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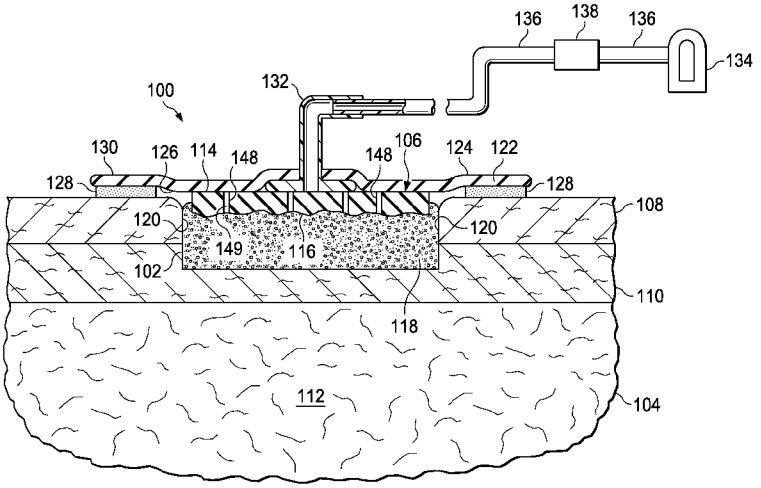

FIG. 1

(57) Abstract: Systems, methods, and apparatuses are presented that involve forming patterns on neo-epithelium that allow increased functionality and may more nearly resemble the original epithelium. In one instance, a patterned neo-epithelium dressing (100, 200) for treating a tissue site having granulation tissue includes an interface member (140, 240) for placing proximate the granulation tissue and a plurality of three-dimensional features (146, 246, 346) formed on a second, patient- facing side (144, 244) of the interface member (140, 240). Other systems, methods, and apparatuses are disclosed.

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TITLE OF THE INVENTION

PATTERNED NEO-EPITHELIALIZATION DRESSINGS, SYSTEMS, AND METHODS

RELATED APPLICATION

[0001] The present invention claims the benefit, under 35 USC § 119(e), of the filing of U.S. Provisional Patent Application serial number 61/314, 274, entitled "Patterned Neo-Epithelialization Dressings, Systems, and Methods," filed 16 March 2010, which is incorporated herein by reference for all purposes, and U.S. Provisional Patent Application serial number 61/314, 236, entitled "Epithelialization Methods, Dressings, and Systems," filed 16 March 2010, which is also incorporated herein by reference for all purposes.

BACKGROUND

[0002] The present disclosure relates generally to medical treatment systems and, more particularly, to patterned neo-epithelialization dressings, system, and methods.

[0003] Depending on the medical circumstances, reduced pressure may be used for, among other things, reduced-pressure therapy to encourage development of granulation tissue at a tissue site. Granulation tissue is connective tissue that forms on wounds during tissue repair. Granulation tissue is typically defined to include new blood vessels, immune cells, fibroblasts, and provisional extracellular matrix. Granulation tissue typically signals the proliferative phase of wound healing. Reduced-pressure therapy typically involves manifolding, or distributing, reduced pressure to the tissue site.

SUMMARY

[0004] An illustrative, non-limiting embodiment of a system for treating a wound having granulation tissue on a patient includes a patterned neo-epithelium dressing for disposing proximate the wound. The patterned neo-epithelium dressing for treating a wound having granulation tissue includes an interface member having a first side and a second, patient-facing side for placing proximate to the granulation tissue and a plurality of three-dimensional features formed on the second, patient-facing side of the interface member. The system further includes a sealing member for placing over the patterned neo-epithelium dressing and the patient's epidermis, a reduced-pressure interface fluidly coupled to the sealing member, and a reduced-pressure source fluidly coupled to the reduced-pressure interface.

[0005] An illustrative, non-limiting embodiment of a patterned neo-epithelium dressing for treating a wound having granulation tissue includes an interface member having a first side and a second, patient-facing side for placing proximate the granulation tissue and a plurality of three-dimensional features formed on the second, patient-facing side of the interface member.

[0006] An illustrative, non-limiting embodiment of a method of treating a wound site of a patient includes optionally forming granulation tissue at the wound site, deploying a patterned neo-epithelium dressing proximate the granulation tissue, and applying a contact pressure on the patterned neo-epithelium dressing. The patterned neo-epithelium dressing for treating a wound having granulation tissue includes an interface member having a first side and a second, patient-facing side for placing proximate the granulation tissue. The patterned neo-epithelium dressing also includes a plurality of three-dimensional features formed on the second, patient-facing side of the interface member.

[0007] An illustrative, non-limiting embodiment of a method of treating a wound site of a patient includes directing flow of endogenous fluids to cause patterned protein deposition, causing guidance of the migrating epithelium on the patterned deposition of proteins to form a neo-epithelium, and forming fissures in the neo-epithelium.

[0008] An illustrative, non-limiting embodiment of a method of manufacturing a patterned neo-epithelium dressing for treating a wound having granulation tissue includes forming an interface member having a first side and a second, patient-facing side for placing

proximate the granulation tissue, and forming a plurality of three-dimensional features on the second, patient-facing side of the interface member.

[0009] Other features and advantages of the illustrative embodiments will become apparent with reference to the drawings and detailed description that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIGURE 1 is a schematic diagram with a portion shown in cross section of an illustrative, non-limiting embodiment of a system for treating a wound on a patient;

[0011] FIGURE 2 is a schematic, perspective view of an illustrative, non-limiting embodiment of a patterned neo-epithelium dressing;

[0012] FIGURE 3 is a schematic, bottom view of the patterned neo-epithelium dressing of FIGURE 2;

[0013] FIGURE 4 is a schematic, cross-sectional view of the patterned neo-epithelium dressing of FIGURE 3 taken along line 4-4;

[0014] FIGURE 5 is a schematic, cross-sectional view of an illustrative, non-limiting embodiment of a patterned neo-epithelium dressing;

[0015] FIGURE 6A is a schematic, cross-sectional view of an illustrative, non-limiting embodiment of a patterned neo-epithelium dressing shown without reduced pressure applied; and

[0016] FIGURE 6B is the patterned neo-epithelium dressing of FIGURE 6A shown with reduced pressure applied.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0017] In the following detailed description of the illustrative embodiments, reference is made to the accompanying drawings that form a part hereof. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is understood that other embodiments may be utilized and that logical structural, mechanical, electrical, and chemical changes may be made without departing from the spirit or scope of the invention. To avoid detail not necessary to enable those skilled in the art to practice the embodiments described herein, the description may omit certain information known to those skilled in the art. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the illustrative embodiments are defined only by the appended claims.

[0018] Referring primarily to FIGURES 1-4, and initially to FIGURE 1, a system 100 for treating a wound 102 on a patient 104 that includes a patterned neo-epithelium dressing 106 is presented. The wound 102 may extend through epidermis 108 and into dermis 110. In some instances, the wound 102 extends into subcutaneous tissue 112. In the illustrative embodiment, the patterned neo-epithelium dressing 106, which has a first side 114 and a second, patient-facing side 116, is shown with the second, patient-facing side 116 against granulation tissue 118. As will be described further below, neo-epithelium tissue will grow from wound edges 120 and is directed and formed under the influence of the patterned neo-epithelium dressing 106.

