Innovation, Sciences et Développement économique Canada
Office de la Propriété Intellectuelle du Canada

Innovation, Science and Economic Development Canada
Canadian Intellectual Property Office

CA 3066090 A1 2019/01/30

(21) 3 066 090

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(86) Date de dépôt PCT/PCT Filing Date: 2018/06/21

(87) Date publication PCT/PCT Publication Date: 2019/01/30

(85) Entrée phase nationale/National Entry: 2019/12/03

(86) N° demande PCT/PCT Application No.: EP 2018/066575

(87) N° publication PCT/PCT Publication No.: 2019/002086

(30) Priorités/Priorities: 2017/06/30 (US62/527,959); 2017/06/30 (US62/527,922)

(51) Cl.Int./Int.Cl. *A61F 13/00* (2006.01), *A61F 13/02* (2006.01)

(71) Demandeur/Applicant:
T. J. SMITH & NEPHEW,LIMITED, GB

(72) Inventeurs/Inventors:
RAWSON, NEILL JOHN, GB;
WHELDRAKE, AMY NICOLE, GB

(74) Agent: BORDEN LADNER GERVAIS LLP

(54) Titre : COUCHE D'ESPACEMENT A UTILISER DANS UN PANSEMENT
(54) Title: SPACER LAYER FOR USE IN A WOUND DRESSING

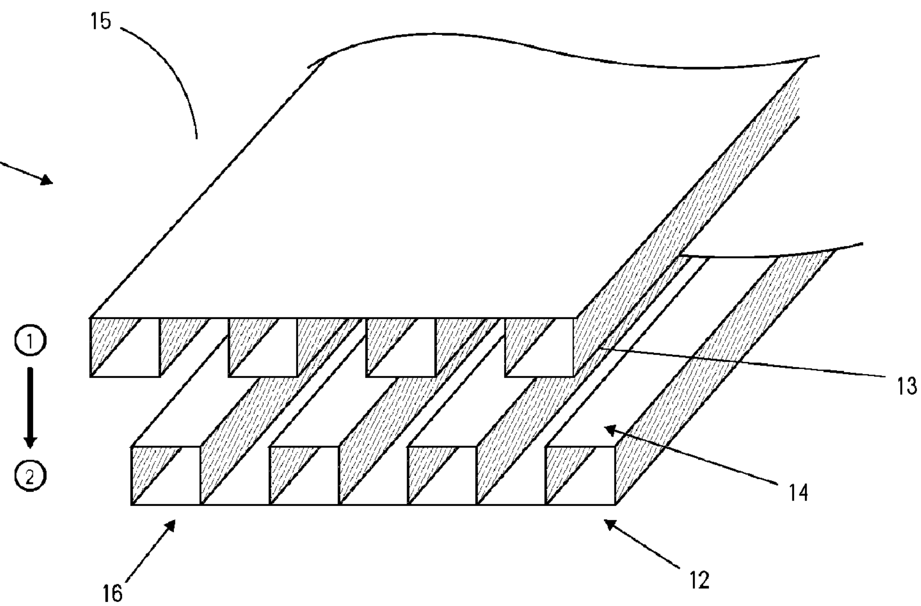


FIGURE 2B

(57) Abrégé/Abstract:
A system, method, and apparatus are disclosed for dressing a wound. In one embodiment, the apparatus can include a spacer layer comprising two nonwoven layers, each nonwoven layer comprising a plurality of channels or apertures therethrough. In other embodiments, the apparatus includes at least one nonwoven spacer layer comprising a three- dimensional structure, such as a corrugated structure, honeycomb structure, cuboid structure, or egg-crate structure. The three-dimensional nonwoven structure can comprise a thermoformed nonwoven layer. The apparatus can also include an absorbent layer for absorbing wound exudate, the absorbent layer overlying the spacer layer, and a gas impermeable cover layer overlying the absorbent layer and comprising at least one orifice, wherein the cover layer is moisture vapor permeable.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
03 January 2019 (03.01.2019)

(10) International Publication Number
WO 2019/002086 A3

(51) International Patent Classification:
A61F 13/00 (2006.01) *A61F 13/02* (2006.01)

(21) International Application Number:
PCT/EP2018/066575

(22) International Filing Date:
21 June 2018 (21.06.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/527,922 30 June 2017 (30.06.2017) US
62/527,959 30 June 2017 (30.06.2017) US

(71) Applicant: T.J.SMITH & NEPHEW,LIMITED [GB/GB]; P.O. Box 81, 101 Hessle Road, Hull HU3 2BN (GB).

(72) Inventors: RAWSON, Neill, John; Smith & Nephew, 101 Hessle Road, Hull HU3 2BN (GB). WHELDRAKE, Amy, Nicole; Smith & Nephew, 101 Hessle Road, Hull HU3 2BN (GB).

(74) Agent: ELLYATT, William; Smith & Nephew, 101 Hessle Road, Hull East Yorkshire HU3 2BN (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,

(54) Title: SPACER LAYER FOR USE IN A WOUND DRESSING

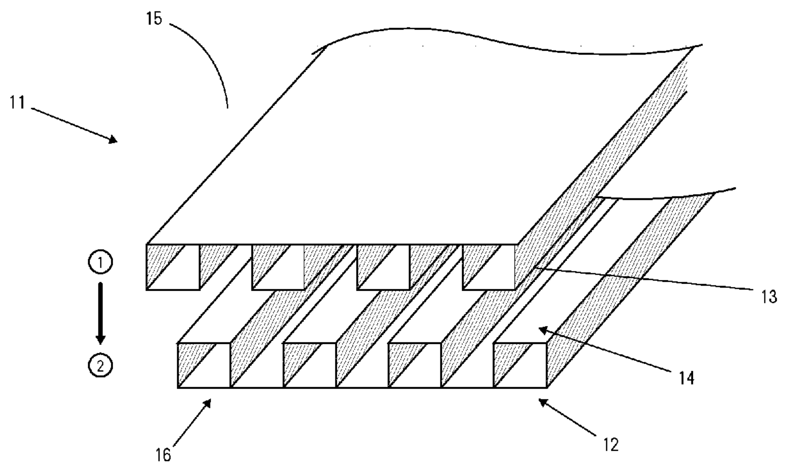


FIGURE 2B

(57) Abstract: A system, method, and apparatus are disclosed for dressing a wound. In one embodiment, the apparatus can include a spacer layer comprising two nonwoven layers, each nonwoven layer comprising a plurality of channels or apertures therethrough. In other embodiments, the apparatus includes at least one nonwoven spacer layer comprising a three- dimensional structure, such as a corrugated structure, honeycomb structure, cuboid structure, or egg-crate structure. The three-dimensional nonwoven structure can comprise a thermoformed nonwoven layer. The apparatus can also include an absorbent layer for absorbing wound exudate, the absorbent layer overlying the spacer layer, and a gas impermeable cover layer overlying the absorbent layer and comprising at least one orifice, wherein the cover layer is moisture vapor permeable.

WO 2019/002086 A3

[Continued on next page]

WO 2019/002086 A3

UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:
07 February 2019 (07.02.2019)

SPACER LAYER FOR USE IN A WOUND DRESSING

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application No. 62/527922, filed on June 30, 2017, and U.S. Provisional Patent Application No. 62/527959, filed on June 30, 2017. All of these applications are hereby incorporated by reference in their entireties and made part of this disclosure.

TECHNICAL FIELD

[0002] The disclosed technology relates to a wound dressing comprising various spacer layers. The disclosed technology relates to a wound dressing comprising an apertured nonwoven fabric spacer layer or a three dimensional nonwoven spacer layer. The disclosed technology further relates to methods and uses of the wound dressing.

BACKGROUND

[0003] In wound treatment there is a balance between providing a wound dressing to remove wound fluid which can accumulate between the dressing and the skin. A build up of fluid between the wound and the dressing can cause separation of the dressing from the skin. Separation of the dressing from the skin can increase the possibility of the wound being contaminated by microorganisms which can cause infection. However, the dressing should be in place for sufficient time to ensure the body can progress biological process required to heal a wound.

[0004] Depending on the nature of the wound, the patient may be immobilized for prolonged periods of time. Immobilization of a patient or neuropathy may also lead to complicating factors such as ulcers (such as a pressure ulcer, or also known as a pressure injury) or bed sores.

[0005] Pressure ulcers (may be referred to as "bed sores" or decubitus ulcers) may be developed by individuals confined for an extended period of time to a particular position in a bed or chair. When a person is bed ridden or wheel chair bound due to such causes as an accident, illness, or extensive period of recovery from surgery, the body tends to be immobilized for an extended period of time. It has been noted that pressure ulcers occur most frequently in certain parts of the body, such as the heel and ankle, the trochanter, the sacrum, the scapulae, at the elbows, knees, occiput, ischial tuberosites and at the coccyx. As presently understood, the weight overlying these body parts exerts sufficient pressure on the underlying soft tissue layers to cause an interruption of the flow of blood to and through the soft tissue layers causing the development of a condition generally referred to as pressure ulcers.

[0006] The treatment of open or chronic wounds that are too large to spontaneously close or otherwise fail to heal by means of applying negative pressure to the site of the wound is well known in the art. Negative pressure wound therapy (NPWT) systems currently known in the art commonly involve placing a cover that is impermeable or semi-permeable to fluids over the wound, using various means to seal the cover to the tissue of the patient surrounding the wound, and connecting a source of negative pressure (such as a vacuum pump) to the cover in a manner so that negative pressure is created and maintained under the cover. It is believed that such negative pressures promote wound healing by facilitating the formation of granulation tissue at the wound site and assisting the body's normal inflammatory process while simultaneously removing excess fluid, which may contain adverse cytokines and/or bacteria. However, further improvements in NPWT are needed to fully realize the benefits of treatment.

[0007] Many different types of wound dressings are known for aiding in NPWT systems. These different types of wound dressings include many different types of materials and layers, for example, gauze, pads, foam pads or multi-layer wound dressings. One example of a multi-layer wound dressing is the PICO dressing, available from Smith & Nephew, which includes a superabsorbent layer beneath a backing layer to provide a canister-less system for treating a wound with NPWT. The wound dressing may be sealed to a suction port providing connection to a length of tubing, which may be used to pump fluid out of the dressing and/or to transmit negative pressure from a pump to the wound dressing.

SUMMARY

[0008] In one embodiment the disclosed technology relates to a wound dressing, and methods and uses of employing the wound dressing. Some embodiments may mitigate/reduce or prevent ulcer formation during wound healing. Some embodiments of the wound dressing may be adapted for use in negative pressure wound therapy.

[0009] As used herein, the transitional term “comprising,” which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, un-recited elements or method steps. However, in each recitation of “comprising” herein, it is intended that the term also encompasses, as alternative embodiments, the phrases “consisting essentially of” and “consisting of,” where “consisting of” excludes any element or step not specified and “consisting essentially of” permits the inclusion of additional un-recited elements or steps that do not materially affect the basic and novel characteristics of the composition, method or use under consideration.

[0010] In some embodiments, a wound treatment apparatus can comprise a wound dressing. The wound dressing can comprise a spacer layer comprising a first nonwoven fabric layer comprising a first fibrous base layer and an interconnected first fibrous face layer, wherein a plurality of channels are disposed between the first fibrous base layer and the first fibrous face layer, and a second nonwoven fabric layer comprising a second fibrous base layer and an interconnected second fibrous face layer, wherein a plurality of channels are disposed between the second fibrous base layer and the second fibrous face layer, wherein the second nonwoven fabric layer is disposed over the first nonwoven fabric layer such that the second fibrous face layer of the second nonwoven fabric is positioned over the first fibrous face layer of the first nonwoven fabric, a cover layer positioned over the spacer layer.

[0011] The apparatus of the preceding paragraph may also include any combination of the features described in the following paragraphs, among others described herein. Each of the features described in the following paragraphs may also be part of another embodiment that does not necessarily include all of the features of the previous paragraph.

[0012] The plurality channels of the first or second nonwoven fabric layers can extend across an entire length of the first and second nonwoven fabric layers.

[0013] The channels of the first nonwoven fabric layer can extend in a first direction and the channels of the second nonwoven fabric layer extend in a second direction.

[0014] The first direction can be parallel to the second direction.

[0015] The first direction can be perpendicular to the second direction.

[0016] The plurality of channels of the second nonwoven fabric layer can be disposed directly over the plurality of channels of the first nonwoven fabric layer.

[0017] The plurality of channels of the second nonwoven fabric layer can be offset from the plurality of channels of the first nonwoven fabric layer.

[0018] Each of the plurality of channels of the first and second nonwoven fabric layers can have a diameter of from about 0.5 mm to about 5 mm.

[0019] The base layer and the face layer of the first and/or second nonwoven fabric layers can be hydroentangled.

[0020] The face layer of the first and/or second nonwoven fabric layers can be hydrophilic.

[0021] The base layer of the first and/or second nonwoven fabric layers can be hydrophobic.

[0022] The wound treatment apparatus can further comprise a pump and a suction port for applying negative pressure to a wound site through an orifice in the cover layer.

[0023] The spacer layer can be configured to remain open upon application of negative pressure to the wound treatment apparatus.

[0024] The wound treatment apparatus can further comprise an absorbent layer for absorbing wound exudate, the absorbent layer positioned over the spacer layer.

[0025] The absorbent layer can comprise a non-woven material containing superabsorbent particles or fibers.

[0026] The wound treatment apparatus can further comprise a masking layer positioned between the absorbent layer and cover layer.

[0027] The wound treatment apparatus can further comprise a second spacer layer positioned over the absorbent layer, wherein the second spacer layer can comprise a third nonwoven fabric layer comprising a third fibrous base layer and an interconnected third fibrous face layer, wherein a plurality of channels are disposed between the third fibrous base layer and the third fibrous face layer, and a fourth nonwoven fabric layer comprising a fourth fibrous base layer and an interconnected fourth fibrous face layer, wherein a plurality of channels are disposed between the fourth fibrous base layer and the fourth fibrous face layer, wherein the fourth nonwoven fabric layer is disposed over the third nonwoven fabric layer such that the fourth fibrous face layer of the fourth nonwoven fabric is in contact with the third fibrous face layer of the third nonwoven fabric.

[0028] The cover layer can comprise an orifice.

[0029] The cover layer can comprise a moisture vapor permeable material.

[0030] The channels can be rounded channels.

[0031] The channels can be rectangular channels.

[0032] The channels can be triangular channels.

[0033] In some embodiments, a spacer layer for use in a wound dressing is provided. The spacer layer can comprise a first nonwoven fabric layer comprising a first fibrous base layer and an interconnected first fibrous face layer, wherein a plurality of channels are disposed between the first fibrous base layer and the first fibrous face layer, and a second nonwoven fabric layer comprising a second fibrous base layer and an interconnected second fibrous face layer, wherein a plurality of channels are disposed between the second fibrous base layer and the second fibrous face layer, wherein the second nonwoven fabric layer is disposed over the first nonwoven fabric layer such that the second face layer of the second nonwoven fabric is positioned over the first face layer of the first nonwoven fabric. The spacer layer of this paragraph can include any of the combination of the features described in the preceding paragraphs, among others described herein. Each of the features described in the preceding paragraphs may also be part of another embodiment that does not necessarily include all of the features of this paragraph.

[0034] In some embodiments, a method for the treatment of a wound, can comprise providing a wound dressing comprising a spacer layer comprising, a first nonwoven fabric layer comprising a first fibrous base layer and an interconnected first fibrous face layer, wherein a plurality of channels are disposed between the first fibrous base layer and the first fibrous face layer, and a second nonwoven fabric layer comprising a second fibrous base layer and an interconnected second fibrous face layer, wherein a plurality of channels are disposed between the second fibrous base layer and the second fibrous face layer, wherein the second nonwoven fabric layer is disposed over the first nonwoven fabric layer such that the second face layer of the second nonwoven fabric is positioned over the first face layer of the first nonwoven fabric, a cover layer positioned over the spacer layer and comprising an orifice; positioning the dressing over a wound site to form a sealed cavity over the wound site; and applying negative pressure to the wound site through the orifice to draw fluid through the spacer layer into the absorbent layer.

[0035] The method of the preceding paragraph may also include any combination of the features described in the following paragraphs, among others described herein. Each of the features described in the following paragraphs may also be part of another embodiment that does not necessarily include all of the features of the previous paragraph.

[0036] The wound dressing can further comprise an absorbent layer for absorbing wound exudate, the absorbent layer positioned over the spacer layer.

[0037] In some embodiments, a wound treatment apparatus can comprise a wound dressing. The wound dressing can comprise a spacer layer comprising at least one nonwoven fabric layer formed into a three dimensional nonwoven structure, wherein the three dimensional nonwoven structure is formed by thermoforming, chemical bonding, or vacuum forming; a cover layer positioned over the spacer layer.

[0038] The apparatus of the preceding paragraph may also include any combination of the features described in the following paragraphs, among others described herein. Each of the features described in the following paragraphs may also be part of another embodiment that does not necessarily include all of the features of the previous paragraph.

[0039] The three dimensional nonwoven structure can be formed by thermoforming.

[0040] The three dimensional nonwoven structure can be formed by chemical bonding.

[0041] The three dimensional nonwoven structure can be formed by vacuum forming.

[0042] The three dimensional nonwoven structure can comprise a corrugated structure.

[0043] The three dimensional nonwoven structure can comprise a honeycomb structure.

[0044] The three dimensional nonwoven structure can comprise a cuboid structure.

[0045] The three dimensional nonwoven structure can comprise an egg-box structure.

[0046] The three dimensional nonwoven structure can comprise a three dimensional zig-zag structure.

[0047] The spacer layer further can comprise one or more support layers, wherein the one or more support layers is positioned over the three dimensional nonwoven structure.

[0048] The spacer layer further can comprise one or more support layers, wherein the one or more support layers is positioned below the three dimensional nonwoven structure.

[0049] The three dimensional nonwoven structure can comprise a thermoformed nonwoven layer.

[0050] The three dimensional nonwoven structure can comprise thermoplastic fibers.

[0051] The three dimensional nonwoven structure can comprise a blend of thermoplastic fibers and other fibers.

[0052] The other fibers can comprise viscose fibers, gellable fibers, binder fibers, and/or bicomponent fibers.

[0053] The three dimensional nonwoven structure can consist essentially of thermoplastic fibers.

[0054] The at least one three dimensional nonwoven structure can have a thickness of 2 to 10 mm.

[0055] The at least one three dimensional nonwoven structure can have a thickness of about 3 mm.

[0056] The nonwoven fabric can be produced by airlaying, carding, or meltspinning.

[0057] The nonwoven fabric can be isotropic.

[0058] The nonwoven fabric can comprise polypropylene.

[0059] The nonwoven fabric can be hydroentangled.

[0060] The wound dressing can further comprise an absorbent layer for absorbing wound exudate, the absorbent layer positioned over the spacer layer.

[0061] The wound dressing can further comprise a second spacer layer positioned over the absorbent layer.

[0062] The spacer layer can further comprise a first thermoformed nonwoven fabric layer and a second thermoformed fabric layer disposed over the first thermoformed nonwoven fabric layer.

[0063] The spacer layer can further comprise a three dimensional knitted or fabric layer.

[0064] The wound treatment apparatus can further comprise a pump, a suction port for applying negative pressure to a wound site through the orifice in the cover layer.

[0065] In some embodiments, a spacer layer for use in a wound dressing is provided. The spacer layer can comprise at least one thermoformed nonwoven fabric layer comprising a three dimensional structure, wherein the thermoformed nonwoven fabric comprises thermoplastic fibers. The spacer layer of this paragraph can include any of the combination of the features described in the preceding paragraphs, among others described herein. Each of the features described in the preceding paragraphs may also be part of another embodiment that does not necessarily include all of the features of this paragraph.

[0066] A method for the treatment of a wound can comprise positioning a dressing over a wound site to form a sealed cavity over the wound site, the dressing comprising a spacer layer comprising at least one nonwoven fabric layer formed into a three dimensional nonwoven structure, and a cover layer overlying the spacer layer; and applying negative pressure to the wound site to draw fluid through the spacer layer.

[0067] The method of the preceding paragraph may also include any combination of the features described in the following paragraphs, among others described herein. Each of the features described in the following paragraphs may also be part of another embodiment that does not necessarily include all of the features of the previous paragraph.

