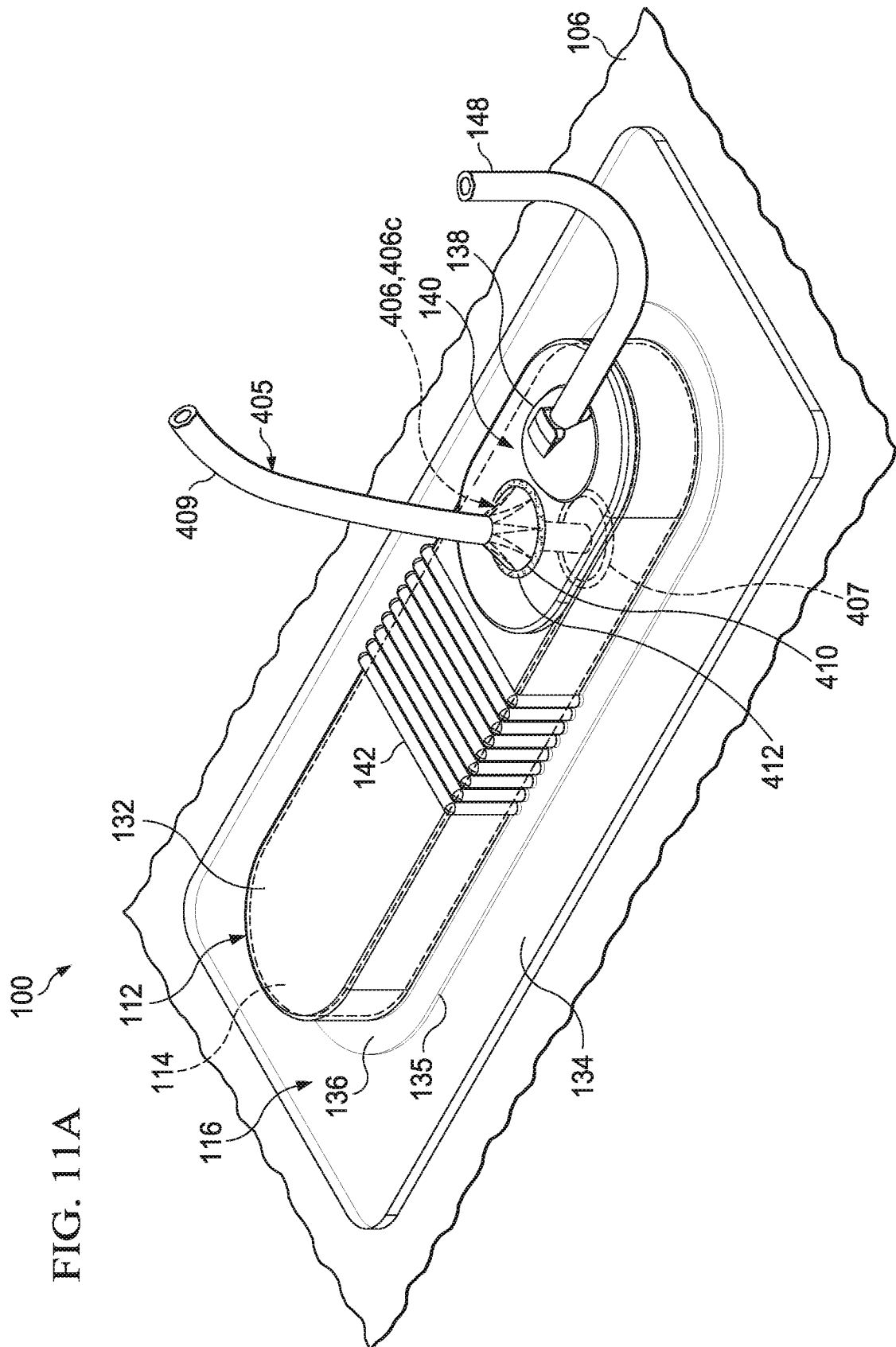


FIG. 10B



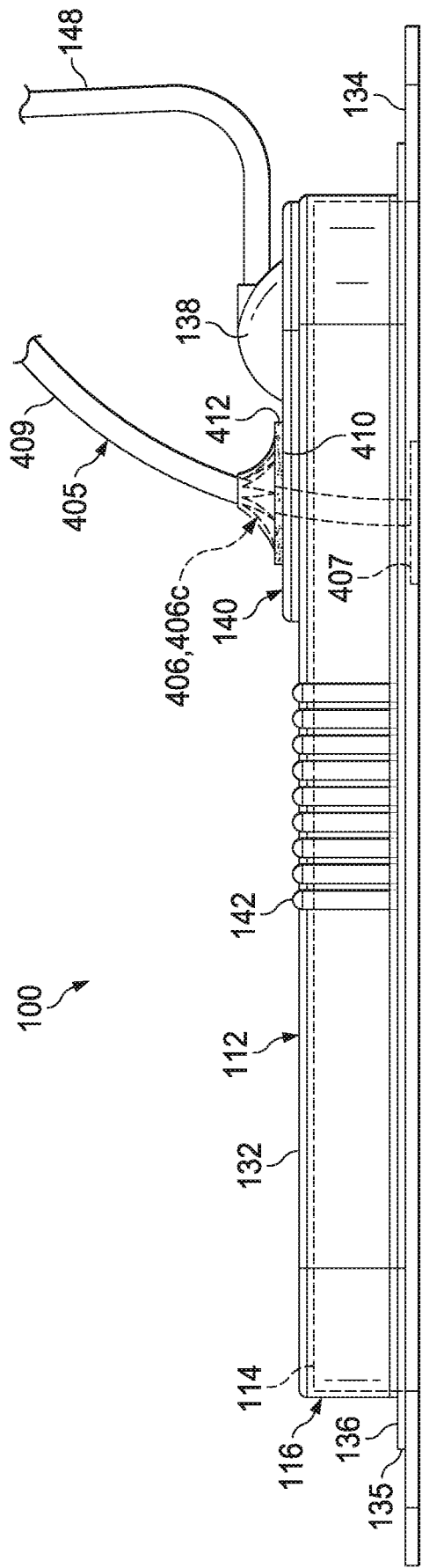


FIG. 11B

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2020/056909

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/00
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

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 2016/135998 A1 (RIESINGER BIRGIT [DE]) 19 May 2016 (2016-05-19)	1,2,6, 8-11,14, 17
Y	paragraphs [0002], [0158], [0159], [0113] - [0118], [0097], [0112]; figures 7,8,21	3-5,7, 12,13, 15,16, 18-20
Y	----- US 2019/167483 A1 (SIMMONS TYLER H [US]) 6 June 2019 (2019-06-06) paragraphs [0059], [0021]; figure 5	1,3-5,7
Y	----- US 2015/057624 A1 (SIMMONS TYLER H [US] ET AL) 26 February 2015 (2015-02-26) paragraph [0023]; figure 5 ----- -/--	1,3-5,7



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

23 September 2020

Date of mailing of the international search report

02/12/2020

Name and mailing address of the ISA/

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

Gennari, Silvia

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2020/056909

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 9 918 879 B2 (WOODROOF E AUBREY [US]) 20 March 2018 (2018-03-20) column 2, lines 56-66; claim 1; figure 1 -----	12,13
Y	US 2011/004173 A1 (HU DEAN [US] ET AL) 6 January 2011 (2011-01-06) paragraph [0045] -----	15,16
Y	TW M 553 191 U (BENQ MATERIALS CORP [TW]) 21 December 2017 (2017-12-21) paragraph [0001] -----	18-20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2020/056909

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.: 74
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☒ Claims Nos.: 75
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

see additional sheet

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.:

1-20