[0019] A sealing member 122 forms a fluid seal over the patterned neo-epithelium dressing 106. "Fluid seal," or "seal," means a seal adequate to maintain reduced pressure at a desired site given the particular reduced-pressure source or subsystem involved. The sealing member 122 has a first side 124 and a second, patient-facing side 126. The sealing member 122 may be any material that provides a fluid seal. The sealing member 122 may, for example, be an impermeable or semi-permeable, elastomeric material. "Elastomeric" means having the properties of an elastomer and generally refers to a polymeric material that has rubber-like properties. More specifically, most elastomers have ultimate elongations greater than 100% and a significant amount of resilience. The resilience of a material refers to the material's ability to recover from an elastic deformation. Examples of elastomers may include, but are not limited to, 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. Additional, specific examples of sealing member materials include a silicone drape, 3M Tegaderm® drape, acrylic drape such as one available from Avery Dennison.

[0020] An attachment device 128 may be used to hold the sealing member 122 against the patient's epidermis 108 or another layer, such as a gasket or additional sealing member. The attachment device 128 may take numerous forms. For example, the attachment device 128 may be a medically acceptable, pressure-sensitive adhesive that extends about a periphery 130, a portion of, or the entirety of the sealing member 122.

[0021] A reduced-pressure interface 132 is fluidly coupled to the second, patient-facing side 126 of the sealing member 122. Reduced pressure developed by a reduced-pressure source 134 is delivered through a reduced-pressure delivery conduit 136 to the reduced-pressure interface 132. In one illustrative embodiment, the reduced-pressure interface 132 is a T.R.A.C.® Pad or Sensa T.R.A.C.® Pad available from KCI of San Antonio, Texas. The reduced-pressure interface 132 allows the reduced pressure to be delivered to the second, patient-facing side 126 of the sealing member 122 and ultimately to the patterned neo-epithelium dressing 106.

[0022] The reduced-pressure source 134 provides reduced pressure. The reduced-pressure source 134 may be any device for supplying a reduced pressure, such as a vacuum pump, wall suction, micro-pump, or other source. While the amount and nature of reduced pressure applied to a tissue site will typically vary according to the application, the reduced pressure will typically be between -5 mm Hg and -500 mm Hg and more typically between -50 mm Hg and -200 mm Hg. For example, and not by way of limitation, the pressure may be -90, -100, -110, -120, -130, -140, -150, -160, -170, -180,-190, -200 mm Hg or another pressure.

[0023] In some embodiments, before the patterned neo-epithelium dressing 106 is deployed on granulation tissue 118. The granulation tissue 118 may be developed using the system 100 but with a manifold (not shown) in the location where the patterned neo-epithelium dressing 106 is presently shown. The term "manifold" as used herein generally refers to a substance or structure that is provided to assist in applying reduced pressure to, delivering fluids to, or removing fluids from the wound 102. The manifold typically includes a plurality of flow channels or pathways that distribute fluids provided to and removed from the tissue site around the manifold. In one illustrative embodiment, the flow channels or pathways are interconnected to improve distribution of fluids provided to or removed from the

wound 102. The manifold may be a biocompatible material that is capable of being placed in contact with the wound 102 and distributing reduced pressure to the wound 102. Examples of manifolds may include, for example, without limitation, devices that have structural elements arranged to form flow channels, such as, for example, cellular foam, open-cell foam, porous tissue collections, liquids, gels, and foams that include, or cure to include, flow channels. The manifold may be porous and may be made from foam, gauze, felted mat, or any other material suited to a particular biological application. In one embodiment, the manifold is a porous foam and includes a plurality of interconnected cells or pores that act as flow channels. The porous foam may be a polyurethane, open-cell, reticulated foam such as GranuFoam® material manufactured by Kinetic Concepts, Incorporated of San Antonio, Texas.

[0024] As used herein, "reduced pressure" generally refers to a pressure less than the ambient pressure at a tissue site that is being subjected to treatment. In most cases, this reduced pressure will be less than the atmospheric pressure at which the patient is located. Alternatively, the reduced pressure may be less than a hydrostatic pressure at the tissue site. Unless otherwise indicated, values of pressure stated herein are gauge pressures. The reduced pressure delivered 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 the wound 102, the actual pressure applied to the wound 102 may be more than the pressure normally associated with a complete vacuum. Consistent with the use herein, an increase in reduced pressure or vacuum pressure typically refers to a relative reduction in absolute pressure.

[0025] The reduced-pressure conduit 136 may have one or more devices, such as device 138. For example, the device 138 may be a fluid reservoir, or collection member, to hold exudates and other fluids removed. Other examples of devices 138 that may be included on the reduced-pressure conduit 136 or otherwise fluidly coupled to the reduced-pressure conduit 136 include the following non-limiting examples: 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.

[0026] Referring now primarily to FIGURES 2-4, the patterned neo-epithelium dressing 106 has an interface member 140 having a first side 142 and a second, patient-facing side 144 for placing proximate the granulation tissue 118 and a plurality of three-dimensional features 146 formed on the second, patient-facing side 144 of the interface member 140. The

interface member 140 may be formed from any medical-grade polymers, thermoplastic polymers, resorbable polymers or materials, biologically derived polymers such as collagen, or other suitable materials, e.g., silicones, polyurethane films. The interface member 140 may also be formed using foam, for example, the embodiment shown in FIGURES 6A and 6B. The interface member 140 may be formed by casting, molding, or other techniques that form the interface member 140. As used herein, unless otherwise indicated, "or" does not require mutual exclusivity.

[0027] The interface member 140 has a plurality of pores large enough to allow fluid transmission and small enough to limit cell migration through the pores. The average pore size is below the minimum size through which cells are typically capable of migrating (giving the interface member 140 a relatively "smooth" overall texture in many embodiments) to prevent tissue ingrowth into the interface member 140 and to promote lateral cell migration parallel to a surface 150 of the interface member 140. Select pores may exceed the minimum size for cell migration, but be contained in sufficiently low density on the material surface to maintain acceptable levels of non-adherence to the wound 102. The average pore size remains in the acceptable range. At the other end of the range of the pore size, to allow for fluid control of the wound 102, pores of adequate size to allow for fluid transmission are typically incorporated throughout the interface member 140 or in organized patterns on the interface member 140 for promoting direct fluid flow. In one embodiment, the interface member may have a plurality of pores having an average pore size greater than 5 micrometers or microns (μm) and smaller than 1000μm. In other non-limiting embodiments, the average pore size may be 10, 40, 80, 100, 120, 150, 200, 250, 300, 350, 400, 450, 500, 550, 600, 650, 700, 750, 800, 850, 900, or 950 μm or any dimension between these or other sizes. While the term "pore" is used, it should be understood that the pores may include slits or other apertures. Where dimensions of pores are specifically given, a generally round pore should be understood and the dimension applies to the diameter.

[0028] The formation process of the interface member 140 may form the plurality of three-dimensional features 146 or the three-dimensional features 146 may be formed separately and then coupled as part of the interface member 140. In another embodiment, the plurality of three-dimensional features 146 may be chemically etched, imprinted, or formed later as an aspect of the interface member 140.