[0068] The dressing can further comprise an absorbent layer for absorbing wound exudate, the absorbent layer positioned over the spacer layer.

[0069] The cover layer can comprise an orifice and negative pressure is applied to the wound site through the orifice.

[0070] Any of the features, components, or details of any of the arrangements or embodiments disclosed in this application, including without limitation any of the dressing embodiments, pump embodiments, and any of the negative pressure wound therapy embodiments disclosed below, are interchangeably combinable with any other features, components, or details of any of the arrangements or embodiments disclosed herein to form new arrangements and embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0071] Embodiments of the present disclosure will now be described hereinafter, by way of example only, with reference to the accompanying drawings in which:

[0072] Figure 1A illustrates a cross section of an embodiment of an apertured nonwoven fabric layer;

[0073] Figure 1B illustrates a cross section of an embodiment of two apertured nonwoven fabric layers;

[0074] Figure 2A illustrates an embodiment of an apertured nonwoven fabric layer;

[0075] Figure 2B illustrates an embodiment of two apertured nonwoven fabric layers with one nonwoven fabric layer inverted over the other to create a spacer layer for use in a wound dressing;

[0076] Figure 3A illustrates an embodiment of a nonwoven spacer layer with a three dimensional structure;

[0077] Figure 3B illustrates a cross section of an embodiment of a spacer layer with a plurality of material layers including a layer with a three dimensional structure;

[0078] Figure 3C illustrates a cross section of an embodiment of a spacer layer with a plurality of nonwoven material layers including a plurality of layers with a three dimensional structure;

[0079] Figure 4A illustrates an embodiment of a negative pressure wound treatment system employing a flexible fluidic connector and a wound dressing capable of absorbing and storing wound exudate;

[0080] Figure 4B illustrates an embodiment of a negative pressure wound treatment system employing a flexible fluidic connector and a wound dressing capable of absorbing and storing wound exudate;

[0081] Figure 4C illustrates an embodiment of a negative pressure wound treatment system employing a flexible fluidic connector and a wound dressing capable of absorbing and storing wound exudate;

[0082] Figure 4D illustrates a cross section of an embodiment of a fluidic connector connected to a wound dressing;

[0083] Figures 5A-5D illustrates an embodiment of a wound treatment system employing a wound dressing capable of absorbing and storing wound exudate to be used without negative pressure;

[0084] Figure 5E illustrates a cross section of an embodiment of a wound treatment system employing a wound dressing capable of absorbing and storing wound exudate to be used without negative pressure;

[0085] Figures 6A-6B illustrate an embodiment of a wound dressing incorporating the source of negative pressure and/or other electronic components within the wound dressing;

[0086] Figure 6C illustrates an embodiment of layers of a wound dressing with the pump and electronic components offset from the absorbent area of the dressing;

[0087] Figure 7A illustrates an embodiment of a negative pressure wound treatment system employing a flexible fluidic connector and a wound dressing with a wrapped around spacer layer, the wound dressing capable of absorbing and storing wound exudate;

[0088] Figure 7B illustrates a cross sectional view of an embodiment of a negative pressure wound treatment system employing a flexible fluidic connector and a wound dressing with a wrapped around spacer layer, the wound dressing capable of absorbing and storing wound exudate;

[0089] Figure 7C illustrates an embodiment of a negative pressure wound treatment system employing a wound dressing capable of absorbing and storing wound exudate;

[0090] Figure 8A illustrates another embodiment of a wound dressing in cross-section; and

[0091] Figure 8B illustrates a perspective view of an embodiment of a wound dressing including an obscuring layer and viewing windows.

DETAILED DESCRIPTION

[0092] The disclosed technology relates to the wound dressing disclosed herein, and to methods and uses disclosed herein.

[0093] At least some embodiments of the disclosed technology disclosed herein are described below.

[0094] Embodiments disclosed herein relate to apparatuses and methods of treating a wound with or without reduced pressure, including optionally a source of negative pressure and wound dressing components and apparatuses. The apparatuses and components comprising the wound overlay and packing materials, if any, are sometimes collectively referred to herein as dressings. In some embodiments, the wound dressing can be provided to be utilized without reduced pressure.

[0095] Preferred embodiments disclosed herein relate to wound therapy for a human or animal body. Therefore, any reference to a wound herein can refer to a wound on a human or animal body, and any reference to a body herein can refer to a human or animal body. The term “wound” as used herein, in addition to having its broad ordinary meaning, includes any body part of a patient that may be treated using negative pressure. It is to be understood that the term wound is to be broadly construed and encompasses open and closed wounds in which skin is torn, cut or punctured or where trauma causes a contusion, or any other superficial or other conditions or imperfections on the skin of a patient or otherwise that benefit from reduced pressure treatment. A wound is thus broadly defined as any damaged region of tissue where fluid may or may not be produced. Examples of such wounds include, but are not limited to, abdominal wounds or other large or incisional wounds, either as a result of surgery, trauma, sterniotomies, fasciotomies, or other conditions, dehisced wounds, acute wounds, chronic wounds, subacute and dehisced wounds, traumatic wounds, flaps and skin grafts, lacerations, abrasions, contusions, bums, diabetic ulcers, pressure ulcers, stoma, surgical wounds, trauma and venous ulcers or the like.

[0096] As used herein a chronic wound is one that does not heal in an orderly set of stages and in a predictable amount of time the way most wounds do; wounds that do not heal within three months are often considered chronic. For example a chronic wound may include an ulcer such as a diabetic ulcer, a pressure ulcer (or pressure injury), or venous ulcer.

[0097] Treatment of such wounds can be performed using negative pressure wound therapy, wherein a reduced or negative pressure can be applied to the wound to facilitate and promote healing of the wound. It will also be appreciated that the wound dressing and methods as disclosed herein may be applied to other parts of the body, and are not necessarily limited to treatment of wounds.

[0098] It will be understood that embodiments of the present disclosure are generally applicable to use in topical negative pressure ("TNP") therapy systems. Briefly, negative pressure wound therapy assists in the closure and healing of many forms of "hard to heal" wounds by reducing tissue oedema; encouraging blood flow and granular tissue formation; removing excess exudate and may reduce bacterial load (and thus infection risk). In addition, the therapy allows for less disturbance of a wound leading to more rapid healing. TNP therapy systems may also assist in the healing of surgically closed wounds by removing fluid and by helping to stabilize the tissue in the apposed position of closure. A further beneficial use of TNP therapy can be found in grafts and flaps where removal of excess fluid is important and close proximity of the graft to tissue is required in order to ensure tissue viability.

[0099] As is used herein, reduced or negative pressure levels, such as -X mmHg, represent pressure levels relative to normal ambient atmospheric pressure, which can correspond to 760 mmHg (or 1 atm, 29.93 inHg, 101.325 kPa, 14.696 psi, etc.). Accordingly, a negative pressure value of -X mmHg reflects absolute pressure that is X mmHg below 760 mmHg or, in other words, an absolute pressure of (760-X) mmHg. In addition, negative pressure that is "less" or "smaller" than X mmHg corresponds to pressure that is closer to atmospheric pressure (e.g.,-40 mmHg is less than -60 mmHg). Negative pressure that is "more" or "greater" than -X mmHg corresponds to pressure that is further from atmospheric pressure (e.g., -80 mmHg is more than -60 mmHg). In some embodiments, local ambient atmospheric pressure is used as a reference point, and such local atmospheric pressure may not necessarily be, for example, 760 mmHg.

[0100] The negative pressure range for some embodiments of the present disclosure can be approximately -80 mmHg, or between about -20 mmHg and -200 mmHg. Note that these pressures are relative to normal ambient atmospheric pressure, which can be 760 mmHg. Thus, -200 mmHg would be about 560 mmHg in practical terms. In some embodiments, the pressure range can be between about -40 mmHg and -150 mmHg. Alternatively a pressure range of up to -75 mmHg, up to -80 mmHg or over -80 mmHg can be used. Also in other embodiments a pressure range of below -75 mmHg can be used. Alternatively, a pressure range of over approximately -100 mmHg, or even -150 mmHg, can be supplied by the negative pressure apparatus.

[0101] In some embodiments of wound closure devices described herein, increased wound contraction can lead to increased tissue expansion in the surrounding wound tissue. This effect may be increased by varying the force applied to the tissue, for example by varying the negative pressure applied to the wound over time, possibly in conjunction with increased tensile forces applied to the wound via embodiments of the wound closure devices. In some embodiments, negative pressure may be varied over time for example using a sinusoidal wave, square wave, or in synchronization with one or more patient physiological indices (e.g., heartbeat). Examples of such applications where additional disclosure relating to the preceding may be found include U.S. Patent No. 8,235,955, titled "Wound treatment apparatus and method," issued on August 7, 2012; and U.S. Patent No. 7,753,894, titled "Wound cleansing apparatus with stress," issued July 13, 2010. The disclosures of both of these patents are hereby incorporated by reference in their entireties.

[0102] Embodiments of the wound dressings, wound dressing components, wound treatment apparatuses and methods described herein may also be used in combination or in addition to those described in International Application No. PCT/IB2013/001469, filed May 22, 2013, published as WO 2013/175306 A2 on November 28, 2013, titled "APPARATUSES AND METHODS FOR NEGATIVE PRESSURE WOUND THERAPY," International Application No. PCT/IB2013/002060, filed on July 31, 2013 published as WO2014/020440, entitled “WOUND DRESSING,” the disclosures of which are hereby incorporated by reference in their entireties. Embodiments of the wound dressings, wound treatment apparatuses and methods described herein may also be used in combination or in addition to those described in U.S. Patent Application No. 13/092,042, filed April 21 2011, US Patent No. 9,061,095, titled "WOUND DRESSING AND METHOD OF USE," and U.S. Patent Application No. 14/715,527, filed May 18, 2015, titled “FLUIDIC CONNECTOR FOR NEGATIVE PRESSURE WOUND THERAPY,” the disclosures of which are hereby incorporated by reference in their entireties, including further details relating to embodiments of wound dressings, the wound dressing components and principles, and the materials used for the wound dressings.

[0103] Additionally, some embodiments related to TNP wound treatment comprising a wound dressing in combination with a pump or associated electronics described herein may also be used in combination or in addition to those described in International Patent Application No. PCT/EP2016/059329, filed on April 26, 2016, entitled “REDUCED PRESSURE APPARATUSES,” published as WO 2016/174048, on November 3, 2016, the entirety of which is hereby incorporated by reference. In some of these embodiments, the pump or associate electronic components may be integrated into the wound dressing to provide a single article to be applied to the wound.

Nonwoven Material

[0104] Figure 1A illustrates an apertured nonwoven fabric material. The apertured nonwoven fabric material can be similar to the nonwoven material as described in European Patent No. 1644564 B1, entitled “NONWOVEN SPACER FABRIC,” publication and mention of the grant of the patent on June 1, 2016, which discloses a method of creating an apertured nonwoven and the contents of which are incorporated by reference in its entirety. In some embodiments, the nonwoven fabric material can be an apertured hydroentangled nonwoven. The hydroentangled nonwoven can consist of two webs of material bonded together with a hydroentanglement process. The hydroentanglement process is a bonding process for wet or dry fibrous webs to form a nonwoven. The hydroentanglement process entangles the fibers by using a fine, high pressure jets of water that penetrate the web, hit the conveyor belt, and bounce back causing the entanglement. Through this process, the two webs of material can be bonded together in a manner which enables the formation of channels or apertures in the structure.

[0105] Figure 1A illustrates an embodiment of a nonwoven fabric layer 11. The nonwoven fabric layer 11 can include an interconnected first fibrous face layer 13 and a first fibrous base layer 15. In some embodiments, the first face can include channels or apertures 18 created by the hydroentanglement process or some other forming process. The channels or apertures 18 create void spaces within the nonwoven. In some embodiments, the channels or apertures 18 can show as a corrugated surface, protruded channels, or more subtle channels depending on the diameter of the material used to produce them and the density of the top web. As used herein, the term “layer” can refer to a single layer of material or multiple layers of materials.

[0106] The channels or apertures created in the nonwoven material can be utilized for the structure they provide in the material. The fiber choice and bonding level can be engineered to provide rigidity and desirable compression/recovery performance. In some embodiments, the nonwoven fabric layer can be a blend of polyester and biocomponent fiber to produce a rigid blend. In some embodiments, the nonwoven fabric layer can include fiber blends or synthetic or cellulosic fibers, including thermoplastic and bi-component fibers. In some embodiments, the nonwoven fabric layer can be engineered with a hydrophilic fabric face and a hydrophobic fabric back or base utilizing web placement and different fiber mixes. In other embodiments, the fabric face can be hydrophobic and the fabric back or base can be hydrophilic.

[0107] As shown in Figure 1A, the apertured nonwoven layer can have a substantially constant cross-section across the length of the apertured nonwoven layer. The channels and apertures 18 can have a rectangular shape similar to that shown in Figure 1A with rectangular depressions 17 forming around the channels. In other embodiments, the channels can be rounded channels in the material or triangular channels in the material. The rounded channels can show as a corrugated surface. In some embodiments, the height and width of the apertured tunnels of the nonwoven fabric layer may vary between 0.5-5mm. In some embodiments, the height and width of the apertured tunnels may be between about 0.5-1 mm, about 1-2 mm, about 2-3 mm, about 3-4 mm, and about 4-5 mm. In order to create two-way conformability, the apertured lines of the nonwoven fabric layer may be slit, zig-zagged, or created to make a checker board affect. In some embodiments, a single layer of the apertured nonwoven layer can be used as a nonwoven fabric spacer layer in a wound dressing.

[0108] In some embodiments, two layers of this structure can be inverted onto one another to create a spacer type layer as shown in Figure 1B. Figure 1B illustrates an embodiment of two nonwoven layers 11, 12 that can form a nonwoven fabric spacer layer. In some embodiments, the nonwoven fabric layers can be a hydroentangled nonwoven layer. The first nonwoven fabric layer 11 can have an interconnected first fibrous face layer 13 and a first fibrous base layer 15. The second nonwoven fabric layer 12 can include an interconnected second fibrous face layer 14 and a second fibrous base layer 16. The first nonwoven fabric layer 11 can be inverted onto the second nonwoven fabric layer 12 to create a spacer type layer for use in a wound dressing. As illustrated in Figure 1B, the first face layer 13 of the first nonwoven fabric layer 11 can be in contact with the second face layer 14 of the second nonwoven fabric layer 12.

[0109] In some embodiments, the layer formed from the two nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. For example, in some embodiments, the spacer layer formed from the nonwoven fabric layers as described herein can remain open upon application of negative pressure to the layer and/or a wound dressing. In some embodiments, the apertures, channels, and/or slits of the nonwoven fabric layer can allow for unique fluid management properties.

[0110] Figure 2A illustrates an embodiment of a nonwoven fabric layer 11 with apertures or channels 18. Figure 2B illustrates an embodiment of two nonwoven fabric layers 11, 12 with one nonwoven fabric layer inverted over the other to create a spacer layer for use in a wound dressing. As illustrated in Figure 2B, a first nonwoven fabric layer 11 can be inverted so that a first face layer 13 of first nonwoven fabric layer 11 is in contact with the second face layer 14 of the second nonwoven fabric layer 12. The plurality of channels of the second nonwoven fabric layer 12 can be disposed embedded within the depressions between the plurality of channels of the first nonwoven fabric layer 11 as shown in Figure 2B. In some embodiments, the plurality of channels of the second nonwoven fabric layer 12 can be disposed directly over the plurality of channels of the first nonwoven fabric layer 11. In such an embodiment, the spacer layer would be different from that shown in Figures 1B and 2B because the second nonwoven fabric layer would sit on top of the first nonwoven fabric layer as opposed to being embedded within each other.

[0111] In some embodiments, the channels of the first or second nonwoven fabric layers extend across an entire length of the first and second nonwoven fabric layers. The channels of the first nonwoven fabric layer extend in a first direction and the channels of the second nonwoven fabric layer extend in a second direction. In some embodiments, the channels of the first nonwoven fabric layer can be parallel to the channels of the second nonwoven fabric layer. In other embodiments, the channels of the first nonwoven fabric layer can be perpendicular to the channels of the second nonwoven fabric layer. In such an embodiment, the spacer layer would be different from that shown in Figures 1A and 2B because the second nonwoven fabric layer would sit on top of the first nonwoven fabric layer as opposed to being embedded within each other. The plurality of channels of the second nonwoven fabric layer can be offset from the plurality of channels of the first nonwoven fabric layer. In some embodiments, the channels can be straight as they extend across the length of the nonwoven fabric layer. In other embodiments, the channels can be zig zag as they extend across the length of the nonwoven fabric layer.

[0112] Figure 3A illustrates an embodiment of a nonwoven spacer layer 12 with a three dimensional structure for use in a wound dressing.

[0113] In some embodiments, the three dimensional nonwoven spacer layer 12 can be used as a spacer or transmission layer in a wound dressing as described herein. In some embodiments, the three dimensional nonwoven material constructions as described herein can provide a high level of compression recovery and a unique compression under loading characteristic which may not be currently available in traditional nonwoven constructions. These properties can allow for the three dimensional nonwoven spacer layer to be used in a wound dressing and allow transmission of fluids through the open channels in the spacer layer even while the dressing is compressed.

[0114] In some embodiments, a typical nonwoven fabric can be constructed into a three dimensional (3D) structure. The three dimensional structure can be an egg-box type construction as illustrated in Figure 3A.

[0115] In some embodiments, heat and pressure can be used to set the nonwoven into a 3D structure such as in a corrugated construction, a three dimensional zig-zag pattern, an egg-box type construction, a checkerboard construction, and a hexagonal (honeycomb) construction. The three dimensional zig zag construction can be similar to the corrugated construction but instead of corrugated lines a shape such as a zig zag can allow for 2-way conformability. The fiber based media of the nonwoven material can enable compression recovery properties of a spacer layer.

[0116] In some embodiments, the nonwoven material can be thermoformed into the three dimensional construction. In other embodiments, the three dimensional nonwoven material can be formed using a chemical bonding and vacuum forming.

[0117] In some embodiments, the three dimensional nonwoven spacer layer can consist of two or three layers of polypropylene based hydroentangled nonwoven molded into an egg-box style pattern to about 2-10 mm thickness each. In some embodiments, the three dimensional nonwoven spacer layer can consist of two or three layers of polypropylene based hydroentangled nonwoven molded into an egg-box style pattern to less than 2 mm, about 2-3 mm, about 3-4 mm, about 4-5 mm, about 5-6 mm, about 6-7 mm, about 7-8 mm, about 8-9 mm, about 9-10 mm, and/or greater than 10 mm thickness each. In some embodiments, the three dimensional nonwoven spacer layer can consist of two or three layers of polypropylene based hydroentangled nonwoven molded into an egg-box style pattern to around 3mm thickness each. The nonwoven can be either 100% thermoplastic fiber content or a blend of thermoplastic fibers and other fibers such as viscose or gellable fibers. In some embodiments, the nonwoven spacer layer may include binder fibers or bicomponent fibers. The nonwoven may be produced by traditional nonwoven technologies such as airlaying, carding, or meltspinning. In some embodiments, isotropic nonwovens may also be used. In some embodiments, the nonwoven can be nonisotropic. In some embodiments, the three dimensional nonwoven material can use shape memory polymers.

[0118] In some embodiments, the three dimensional construction can be layered with other nonwovens and/or multiple layers of three dimensional nonwoven layers to form the spacer layer. Figure 3B illustrates a cross section of an embodiment of a nonwoven spacer layer with a plurality of material layers including a layer with a three dimensional nonwoven structure. The three dimensional nonwoven spacer layer 31 includes a three dimensional nonwoven layer 32 and support layers 33 and 34. The support layers 33 and 34 can be positioned above and below the three dimensional nonwoven layer 32 as shown in Figure 3B. The support layers 33 and 34 can be a nonwoven material or any other material described herein for use in the spacer layer or transmission layer. In some embodiments, the support layers 33 and 34 can be the same materials and material construction. In other embodiments, the support layers 33 and 34 can be formed of different materials and different material construction. In some embodiments, the support layer 33 and 34 can include open fibers that are perforated to provide a clear channel for the transfer of negative pressure through the three dimensional nonwoven spacer layer 31 and through other wound dressing layers. In some embodiments, the support layers can be a traditional nonwoven such as needlepunched or meltspun nonwovens. In some embodiments, the support layer can be a knitted or woven textile or a foam. In some embodiments, the support layer can be an extruded web, net or film or a 3D printed structure. The support layer can be perforated films, nets, webs, and/or pulp based materials such as a cellulose “paper”. The support layer can be acting as a bridging layer to keep the channels or fluid flow path through the material open. In some embodiments, the nonwovens could contain superabsorbent fibers or particles.