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-20

system for treating a tissue site with enveloped bolster

2. claims: 21-39

system for treating a tissue site comprising a gasket

3. claims: 40-73

dressings with auxiliary port assembly and port assembly

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2020/056909

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2016135998 A1	19-05-2016	AU 2014267236 A1 BR 112015028665 A2 CA 2914655 A1 CN 105338934 A EP 2996650 A1 JP 2016524490 A US 2016135998 A1 WO 2014184366 A1	10-12-2015 05-06-2018 20-11-2014 17-02-2016 23-03-2016 18-08-2016 19-05-2016 20-11-2014
US 2019167483 A1	06-06-2019	AU 2017266861 A1 CA 3024302 A1 EP 3458004 A1 JP 2019521731 A US 2019167483 A1 WO 2017200814 A1	06-12-2018 23-11-2017 27-03-2019 08-08-2019 06-06-2019 23-11-2017
US 2015057624 A1	26-02-2015	EP 3038667 A1 EP 3578209 A1 US 2015057624 A1 US 2019022290 A1 WO 2015030963 A1	06-07-2016 11-12-2019 26-02-2015 24-01-2019 05-03-2015
US 9918879 B2	20-03-2018	NONE	
US 2011004173 A1	06-01-2011	AU 2008310622 A1 CA 2702338 A1 EP 2203137 A1 EP 3053554 A1 EP 3590480 A1 JP 5511670 B2 JP 2011500170 A US 2009259203 A1 US 2011004173 A1 US 2011105963 A1 US 2014107597 A1 US 2015005722 A1 US 2016324693 A1 US 2019254879 A1 WO 2009049232 A1	16-04-2009 16-04-2009 07-07-2010 10-08-2016 08-01-2020 04-06-2014 06-01-2011 15-10-2009 06-01-2011 05-05-2011 17-04-2014 01-01-2015 10-11-2016 22-08-2019 16-04-2009
TW M553191 U	21-12-2017	DE 202017005574 U1 TW M553191 U US 2019083322 A1	11-12-2017 21-12-2017 21-03-2019

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 74

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Continuation of Box II.2

Claims Nos.: 75

Claim too broad, without any technical limitation, no meaningful search possible.

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