[0029] The interface member 140 is formed with one or more fluid passageways 148, such as channels 149, that fluidly couple the first side 142 and second, patient-facing side 144 of the interface member 140. The fluid passageways 148 may be apertures, conduits, or inherent porous pathways in the subsisting material of the interface member 140.

[0030] The three-dimensional features 146 may include a plurality of ridges 152 or a plurality of grooves 154. The three-dimensional features 146 help direct the flow of fluids, e.g., endogenous fluids, such as exudates, to one or more of the fluid passageways 148. The three-dimensional features 146 or a portion of the three-dimensional features 146 may be coated with one or more proteins, e.g., growth factors, integrins, integrin receptors, antibodies, peptides, aptomers, or other suitable materials.

[0031] The three-dimensional features 146 may be formed as a pattern on the surface 150 that mimics or substantially replicates a human skin pattern. At least three approaches may be used to develop the pattern for the three-dimensional features 146. First, a "generic human skin pattern" may be used that includes a pattern that is modeled on a general or generic pattern for human skin. This pattern may not be specific to a particular location on a body, but is a more general pattern having wrinkles and general features.

[0032] Second, a "location-specific human skin pattern" may be used. With this second approach, a general skin pattern is used that is patterned on the general features for a specific area of a body. For example, a generic representation of skin on the back of a hand may be used for wound on the back of a hand.

[0033] Third, an "intact analogous human skin pattern" may be used. With this third approach, the pattern may be developed based on the specific patient's skin near the wound or on a duplicate body part. The pattern mimics or substantially replicates the skin near the wound or on the duplicate body part. For example, if a wound were on the back of the patient's left hand, either skin near the wound would be used as a model or the intact skin on the right hand would be used to form the three-dimensional features 146. This latter approach produces a custom symmetric dressing. In still other embodiments, the three-dimensional features 146 may be organized in other patterns such as a radial pattern to direct migration from a periphery to a center of the patterned neo-epithelium dressing 106.

[0034] Referring now primarily to FIGURE 5, another illustrative embodiment of a system 200 for treating a wound 202. The system 200 is analogous in many respects to system 100 of FIGURE 1 and analogous elements have been indicated by indexing the reference numerals by 100. The wound 202 is shown going through epidermis 208 and dermis 210 and almost into subcutaneous tissue 212. Granulation tissue 218 is shown formed on the bed of the wound 202 and neo-epithelium 219 is shown formed over the granulation tissue 218.

[0035] The system 200 includes a patterned neo-epithelium dressing 206 that includes an interface member 240, which has a first side 242 and a second, patient-facing side 244. The interface member 240 includes a thin member 256 and a foam member 258. The thin member 256, such as a polyurethane film or member made from other materials listed herein, has a first side 260 and a second, patient-facing side 262. The foam member 258 has a first side 264 and a second, patient-facing side 266. The first side 260 of the thin member 256 is adjacent to the second, patient-facing side 266 of the foam member 258 and may be coupled thereto by any known technique, including without limitation welding (e.g., ultrasonic or RF welding), flame lamination, bonding, adhesives, or cements. The thin member 256 may be formed from any medical-grade polymers, thermoplastic polymers, resorbable polymers or materials, biologically derived polymers such as collagen, or other suitable materials, e.g., silicones, polyurethane films.

[0036] A plurality of three-dimensional features 246 may be formed on the second, patient-facing side 262 of the thin member 256. The three-dimensional features 246 may be formed by imprinting, etching, or casting, or other techniques onto the thin member 256. As before, the three-dimensional features 246 may include a plurality of ridges 252 or a plurality of grooves 254. The three-dimensional features 246 may be formed as a pattern on the surface that mimics or substantially replicates a human skin pattern.

[0037] A contact pressure, or an inward pressure, is developed on the patterned neo-epithelium dressing 206. In this embodiment, the contact pressure is developed using the foam member 258 as a bolster and applying a sealing member 222 over the foam member 258 to create the contact force. Reduced pressure could also be used in the system 100 of FIGURE 1. An attachment device 228 may be used to form a fluid seal with the sealing member 222 and the patient's epidermis 208.

[0038] The second, patient-facing side 244 and the first side 242 of the interface member 240 are in fluid communication through pores, which form fluid passageways, in the interface member 240. In addition to the pores or alternatively, channels (not shown but analogous to channels 149 in FIG. 1) may be formed.

[0039] The foam member 258 may be a hydrophilic foam that wicks fluids from the thin member 256. The foam member 258 may be an open-cell foam. In still another embodiment, the foam member 258 may be hydrophobic foam.

[0040] Referring now primarily to FIGURES 6A and 6B, another illustrative, non-limiting embodiment of a patterned neo-epithelium dressing 306 is presented on granulation tissue 318. The patterned neo-epithelium dressing 306 is formed from a foam 368 having rigid portions 370 and less rigid portions 372 that are apparent under reduced pressure as shown in FIGURE 6B. Because of the differing rigidity, the foam 368 forms a plurality of three-dimensional features 346 in the form of ridges 352 and grooves 354 when placed under reduced pressure. A first side 369 and a second, patient-facing side 371 are in fluid communication via fluid passageways formed by open cells in the foam 368. The three-dimensional features 346 may be formed as a pattern on the surface that mimics or substantially replicates a human skin pattern.

[0041] Referring now to FIGURES 1-6B, in use, according to one illustrative embodiment, granulation tissue 118, 218, 318 may be formed by placing the manifold (not shown) proximate the wound 102, 202 and forming a fluid seal using a sealing member 122, 222. Reduced pressure is applied to facilitate formation of the granulation tissue 118, 218, 318. Alternatively, the granulation tissue may be formed without assistance. As the granulation tissue 118, 218, 318 is formed, the patterned neo-epithelium dressing 106, 206, 306 may be placed proximate the granulation tissue 118, 218, 318 and covered by the sealing member 122, 222 to transition from granulation to epithelialization. Contact pressure is developed by using reduced pressure, a pressure wrap, a foam bolster with tensioning member or sealing member pressing on the bolster.

[0042] In many embodiments, reduced pressure is used to hold contact pressure and to remove fluids through the fluid passageways 148. The reduced pressure pulls endogenous fluids from the wound 102, 202 directed by the three-dimensional features 146 to the fluid passageways 148. As the endogenous fluids flow along the path directed by the three-dimensional features 146, patterned proteins or extracellular matrix (ECM), (e.g., fibrin or

collagen) are deposited or formed. As migrating epithelium migrates from the wound edges 120, the epithelium is guided by the patterned protein deposition and forms the neo-epithelium in the desired pattern. The ridges 152 form fissures (e.g., fissures 253 in FIG. 5) in the neo-epithelium. These fissures or grooves in the neo-epithelium act as points of stress relief for flexion when exposed to bodily movement. The formation of the neo-epithelium in this way involves tissue formation according to the integrated principles of fluid flow, contact guidance, microstrain, and mechanotransduction.

[0043] In one embodiment, contact pressure is provided without reduced pressure. In this instance, the three-dimensional features 146 may be used primarily to direct cell migration. In addition, a hydrophilic member may be used to help manage fluids.