[0119] Figure 3C illustrates a cross section of an embodiment of a spacer layer with a plurality of material layers including a plurality of layers with a three dimensional structure. The three dimensional nonwoven 31 includes a first three dimensional nonwoven layer 35, a second three dimensional nonwoven layer 36, and a support layer 37. The support layer 37 can be positioned between the first and second three dimensional nonwoven layers 35 and 36. The support layer 37 can be a nonwoven material or any other material described herein for use in the spacer layer or transmission layer. In some embodiments, the support layer 37 can include open fibers that are perforated to provide a clear channel for the transfer of negative pressure through the three dimensional nonwoven spacer layer 31 and through other wound dressing layers. In some embodiments, the support layers can be a traditional nonwoven such as needlepunched or meltspun nonwovens. In some embodiments, the support layer can be a knitted or woven textile or a foam. In some embodiments, the support layer can be an extruded web, net or film or a 3D printed structure. The support layer can be perforated films, nets, webs, and/or a pulp based materials such as a cellulose “paper”. The support layer can be acting as a bridging layer to keep the channels or fluid flow path through the material open. In some embodiments, the nonwovens could contain superabsorbent fibers or particles.

[0120] In some embodiments, the spacer layer can include a first three dimensional nonwoven spacer layer and a second three dimensional nonwoven spacer layer. The first three dimensional nonwoven spacer layer can be disposed over the second three dimensional nonwoven spacer layer. The first and second three dimensional nonwoven spacer layer can be a thermoformed nonwoven fabric layer.

Wound Dressing

[0121] In some embodiments, the one or more layers of apertured nonwoven layers, similar to the aperture nonwoven layers described with reference to Figures 1A-2B, may be placed into a wound dressing. In some embodiments, the wound dressing can include a wound contact layer, two hydroentangled nonwoven layers with one inverted over the other to create a spacer type layer, an absorbent layer, and a top film or backing layer. In some embodiments, the absorbent layer can overly and directly contact the spacer layer.

[0122] In some embodiments, the constructed three dimensional nonwoven, similar to the three dimensional nonwoven spacer layers described with reference to Figures 3A-3C, may be placed into a wound dressing. In some embodiments, the wound dressing can include a wound contact layer, a three dimensional nonwoven spacer layer, an absorbent layer, and a top film or backing layer.

[0123] In some embodiments, the absorbent layer can comprise a nonwoven containing superabsorbent particles or fibers. In some embodiments, the top film or backing layer can be a moisture vapor permeable material. In some embodiments, the dressing can include a masking layer positioned below the top film or backing layer. In some embodiments, the absorbent layer can overly and directly contact the spacer layer.

[0124] The wound dressing may be suitable to include within a negative pressure wound apparatus.

[0125] The wound dressing may be suitable to include within a non-negative pressure wound apparatus.

[0126] The dressing is designed to be easy to apply and may be removed in one piece.

[0127] In one embodiment the dressing does not require secondary retention.

[0128] The wound dressing may be wrapped and sterile.

[0129] The wound dressing may be a negative pressure wound dressing, or a non-negative pressure wound dressing.

[0130] The disclosed technology in one embodiment relates to a non-negative pressure wound therapy kit comprising the wound dressing.

[0131] The wound dressing may be used as the dressing component of a negative pressure wound dressing apparatus. The apparatus in different embodiments comprises a canister and is free of the canister.

[0132] In one embodiment the disclosed technology relates to a negative pressure wound therapy kit comprising a wound dressing outlined above and a negative pressure source configured to be fluidically connected to the wound dressing.

[0133] In one embodiment the disclosed technology relates to a method of providing negative pressure wound therapy to a wound, the method comprising:

placing the wound dressing outlined above over a wound;

forming a fluid flow path between the wound dressing and a negative pressure source; and

operating the negative pressure source to provide negative pressure to the wound.

[0134] In one embodiment the disclosed technology relates to a method of operating a negative pressure wound system, the method comprising:

operating a negative pressure source fluidically connected to a wound dressing outlined above, the wound dressing configured to be positioned over a wound.

[0135] The wound dressing may be used as wound dressing for a non-negative pressure wound dressing apparatus.

[0136] In one embodiment the disclosed technology relates to a method of placing the wound dressing disclosed herein comprising an absorbent layer, wherein the wound dressing configured to be positioned over a wound, and exudate may be removed by evaporating exudate through an absorbent layer.

[0137] The wound dressing disclosed herein may be placed over a wound for 1 to 10 days, typically 3-7 days. The wound dressing may be replaced either when the wound is in the opinion of the HCP sufficiently healed, and/or when any absorbent layer/canister is saturated/full. The wound dressing can be replaced and/or canister can be replaced leaving the original dressing in place.

[0138] In one embodiment the non-negative pressure wound therapy kit comprises or consists of:

a wound dressing disclosed herein; and

a dressing fixative (may also be defined as a secondary retention).

[0139] The dressing fixative may be securing means that can include adhesive (e.g. with pressure-sensitive adhesive) and non-adhesive, and elastic and non-elastic straps, bands, loops, strips, ties, bandages, e.g. compression bandages, sheets, covers, sleeves, jackets, sheathes, wraps, stockings and hose, e.g. elastic tubular hose or elastic tubular stockings that are a compressive fit over a limb wound to apply suitable pressure to it when the therapy is applied in this way; and inflatable cuffs, sleeves, jackets, trousers, sheathes, wraps, stockings and hose that are a compressive fit over a limb wound to apply suitable pressure to it when the therapy is applied in this way.

[0140] Such securing means may each be laid out over the wound dressing to extend beyond the periphery of the backing layer of the wound dressing, and as appropriate will be adhered or otherwise secured to the skin around the wound and/or itself and as appropriate will apply compression (e.g. with elastic bandages, stockings) to a degree that is sufficient to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound.

[0141] Such securing means may each be integral with the other components of the dressing, in particular the backing layer.

[0142] Alternatively, it may be permanently attached or releasably attached to the dressing, in particular the backing layer, with an adhesive film, for example, or these components may be a Velcro ™, push snap or twist-lock fit with each other.

[0143] The securing means and the dressing may be separate structures, permanently unattached to each other.

[0144] In one embodiment the dressing fixative may include a bandage, tubular or compression bandage, tape, gauze, or backing layer.

[0145] In one embodiment the disclosed technology relates to a non-negative pressure method of providing wound therapy to a wound, the method comprising: placing the wound dressing disclosed herein over a wound; and securing the wound dressing with a dressing fixative such as a bandage, tape, gauze, or backing layer.

Backing Layer

[0146] In one embodiment the wound dressing further comprises a backing layer.

[0147] The backing layer may be transparent or opaque film. The transparent backing layer (may be referred to as top layer or top film) may provide the healthcare professional (HCP) with the ability to carry out regular assessments of the wound site including the peri-wound area and the wound itself without the need to lift or remove the dressing. This may allow the HCP to react early to signs that could potentially delay the healing process. Encouraging healing and reducing the chance of infection can lead to shorter recovery times and lower treatment costs.

[0148] The material used to form the transparent backing layer may have a high Moisture Vapor Transmission Rate (MVTR), thereby allowing unwanted moisture to transpire and helps prevent infection and maceration.

[0149] The transparent backing layer may be waterproof, thereby enabling the patient to shower/bathe with the dressing in situ.

[0150] The transparent backing layer may provide a barrier against bacteria, including methicillin-resistant staphylococcus aureus (MRSA). This will reduce the incidences of surgical site infections (SSI) and healthcare associated infections (HAI), reducing possible associated costs to healthcare provider and extended hospital stay for the patient.

[0151] The transparent backing layer may further act as a barrier to water and dirt.

[0152] The backing layer may be a film. In one embodiment the backing layer is a polyurethane film. The polyurethane film may be optionally functionalized with additives such as antimicrobial agents, odor control, pigments, dyes or UV disruptors. The backing layer may be a monolithic or microporous film or a foam. It may also be an impermeable film.

[0153] In one embodiment the wound dressing does not further comprise a backing layer.

<u>Adhesive Layer</u>

[0154] In one embodiment the wound dressing further comprises an adhesive layer.

[0155] The adhesive layer may be located:

(i) between the first layer and the second layer of the disclosed technology and/or

(ii) at the peripheral edges of the backing layer if present (typically a transparent film layer) that extend beyond the peripheral edges of any absorbent layer present.

[0156] The adhesive may be a silicone adhesive or an acrylic adhesive.

[0157] The adhesive may be spread evenly across the surfaces of the first and second layer of the disclosed technology. An even spread of adhesive may ensure that the surfaces of the layers of the disclosed technology are securely joined.

[0158] If the adhesive layer is on the underside of the backing layer it provides adhesion to the wound dressing to a peri-wound area.

[0159] Alternatively, the adhesive can be spread in a pattern to increase breathability of the film and improve comfort upon removal.

[0160] The adhesive used may be low allergy. This type of adhesive reduces the trauma upon removal of the dressings and/or lessens the risk of an allergic reaction.

[0161] In one embodiment the wound dressing may include a number of layers that are built up in a generally laminar fashion to form a dressing having a relatively planar form. Examples of such a wound dressing may for instance be disclosed in WO2013/007793.

[0162] In one embodiment the wound dressing may include a border region extending around the outer periphery of the dressing and a raised central region (or pouch) in the center of the dressing (in plain view). The precise dimensions of the border region and the central region may be predetermined to suit a particular wound or particular wound type.

[0163] Alternatively in another embodiment there may be no border region required. Here the border region has the general function of providing an area for sealingly engaging with a patient's skin surrounding a wound site to form a sealed cavity over the wound site. The central region is the location of further functional elements of the wound dressing.

[0164] The wound dressing disclosed herein may include a perforated wound contact layer and a top film. Further components of the wound dressing optionally include in no particular order:

- A layer of polyurethane hydrocellular foam of a suitable size to cover the wound and peri-wound,
- A layer of activated charcoal cloth of similar or slightly smaller dimensions than, to allow for odor control with limited aesthetic impact on the wound side,
- A layer of superabsorbent air-laid material containing cellulose fibers and a superabsorbent polyacrylate particulates, of dimensions slightly larger than to allow for an overlap of superabsorbent material acting as leak prevention,
- A layer of three-dimensional knitted spacer fabric, providing protection from pressure, while allowing partial masking of the top surface of the superabsorber, where colored exudate would remain. In this embodiment this is of smaller dimension (in plain view) than the layer, to allow for visibility of the edge of the absorbent layer, which can be used by clinicians to assess whether the dressing needs to be changed. In this embodiment the wound contact layer may be a perforated polyurethane film that is coated with a skin-compatible adhesive, such as pressure sensitive acrylic adhesive or silicone adhesive.

[0165] In separate embodiments the wound dressing comprises two, three, or all of the layers disclosed above.

[0166] In one embodiment the wound dressing comprises all of the layers disclosed above in the order of a layer of polyurethane hydrocellular foam to the three-dimensional knitted spacer fabric in the specified order.

[0167] Alternatively the wound contact layer may be formed from any suitable polymer, e.g. silicone, ethylvinyl acetate, polyethylene, polypropylene, or polyester, or a combination thereof. The skin-compatible adhesive is coated on the lower side of the layer, i.e. the side that is to contact the patient. Aptly the adhesive is coated as a continuous layer on the underside of the layer. The adhesive may be coated in a semi-continuous layer such as in a pattern such as a checkerboard pattern, polka dot pattern, herring bone pattern, mesh pattern or other suitable pattern.

Dressings

[0168] Figures 4A-B illustrate embodiments of a negative pressure wound treatment system 10 employing a wound dressing 100 in conjunction with a fluidic connector 110. Additional examples related to negative pressure wound treatment comprising a wound dressing in combination with a pump as described herein may also be used in combination or in addition to those described in US Patent No. 9,061,095, which is incorporated by reference in its entirety. Here, the fluidic connector 110 may comprise an elongate conduit, more preferably a bridge 120 having a proximal end 130 and a distal end 140, and an applicator 180 at the distal end 140 of the bridge 120. An optional coupling 160 is preferably disposed at the proximal end 130 of the bridge 120. A cap 170 may be provided with the system (and can in some cases, as illustrated, be attached to the coupling 160). The cap 170 can be useful in preventing fluids from leaking out of the proximal end 130. The system 10 may include a source of negative pressure such as a pump or negative pressure unit 150 capable of supplying negative pressure. The pump may comprise a canister or other container for the storage of wound exudates and other fluids that may be removed from the wound. A canister or container may also be provided separate from the pump. In some embodiments, such as illustrated in Figures 4A-4B, the pump 150 can be a canisterless pump such as the PICO™ pump, as sold by Smith & Nephew. The pump 150 may be connected to the coupling 160 via a tube 190, or the pump 150 may be connected directly to the coupling 160 or directly to the bridge 120. In use, the dressing 100 is placed over a suitably-prepared wound, which may in some cases be filled with a wound packing material such as foam or gauze. The applicator 180 of the fluidic connector 110 has a sealing surface that is placed over an aperture in the dressing 100 and is sealed to the top surface of the dressing 100. Either before, during, or after connection of the fluidic connector 110 to the dressing 100, the pump 150 is connected via the tube 190 to the coupling 160, or is connected directly to the coupling 160 or to the bridge 120. The pump is then activated, thereby supplying negative pressure to the wound. Application of negative pressure may be applied until a desired level of healing of the wound is achieved.

[0169] As shown in Figure 4C, the fluidic connector 110 preferably comprises an enlarged distal end, or head 140 that is in fluidic communication with the dressing 100 as will be described in further detail below. In one embodiment, the enlarged distal end has a round or circular shape. The head 140 is illustrated here as being positioned near an edge of the dressing 100, but may also be positioned at any location on the dressing. For example, some embodiments may provide for a centrally or off-centered location not on or near an edge or corner of the dressing 100. In some embodiments, the dressing 10 may comprise two or more fluidic connectors 110, each comprising one or more heads 140, in fluidic communication therewith. In a preferred embodiment, the head 140 may measure 30mm along its widest edge. The head 140 forms at least in part the applicator 180, described above, that is configured to seal against a top surface of the wound dressing.

[0170] Figure 4D illustrates a cross-section through a wound dressing 100 similar to the wound dressing 10 as shown in Figure 4B and described in International Patent Publication WO2013175306 A2, which is incorporated by reference in its entirety, along with fluidic connector 110. The wound dressing 100, which can alternatively be any wound dressing embodiment disclosed herein or any combination of features of any number of wound dressing embodiments disclosed herein, can be located over a wound site to be treated. The dressing 100 may be placed as to form a sealed cavity over the wound site. In a preferred embodiment, the dressing 100 comprises a top or cover layer, or backing layer 220 attached to an optional wound contact layer 222, both of which are described in greater detail below.

These two layers 220, 222 are preferably joined or sealed together so as to define an interior space or chamber. This interior space or chamber may comprise additional structures that may be adapted to distribute or transmit negative pressure, store wound exudate and other fluids removed from the wound, and other functions which will be explained in greater detail below. Examples of such structures, described below, include a transmission layer 226 and an absorbent layer 221.

[0171] As used herein the upper layer, top layer, or layer above refers to a layer furthest from the surface of the skin or wound while the dressing is in use and positioned over the wound. Accordingly, the lower surface, lower layer, bottom layer, or layer below refers to the layer that is closest to the surface of the skin or wound while the dressing is in use and positioned over the wound.

[0172] As illustrated in Figure 4D, the wound contact layer 222 can be a polyurethane layer or polyethylene layer or other flexible layer which is perforated, for example via a hot pin process, laser ablation process, ultrasound process or in some other way or otherwise made permeable to liquid and gas. The wound contact layer 222 has a lower surface 224 and an upper surface 223. The perforations 225 preferably comprise through holes in the wound contact layer 222 which enable fluid to flow through the layer 222. The wound contact layer 222 helps prevent tissue ingrowth into the other material of the wound dressing. Preferably, the perforations are small enough to meet this requirement while still allowing fluid to flow therethrough. For example, perforations formed as slits or holes having a size ranging from 0.025 mm to 1.2 mm are considered small enough to help prevent tissue ingrowth into the wound dressing while allowing wound exudate to flow into the dressing. In some configurations, the wound contact layer 222 may help maintain the integrity of the entire dressing 100 while also creating an air tight seal around the absorbent pad in order to maintain negative pressure at the wound.

[0173] Some embodiments of the wound contact layer 222 may also act as a carrier for an optional lower and upper adhesive layer (not shown). For example, a lower pressure sensitive adhesive may be provided on the lower surface 224 of the wound dressing 100 whilst an upper pressure sensitive adhesive layer may be provided on the upper surface 223 of the wound contact layer. The pressure sensitive adhesive, which may be a silicone, hot melt, hydrocolloid or acrylic based adhesive or other such adhesives, may be formed on both sides or optionally on a selected one or none of the sides of the wound contact layer. When a lower pressure sensitive adhesive layer is utilized may be helpful to adhere the wound dressing 100 to the skin around a wound site. In some embodiments, the wound contact layer may comprise perforated polyurethane film. The lower surface of the film may be provided with a silicone pressure sensitive adhesive and the upper surface may be provided with an acrylic pressure sensitive adhesive, which may help the dressing maintain its integrity. In some embodiments, a polyurethane film layer may be provided with an adhesive layer on both its upper surface and lower surface, and all three layers may be perforated together.

[0174] A transmission layer 226 can be located above the wound contact layer 222. In some embodiments, the transmission layer can be a porous material. As used herein the transmission layer can be referred to as a spacer layer and the terms can be used interchangeably to refer to the same component described herein. This transmission layer 226 allows transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing. In particular, the transmission layer 226 preferably ensures that an open air channel can be maintained to communicate negative pressure over the wound area even when the absorbent layer has absorbed substantial amounts of exudates. The layer 226 should preferably remain open under the typical pressures that will be applied during negative pressure wound therapy as described above, so that the whole wound site sees an equalized negative pressure. The layer 226 may be formed of a material having a three dimensional structure. For example, a knitted or woven spacer fabric (for example Baltex 7970 weft knitted polyester) or a non-woven fabric could be used. The three dimensional material can comprise a 3D spacer fabric material similar to the material described in International Application WO 2013/175306 A2 and International Application WO2014/020440, the disclosures of which are incorporated by reference in their entireties.

[0175] In some embodiments, the layer 226 can comprise an apertured nonwoven fabric spacer layer formed from the two layers of nonwoven fabric as described previously herein and illustrated in Figures 1A-2B. In some embodiments, the apertured nonwoven fabric spacer layer can include a first nonwoven fabric layer and a second nonwoven fabric layer. The first nonwoven fabric layer may be formed from an interconnected first fibrous face layer and a first fibrous base layer. The second nonwoven fabric layer can include an interconnected second fibrous face layer and a second fibrous base layer. The first nonwoven fabric layer can be inverted onto the second nonwoven fabric layer to create a spacer type layer for use in a wound dressing. The first face layer of the first nonwoven fabric layer can be in contact with and/or positioned on top of the second face layer of the second nonwoven fabric layer. In some embodiments, the nonwoven fabric layers can be a hydroentangled nonwoven layer.

[0176] In some embodiments, the plurality apertures of the nonwoven fabric layer can form a channel. The channels or apertures created in the nonwoven material can be utilized for the structure they provide in the material. For example, in some embodiments, the spacer layer formed from the nonwoven fabric layers as described herein can remain open upon application of negative pressure to the layer and/or a wound dressing. In some embodiments, the apertures, channels, and/or slits of the nonwoven fabric layer can allow for unique fluid management properties. In some embodiments, the layer formed from the two nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the apertured nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0177] In some embodiments, the layer 226 can comprise a three dimensional nonwoven spacer layer construction as described previously herein and illustrated in Figures 3A-3C. In some embodiments, heat and pressure can be used to set the nonwoven into a 3D structure such as in a corrugated construction, a three dimensional zig-zag pattern, an egg-box type construction, a checkerboard construction, and a hexagonal (honeycomb) construction. In some embodiments, the nonwoven material can be thermoformed into the three dimensional construction. In other embodiments, the three dimensional nonwoven material can be formed using a chemical bonding and vacuum forming.