[0044] The patterned neo-epithelium dressing 106, 206 may influence protein adhesion, cell behavior (migration), and ECM production by the surface topography, or the three-dimensional features 146. The three-dimensional features 146 may also influence orientation of cells and ECM within the granulation tissue and thereby the neo-epithelium. In this manner, the features transmit contact guidance to a pericellular (cell-derived) matrix. The fibroblasts of the granulation tissue 118, 218 may start to align when placed in contact with the grooves 154 or ridges 152 of the patterned neo-epithelium dressing 106. The fibroblasts may align cytoskeleton, or the scaffolding, in substantially the same direction as directed by the three-dimensional features 146 of the patterned neo-epithelium dressing 106. The keratinocytes may follow the pattern expressed by the fibroblasts.

[0045] The fissures formed mimic those in intact skin. The three-dimensional features 146, 246 direct elements within the granulation tissue 118, 218 of healing wounds that could translate to the development of the overlying neo-epithelium 219 and result in a patterned epithelium with appropriate creases or fissures and ECM deposition for improved regeneration and functionality, including physiologically-equivalent flexion of the tissue and aesthetic appearance. This flexion is supported by the patterned deposition of ECM both within the underlying granulation layers and in the neo-epithelium. These structures provide points of stress relief and structural support to enhance bodily movement. In addition, the rate of re-epithelialization may be increased using the systems 100, 200. Another possible explanation for the re-epithelialization with the patterned neo-epithelium dressings 106, 206, 306 is that the directed fluid flow by the three-dimensional features 146, 246, 346 may lead to deposition

of structural proteins in a haptotactic or chemotactic gradient, which could enhance the rate of outgrowth of keratinocytes.

[0046] In other embodiments, surface patterning or wrinkling on the surface of the epithelium may be induced upon introduction of fluids, application of negative pressure, or induction by electrical, light, or other stimulatory device. In other embodiments, backing layers or other layers may be added to the neo-epithelium dressing. While the systems 100, 200 and patterned neo-epithelium dressings 106, 206, 306 are shown in the context of epithelium on a wound bed, similar approaches may be taken to pattern the surface of other epithelial or endothelial linings including those within the vascular, respiratory, visual, and digestive systems.

[0047] In another embodiment, an interface member may be formed with a thin member coupled to a foam and wherein the thin member contracts after coupling to the foam. The contraction creates the ridges and grooves.

[0048] Although the present invention and its advantages have been disclosed in the context of certain illustrative, non-limiting embodiments, it should be understood that various changes, substitutions, permutations, and alterations can be made without departing from the scope of the invention as defined by the appended claims. It will be appreciated that any feature that is described in connection to any one embodiment may also be applicable to any other embodiment, and descriptions related one embodiment may be applied to other embodiment as indicated by the context.

[0049] It will be understood that the benefits and advantages described above may relate to one embodiment or may relate to several embodiments. It will further be understood that reference to 'an' item refers to one or more of those items.

[0050] The steps of the methods described herein may be carried out in any suitable order, or simultaneously where appropriate.

[0051] Where appropriate, aspects of any of the examples described above may be combined with aspects of any of the other examples described to form further examples having comparable or different properties and addressing the same or different problems.

[0052] It will be understood that the above description of preferred embodiments is given by way of example only and that various modifications may be made by those skilled in the art. The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments of the invention. Although various embodiments

of the invention have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of the claims.

CLAIMS

We claim:

Claim 1. A system for treating a tissue site having granulation tissue on a patient, the system comprising:

a patterned neo-epithelium dressing for disposing proximate to granulation tissue on the tissue site, wherein the patterned neo-epithelium dressing comprises:

an interface member having a first side and a second, patient-facing side for placing proximate the granulation tissue, and

a plurality of three-dimensional features formed on the second, patient-facing side of the interface member and comprising a pattern that mimics human skin;

a sealing member for placing over the patterned neo-epithelium dressing and the patient's epidermis;

a reduced-pressure interface fluidly coupled to the sealing member;

a reduced-pressure source fluidly coupled to the reduced-pressure interface; and

wherein the three-dimensional features are adapted to promote epithelium growth with a pattern analogous to human skin.

Claim 2. The system of claim 1, wherein the interface member is formed with a fluid passageway that fluidly couples the first side and the second, patient-facing side.

Claim 3. The system of claim 1, wherein the interface member has a plurality of pores large enough to allow fluid transmission and small enough to limit cell migration.

Claim 4. The system of claim 1 or claim 2, wherein the interface member has a plurality of pores having an average pore size large enough to allow fluid transmission and small enough to limit cell migration.

Claim 5. The system of claim 1 or claim 2, the interface member has a plurality of pores having an average pore size larger than 5μm and smaller than 1000μm.

Claim 6. The system of claim 1 or any preceding claim, wherein the plurality of three-dimensional features comprises a plurality of ridges.

Claim 7. The system of claim 1 or any preceding claim, wherein the plurality of three-dimensional features comprises a plurality of grooves.

Claim 8. The system of claim 1 or any of claims 2-5, wherein the plurality of three-dimensional features comprises an intact analogous human skin pattern.

Claim 9. The system of claim 1 or any of claims 2-5, wherein the plurality of three-dimensional features comprises a location-specific human skin pattern.

Claim 10. The system of claim 1 or any of claims 2-9, wherein the interface member comprises a medical-grade polymer.

Claim 11. The system of claim 1 or any of claims 2-9, wherein the interface member comprises silicone.

Claim 12. The system of claim 1 or any of claims 2-9, wherein the interface member comprises a polyurethane film.

Claim 13. The system of claim 1 or any of claims 2-9, wherein the interface member comprises a polyurethane film bonded to a foam.

Claim 14. The system of claim 1 or any of claims 2-9, wherein the interface member comprises a foam having rigid portions and less rigid portions, wherein, under reduced pressure, the less rigid portions compress more than the more rigid portions.

Claim 15. The system of claim 1 or any of claims 2-14, further comprising a protein coated on the plurality of three-dimensional features.

Claim 16. A system for treating a tissue site having granulation tissue on a patient, the system comprising:

a patterned neo-epithelium dressing for disposing proximate granulation tissue on the tissue site, wherein the patterned neo-epithelium dressing comprises:

an interface member having a first side and a second, patient-facing side for placing proximate the granulation tissue, wherein the interface member has a plurality of pores that extend over a majority of the interface member and are large enough to allow fluid transmission and small enough to limit cell migration, and

a plurality of three-dimensional features formed on the second, patient-facing side of the interface member, wherein the plurality of three-dimensional features comprises a pattern that mimics human skin;

a sealing member for placing over the patterned neo-epithelium dressing and the patient's epidermis;

a reduced-pressure interface fluidly coupled to the sealing member;

a reduced-pressure source fluidly coupled to the reduced-pressure interface; and

wherein the three-dimensional features are adapted to promote epithelium growth with a pattern analogous to human skin.

Claim 17. The system of claim 16, wherein the plurality of three-dimensional features comprises an intact analogous human skin pattern.

Claim 18. The system of claim 16, wherein the plurality of three-dimensional features comprises a location-specific human skin pattern.