[0178] In some embodiments, the 3D structure can be layered on top of one another or with traditional nonwovens to create a spacer type layer for use in a wound dressing.

[0179] For example, in some embodiments, the spacer layer formed from the nonwoven layers as described herein can remain open upon compression and/or application of negative pressure to the layer and/or a wound dressing. In some embodiments, the three dimensional structure of the nonwoven spacer layer can allow for unique fluid management properties. In some embodiments, the three dimensional nonwoven spacer layer formed from the nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the three dimensional nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0180] In some embodiments, a layer 221 of absorbent material is provided above the transmission layer 226. The absorbent material, which can comprise a foam or non-woven natural or synthetic material, and which may optionally comprise a super-absorbent material, forms a reservoir for fluid, particularly liquid, removed from the wound site. In some embodiments, the layer 221 may also aid in drawing fluids towards the backing layer 220.

[0181] The material of the absorbent layer 221 may also prevent liquid collected in the wound dressing 100 from flowing freely within the dressing, and preferably acts so as to contain any liquid collected within the dressing. The absorbent layer 221 also helps distribute fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and stored throughout the absorbent layer. This helps prevent agglomeration in areas of the absorbent layer. The capacity of the absorbent material must be sufficient to manage the exudates flow rate of a wound when negative pressure is applied. Since in use the absorbent layer experiences negative pressures the material of the absorbent layer is chosen to absorb liquid under such circumstances. A number of materials exist that are able to absorb liquid when under negative pressure, for example superabsorber material. The absorbent layer 221 may typically be manufactured from ALLEVYN™ foam, Freudenberg 114-224-4 or Chem-Posite™11C-450. In some embodiments, the absorbent layer 221 may comprise a composite comprising superabsorbent powder, fibrous material such as cellulose, and bonding fibers. In a preferred embodiment, the composite is an airlaid, thermally-bonded composite.

[0182] In some embodiments, the absorbent layer 221 is a layer of non-woven cellulose fibers having super-absorbent material in the form of dry particles dispersed throughout. Use of the cellulose fibers introduces fast wicking elements which help quickly and evenly distribute liquid taken up by the dressing. The juxtaposition of multiple strand-like fibers leads to strong capillary action in the fibrous pad which helps distribute liquid. In this way, the super-absorbent material is efficiently supplied with liquid. The wicking action also assists in bringing liquid into contact with the upper cover layer to aid increase transpiration rates of the dressing.

[0183] An aperture, hole, or orifice 227 is preferably provided in the backing layer 220 to allow a negative pressure to be applied to the dressing 100. The fluidic connector 110 is preferably attached or sealed to the top of the backing layer 220 over the orifice 227 made into the dressing 100, and communicates negative pressure through the orifice 227. A length of tubing may be coupled at a first end to the fluidic connector 110 and at a second end to a pump unit (not shown) to allow fluids to be pumped out of the dressing. Where the fluidic connector is adhered to the top layer of the wound dressing, a length of tubing may be coupled at a first end of the fluidic connector such that the tubing, or conduit, extends away from the fluidic connector parallel or substantially to the top surface of the dressing. The fluidic connector 110 may be adhered and sealed to the backing layer 220 using an adhesive such as an acrylic, cyanoacrylate, epoxy, UV curable or hot melt adhesive. The fluidic connector 110 may be formed from a soft polymer, for example a polyethylene, a polyvinyl chloride, a silicone or polyurethane having a hardness of 30 to 90 on the Shore A scale. In some embodiments, the fluidic connector 110 may be made from a soft or conformable material.

[0184] Optionally, the absorbent layer 221 includes at least one through hole 228 located so as to underlie the fluidic connector 110. The through hole 228 may in some embodiments be the same size as the opening 227 in the backing layer, or may be bigger or smaller. As illustrated in Figure 4D a single through hole can be used to produce an opening underlying the fluidic connector 110. It will be appreciated that multiple openings could alternatively be utilized. Additionally should more than one port be utilized according to certain embodiments of the present disclosure one or multiple openings may be made in the absorbent layer and the obscuring layer in registration with each respective fluidic connector. Although not essential to certain embodiments of the present disclosure the use of through holes in the super-absorbent layer may provide a fluid flow pathway which remains unblocked in particular when the absorbent layer is near saturation.

[0185] The aperture or through-hole 228 is preferably provided in the absorbent layer 221 beneath the orifice 227 such that the orifice is connected directly to the transmission layer 226 as illustrated in Figure 4D. This allows the negative pressure applied to the fluidic connector 110 to be communicated to the transmission layer 226 without passing through the absorbent layer 221. This ensures that the negative pressure applied to the wound site is not inhibited by the absorbent layer as it absorbs wound exudates. In other embodiments, no aperture may be provided in the absorbent layer 221, or alternatively a plurality of apertures underlying the orifice 227 may be provided. In further alternative embodiments, additional layers such as another transmission layer or an obscuring layer such as described with reference to Figures 8A-8B and in International Patent Publication WO2014/020440, the entirety of which is hereby incorporated by reference, may be provided over the absorbent layer 221 and beneath the backing layer 220.

[0186] The backing layer 220 is preferably gas impermeable, but moisture vapor permeable, and can extend across the width of the wound dressing 100. The backing layer 220, which may for example be a polyurethane film (for example, Elastollan SP9109) having a pressure sensitive adhesive on one side, is impermeable to gas and this layer thus operates to cover the wound and to seal a wound cavity over which the wound dressing is placed. In this way, an effective chamber is made between the backing layer 220 and a wound site where a negative pressure can be established. The backing layer 220 is preferably sealed to the wound contact layer 222 in a border region around the circumference of the dressing, ensuring that no air is drawn in through the border area, for example via adhesive or welding techniques. The backing layer 220 protects the wound from external bacterial contamination (bacterial barrier) and allows liquid from wound exudates to be transferred through the layer and evaporated from the film outer surface. The backing layer 220 preferably comprises two layers; a polyurethane film and an adhesive pattern spread onto the film. The polyurethane film is preferably moisture vapor permeable and may be manufactured from a material that has an increased water transmission rate when wet. In some embodiments, the moisture vapor permeability of the backing layer increases when the backing layer becomes wet. The moisture vapor permeability of the wet backing layer may be up to about ten times more than the moisture vapor permeability of the dry backing layer.

[0187] The absorbent layer 221 may be of a greater area than the transmission layer 226, such that the absorbent layer overlaps the edges of the transmission layer 226, thereby ensuring that the transmission layer does not contact the backing layer 220. This provides an outer channel of the absorbent layer 221 that is in direct contact with the wound contact layer 222, which aids more rapid absorption of exudates to the absorbent layer. Furthermore, this outer channel ensures that no liquid is able to pool around the circumference of the wound cavity, which may otherwise seep through the seal around the perimeter of the dressing leading to the formation of leaks. As illustrated in Figures 4C-4D, the absorbent layer 221 may define a smaller perimeter than that of the backing layer 220, such that a boundary or border region is defined between the edge of the absorbent layer 221 and the edge of the backing layer 220.

[0188] As shown in Figure 4D, one embodiment of the wound dressing 100 comprises an aperture 228 in the absorbent layer 221 situated underneath the fluidic connector 110. In use, for example when negative pressure is applied to the dressing 100, a wound facing portion of the fluidic connector may thus come into contact with the transmission layer 226, which can thus aid in transmitting negative pressure to the wound site even when the absorbent layer 221 is filled with wound fluids. Some embodiments may have the backing layer 220 be at least partly adhered to the transmission layer 226. In some embodiments, the aperture 228 is at least 1-2 mm larger than the diameter of the wound facing portion of the fluidic connector 110, or the orifice 227.

[0189] In particular for embodiments with a single fluidic connector 110 and through hole, it may be preferable for the fluidic connector 110 and through hole to be located in an off-center position as illustrated in Figure 4C. Such a location may permit the dressing 100 to be positioned onto a patient such that the fluidic connector 110 is raised in relation to the remainder of the dressing 100. So positioned, the fluidic connector 110 and the filter 214 may be less likely to come into contact with wound fluids that could prematurely occlude the filter 214 so as to impair the transmission of negative pressure to the wound site.

[0190] Turning now to the fluidic connector 110, preferred embodiments comprise a sealing surface 216, a bridge 211 (corresponding to bridge 120 in Figures 4A-4B) with a proximal end 130 and a distal end 140, and a filter 214. The sealing surface 216 preferably forms the applicator previously described that is sealed to the top surface of the wound dressing. In some embodiments a bottom layer of the fluidic connector 110 may comprise the sealing surface 216. The fluidic connector 110 may further comprise an upper surface vertically spaced from the sealing surface 216, which in some embodiments is defined by a separate upper layer of the fluidic connector. In other embodiments, the upper surface and the lower surface may be formed from the same piece of material. In some embodiments, the sealing surface 216 may comprise at least one aperture 229 therein to communicate with the wound dressing. In some embodiments, the filter 214 may be positioned across the opening 229 in the sealing surface, and may span the entire opening 229. The sealing surface 216 may be configured for sealing the fluidic connector to the cover layer of the wound dressing, and may comprise an adhesive or weld. In some embodiments, the sealing surface 216 may be placed over an orifice in the cover layer. In other embodiments, the sealing surface 216 may be positioned over an orifice in the cover layer and an aperture in the absorbent layer 221, permitting the fluidic connector 110 to provide air flow through the transmission layer 226. In some embodiments, the bridge 211 may comprise a first fluid passage 212 in communication with a source of negative pressure, the first fluid passage 212 comprising a porous material which may be the same or different than the porous layer 226 described previously. In some embodiments, the porous material or transmission material can be an apertured nonwoven fabric spacer layer as described herein with reference to Figures 1A-2B or a three dimensional nonwoven spacer layer construction as described herein with reference to Figures 3A-3C. In some embodiments, the porous material or transmission material can be a 3D knitted material. The bridge 211 is preferably encapsulated by at least one flexible film layer 208, 210 having a proximal and distal end and configured to surround the first fluid passage 212, the distal end of the flexible film being connected the sealing surface 216. The filter 214 is configured to substantially prevent wound exudate from entering the bridge.

[0191] Some embodiments may further comprise an optional second fluid passage positioned above the first fluid passage 212. For example, some embodiments may provide for an air leak may be disposed at the proximal end of the top layer that is configured to provide an air path into the first fluid passage 212 and dressing 100 similar to the suction adapter as described in U.S. Application No. 13/381885, filed December 20, 2011, entitled "APPARATUSES AND METHODS FOR NEGATIVE PRESSURE WOUND THERAPY," and patented as U.S. Patent No 8,801,685, which is incorporated by reference herein in its entirety.

[0192] Preferably, the fluid passage 212 is constructed from a compliant material that is flexible and that also permits fluid to pass through it if the spacer is kinked or folded over. Suitable materials for the fluid passage 212 include without limitation foams, including open-cell foams such as polyethylene or polyurethane foam, meshes, 3D knitted fabrics, apertured nonwoven fabric spacer layer as described herein with reference to Figures 1A-2B, a three dimensional nonwoven spacer layer construction as described herein with reference to Figures 3A-3C, non-woven materials, and fluid channels. In some embodiments, the fluid passage 212 may be constructed from materials similar to those described above in relation to the transmission layer 226. Advantageously, such materials used in the fluid passage 212 not only permit greater patient comfort, but may also provide greater kink resistance, such that the fluid passage 212 is still able to transfer fluid from the wound toward the source of negative pressure while being kinked or bent.

[0193] In some embodiments, the fluid passage 212 may be comprised of a wicking fabric, for example apertured nonwoven fabric spacer layer as described herein with reference to Figures 1A-2B or a three dimensional nonwoven spacer layer construction as described herein with reference to Figures 3A-3C. These materials selected are preferably suited to channeling wound exudate away from the wound and for transmitting negative pressure or vented air to the wound site, and may also confer a degree of kinking or occlusion resistance to the fluid passage 212. In some embodiments, the wicking fabric may have an apertured nonwoven fabric spacer layer as described herein with reference to Figures 1A-2B or a three dimensional nonwoven spacer layer construction as described herein with reference to Figures 3A-3C, which in some cases may aid in wicking fluid or transmitting negative pressure. In certain embodiments, including wicking fabrics, these materials remain open and capable of communicating negative pressure to a wound area under the typical pressures used in negative pressure therapy, for example between 40 to 150 mmHg. In some embodiments, the wicking fabric may comprise several layers of material stacked or layered over each other, which may in some cases be useful in preventing the fluid passage 212 from collapsing under the application of negative pressure. In other embodiments, the wicking fabric used in the fluid passage 212 may be between 1.5 mm and 6 mm thick; more preferably, the wicking fabric may be between 3 mm and 6 mm thick, and may be comprised of either one or several individual layers of wicking fabric. In other embodiments, the fluid passage 212 may be between 1.2-3 mm thick, and preferably thicker than 1.5 mm. Some embodiments, for example a suction adapter used with a dressing which retains liquid such as wound exudate, may employ hydrophobic layers in the fluid passage 212, and only gases may travel through the fluid passage 212. Additionally, and as described previously, the materials used in the system are preferably conformable and soft, which may help to avoid pressure ulcers and other complications which may result from a wound treatment system being pressed against the skin of a patient.

[0194] Preferably, the filter element 214 is impermeable to liquids, but permeable to gases, and is provided to act as a liquid barrier and to ensure that no liquids are able to escape from the wound dressing 100. The filter element 214 may also function as a bacterial barrier. Typically the pore size is 0.2μm. Suitable materials for the filter material of the filter element 214 include 0.2 micron Gore™ expanded PTFE from the MMT range, PALL Versapore™ 200R, and Donaldson™ TX6628. Larger pore sizes can also be used but these may require a secondary filter layer to ensure full bioburden containment. As wound fluid contains lipids it is preferable, though not essential, to use an oleophobic filter membrane for example 1.0 micron MMT-332 prior to 0.2 micron MMT-323. This prevents the lipids from blocking the hydrophobic filter. The filter element can be attached or sealed to the port or the cover film over the orifice. For example, the filter element 214 may be molded into the fluidic connector 110, or may be adhered to one or both of the top of the cover layer and bottom of the suction adapter 110 using an adhesive such as, but not limited to, a UV cured adhesive.

[0195] It will be understood that other types of material could be used for the filter element 214. More generally a microporous membrane can be used which is a thin, flat sheet of polymeric material, this contains billions of microscopic pores. Depending upon the membrane chosen these pores can range in size from 0.01 to more than 10 micrometers. Microporous membranes are available in both hydrophilic (water filtering) and hydrophobic (water repellent) forms. In some embodiments, filter element 214 comprises a support layer and an acrylic co-polymer membrane formed on the support layer. Preferably the wound dressing 100 according to certain embodiments uses microporous hydrophobic membranes (MHMs). Numerous polymers may be employed to form MHMs. For example, the MHMs may be formed from one or more of PTFE, polypropylene, PVDF and acrylic copolymer. All of these optional polymers can be treated in order to obtain specific surface characteristics that can be both hydrophobic and oleophobic. As such these will repel liquids with low surface tensions such as multi-vitamin infusions, lipids, surfactants, oils and organic solvents.

[0196] MHMs block liquids whilst allowing air to flow through the membranes. They are also highly efficient air filters eliminating potentially infectious aerosols and particles. A single piece of MHM is well known as an option to replace mechanical valves or vents. Incorporation of MHMs can thus reduce product assembly costs improving profits and costs/benefit ratio to a patient.

[0197] The filter element 214 may also include an odor absorbent material, for example activated charcoal, carbon fiber cloth or Vitec Carbotec-RT Q2003073 foam, or the like. For example, an odor absorbent material may form a layer of the filter element 214 or may be sandwiched between microporous hydrophobic membranes within the filter element. The filter element 214 thus enables gas to be exhausted through the orifice. Liquid, particulates and pathogens however are contained in the dressing.

[0198] Similar to the embodiments of wound dressings described above, some wound dressings comprise a perforated wound contact layer with silicone adhesive on the skin-contact face and acrylic adhesive on the reverse. Above this bordered layer sits a transmission layer. Above the transmission layer, sits an absorbent layer. The absorbent layer can include a superabsorbent non-woven (NW) pad. The absorbent layer can over-border the transmission layer by approximately 5mm at the perimeter. The absorbent layer can have an aperture or through-hole toward one end. The aperture can be about 10 mm in diameter. Over the transmission layer and absorbent layer lies a backing layer. The backing layer can be a high moisture vapor transmission rate (MVTR) film, pattern coated with acrylic adhesive. The high MVTR film and wound contact layer encapsulate the transmission layer and absorbent layer, creating a perimeter border of approximately 20 mm. The backing layer can have a 10 mm aperture that overlies the aperture in the absorbent layer. Above the hole can be bonded a fluidic connector that comprises a liquid-impermeable, gas-permeable semi-permeable membrane (SPM) or filter that overlies the aforementioned apertures.

[0199] Figures 5A-5D illustrates various embodiments of a wound dressing that can be used for healing a wound without negative pressure. Figure 5E illustrates a cross-section of the wound dressing in Figures 5A-5D. As shown in the dressings of Figures 5A-E, the wound dressings can have multiple layers similar to the dressings described with reference to Figures 4A-D except the dressings of Figures 5A-E do not include a port or fluidic connector. The wound dressings of Figures 5A-E can include a cover layer 501 and wound contact layer 505 as described herein. The wound dressing can include various layers positioned between the wound contact layer 505 and cover layer 501. For example, the dressing can include one or more absorbent layers 502 or one or more transmission layers 503 and 504 as described herein with reference to Figures 4A-D.

[0200] In some embodiments, the one or more transmission layers 503 and 504 can comprise an apertured nonwoven fabric spacer layer formed from the two layers of nonwoven fabric as described previously herein and illustrated in Figures 1A-2B. In some embodiments, the apertured nonwoven fabric spacer layer can include a first nonwoven fabric layer and a second nonwoven fabric layer. The first nonwoven fabric layer may be formed from an interconnected first fibrous face layer and a first fibrous base layer. The second nonwoven fabric layer can include an interconnected second fibrous face layer and a second fibrous base layer. The first nonwoven fabric layer can be inverted onto the second nonwoven fabric layer to create a spacer type layer for use in a wound dressing. The first face layer of the first nonwoven fabric layer can be in contact with and/or positioned on top of the second face layer of the second nonwoven fabric layer. In some embodiments, the nonwoven fabric layers can be a hydroentangled nonwoven layer.

[0201] In some embodiments, the plurality apertures of the nonwoven fabric layer can form a channel. The channels or apertures created in the nonwoven material can be utilized for the structure they provide in the material. For example, in some embodiments, the spacer layer formed from the nonwoven fabric layers as described herein can remain open upon application of negative pressure to the layer and/or a wound dressing. In some embodiments, the apertures, channels, and/or slits of the nonwoven fabric layer can allow for unique fluid management properties. In some embodiments, the layer formed from the two nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the apertured nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0202] In some embodiments, the one or more transmission layers 503 and 504 can comprise a three dimensional nonwoven spacer layer construction as described previously herein and illustrated in Figures 3A-3C. In some embodiments, heat and pressure can be used to set the nonwoven into a 3D structure such as in a corrugated construction, a three dimensional zig-zag pattern, an egg-box type construction, a checkerboard construction, and a hexagonal (honeycomb) construction. In some embodiments, the nonwoven material can be thermoformed into the three dimensional construction. In other embodiments, the three dimensional nonwoven material can be formed using a chemical bonding and vacuum forming.

[0203] In some embodiments, the 3D structure can be layered on top of one another or with traditional nonwovens to create a spacer type layer for use in a wound dressing.

[0204] For example, in some embodiments, the spacer layer formed from the nonwoven layers as described herein can remain open upon compression and/or application of negative pressure to the layer and/or a wound dressing. In some embodiments, the three dimensional structure of the nonwoven spacer layer can allow for unique fluid management properties. In some embodiments, the three dimensional nonwoven spacer layer formed from the nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the three dimensional nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0205] In some embodiments, additional layers such as another transmission layer or an obscuring layer 503 may be provided over the absorbent layer 503 and beneath the backing layer 501. Additionally, some embodiments related to wound treatment comprising a wound dressing described herein may also be used in combination or in addition to those described in U.S. Application Publication No. 2014/0249495, filed May 21, 2014, entitled "WOUND DRESSING AND METHOD OF TREATMENT" the disclosure of which are hereby incorporated by reference in its entirety, including further details relating to embodiments of wound dressings, the wound dressing components and principles, and the materials used for the wound dressings.

[0206] In some embodiments, a source of negative pressure (such as a pump) and some or all other components of the TNP system, such as power source(s), sensor(s), connector(s), user interface component(s) (such as button(s), switch(es), speaker(s), screen(s), etc.) and the like, can be integral with the wound dressing. Additionally, some embodiments related to wound treatment comprising a wound dressing described herein may also be used in combination or in addition to those described in International Application WO 2016/174048 and International Patent Application PCT/EP2017/055225, filed on March 6, 2017, entitled "WOUND TREATMENT APPARATUSES AND METHODS WITH NEGATIVE PRESSURE SOURCE INTEGRATED INTO THE WOUND DRESSING," the disclosure of which is hereby incorporated by reference in its entirety herein, including further details relating to embodiments of wound dressings, the wound dressing components and principles, and the materials used for the wound dressings and wound dressing components.

[0207] In some embodiments, the pump and/or other electronic components can be configured to be positioned adjacent to or next to the absorbent and/or transmission layers in the wound dressing so that the pump and/or other electronic components are still part of a single apparatus to be applied to a patient with the pump and/or other electronics positioned away from the wound site. Figures 6A-6B illustrates a wound dressing incorporating the source of negative pressure and/or other electronic components within the wound dressing.

Figures 6A-6B illustrates a wound dressing 1200 with the pump and/or other electronics positioned away from the wound site. The wound dressing can include an electronics area 1261 and an absorbent area 1260. The dressing can comprise a wound contact layer (not shown) and a moisture vapor permeable film or cover layer 1213 positioned above the contact layer and other layers of the dressing. The wound dressing layers and components of the electronics area as well as the absorbent area can be covered by one continuous cover layer 1213 as shown in Figures 6A-6B.

[0208] The electronics area 1261 can include a source of negative pressure (such as a pump) and some or all other components of the TNP system, such as power source(s), sensor(s), connector(s), user interface component(s) (such as button(s), switch(es), speaker(s), screen(s), etc.) and the like, that can be integral with the wound dressing. For example, the electronics area 1261 can include a button or switch 1211 as shown in Figure 6A-6B. The button or switch 1211 can be used for operating the pump (e.g., turning the pump on/off).

[0209] The absorbent area 1260 can include an absorbent material 1212 and can be positioned over the wound site. The electronics area 1261 can be positioned away from the wound site, such as by being located off to the side from the absorbent area 1260. The electronics area 1261 can be positioned adjacent to or next to and in fluid communication with the absorbent area 1260 as shown in Figures 6A-6B. In some embodiments, each of the electronics area 1261 and absorbent area 1260 may be rectangular in shape and positioned adjacent to one another.

[0210] In some embodiments, additional layers of dressing material can be included in the electronics area 1261, the absorbent area 1260, or both areas. In some embodiments, the dressing can comprise one or more spacer or transmission layers and/or one or more absorbent layer positioned above the contact layer and below the wound cover layer 1213 of the dressing.

[0211] The dressing can comprise a wound contact layer (not shown), a transmission layer (not shown), an absorbent layer 1212 over the transmission layer, a moisture vapor permeable film or cover layer 1213 positioned above the wound contact layer, transmission layer, absorbent layer, or other layers of the dressing. The wound contact layer can be configured to be in contact with the wound. The wound contact layer can include an adhesive on the patient facing side for securing the dressing to the surrounding skin or on the top side for securing the wound contact layer to a cover layer or other layer of the dressing. In operation, the wound contact layer can be configured to provide unidirectional flow so as to facilitate removal of exudate from the wound while blocking or substantially preventing exudate from returning to the wound. The one or more transmission layers assist in distributing negative pressure over the wound site and facilitating transport of wound exudate and fluids into the wound dressing. In some embodiments, the transmission layer can be formed at least partially from a three dimensional (3D) fabric. Further, an absorbent layer (such as layer 1212) for absorbing and retaining exudate aspirated from the wound can be utilized. In some embodiments, a superabsorbent material can be used in the absorbent layer 1212. In some embodiments, the absorbent includes a shaped form of a superabsorber layer. In some embodiments, the transmission layer can be formed at least partially from an apertured nonwoven fabric spacer layer as described herein with reference to Figures 1A-2B or a three dimensional nonwoven spacer layer construction as described herein with reference to Figures 3A-3C. The wound dressing layers of the electronics area and the absorbent layer can be covered by one continuous cover layer 1213. In some embodiments, the cover layer can include a moisture vapor permeable material that prevents liquid exudate removed from the wound and other liquids from passing through, while allowing gases through.

[0212] Figure 6C illustrates an embodiment of layers of a wound dressing with the pump and electronic components offset from the absorbent area of the dressing. As illustrated in Figure 6C, the dressing can include a wound contact layer 1310 for placing in contact with the wound. Lower spacer or transmission layers 1311 and 1311' are provided above the wound contact layer 1310. In some embodiments, the transmission layer 1311 can be a separate layer from spacer layer 1311' as shown in Figure 6C. The lower transmission layers 1311 and/or 1311' can assist in distributing pressure evenly to the wound surface and/or wicking fluid away from the wound. An absorbent layer 1322 can be positioned above the lower transmission layer 1311. A dressing layer 1351 can include cutouts or recesses 1328 for embedding the electronic components 1350 within the layer 1351. In some embodiments, the cutouts or recesses 1328 can be sized and shaped to embed a pump 1327, power source 1326, and/or other electronic components. In some embodiments, the layer 1351 can include multiple spacer or transmission layers stacked together. In some embodiments, the layer 1351 can include multiple spacer or transmission layers pieced together to surround the electronic components 1350. An upper transmission layer 1317 can be provided above the absorbent layer 1322, layer 1351, and/or electronic components 1350.

[0213] In some embodiments, the one or more transmission layers can comprise an apertured nonwoven fabric spacer layer formed from the two layers of nonwoven fabric as described previously herein and illustrated in Figures 1A-2B. In some embodiments, the apertured nonwoven fabric spacer layer can include a first nonwoven fabric layer and a second nonwoven fabric layer. The first nonwoven fabric layer may be formed from an interconnected first fibrous face layer and a first fibrous base layer. The second nonwoven fabric layer can include an interconnected second fibrous face layer and a second fibrous base layer. The first nonwoven fabric layer can be inverted onto the second nonwoven fabric layer to create a spacer type layer for use in a wound dressing. The first face layer of the first nonwoven fabric layer can be in contact with and/or positioned on top of the second face layer of the second nonwoven fabric layer. In some embodiments, the nonwoven fabric layers can be a hydroentangled nonwoven layer.

[0214] In some embodiments, the plurality apertures of the nonwoven fabric layer can form a channel. The channels or apertures created in the nonwoven material can be utilized for the structure they provide in the material. For example, in some embodiments, the spacer layer formed from the nonwoven fabric layers as described herein can remain open upon application of negative pressure to the layer and/or a wound dressing. In some embodiments, the apertures, channels, and/or slits of the nonwoven fabric layer can allow for unique fluid management properties. In some embodiments, the layer formed from the two nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the apertured nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0215] In some embodiments, the one or more transmission layers can comprise a three dimensional nonwoven spacer layer construction as described previously herein and illustrated in Figures 3A-3C. In some embodiments, heat and pressure can be used to set the nonwoven into a 3D structure such as in a corrugated construction, a three dimensional zig-zag pattern, an egg-box type construction, a checkerboard construction, and a hexagonal (honeycomb) construction. In some embodiments, the nonwoven material can be thermoformed into the three dimensional construction. In other embodiments, the three dimensional nonwoven material can be formed using a chemical bonding and vacuum forming.

[0216] In some embodiments, the 3D structure can be layered on top of one another or with traditional nonwovens to create a spacer type layer for use in a wound dressing.

[0217] For example, in some embodiments, the spacer layer formed from the nonwoven layers as described herein can remain open upon compression and/or application of negative pressure to the layer and/or a wound dressing. In some embodiments, the three dimensional structure of the nonwoven spacer layer can allow for unique fluid management properties. In some embodiments, the three dimensional nonwoven spacer layer formed from the nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the three dimensional nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0218] A cover layer or backing layer 1313 can be positioned over the upper transmission layer. The backing layer 1313 can form a seal to the wound contact layer 1310 at a perimeter region enclosing the transmission layers 1311, 1311', and 1317, the absorbent layer 1322, layer 1351, and electronic components 1350. In some embodiments, the backing layer 1313 can be a flexible sheet of material that forms and molds around the dressing components when they are applied to the wound. In other embodiments, the backing layer 1313 can be a material that is preformed or premolded to fit around the dressing components as shown in Figure 6C.

[0219] Figure 7A illustrates an embodiment of a TNP wound treatment device comprising a wound dressing. As stated above, the wound dressing 400 can be any wound dressing embodiment disclosed herein or have any combination of features of any number of wound dressing embodiments disclosed herein. For example, the wound dressing 400 may be similar to a PICO single unit dressing available from Smith & Nephew as described previously. The wound dressing 400 and associated system may also be similar to the system described in Figures 4A-4D previously. Embodiments of the wound dressings, wound dressing components, wound treatment apparatuses and methods described herein and with reference to Figures 7A-7C may also be used in combination or in addition to those described in International Application No. PCT/EP2016/082353, filed December 22, 2016, titled "NEGATIVE PRESSURE WOUND THERAPY APPARATUS," the disclosure of which is hereby incorporated by reference in its entirety.

[0220] The dressing 400 may be placed over a wound, and a port 460 (which together with conduit 401 may form a fluidic connector as described with respect to Figures 4A-4D) may be used to provide negative pressure from a vacuum source to the wound. In the embodiment shown in Figure 7A the dressing 400 may be provided with at least a portion of the conduit 401 pre-attached to the port 460. For example, the port/conduit combination may be a flexible suction adapter as described herein with reference to Figures 4A-4D. In some embodiments, the pre-attached conduit 401 can connect to a conduit extension, for example, a tubing (not shown). Preferably, the dressing 400 is provided as a single article with all wound dressing elements (including the port 460 and conduit 401) pre-attached and integrated into a single unit. The wound dressing 400 may then be connected, via the conduit 401 and/or conduit extension, to a source of negative pressure such as the pump as described with reference to Figures 4A-4D.

[0221] The cover layer 430, 320, which can be more clearly seen in Figure 7B-7C, can be formed of substantially fluid impermeable material, such as film. The cover layer 430, 320 can be similar to the cover layer or backing layer described in Figures 4A-4D previously. The film may be transparent, such that from the top view of Figure 7A, other layers underneath the cover layer are also visible. The cover layer can include an adhesive for securing the dressing to the surrounding skin or a wound contact layer. The dressing can utilize a wound contact layer 440, 322 and an absorbent layer 450, 321 within the dressing. The wound contact layer and the absorbent layer can be similar to the wound contact layer and absorbent layers described in Figures 4A-4D previously. The wound contact layer can be configured to be in contact with the wound. The wound contact layer can include an adhesive on the patient facing side for securing the dressing to the surround skin or on the top side for securing the wound contact layer 440, 322 to a cover layer 430, 320 or other layer of the dressing. In operation, in some embodiments the wound contact layer can be configured to provide unidirectional flow so as to facilitate removal of exudate from the wound while blocking or substantially preventing exudate from returning to the wound. Further, an absorbent layer (such as layer 450, 321) for absorbing and retaining exudate aspirated from the wound can be utilized. In some embodiments, the absorbent layer can include an absorbent material, for example, a superabsorbent material or other absorbent material known in the art. In some embodiments, the absorbent layer can include a shaped form of a superabsorber layer with recesses or compartments for the pump, electronics, and accompanying components. In some embodiments, the wound dressing can include multiple absorbent layers.

[0222] The absorbent material 450 as shown in Figure 7A which may be a foam or non-woven natural or synthetic material and which may optionally include or be super-absorbent material, forms a reservoir for fluid, particularly liquid, removed from the wound site and draws those fluids towards a cover layer 430. The material of the absorbent layer can be similar to the absorbent material described with reference to Figures 4A-4D. The material of the absorbent layer also prevents liquid collected in the wound dressing from flowing in a sloshing manner. The absorbent layer 450 also helps distribute fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and stored throughout the absorbent layer. This helps prevent agglomeration in areas of the absorbent layer.

[0223] In some embodiments, the absorbent layer is a layer of non-woven cellulose fibers having super-absorbent material in the form of dry particles dispersed throughout. Use of the cellulose fibers introduces fast wicking elements which help quickly and evenly distribute liquid taken up by the dressing. The juxtaposition of multiple strand-like fibers leads to strong capillary action in the fibrous pad which helps distribute liquid. In this way, the super-absorbent material is efficiently supplied with liquid. Also, all regions of the absorbent layer are provided with liquid.

[0224] The wicking action also assists in bringing liquid into contact with the upper cover layer to aid increase transpiration rates of the dressing.

[0225] The wicking action also assists in delivering liquid downwards towards the wound bed when exudation slows or halts. This delivery process helps maintain the transmission layer or lower spacer layer and lower wound bed region in a moist state which helps prevent crusting within the dressing (which could lead to blockage) and helps maintain an environment optimized for wound healing.

[0226] In some embodiments, the absorbent layer may be an air-laid material. Heat fusible fibers may optionally be used to assist in holding the structure of the pad together. It will be appreciated that rather than using super-absorbing particles or in addition to such use, super-absorbing fibers may be utilized according to certain embodiments of the present invention. An example of a suitable material is the Product Chem-Posite™ 11 C available from Emerging Technologies Inc (ETi) in the USA.

[0227] Optionally, according to certain embodiments of the present invention, the absorbent layer may include synthetic stable fibers and/or bi-component stable fibers and/or natural stable fibers and/or super-absorbent fibers. Fibers in the absorbent layer may be secured together by latex bonding or thermal bonding or hydrogen bonding or a combination of any bonding technique or other securing mechanism. In some embodiments, the absorbent layer is formed by fibers which operate to lock super-absorbent particles within the absorbent layer. This helps ensure that super-absorbent particles do not move external to the absorbent layer and towards an underlying wound bed. This is particularly helpful because when negative pressure is applied there is a tendency for the absorbent pad to collapse downwards and this action would push super-absorbent particle matter into a direction towards the wound bed if they were not locked away by the fibrous structure of the absorbent layer.

[0228] The absorbent layer may comprise a layer of multiple fibers. Preferably, the fibers are strand-like and made from cellulose, polyester, viscose or the like. Preferably, dry absorbent particles are distributed throughout the absorbent layer ready for use. In some embodiments, the absorbent layer comprises a pad of cellulose fibers and a plurality of super absorbent particles. In additional embodiments, the absorbent layer is a non-woven layer of randomly orientated cellulose fibers.

[0229] Super-absorber particles/fibers may be, for example, sodium polyacrylate or carbomethoxycellulose materials or the like or any material capable of absorbing many times its own weight in liquid. In some embodiments, the material can absorb more than five times its own weight of 0.9% W/W saline, etc. In some embodiments, the material can absorb more than 15 times its own weight of 0.9% W/W saline, etc. In some embodiments, the material is capable of absorbing more than 20 times its own weight of 0.9% W/W saline, etc. Preferably, the material is capable of absorbing more than 30 times its own weight of 0.9% W/W saline, etc.

[0230] Preferably, the particles of superabsorber are very hydrophilic and grab the fluid as it enters the dressing, swelling up on contact. An equilibrium is set up within the dressing core whereby moisture passes from the superabsorber into the dryer surrounding area and as it hits the top film the film switches and the fluid vapor starts to be transpired. A moisture gradient is established within the dressing to continually remove fluid from the wound bed and ensure the dressing does not become heavy with exudate.

[0231] The absorbent layer can include at least one through hole. The through hole can be located so as to underlie the suction port as described with reference to Figure 4D. A single through hole can be used to produce an opening underlying the port 460 (not shown in Figure 7B). It will be appreciated that multiple openings could alternatively be utilized. Additionally, should more than one port be utilized according to certain embodiments of the present invention one or multiple openings may be made in the super-absorbent layer in registration with each respective port. Although not essential to certain embodiments of the present invention the use of through holes in the super-absorbent layer provide a fluid flow pathway which is particularly unhindered and this is useful in certain circumstances.

[0232] Use of one or more through holes in the absorption layer also has the advantage that during use if the absorbent layer contains a gel forming material, such as superabsorber, that material as it expands to absorb liquid, does not form a barrier through which further liquid movement and fluid movement in general cannot pass. In this way each opening in the absorbent layer provides a fluid pathway between the lower transmission or spacer layer and the upper transmission or spacer layer to the wound facing surface of the filter and then onwards into the interior of the port.

[0233] These layers can be covered with one layer of a film or cover layer. The cover layer can include a filter that can be positioned over the absorbent layer, or a filter may be incorporated in the port 460 as described in International Application Publication No. WO 2013/175306 A2, U.S. Publication No. US2011/0282309, and U.S. Publication No. 2016/0339158 the entirety of which is hereby incorporated by reference. As shown in Figure 7A gas impermeable, but moisture vapor permeable, cover layer 430 extends across the width of the wound dressing. The cover layer may be similar to the cover layer or backing layer described with reference to Figure 4A-4D. The cover layer, which may for example be a polyurethane film (for example, Elastollan SP9109) having a pressure sensitive adhesive on one side, is impermeable to gas and this layer thus operates to cover the wound and to seal a wound cavity over which the wound dressing is placed. In this way an effective chamber is made between the cover layer and a wound site where a negative pressure can be established. The cover layer 430 is sealed to the wound contact layer 440 in a border region 410 around the circumference of the dressing, ensuring that no air is drawn in through the border area, for example via adhesive or welding techniques. The cover layer 430 protects the wound from external bacterial contamination (bacterial barrier) and allows liquid from wound exudates to be transferred through the layer and evaporated from the film outer surface. The cover layer 430 typically comprises two layers; a polyurethane film and an adhesive pattern spread onto the film. The polyurethane film is moisture vapor permeable and may be manufactured from a material that has an increased water transmission rate when wet.

[0234] The cover layer can include an aperture within the cover layer for providing fluid communication with a source of negative pressure or pump. The filter can be positioned in communication with the aperture in the wound cover. The aperture in the wound cover can be covered by a port 460. In some embodiments, the port 460 connects to a conduit for communication with a negative pressure source or pump. The port 460 can include a filter 420 provided to cover the aperture in the cover layer 430. In some embodiments, the filter 420 can be integral to the port 460. The filter 420 can include hydrophobic material to protect the pump and/or other components from liquid exudates. The filter 420 can block fluids while permitting gases to pass through. In some embodiments, the filter can be similar to the filter or filter system described in Figures 4A-4D previously. In some embodiments, the aperture in the cover layer 430 and the port 460 provide fluid communication between the wound dressing and a pump. In some embodiments, the pump, electronics, switch and battery can be positioned at a remote location from the dressing. In some embodiments, the pump, electronics, switch and battery can be positioned on top of the first cover layer and a second filter and second cover layer can be alternative or additionally used. For example, the second filter can be constructed from antibacterial and/or antimicrobial materials so that the pump can exhaust gases into the atmosphere. The second filter can also help to reduce noise produced by the pump.

[0235] Negative pressure can be lost at the wound bed when free absorbent capacity remains in the dressing. This can occur because some or all of the pores in the filter are blocked with liquid or particulates. In some embodiments, solutions are utilized to allow the full capacity of the dressing absorbent layer to be utilized whilst maintaining the air path between the source of negative pressure and the wound bed.

[0236] In dressing embodiments that utilize a cover layer directly over the absorbent layer the dressing can have a void underneath the filter which can fill with liquid, thus blocking the filter pores and preventing air flow to the wound bed. A spacer layer or transmission layer 490 can be used to provide a fluid flow path above the absorbent layer 450 preventing the blocking of the port 460. In some embodiments, the transmission layer 490 in the dressing can be provided above and below the absorbent layer. The transmission layer can be incompressible and maintain a path for fluid flow between the source of negative pressure and the wound bed, via the filter. In some embodiments, the transmission layer can encapsulate or wrap around the absorbent layer as shown in Figure 7A and 7B. The wrapped transmission layer can provide an uninterrupted length of transmission material from the filter 420 to the wound bed. The transmission layer can traverse the length of the top surface of the absorbent layer and wrap around at least one side of the absorbent layer and traverse the length of the bottom surface (wound facing surface) of the absorbent layer. In some embodiments, the transmission layer can wrap around two sides of the absorbent layer as shown in Figure 7A.