Claim 19. The system of claim 16 or claim 17 or claim 18, wherein the plurality of pores have an average pore size larger than 5μm and smaller than 1000μm.

Claim 20. A patterned neo-epithelium dressing for treating a tissue site having granulation tissue, the patterned neo-epithelium dressing comprising:

an interface member having a first side and a second, patient-facing side for placing proximate to the granulation tissue; and

a plurality of three-dimensional features formed on the second, patient-facing side of the interface member and comprising a pattern that mimics human skin.

Claim 21. The patterned neo-epithelium dressing of claim 20, wherein the interface member is formed with a fluid passageway that fluidly couples the first side and the second, patient-facing side.

Claim 22. The patterned neo-epithelium dressing of claim 20 or claim 21, wherein the interface member has a plurality of pores having an average pore size large enough to allow fluid transmission and small enough to limit cell migration.

Claim 23. The patterned neo-epithelium dressing of claim 20 or claim 21 or claim 22, wherein the interface member has a plurality of pores having an average pore size greater than 5μm and smaller than 1000μm.

Claim 24. The patterned neo-epithelium dressing of claim 20 or claim 21 or claim 22, wherein the plurality of three-dimensional features comprises a plurality of ridges.

Claim 25. The patterned neo-epithelium dressing of claim 20 or claim 21 or claim 22, wherein the plurality of three-dimensional features comprises a plurality of grooves.

Claim 26. The patterned neo-epithelium dressing of claim 20 or claim 21 or claim 22, wherein the plurality of three-dimensional features comprises an intact analogous human skin pattern.

Claim 27. The patterned neo-epithelium dressing of claim 20 or claim 21 or claim 22, wherein the plurality of three-dimensional features comprises a location-specific human skin pattern.

Claim 28. The patterned neo-epithelium dressing of claim 20 or any of claims 21-26, wherein the interface member comprises a medical-grade polymer.

Claim 29. The patterned neo-epithelium dressing of claim 20 or any of claims 21-26, wherein the interface member comprises silicone.

Claim 30. The patterned neo-epithelium dressing of claim 20 or any of claims 21-26, wherein the interface member comprises a polyurethane film.

Claim 31. The patterned neo-epithelium dressing of claim 20 or any of claims 21-26, wherein the interface member comprises a thin member bonded to a foam.

Claim 32. The patterned neo-epithelium dressing of claim 20 or any of claims 21-26, wherein the interface member comprises a foam having rigid portions and less rigid portions that compress under reduced pressure.

Claim 33. The patterned neo-epithelium dressing of claim 20 or any of claims 21-26, wherein the interface member comprises:

a thin member having a first side and a second, patient-facing side;

a hydrophilic material having a first side and a second, patient-facing side; and

wherein the second, patient-facing side of the hydrophilic material is coupled to the first side of the thin member.

Claim 34. The patterned neo-epithelium dressing of claim 20 or any of claims 21-33, further comprising a protein coated on the plurality of three-dimensional features.

Claim 35. A method of treating a tissue site of a patient, the method comprising:

locating granulation tissue at the tissue site;

deploying a patterned neo-epithelium dressing comprising:

an interface member having a first side and a second, patient-facing side for placing proximate the granulation tissue, and

a plurality of three-dimensional features formed on the second, patient-facing side of the interface member, wherein the plurality of three-dimensional features comprises ridges mimicking human skin; and

applying a contact pressure on the patterned neo-epithelium dressing.

Claim 36. The method of claim 35, further comprising the step of promoting the formation of granulation tissue using reduced pressure.

Claim 37. The method of claim 36, wherein the step of promoting the formation of granulation tissue comprises applying a reduced-pressure manifold proximate to the tissue site, covering the reduced-pressure manifold with a sealing member, and providing reduced pressure to the reduced-pressure manifold.

Claim 38. The method of claim 35, wherein applying the contact pressure comprises:

deploying a sealing member over the patterned neo-epithelium dressing and a portion of the patient's skin, the sealing member having a first side and a second, patient-facing side; and

providing reduced pressure to the second, patient-facing side of the sealing member.

Claim 39. The method of claim 35, wherein applying the contact pressure comprises deploying a pressure wrap over the first side of the patterned neo-epithelium dressing.

Claim 40. The method of claim 35, wherein the interface member has a plurality of pores having an average pore size greater than 5μm and smaller than 1000μm.

Claim 41. A method of treating a tissue site of a patient, the method comprising:

promoting the formation of granulation tissue using reduced pressure;

deploying a patterned neo-epithelium dressing comprising:

an interface member having a first side and a second, patient-facing side for placing proximate the granulation tissue, and

a plurality of three-dimensional features formed on the second, patient-facing side of the interface member, wherein the plurality of three-dimensional features comprises ridges mimicking human skin; and

applying a contact pressure on the patterned neo-epithelium dressing using reduced pressure.

Claim 42. The method of treating a tissue site of claim 41, wherein the interface member has a plurality of pores having an average pore size large enough to allow fluid transmission and small enough to limit cell migration.

Claim 43. The method of treating a tissue site of claim 41, wherein the interface member has a plurality of pores having an average pore size greater than 5μm and smaller than 1000μm.

Claim 44. The method of treating a tissue site of claim 41, wherein the step of applying the contact pressure comprises deploying a pressure wrap over the first side of the patterned neo-epithelium dressing.

Claim 45. A method of treating a tissue site of a patient, the method comprising:

directing flow of endogenous fluids to cause a patterned protein deposition;

causing guidance of the migrating epithelium by the patterned protein deposition to form a new-epithelium; and

forming fissures in the neo-epithelium.

Claim 46. The method of claim 45, wherein directing flow of the endogenous fluids comprises:

deploying a patterned neo-epithelium dressing proximate the tissue site;

forming a fluid seal over the patterned neo-epithelium dressing; and

providing reduced pressure to the patterned neo-epithelium dressing, whereby the endogenous fluids are removed along the fissures.

Claim 47. The method of claim 45, wherein causing guidance of the migrating epithelium comprises:

deploying a patterned neo-epithelium dressing proximate the tissue site;

forming a fluid seal over the patterned neo-epithelium dressing;

providing reduced pressure to the patterned neo-epithelium dressing whereby endogenous fluids are removed;

removing the endogenous fluids until the patterned protein deposition occurs along one or more flow paths; and

allowing epithelium to migrate along the patterned protein deposition.

Claim 48. The method of claim 45, wherein forming the fissures in the neo-epithelium comprises:

deploying a patterned neo-epithelium dressing proximate the tissue site, wherein the patterned neo-epithelium dressing comprises a plurality of three-dimensional features;

forming a fluid seal over the patterned neo-epithelium dressing; and

causing the plurality of three-dimensional features to contact the neo-epithelium.

Claim 49. A method of manufacturing a patterned neo-epithelium dressing for treating a tissue site having granulation tissue, the method comprising:

forming an interface member having a first side and a second, patient-facing side for placing proximate the granulation tissue; and

forming a plurality of three-dimensional features with a pattern analogous to human skin on the second, patient-facing side of the interface member.

Claim 50. The method of claim 49, wherein forming the interface member further comprises forming the interface member with a fluid passageway that fluidly couples the first side and the second, patient-facing side.