[0237] In some embodiments, the transmission layer can be utilized to assist in distributing negative pressure over the wound site and facilitating transport of wound exudate and fluids into the wound dressing.

[0238] A lower portion of the transmission layer 490 of porous material can be located above the wound contact layer and below the absorbent layer and wrapped around the edges of the absorbent layer. As the transmission layer is wrapped around at least one edge of the absorbent layer, the transmission layer has an upper portion of the transmission layer that can be positioned between the cover layer and the absorbent layer. As used herein the edge of the absorbent layer or the dressing refers to the sides of the material that are substantially perpendicular to the wound surface and run along the height of the material.

[0239] In some embodiments, the transmission layer can be a porous layer. This spacer layer, or transmission layer, 490 allows transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing as described with reference to Figure 4D. In particular, the transmission layer 490 ensures that an open air channel can be maintained to communicate negative pressure over the wound area even when the absorbent layer has absorbed substantial amounts of exudates. The layer should remain open under the typical pressures that will be applied during negative pressure wound therapy as described previously, so that the whole wound site sees an equalized negative pressure. The transmission layer 490 may be formed of a material having a three dimensional structure. For example, a knitted or woven spacer fabric (for example Baltex 7970 weft knitted polyester) or a non-woven fabric could be used. Other materials, such as those described previously herein, could of course be utilized.

[0240] In some embodiments, the transmission layer can be formed from an apertured nonwoven fabric spacer layer formed from the two layers of nonwoven fabric as described previously herein and illustrated in Figures 1A-2B. In some embodiments, the apertured nonwoven fabric spacer layer can include a first nonwoven fabric layer and a second nonwoven fabric layer. The first nonwoven fabric layer may be formed from an interconnected first fibrous face layer and a first fibrous base layer. The second nonwoven fabric layer can include an interconnected second fibrous face layer and a second fibrous base layer. The first nonwoven fabric layer can be inverted onto the second nonwoven fabric layer to create a spacer type layer for use in a wound dressing. The first face layer of the first nonwoven fabric layer can be in contact with and/or positioned on top of the second face layer of the second nonwoven fabric layer. In some embodiments, the nonwoven fabric layers can be a hydroentangled nonwoven layer.

[0241] In some embodiments, the plurality apertures of the nonwoven fabric layer can form a channel. The channels or apertures created in the nonwoven material can be utilized for the structure they provide in the material. For example, in some embodiments, the spacer layer formed from the nonwoven fabric layers as described herein can remain open upon application of negative pressure to the layer and/or a wound dressing. In some embodiments, the apertures, channels, and/or slits of the nonwoven fabric layer can allow for unique fluid management properties. In some embodiments, the layer formed from the two nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the apertured nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0242] In some embodiments, the transmission layer can be formed from a three dimensional nonwoven spacer layer construction as described previously herein and illustrated in Figures 3A-3C. In some embodiments, heat and pressure can be used to set the nonwoven into a 3D structure such as in a corrugated construction, a three dimensional zig-zag pattern, an egg-box type construction, a checkerboard construction, and a hexagonal (honeycomb) construction. In some embodiments, the nonwoven material can be thermoformed into the three dimensional construction. In other embodiments, the three dimensional nonwoven material can be formed using a chemical bonding and vacuum forming.

[0243] In some embodiments, the 3D structure can be layered on top of one another or with traditional nonwovens to create a spacer type layer for use in a wound dressing.

[0244] For example, in some embodiments, the spacer layer formed from the nonwoven layers as described herein can remain open upon compression and/or application of negative pressure to the layer and/or a wound dressing. In some embodiments, the three dimensional structure of the nonwoven spacer layer can allow for unique fluid management properties. In some embodiments, the three dimensional nonwoven spacer layer formed from the nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the three dimensional nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0245] Figure 7A illustrates a top view of an embodiment of a wound dressing with a transmission layer 490 wrapped around an absorbent layer 450. The wound dressing can be constructed with a wound contact layer 440 and a top film or cover layer 430 enclosing an absorbent layer 450. A hole or aperture in the top film 430 can be entirely covered by a port 460 which leads to a source of negative pressure. The port 460 can contain a filter 420 or can be positioned over the filter 420. The dressing absorbent layer 450 can comprise a superabsorbent material. The absorbent layer 450 can be surrounded fully or in part by a spacer fabric or transmission layer 490. The transmission layer 490 can be provided above and below the absorbent layer 450. In some embodiments, the transmission layer 490 can be wrapped around and cover two sides the absorbent layer 450. For example, in some embodiments, a length of the transmission layer 490 can be configured to provide a fluid flow that connects the wound contact surface 440 and the filter 420. As illustrated in Figure 7A, the transmission layer can extend around the absorbent layer 450 running along the length of the bottom surface and top surface of the absorbent layer and wrapping around at least one side of the absorbent layer but not fully encapsulating the absorbent layer. In some embodiments, as shown in Figure 7A, the transmission layer 490 extends to the periphery of the absorbent layer but does not extend over the ends of the width of the dressing. For example, as illustrated in Figure 7A, the periphery of two sides of the absorbent layer 450 extend beyond the transmission layer 490 while the spacer layer extends over and wraps around the other two sides of the absorbent layer. In other embodiments, the transmission layer 490 fully encapsulates and all sides of the absorbent layer 450.

[0246] The port 460 can be positioned either above the top film or cover layer 430 at one end or in the center of the dressing. The port can be positioned over the aperture in the top film and can contain or be placed over the filter 420. As described herein, providing the transmission layer above and below and wrapped around at least one side of the absorbent layer can prevent the filter from becoming blocked with liquid or particulates, by allowing the distribution of fluid through the wrapped spacer layer until the full absorbent capacity of the dressing materials have been reached. This can increase the wear time of the wound dressing by prolonging delivery of negative pressure to the wound bed. In some embodiments, the dressing with the configuration of layers as described herein has demonstrated a longer delivery period of NPWT to the wound contact surface compared to wound dressing without the transmission layer between the absorbent layer and the cover layer and without the transmission layer wrapped around the absorbent layer.

[0247] Figure 7B illustrates a cross-sectional view of the wound dressing with the transmission layer 490 wrapped around the absorbent layer 450. As shown in Figure 7B, the wound contact layer 440 can be provided as the bottom layer of the dressing configured to contact the wound surface. The top film or cover layer 430 is provided as a top layer enclosing the transmission layer 490 and the absorbent layer 450 with the wound contact layer 440. The cover layer 430 can seal to the border region around the periphery of the wound contact layer 440, the skin of a patient, and/or the wound bed. The port 460 can be positioned above the cover layer 430 and over an aperture in the cover layer 430. As illustrated in Figure 7B, the cross section of the wound dressing shows the transmission layer 490 surrounding the absorbent layer 450 so that the port 460 is in communication with the upper portion of the transmission material and the wound contact layer is in contact with the lower portion of the transmission material. The configuration of the transmission layer surrounding the absorbent material allows a fluid flow path from the wound bed or wound contact layer to the port without passing through the absorbent layer.

[0248] The transmission layer 490 can be wrapped around the absorbent layer 450 to disperse the vacuum throughout the dressing. In some embodiments, the transmission layer

490 can be manufactured as one flat piece of material that during assembly of the dressing is positioned on the bottom surface of the absorbent layer 450, wrapped around the ends of the absorbent layer 450, and the two ends of the spacer layer 490 are folded over the top surface of the absorbent layer 450 completely or partially covering the top surface of the absorbent layer 450. In such embodiments, the upper transmission layer 490 can have a break 495 in the transmission material where the two folded over ends of the transmission material 490 meet as shown in Figure 7B. In alternative embodiments, the transmission layer 490 can be manufactured as one piece of transmission material that is pre-shaped to fit around the absorbent layer 450 and fully encapsulates the absorbent layer 450 with no break in the transmission material.

[0249] Providing the transmission layer between the port and the absorbent layer prevents fluid or exudate removed from the wound from blocking the port and/or filter within the port. There can be some free particles in the hole of the absorbent layer positioned below the filter. The loose free particles in the hole can gel and block the hole and/or filter area. Therefore, the upper transmission layer can keep the superabsorber particles clear from the filter and allow the dressing to fill completely. In some embodiments, the transmission layer wrapped around the absorbent layer allow the port to be located at any location with respect to gravity. The transmission layer positioned above the absorbent layer can eliminate the concerns of the fluid or exudate removed from the wound from blocking the port and/or filter within the port on the section of the absorbent layer that is filled first.

[0250] As shown in Figure 7C, the wound dressing 300 can include a wound contact layer 322. The wound contact layer can be similar to the wound contact layer 322 described with reference to Figure 4D. In some embodiments, the wound contact layer 322 can be a double-face coated (silicone-acrylic) perforated adhesive wound contact layer. A transmission layer 326a and absorbent layer 321 can be provided similar to the dressing described with reference to Figure 4D but the transmission layer 326a over-borders the absorbent layer. The wound dressing 300 can include a second transmission layer 326b between the absorbent layer and the backing layer that over-borders the absorbent layer. The first and second transmission layers 326a and 326b can over-border the absorbent layer by 5 mm at the perimeter. This can be the reverse of the cut geometry in the dressings as described previously. In some embodiments, there is no through-hole or aperture in the absorbent layer 321 or second transmission layer 326b. In some embodiments, the hole in the absorbent layer could be disadvantageous because it could become filled with superabsorbent particles or other material and block the filter in the standard dressing. A backing layer 320 sits over the second transmission layer 326b and the backing layer can include an orifice 327 that allows connection of the fluidic connector to communicate negative pressure to the dressing.

[0251] In some embodiments, the first and second transmission layer 326a, 326b can include a 3D fabric. In some embodiments, the first and second transmission layers can include an apertured nonwoven fabric spacer layer formed from the two layers of nonwoven fabric as described previously herein and illustrated in Figures 1A-2B. In some embodiments, the apertured nonwoven fabric spacer layer can include a first nonwoven fabric layer and a second nonwoven fabric layer. The first nonwoven fabric layer may be formed from an interconnected first fibrous face layer and a first fibrous base layer. The second nonwoven fabric layer can include an interconnected second fibrous face layer and a second fibrous base layer. The first nonwoven fabric layer can be inverted onto the second nonwoven fabric layer to create a spacer type layer for use in a wound dressing. The first face layer of the first nonwoven fabric layer can be in contact with and/or positioned on top of the second face layer of the second nonwoven fabric layer. In some embodiments, the nonwoven fabric layers can be a hydroentangled nonwoven layer.

[0252] In some embodiments, the plurality apertures of the nonwoven fabric layer can form a channel. The channels or apertures created in the nonwoven material can be utilized for the structure they provide in the material. For example, in some embodiments, the spacer layer formed from the nonwoven fabric layers as described herein can remain open upon application of negative pressure to the layer and/or a wound dressing. In some embodiments, the apertures, channels, and/or slits of the nonwoven fabric layer can allow for unique fluid management properties. In some embodiments, the layer formed from the two nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the apertured nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0253] In some embodiments, the first and second transmission layers 326a, 326b may be formed of a material having a three dimensional structure. For example, a knitted or woven spacer fabric (for example Baltex 7970 weft knitted polyester) or a non-woven fabric could be used as described previously. The first and second transmission layers 326a, 326b can allow transmission of fluid including liquid and gas away from a wound site into the layers of the wound dressing. In particular, the first and second transmission layers 326a, 326b preferably ensures that an open air channel can be maintained to communicate negative pressure over the wound area and throughout the wound dressing even when the absorbent layer has absorbed substantial amounts of exudates.

[0254] In some embodiments, the first and second transmission layer 326a, 326b can include a 3D fabric. In some embodiments, the first and second transmission layers can include a three dimensional nonwoven spacer layer construction as described previously herein and illustrated in Figures 3A-3C. In some embodiments, heat and pressure can be used to set the nonwoven into a 3D structure such as in a corrugated construction, a three dimensional zig-zag pattern, an egg-box type construction, a checkerboard construction, and a hexagonal (honeycomb) construction. In some embodiments, the nonwoven material can be thermoformed into the three dimensional construction. In other embodiments, the three dimensional nonwoven material can be formed using a chemical bonding and vacuum forming.

[0255] In some embodiments, the 3D structure can be layered on top of one another or with traditional nonwovens to create a spacer type layer for use in a wound dressing.

[0256] For example, in some embodiments, the spacer layer formed from the nonwoven layers as described herein can remain open upon compression and/or application of negative pressure to the layer and/or a wound dressing. In some embodiments, the three dimensional structure of the nonwoven spacer layer can allow for unique fluid management properties. In some embodiments, the three dimensional nonwoven spacer layer formed from the nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the three dimensional nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0257] Figure 8A illustrates a cross-section through a wound dressing 2100 similar to the wound dressing of Figures 4A-4D according to an embodiment of the disclosure. The wound dressing 2100, which can alternatively be any wound dressing embodiment disclosed herein including without limitation wound dressing 110 or any combination of features of any number of wound dressing embodiments disclosed herein, can be located over a wound site to be treated. The dressing 2100 may be placed to as to form a sealed cavity over the wound site. In a preferred embodiment, the dressing 2100 comprises a backing layer 2140 attached to a wound contact layer 2102, similar to the cover layer and wound contact layer described with reference to Figures 4A-4D. These two layers 2140, 2102 are preferably joined or sealed together so as to define an interior space or chamber. This interior space or chamber may comprise additional structures that may be adapted to distribute or transmit negative pressure, store wound exudate and other fluids removed from the wound, and other functions as described herein. Examples of such structures, described below, include a transmission layer 2105 and an absorbent layer 2110, similar to the transmission layer and absorbent layer described with reference to Figures 4A-4D.

[0258] A layer 2105 of porous material can be located above the wound contact layer 2102. This porous layer, or transmission layer, 2105 allows transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing. In particular, the transmission layer 2105 preferably ensures that an open air channel can be maintained to communicate negative pressure over the wound area even when the absorbent layer has absorbed substantial amounts of exudates. The layer 2105 should preferably remain open under the typical pressures that will be applied during negative pressure wound therapy as described above, so that the whole wound site sees an equalized negative pressure.

[0259] In some embodiments, the transmission layer 2105 may be an apertured nonwoven fabric spacer layer formed from the two layers of nonwoven fabric as described previously herein and illustrated in Figures 1A-2B. In some embodiments, the apertured nonwoven fabric spacer layer can include a first nonwoven fabric layer and a second nonwoven fabric layer. The first nonwoven fabric layer may be formed from an interconnected first fibrous face layer and a first fibrous base layer. The second nonwoven fabric layer can include an interconnected second fibrous face layer and a second fibrous base layer. The first nonwoven fabric layer can be inverted onto the second nonwoven fabric layer to create a spacer type layer for use in a wound dressing. The first face layer of the first nonwoven fabric layer can be in contact with and/or positioned on top of the second face layer of the second nonwoven fabric layer. In some embodiments, the nonwoven fabric layers can be a hydroentangled nonwoven layer.

[0260] In some embodiments, the plurality apertures of the nonwoven fabric layer can form a channel. The channels or apertures created in the nonwoven material can be utilized for the structure they provide in the material. For example, in some embodiments, the spacer layer formed from the nonwoven fabric layers as described herein can remain open upon application of negative pressure to the layer and/or a wound dressing. In some embodiments, the apertures, channels, and/or slits of the nonwoven fabric layer can allow for unique fluid management properties. In some embodiments, the layer formed from the two nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the apertured nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0261] In some embodiments, the transmission layer 2105 may be a three dimensional nonwoven spacer layer construction as described previously herein and illustrated in Figures 3A-3C. In some embodiments, heat and pressure can be used to set the nonwoven into a 3D structure such as in a corrugated construction, a three dimensional zig-zag pattern, an egg-box type construction, a checkerboard construction, and a hexagonal (honeycomb) construction. In some embodiments, the nonwoven material can be thermoformed into the three dimensional construction. In other embodiments, the three dimensional nonwoven material can be formed using a chemical bonding and vacuum forming.

[0262] In some embodiments, the 3D structure can be layered on top of one another or with traditional nonwovens to create a spacer type layer for use in a wound dressing.

[0263] For example, in some embodiments, the spacer layer formed from the nonwoven layers as described herein can remain open upon compression and/or application of negative pressure to the layer and/or a wound dressing. In some embodiments, the three dimensional structure of the nonwoven spacer layer can allow for unique fluid management properties. In some embodiments, the three dimensional nonwoven spacer layer formed from the nonwoven fabric layers can have the performance benefits of a 3D spacer fabric or other spacer fabric described herein in terms of compression under loading and compression recovery. In such embodiments, the three dimensional nonwoven spacer layer can allow transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing.

[0264] In some embodiments, the layer 2105 may be formed of a material having a three dimensional structure. For example, a knitted or woven spacer fabric (for example Baltex 7970 weft knitted polyester) or a non-woven fabric could be used.

[0265] A layer 2110 of absorbent material is provided above the transmission layer 2105. The absorbent material, which comprise a foam or non-woven natural or synthetic material, and which may optionally comprise a super-absorbent material, forms a reservoir for fluid, particularly liquid, removed from the wound site. In some embodiments, the layer 2100 may also aid in drawing fluids towards the backing layer 2140.

[0266] With reference to Figure 8A, a masking or obscuring layer 2107 can be positioned beneath at least a portion of the backing layer 2140. In some embodiments, the obscuring layer 2107 can have any of the same features, materials, or other details of any of the other embodiments of the obscuring layers disclosed herein, including but not limited to having any viewing windows or holes. Examples of wound dressings with obscuring layers and viewing windows are described in International Patent Publication WO2014/020440, the entirety of which is incorporated by reference in its entirety. Additionally, the obscuring layer 2107 can be positioned adjacent to the backing layer, or can be positioned adjacent to any other dressing layer desired. In some embodiments, the obscuring layer 2107 can be adhered to or integrally formed with the backing layer. Preferably, the obscuring layer 2107 is configured to have approximately the same size and shape as the absorbent layer 2110 so as to overlay it. As such, in these embodiments the obscuring layer 2107 will be of a smaller area than the backing layer 2140.

[0267] The material of the absorbent layer 2110 may also prevent liquid collected in the wound dressing 2100 from flowing freely within the dressing, and preferably acts so as to contain any liquid collected within the absorbent layer 2110. The absorbent layer 2110 also helps distribute fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and stored throughout the absorbent layer. This helps prevent agglomeration in areas of the absorbent layer. The capacity of the absorbent material must be sufficient to manage the exudates flow rate of a wound when negative pressure is applied. Since in use the absorbent layer experiences negative pressures the material of the absorbent layer is chosen to absorb liquid under such circumstances. A number of materials exist that are able to absorb liquid when under negative pressure, for example superabsorber material. The absorbent layer 2110 may typically be manufactured from ALLEVYN™ foam, Freudenberg 114-224-4 and/or Chem-Posite™11C-450. In some embodiments, the absorbent layer 2110 may comprise a composite comprising superabsorbent powder, fibrous material such as cellulose, and bonding fibers. In a preferred embodiment, the composite is an airlaid, thermally-bonded composite.

[0268] An orifice 2144 is preferably provided in the backing layer 2140 to allow a negative pressure to be applied to the dressing 2100. A suction port 2150 is preferably attached or sealed to the top of the backing layer 2140 over an orifice 2144 made into the dressing 2100, and communicates negative pressure through the orifice 2144. A length of tubing may be coupled at a first end to the suction port 2150 and at a second end to a pump unit (not shown) to allow fluids to be pumped out of the dressing. The port may be adhered and sealed to the backing layer 2140 using an adhesive such as an acrylic, cyanoacrylate, epoxy, UV curable or hot melt adhesive. The port 2150 is formed from a soft polymer, for example a polyethylene, a polyvinyl chloride, a silicone or polyurethane having a hardness of 30 to 90 on the Shore A scale. In some embodiments, the port 2150 may be made from a soft or conformable material.

[0269] Preferably the absorbent layer 2110 and the obscuring layer 2107 include at least one through hole 2145 located so as to underlie the port 2150. Of course, the respective holes through these various layers 2107, 2140, and 2110 may be of different sizes with respect to each other. As illustrated in Figure 8A a single through hole can be used to produce an opening underlying the port 2150. It will be appreciated that multiple openings could alternatively be utilized. Additionally should more than one port be utilized according to certain embodiments of the present disclosure one or multiple openings may be made in the absorbent layer and the obscuring layer in registration with each respective port. Although not essential to certain embodiments of the present disclosure the use of through holes in the super-absorbent layer may provide a fluid flow pathway which remains unblocked in particular when the absorbent layer 2110 is near saturation.

[0270] The aperture or through-hole 2144 is preferably provided in the absorbent layer 2110 and the obscuring layer 2107 beneath the orifice 2144 such that the orifice is connected directly to the transmission layer 2105. This allows the negative pressure applied to the port 2150 to be communicated to the transmission layer 2105 without passing through the absorbent layer 2110. This ensures that the negative pressure applied to the wound site is not inhibited by the absorbent layer as it absorbs wound exudates. In other embodiments, no aperture may be provided in the absorbent layer 2110 and/or the obscuring layer 2107, or alternatively a plurality of apertures underlying the orifice 2144 may be provided.

[0271] The backing layer 2140 is preferably gas impermeable, but moisture vapor permeable, and can extend across the width of the wound dressing 2100. The backing layer 2140, which may for example be a polyurethane film (for example, Elastollan SP9109) having a pressure sensitive adhesive on one side, is impermeable to gas and this layer thus operates to cover the wound and to seal a wound cavity over which the wound dressing is placed. In this way an effective chamber is made between the backing layer 2140 and a wound site where a negative pressure can be established. The backing layer 2140 is preferably sealed to the wound contact layer 2102 in a border region 2200 around the circumference of the dressing, ensuring that no air is drawn in through the border area, for example via adhesive or welding techniques. The backing layer 2140 protects the wound from external bacterial contamination (bacterial barrier) and allows liquid from wound exudates to be transferred through the layer and evaporated from the film outer surface. The backing layer 2140 preferably comprises two layers; a polyurethane film and an adhesive pattern spread onto the film. The polyurethane film is preferably moisture vapor permeable and may be manufactured from a material that has an increased water transmission rate when wet.

[0272] In some embodiments, the absorbent layer 2110 may be of a greater area than the transmission layer 2105, such that the absorbent layer overlaps the edges of the transmission layer 2105, thereby ensuring that the transmission layer does not contact the backing layer 2140. This provides an outer channel 2115 of the absorbent layer 2110 that is in direct contact with the wound contact layer 2102, which aids more rapid absorption of exudates to the absorbent layer. Furthermore, this outer channel 2115 ensures that no liquid is able to pool around the circumference of the wound cavity, which may otherwise seep through the seal around the perimeter of the dressing leading to the formation of leaks.

[0273] Figure. 8B illustrates a view of an embodiment of a wound dressing with a waisted portion, an obscuring layer, and viewing windows. Figure. 8B illustrates a perspective view of an embodiment of a wound dressing 1400. The wound dressing 1400 preferably comprises a port 1406. The port 1406 is preferably configured to be in fluid communication with a pump, and may include a tube or conduit pre-attached to the port. Alternatively, negative pressure can be supplied to the wound dressing through other suitable fluidic connectors, including but not limited to the fluidic connectors of the type described below in Figures 4A-4D.

[0274] The wound dressing 1400 can be constructed similar to the embodiments of Figure 8A above, and may comprise an absorbent material 1402 underneath or within a backing layer 1405. Optionally, a wound contact layer and a transmission layer may also be provided as part of the wound dressing 1400 as described above with reference to Figure 8A. In some embodiments, the transmission layer can be an apertured nonwoven fabric spacer layer as described herein with reference to Figures 1A-2B or a three dimensional nonwoven spacer layer construction as described herein with reference to Figures 3A-3C. The absorbent material 1402 can contain a narrowed central or waisted portion 1408 to increase flexibility and conformability of the wound dressing to the skin surface. The backing layer 1405 may have a border region 1401 that extends beyond the periphery of the absorbent material 1402.

The backing layer 1405 may be a translucent or transparent backing layer, such that the border region 1401 created from the backing layer 1405 can be translucent or transparent. The area of the border region 1401 of the backing layer 405 can be approximately equal around the perimeter of the entire dressing with the exception of the narrowed central portion, where the area of the border region is larger. One will recognize that the size of the border region 1401 will depend on the full dimensions of the dressing and any other design choices.

[0275] As illustrated in Figure 8B, provided at least at the top of or over the absorbent layer 1402 and under the backing layer 1405 may be an obscuring layer 1404 that optionally has one or more viewing windows 1403. The obscuring layer 1404 may partially or completely obscure contents (such as fluids) contained within the wound dressing 1400 and/or the absorbent material (i.e., within the absorbent material 1402 or under the backing layer 1405). The obscuring layer may be a colored portion of the absorbent material, or may be a separate layer that covers the absorbent material. In some embodiments, the absorbent material 1402 may be hidden (partially or completely), colored, or tinted, via the obscuring layer 1404, so as to provide cosmetic and/or aesthetic enhancements, in a similar manner to what is described above. The obscuring layer is preferably provided between the topmost backing layer 1405 and the absorbent material 1402, although other configurations are possible. The cross-sectional view in Figure 8A illustrates this arrangement with respect to the masking or obscuring layer 2107. Other layers and other wound dressing components can be incorporated into the dressing as herein described.

[0276] The obscuring layer 1404 can be positioned at least partially over the absorbent material 1402. In some embodiments, the obscuring layer 1404 can be positioned adjacent to the backing layer, or can be positioned adjacent to any other dressing layer desired. In some embodiments, the obscuring layer 1404 can be adhered to or integrally formed with the backing layer and/or the absorbent material.

[0277] As illustrated in Figure 8B, the obscuring layer 1404 can have substantially the same perimeter shape and size as the absorbent material 1402. The obscuring layer 1404 and absorbent material 1402 can be of equal size so that the entirety of the absorbent material 1402 can be obscured by the obscuring layer 1404. The obscuring layer 1404 may allow for obscuring of wound exudate, blood, or other matter released from a wound. Further, the obscuring layer 1404 can be completely or partially opaque having cut-out viewing windows or perforations.

[0278] In some embodiments, the obscuring layer 1404 can help to reduce the unsightly appearance of a dressing during use, by using materials that impart partial obscuring or masking of the dressing surface. The obscuring layer 1404 in one embodiment only partially obscures the dressing, to allow clinicians to access the information they require by observing the spread of exudate across the dressing surface. The partial masking nature of this embodiment of the obscuring layer enables a skilled clinician to perceive a different color caused by exudate, blood, by-products etc. in the dressing allowing for a visual assessment and monitoring of the extent of spread across the dressing. However, since the change in color of the dressing from its clean state to a state containing exudate is only a slight change, the patient is unlikely to notice any aesthetic difference. Reducing or eliminating a visual indicator of wound exudate from a patient's wound is likely to have a positive effect on their health, reducing stress for example.

[0279] In some embodiments, the obscuring layer can be formed from a non-woven fabric (for example, polypropylene), and may be thermally bonded using a diamond pattern with 19% bond area. In various embodiments, the obscuring layer can be hydrophobic or hydrophilic. Depending on the application, in some embodiments, a hydrophilic obscuring layer may provide added moisture vapor permeability. In some embodiments, however, hydrophobic obscuring layers may still provide sufficient moisture vapor permeability (i.e., through appropriate material selection, thickness of the obscuring layer), while also permitting better retention of dye or color in the obscuring layer. As such, dye or color may be trapped beneath the obscuring layer. In some embodiments, this may permit the obscuring layer to be colored in lighter colors or in white. In the preferred embodiment, the obscuring layer is hydrophobic. In some embodiments, the obscuring layer material can be sterilizable using ethylene oxide. Other embodiments may be sterilized using gamma irradiation, an electron beam, steam or other alternative sterilization methods. Additionally, in various embodiments the obscuring layer can colored or pigmented, e.g., in medical blue. The obscuring layer may also be constructed from multiple layers, including a colored layer laminated or fused to a stronger uncolored layer. Preferably, the obscuring layer is odorless and exhibits minimal shedding of fibers.

[0280] The absorbent layer 1402, itself may be colored or tinted in some embodiments, however, so that an obscuring layer is not necessary. The dressing may optionally include a means of partially obscuring the top surface. This could also be achieved using a textile (knitted, woven, or non-woven) layer without openings, provided it still enables fluid evaporation from the absorbent structure. It could also be achieved by printing an obscuring pattern on the top film, or on the top surface of the uppermost pad component, using an appropriate ink or colored pad component (yarn, thread, coating) respectively. Another way of achieving this would be to have a completely opaque top surface, which could be temporarily opened by the clinician for inspection of the dressing state (for example through a window), and closed again without compromising the environment of the wound. Additionally, Figure 8B illustrates an embodiment of the wound dressing including one or more viewing windows 1403. The one or more viewing windows 1403 preferably extend through the obscuring layer 1404. These viewing windows 1403 may allow visualization by a clinician or patient of the wound exudate in the absorbent material below the obscuring layer. Figure 8B illustrates an array of dots (e.g., in one or more parallel rows) that can serve as viewing windows 1403 in the obscuring layer 1404 of the wound dressing. In a preferred embodiment, two or more viewing windows 1403 may be parallel with one or more sides of the dressing 1400. In some embodiments, the one or more viewing windows may measure between 0.1 mm and 20 mm, preferably 0.4 mm to 10 mm, and even more preferably, 1 mm to 4 mm. The viewing windows 1403 may be cut through the obscuring layer 1404 or may be part of an uncolored area of the obscuring layer 1404 and therefore may allow visualization of the absorbent material 1402. The one or more viewing windows 1403 can be arranged in a repeating pattern across the obscuring layer 1404 or can be arranged at random across the obscuring layer. Additionally, the one or more viewing windows can be a circular shape or dots. Preferably, the one or more viewing windows 1403 are configured so as to permit not only the degree of saturation, but also the progression or spread of fluid toward the fluid port 1406, as in some embodiments, dressing performance may be adversely affected when the level of fluid has saturated the fluid proximate the port 1406. In some embodiments, a “starburst” array of viewing windows 1403 emanating around the port 1406 may be suitable to show this progression, although of course other configurations are possible. In some embodiments, the viewing windows 1403 correspond to the area of the absorbent material 1402 that is not covered by the obscuring layer 1404. As such, the absorbent material 1402 is directly adjacent the backing layer 1405 in this area. Since the obscuring layer 1404 acts as a partial obscuring layer, the viewing windows 1403 may be used by a clinician or other trained user to assess the spread of wound exudate throughout the dressing. In some embodiments, the viewing windows 1403 can comprise an array of dots or crescent shaped cut-outs. For example, an array of dots as viewing windows 1403 are illustrated in Figure 8B in which the array of dots are arranged in an 5×2 array. Additionally, in some embodiments, the dot pattern can be distributed evenly throughout the obscuring layer and across the entire or substantially the entire surface of the obscuring layer. In some embodiments, the viewing windows 1403 may be distributed randomly throughout the obscuring layer. Preferably, the area of the obscuring layer 1404 uncovered by the one or more viewing windows 1403 is balanced to as to minimize the appearance of exudate while permitting the inspection of the dressing 1400 and/or absorbent material 1402. In some embodiments, the area exposed by the one or more viewing windows 1403 does not exceed 20% of the area of the obscuring layer 1404, preferably 10%, and even more preferably 5%.

[0281] The viewing windows 1403 may take several configurations. In some embodiments, the viewing windows 1403 may comprise an array of regularly spaced uncolored dots (holes) made into the obscuring layer 1404. While the dots illustrated here are in a particular pattern, the dots may be arranged in different configurations, or at random. The viewing windows 1403 are preferably configured so as to permit a patient or caregiver to ascertain the status of the absorbent layer, in particular to determine its saturation level, as well as the color of the exudate (e.g., whether excessive blood is present). By having one or more viewing windows, the status of the absorbent layer can be determined in an unobtrusive manner that is not aesthetically unpleasing to a patient. Because a large portion of the absorbent layer may be obscured, the total amount of exudate may therefore be hidden. As such, the status and saturation level of the absorbent layer 1402 may therefore present a more discreet external appearance so as to reduce patient embarrassment and visibility and thereby enhance patient comfort. In some configurations, the one or more viewing windows 1403 may be used to provide a numerical assessment of the degree of saturation of the dressing 1400. This may be done electronically (e.g., via a digital photograph assessment), or manually. For example, the degree of saturation may be monitored by counting the number of viewing windows 1403 which may be obscured or tinted by exudate or other wound fluids.

[0282] In some embodiments, the absorbent layer 1402 or the obscuring layer 1404, in particular the colored portion of the absorbent layer, may comprise (or be colored because of) the presence of an auxiliary compound. The auxiliary compound may in some embodiments be activated charcoal, which can act to absorb odors. The use of antimicrobial, antifungal, anti-inflammatory, and other such therapeutic compounds is also possible. In some embodiments, the color may change as a function of time (e.g., to indicate when the dressing needs to be changed), if the dressing is saturated, or if the dressing has absorbed a certain amount of a harmful substance (e.g., to indicate the presence of infectious agents). In some embodiments, the one or more viewing windows 1403 may be monitored electronically, and may be used in conjunction with a computer program or system to alert a patient or physician to the saturation level of the dressing 1400.

[0283] Each of the documents referred to above is incorporated herein by reference.

[0284] Except in the Examples, or where otherwise explicitly indicated, all numerical quantities in this description specifying amounts of materials, processing conditions and the like, are to be understood as modified by the word “about.”

[0285] While the invention has been explained in relation to its preferred embodiments, it is to be understood that various modifications thereof will become apparent to those skilled in the art upon reading the specification. Therefore, it is to be understood that the invention disclosed herein is intended to cover such modifications as fall within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A wound treatment apparatus comprising:

a wound dressing comprising:

a spacer layer comprising:

a first nonwoven fabric layer comprising a first fibrous base layer and an interconnected first fibrous face layer, wherein a plurality of channels are disposed between the first fibrous base layer and the first fibrous face layer; and

a second nonwoven fabric layer comprising a second fibrous base layer and an interconnected second fibrous face layer, wherein a plurality of channels are disposed between the second fibrous base layer and the second fibrous face layer;

wherein the second nonwoven fabric layer is disposed over the first nonwoven fabric layer such that the second fibrous face layer of the second nonwoven fabric is positioned over the first fibrous face layer of the first nonwoven fabric; and

a cover layer positioned over the spacer layer.

2. The wound treatment apparatus of Claim 1, wherein each of the plurality channels of the first or second nonwoven fabric layers extends across an entire length of the first and second nonwoven fabric layers.

3. The wound treatment apparatus of Claim 2, wherein the channels of the first nonwoven fabric layer extend in a first direction and the channels of the second nonwoven fabric layer extend in a second direction.

4. The wound treatment apparatus of Claim 3, wherein the first direction is parallel to the second direction.

5. The wound treatment apparatus of Claim 3, wherein the first direction is perpendicular to the second direction.

6. The wound treatment apparatus in any of Claims 2-4, wherein the plurality of channels of the second nonwoven fabric layer are disposed directly over the plurality of channels of the first nonwoven fabric layer.

7. The wound treatment apparatus in any of Claims 2-4, wherein the plurality of channels of the second nonwoven fabric layer are offset from the plurality of channels of the first nonwoven fabric layer.

8. The wound treatment apparatus in any of Claims 2-7, wherein each of the plurality of channels of the first and second nonwoven fabric layers has a diameter of from about 0.5 mm to about 5 mm

9. The wound treatment apparatus in any of Claims 1-8, wherein the base layer and the face layer of the first and/or second nonwoven fabric layers are hydroentangled.

10. The wound treatment apparatus in any of Claims 1-9, wherein the face layer of the first and/or second nonwoven fabric layers is hydrophilic.

11. The wound treatment apparatus in any of Claims 1-10, wherein the base layer of the first and/or second nonwoven fabric layers is hydrophobic.

12. The wound treatment apparatus in any of Claims 1-11, further comprising:

a pump;

a suction port for applying negative pressure to a wound site through an orifice in the cover layer.

13. The wound treatment apparatus in any of Claims 1-12, wherein the spacer layer is configured to remain open upon application of negative pressure to the wound treatment apparatus.

14. The wound treatment apparatus in any of Claims 1-13, further comprising an absorbent layer for absorbing wound exudate, the absorbent layer positioned over the spacer layer.

15. The wound treatment apparatus of Claim 14, wherein the absorbent layer comprises a non-woven material containing superabsorbent particles or fibers.

16. The wound treatment apparatus of Claim 14, further comprising a masking layer positioned between the absorbent layer and cover layer.

17. The wound treatment apparatus of Claim 14, further comprising a second spacer layer positioned over the absorbent layer, wherein the second spacer layer comprises:

a third nonwoven fabric layer comprising a third fibrous base layer and an interconnected third fibrous face layer, wherein a plurality of channels are disposed between the third fibrous base layer and the third fibrous face layer; and

a fourth nonwoven fabric layer comprising a fourth fibrous base layer and an interconnected fourth fibrous face layer, wherein a plurality of channels are disposed between the fourth fibrous base layer and the fourth fibrous face layer;

wherein the fourth nonwoven fabric layer is disposed over the third nonwoven fabric layer such that the fourth fibrous face layer of the fourth nonwoven fabric is in contact with the third fibrous face layer of the third nonwoven fabric.

18. The wound treatment apparatus in any of Claims 1-17, wherein the cover layer comprises an orifice.

19. The wound treatment apparatus in any of Claims 1-18, wherein the cover layer comprises a moisture vapor permeable material.

20. The wound treatment apparatus in any of Claims 1-19, wherein the channels are rounded channels.

21. The wound treatment apparatus in any of Claims 1-20, wherein the channels are rectangular channels.

22. The wound treatment apparatus in any of Claims 1-21, wherein the channels are triangular channels.

23. A spacer layer for use in a wound dressing, the spacer layer comprising:

a first nonwoven fabric layer comprising a first fibrous base layer and an interconnected first fibrous face layer, wherein a plurality of channels are disposed between the first fibrous base layer and the first fibrous face layer; and

a second nonwoven fabric layer comprising a second fibrous base layer and an interconnected second fibrous face layer, wherein a plurality of channels are disposed between the second fibrous base layer and the second fibrous face layer;

wherein the second nonwoven fabric layer is disposed over the first nonwoven fabric layer such that the second face layer of the second nonwoven fabric is positioned over the first face layer of the first nonwoven fabric.

24. A method for the treatment of a wound, comprising:

providing a wound dressing comprising:

a spacer layer comprising;

a first nonwoven fabric layer comprising a first fibrous base layer and an interconnected first fibrous face layer, wherein a plurality of channels are disposed between the first fibrous base layer and the first fibrous face layer; and

a second nonwoven fabric layer comprising a second fibrous base layer and an interconnected second fibrous face layer, wherein a plurality of channels are disposed between the second fibrous base layer and the second fibrous face layer;

wherein the second nonwoven fabric layer is disposed over the first nonwoven fabric layer such that the second face layer of the second nonwoven fabric is positioned over the first face layer of the first nonwoven fabric;

a cover layer positioned over the spacer layer and comprising an orifice;

positioning the dressing over a wound site to form a sealed cavity over the wound site; and

applying negative pressure to the wound site through the orifice to draw fluid through the spacer layer into the absorbent layer.

25. The method of Claim 24, wherein the wound dressing further comprises an absorbent layer for absorbing wound exudate, the absorbent layer positioned over the spacer layer.

26. A wound treatment apparatus comprising:

a wound dressing comprising:

a spacer layer comprising:

at least one nonwoven fabric layer formed into a three dimensional nonwoven structure, wherein the three dimensional nonwoven structure is formed by thermoforming, chemical bonding, or vacuum forming; and a cover layer positioned over the spacer layer.

27. The wound treatment apparatus of Claim 26, wherein the three dimensional nonwoven structure is formed by thermoforming.

28. The wound treatment apparatus of Claim 26, wherein the three dimensional nonwoven structure is formed by chemical bonding.

29. The wound treatment apparatus of Claim 26, wherein the three dimensional nonwoven structure is formed by vacuum forming.