Claim 51. The method of claim 49 or claim 50, wherein the interface member has a plurality of pores having an average pore size large enough to allow fluid transmission and small enough to limit cell migration.

Claim 52. The method of claim 49 or claim 50 or claim 51, wherein the interface member has a plurality of pores having an average pore size greater than 5μm and smaller than

1000μm.

Claim 53. The method of claim 49 any of claims 50-52, wherein the plurality of three-dimensional features comprises a plurality of ridges.

Claim 54. The method of claim 49 or any of claims 50-52, wherein the plurality of three-dimensional features comprises a plurality of grooves.

Claim 55. The method of claim 49 or any of claims 50-52, wherein the plurality of three-dimensional features comprises a pattern that mimics intact, analogous skin of the patient.

Claim 56. The method of claim 49 or any of claims 50-52, wherein the plurality of three-dimensional features comprises a pattern mimicking representative, intact, analogous skin.

Claim 57. The method of claim 49 or any of claims 49-56, wherein forming the interface member comprises forming the interface member from a medical-grade polymer.

Claim 58. The method of claim 49 or any of claims 49-56, wherein forming the interface member comprises forming the interface member from silicone.

Claim 59. The method of claim 49 or any of claims 49-56, wherein forming the interface member comprises forming the interface member from a polyurethane film.

Claim 60. The method of claim 49 or any of claims 49-56, wherein forming the interface member comprises bonding a polyurethane film to a foam.

Claim 61. The method of claim 49 or any of claims 49-56, wherein the interface member comprises a foam having rigid portions and less rigid portions that compress under reduced pressure.

Claim 62. The method of claim 49 or any of claims 49-56, wherein forming the interface member comprises:

providing a thin member having a first side and a second, patient-facing side;

providing a hydrophilic material having a first side and a second, patient-facing side; and

coupling the second, patient-facing side of the hydrophilic material to the first side of the thin member.

Claim 63. The method of claim 49 or any of claims 49-62, further comprising coating a protein on the plurality of three-dimensional features.

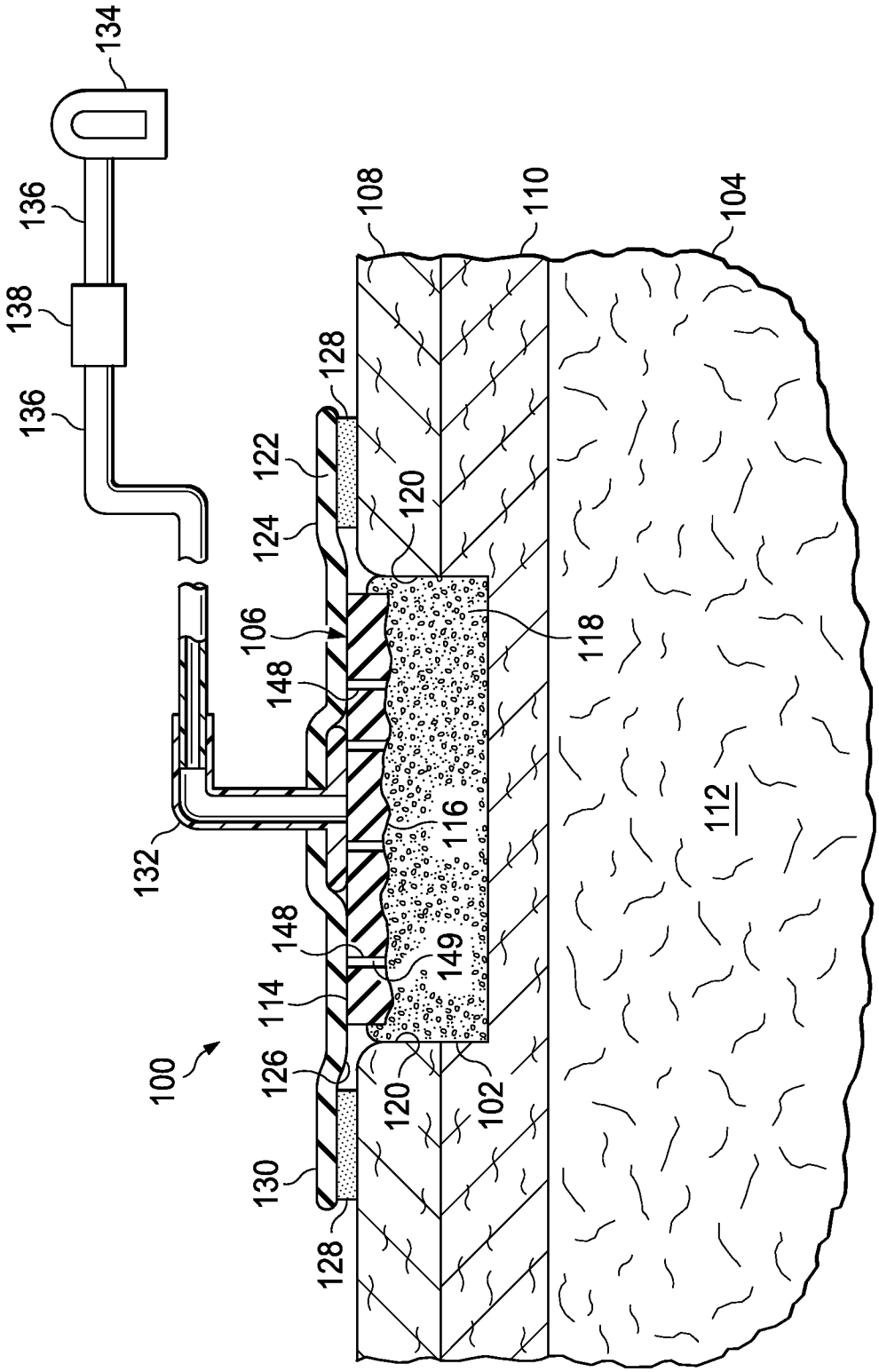
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FIG. 1

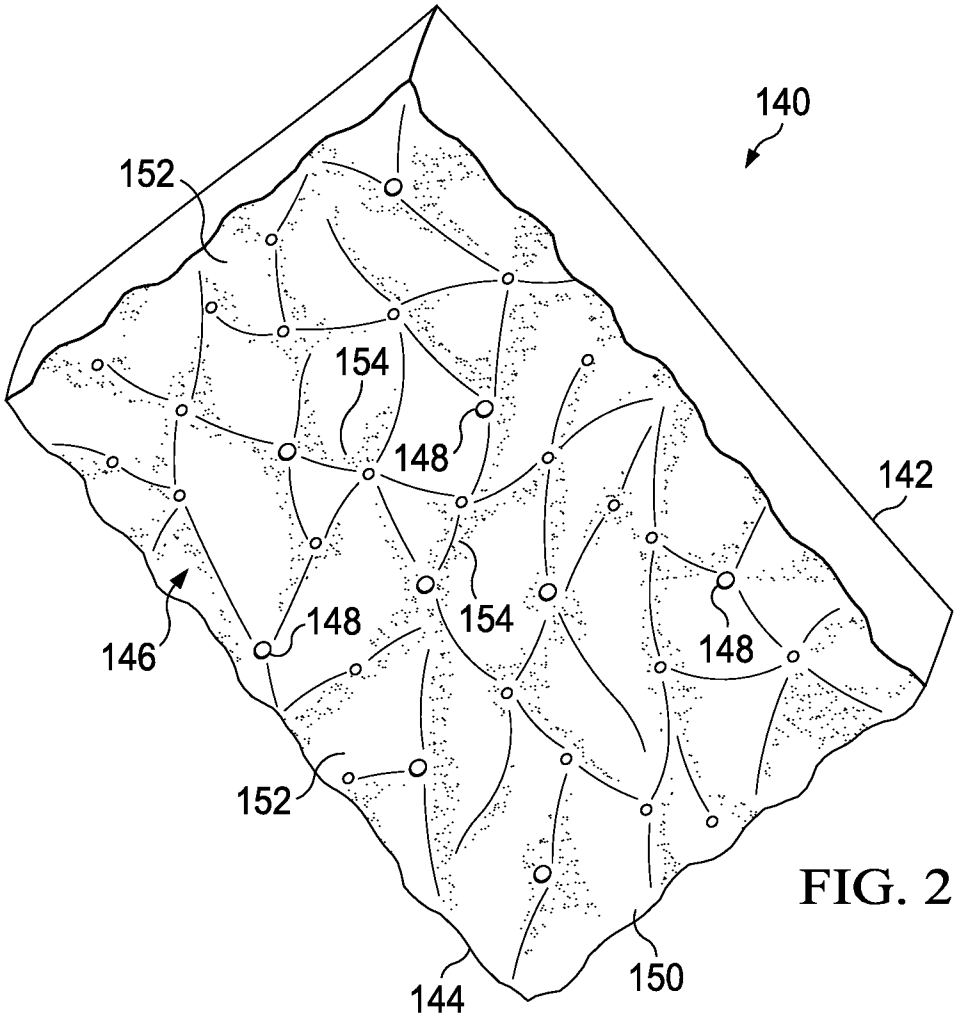

FIG. 2

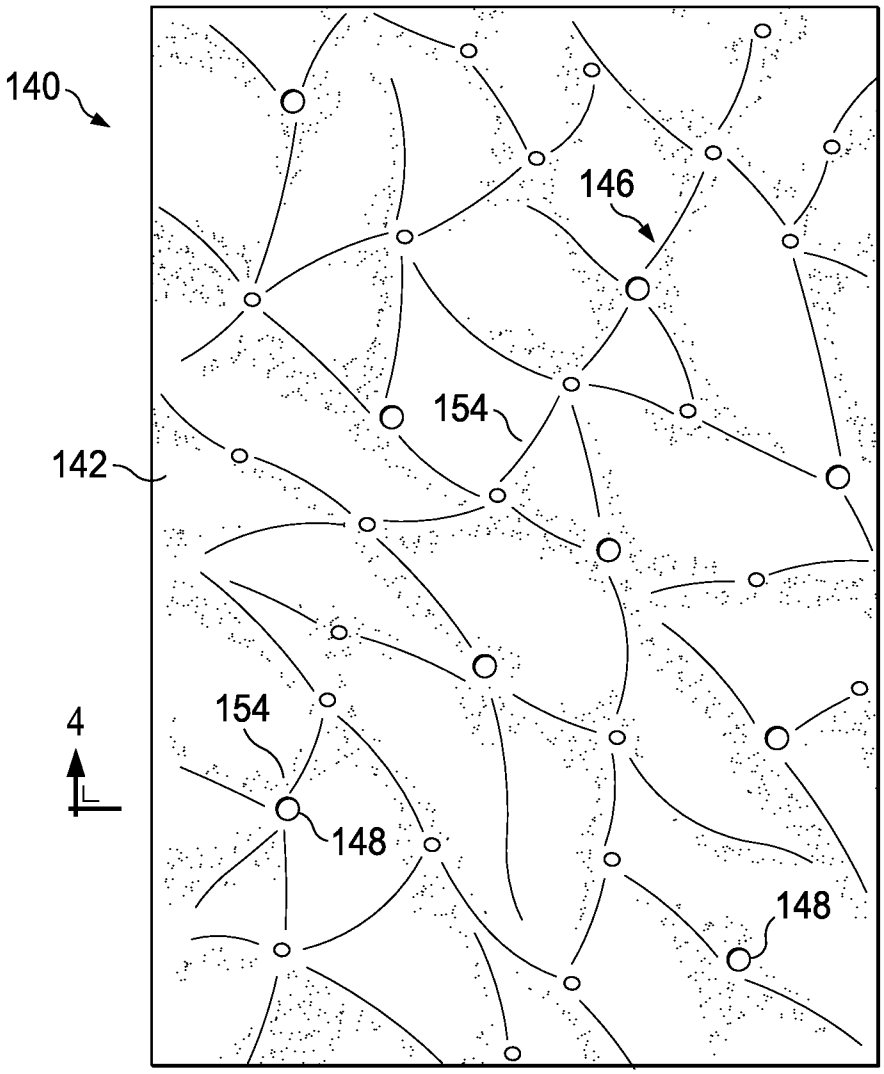
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FIG. 3

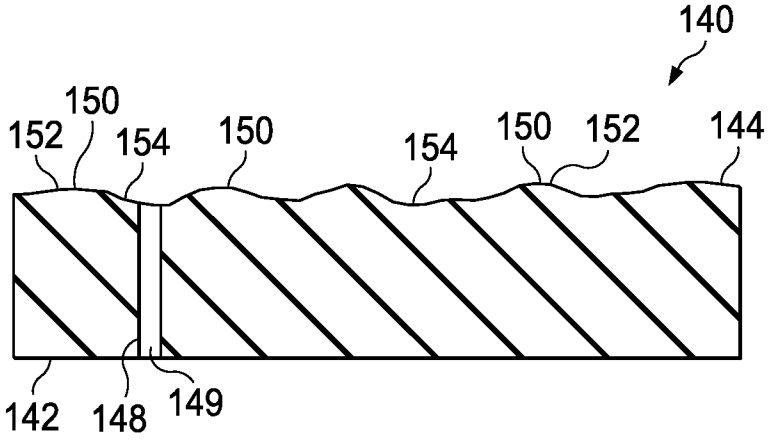
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FIG. 4

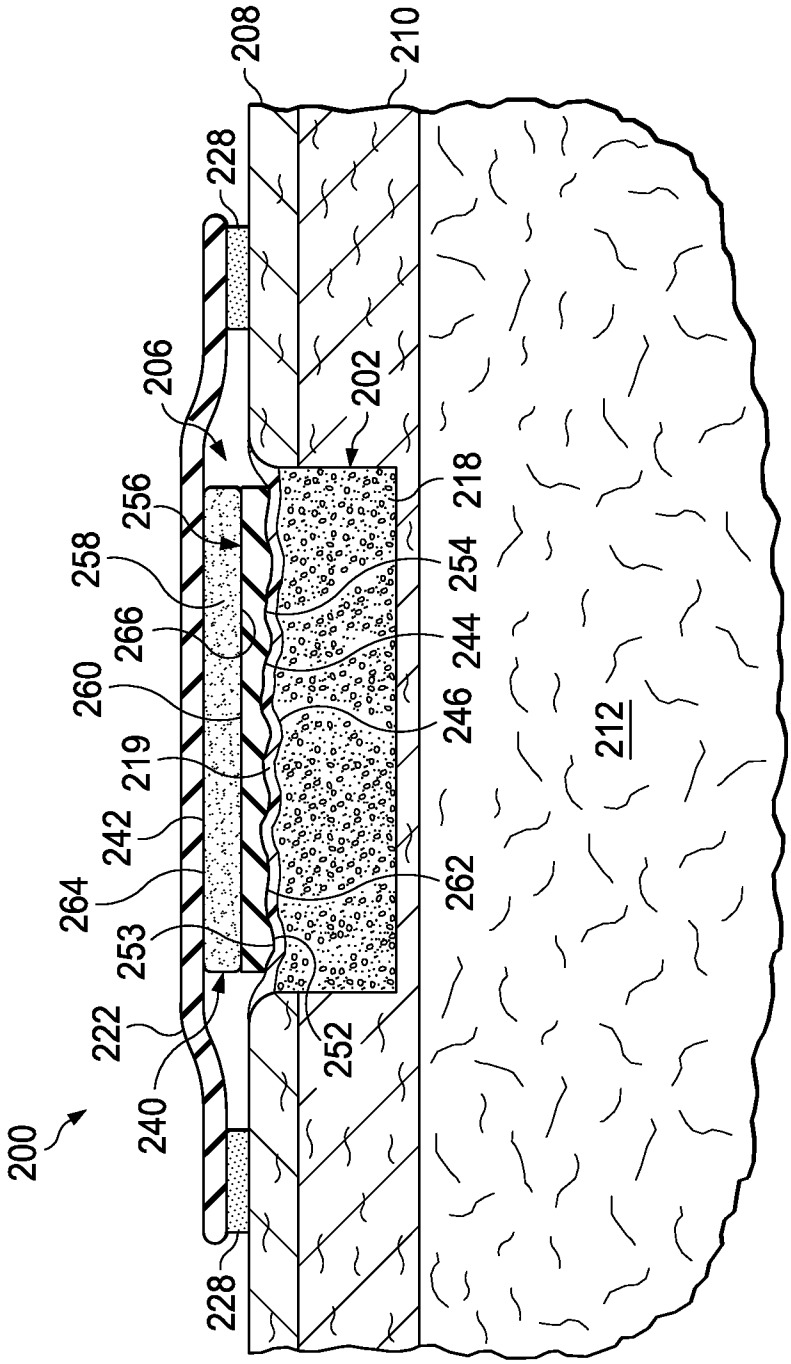
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FIG. 5

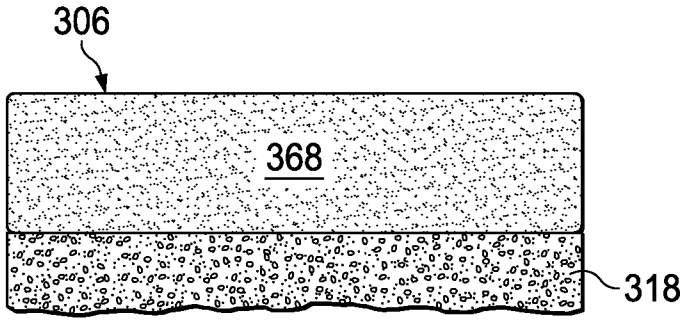

FIG. 6A

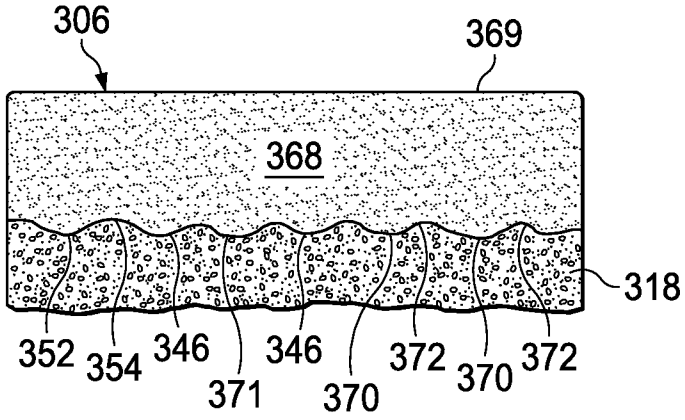

FIG. 6B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/028189

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/02 A61M27/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/275409 A1 (KANE BARTHOLOMEW J [US] ET AL) 6 November 2008 (2008-11-06)	1-7, 10-16, 19-25, 28-32, 34, 49-54, 57-61,63
Y	paragraph [0023] paragraph [0060] paragraphs [0079] - [0094] paragraphs [0140] - [0158] figures 1a, 2a-b, 7, 8a-c, 9	33,62

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[X] Further documents are listed in the continuation of Box C.

[X] 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 document 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	Date of mailing of the international search report
30 June 2011	08/07/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schlaug, Martin

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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/032762 A1 (VOGEL RICHARD C [US]) 8 February 2007 (2007-02-08) paragraphs [0053] - [0054] figure 10	1-3,8, 10,12, 13,20, 21,26, 28,30, 31,49, 50,55, 57,59,60
Y	WO 2005/123170 A1 (ETHICON INC [US]; WATT PAUL WILLIAM [GB]; GREGORY SARA JAYNE [GB]; TRO) 29 December 2005 (2005-12-29)	33,62
A	page 19, line 28 - page 20, line 8; figure 3	1,16,20, 49
A	WO 2008/141228 A1 (KCI LICENSING INC [US]; OLSON JONATHAN S [US]; GINTHER DEVIN C [US]; S) 20 November 2008 (2008-11-20) page 5, line 21 - page 10, line 6 figures 1-6	1,16,20, 49
A	US 2005/228329 A1 (BOEHRINGER JOHN R [US] ET AL) 13 October 2005 (2005-10-13) paragraphs [0028] - [0057] figures 1-5	1,16,20, 49
A	US 2003/077311 A1 (VYAKARNAM MURTY N [US] ET AL) 24 April 2003 (2003-04-24) paragraphs [0008] - [0009]	1,16,20, 49
A	WO 2005/115259 A2 (BIOMEDICAL STRATEGIES [US]; WHITE MORENO [US]; CAHN FREDERICK [US]) 8 December 2005 (2005-12-08) page 11, line 6 - page 12, line 11	1,16,20, 49

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/028189

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. [X] Claims Nos.: 35-48
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

Continuation of Box II.1

Claims Nos.: 35-48

Methods of treating a tissue site of a patient comprising steps such as applying a contact pressure on the patterned neo-epithelium dressing and / or promoting the formation of granulation tissue using reduced pressure and / or forming fissures in the neo-epithelium are considered methods for treatment of the human or animal body by therapy and / or surgery. The subject matter of claims 35-40, 41-44 and 45-48 was therefore not searched (Article 17(2)(a)(i) /(ii) and Rule 39.1 (iv) PCT) and consequently no opinion will be formulated on the subject matter of those claims (Article 34(4)(a)(i) and Rule 67.1(iv) PCT).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/028189

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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