30. The wound treatment apparatus of Claim 26, wherein the three dimensional nonwoven structure comprises a corrugated structure.

31. The wound treatment apparatus of Claim 26, wherein the three dimensional nonwoven structure comprises a honeycomb structure.

32. The wound treatment apparatus of Claim 26, wherein the three dimensional nonwoven structure comprises a cuboid structure.

33. The wound treatment apparatus of Claim 26, wherein the three dimensional nonwoven structure comprises an egg-box structure.

34. The wound treatment apparatus of Claim 26, wherein the three dimensional nonwoven structure comprises a three dimensional zig-zag structure.

35. The wound treatment apparatus of any one of Claims 26-34, wherein the spacer layer further comprises one or more support layers, wherein the one or more support layers is positioned over the three dimensional nonwoven structure.

36. The wound treatment apparatus of any one of Claims 26-35, wherein the spacer layer further comprises one or more support layers, wherein the one or more support layers is positioned below the three dimensional nonwoven structure.

37. The wound treatment apparatus of any one of Claims 26-36, wherein the three dimensional nonwoven structure comprises a thermoformed nonwoven layer.

38. The wound treatment apparatus of any one of Claims 26-37, wherein the three dimensional nonwoven structure comprises thermoplastic fibers.

39. The wound treatment apparatus of any one of Claims 26-38, wherein the three dimensional nonwoven structure comprise a blend of thermoplastic fibers and other fibers.

40. The wound treatment apparatus of Claim 39, wherein the other fibers comprise viscose fibers, gellable fibers, binder fibers, and/or bicomponent fibers.

41. The wound treatment apparatus of any one of Claims 26-40, wherein the three dimensional nonwoven structure consists essentially of thermoplastic fibers.

42. The wound treatment apparatus of any one of Claims 26-41, wherein the at least one three dimensional nonwoven structure has a thickness of 2 to 10 mm.

43. The wound treatment apparatus of any one of Claims 26-42, wherein the at least one three dimensional nonwoven structure has a thickness of about 3 mm.

44. The wound treatment apparatus of any one of Claims 26-43, wherein the nonwoven fabric is produced by airlaying, carding, or meltspinning.

45. The wound treatment apparatus of any one of Claims 26-44, wherein the nonwoven fabric is isotropic.

46. The wound treatment apparatus of any one of Claims 26-45, wherein the nonwoven fabric comprises polypropylene.

47. The wound treatment apparatus of any one of Claims 26-46, wherein the nonwoven fabric is hydroentangled.

48. The wound treatment apparatus of any one of Claims 26-47, wherein the wound dressing further comprises an absorbent layer for absorbing wound exudate, the absorbent layer positioned over the spacer layer.

49. The wound treatment apparatus of Claim 48, wherein the wound dressing further comprises a second spacer layer positioned over the absorbent layer.

50. The wound treatment apparatus of any one of Claims 26-49, wherein the spacer layer further comprising a first thermoformed nonwoven fabric layer and a second thermoformed fabric layer disposed over the first thermoformed nonwoven fabric layer.

51. The wound treatment apparatus of any one of Claims 26-50, the spacer layer further comprising a three dimensional knitted or fabric layer.

52. The wound treatment apparatus of any one of Claims 26-51, further comprising:

a pump;

a suction port for applying negative pressure to a wound site through the orifice in the cover layer.

53. A method of using the wound treatment apparatus of any of Claims 26-52 to treat a wound.

54. A spacer layer for use in a wound dressing, the spacer layer comprising:

at least one thermoformed nonwoven fabric layer comprising a three dimensional structure,

wherein the thermoformed nonwoven fabric comprises thermoplastic fibers.

55. A method for the treatment of a wound, comprising:

positioning a dressing over a wound site to form a sealed cavity over the wound site, the dressing comprising:

a spacer layer comprising at least one nonwoven fabric layer formed into a three dimensional nonwoven structure, wherein the three dimensional nonwoven structure is formed by thermoforming, chemical bonding, or vacuum forming;

and

a cover layer overlying the spacer layer; and

applying negative pressure to the wound site to draw fluid through the spacer layer.

56. The method of Claim 55, wherein the dressing further comprises an absorbent layer for absorbing wound exudate, the absorbent layer positioned over the spacer layer.

57. The method of any one of Claims 55 or 56, wherein the cover layer comprises an orifice and negative pressure is applied to the wound site through the orifice.

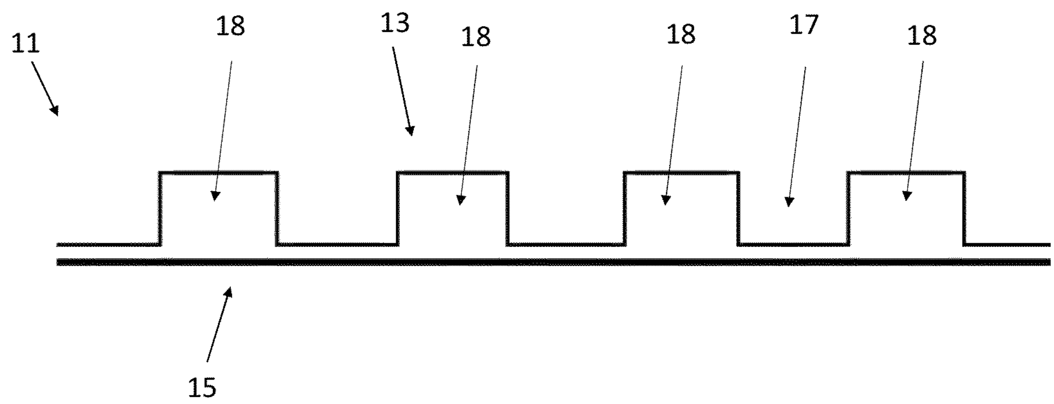


FIGURE 1A

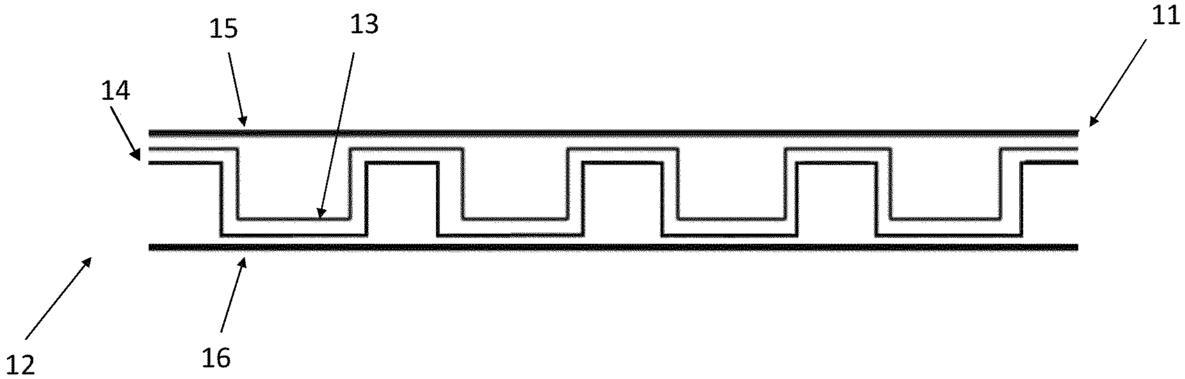


FIGURE 1B

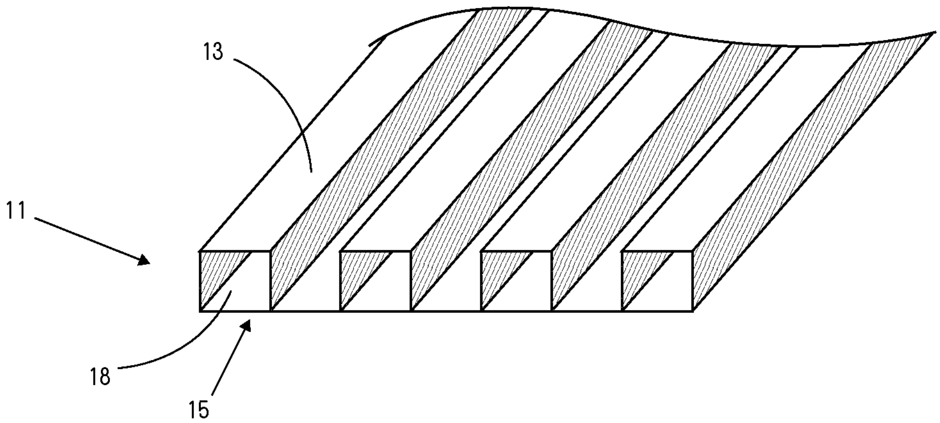


FIGURE 2A

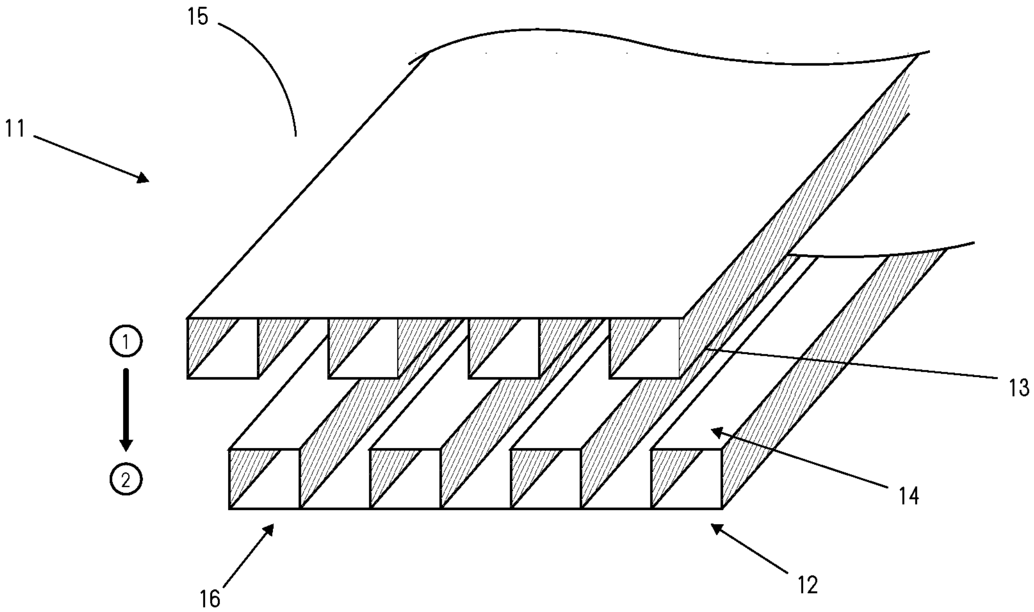


FIGURE 2B

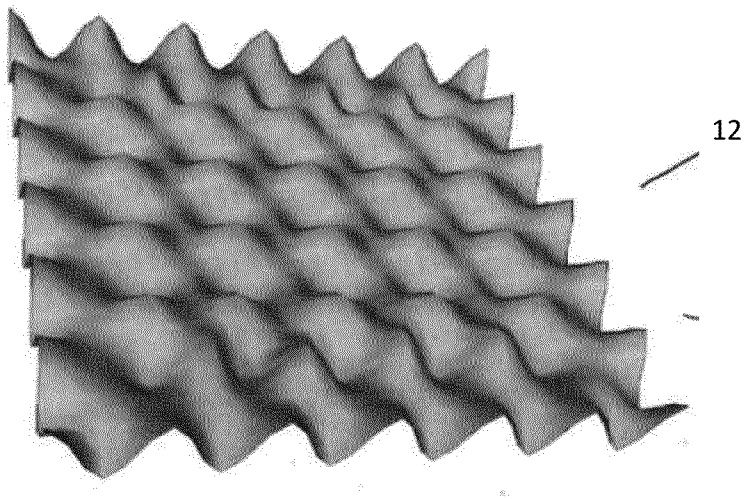


FIGURE 3A

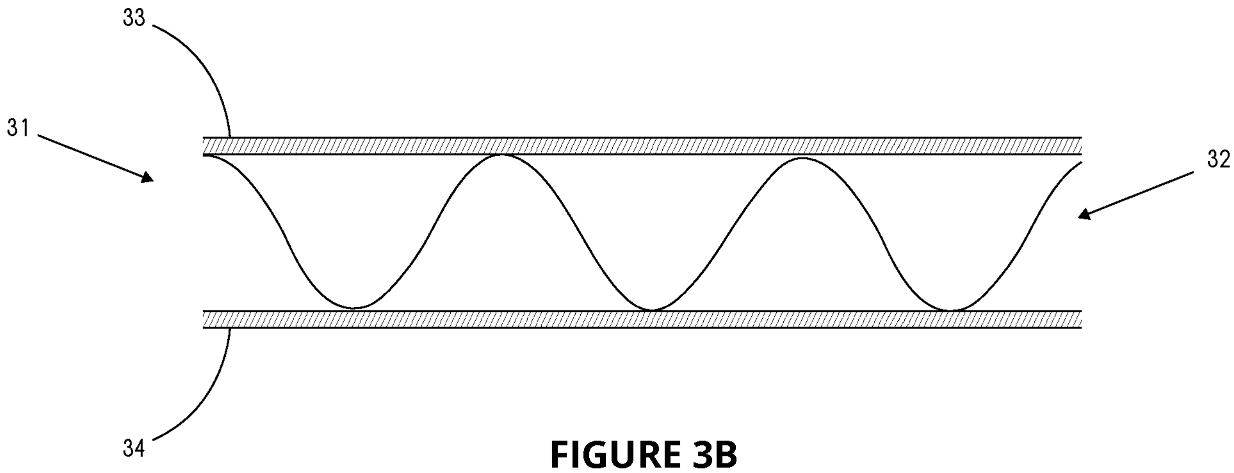


FIGURE 3B

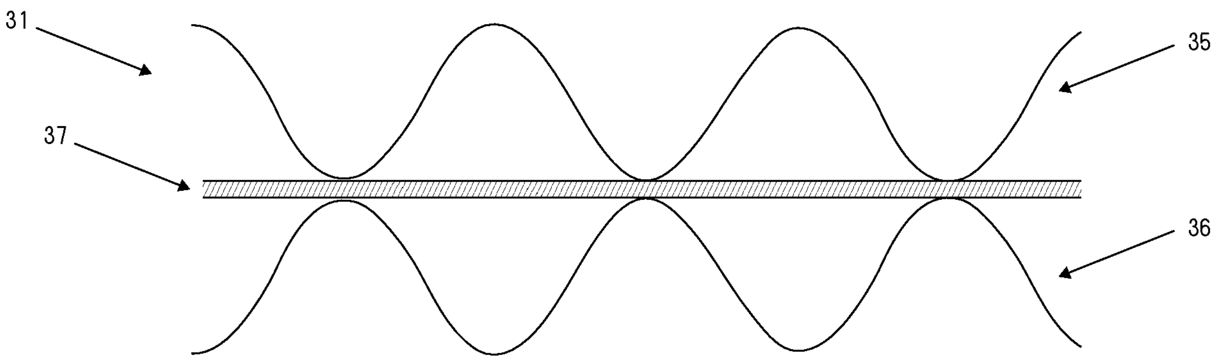
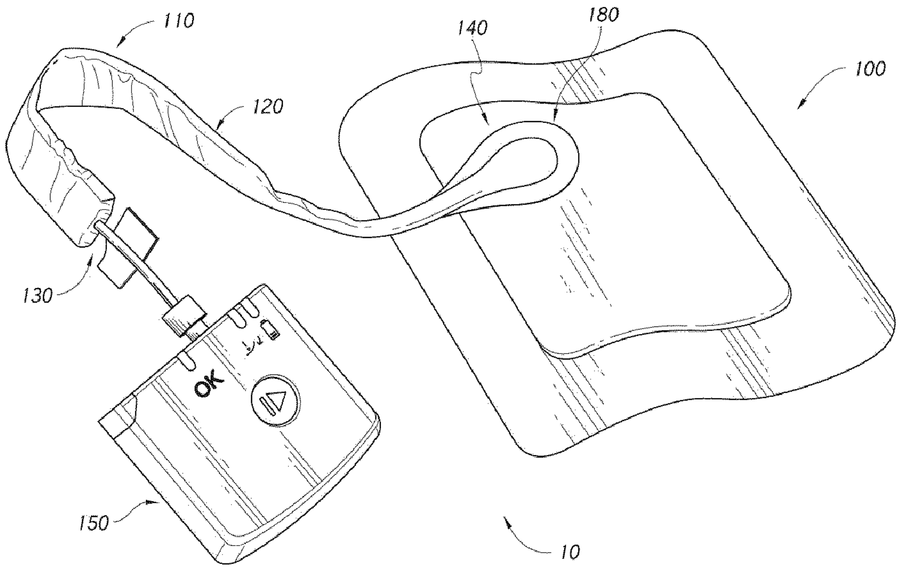


FIGURE 3C

FIGURE 4A



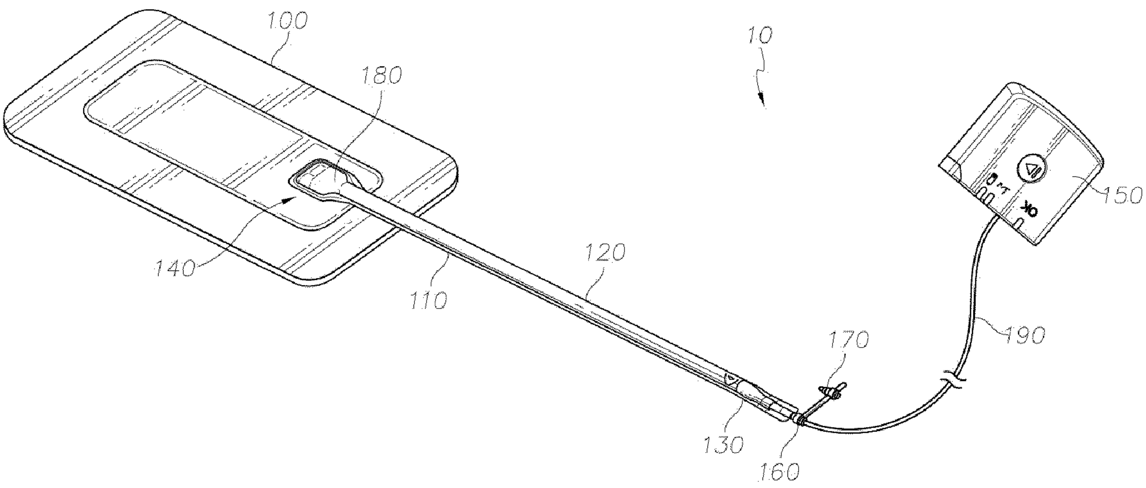


FIGURE 4B

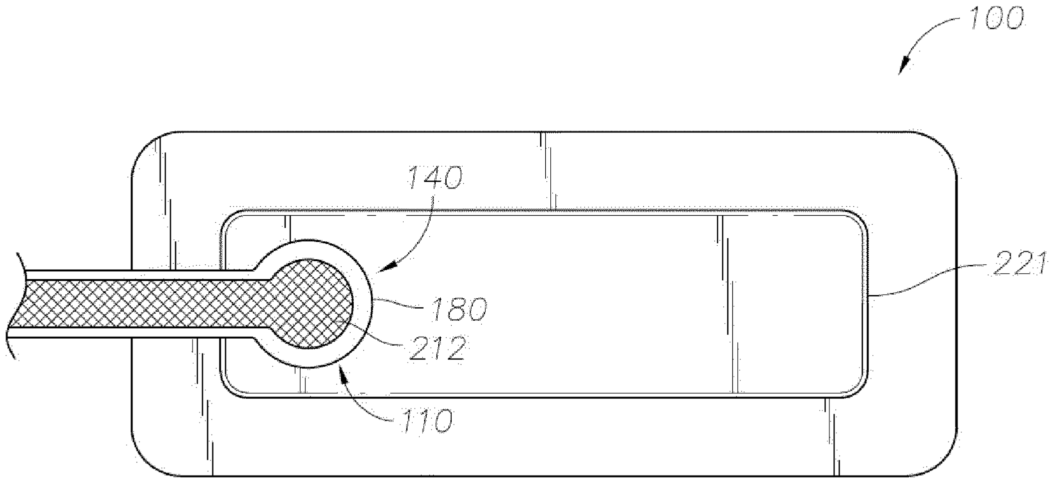


FIGURE 4C

FIGURE 4D

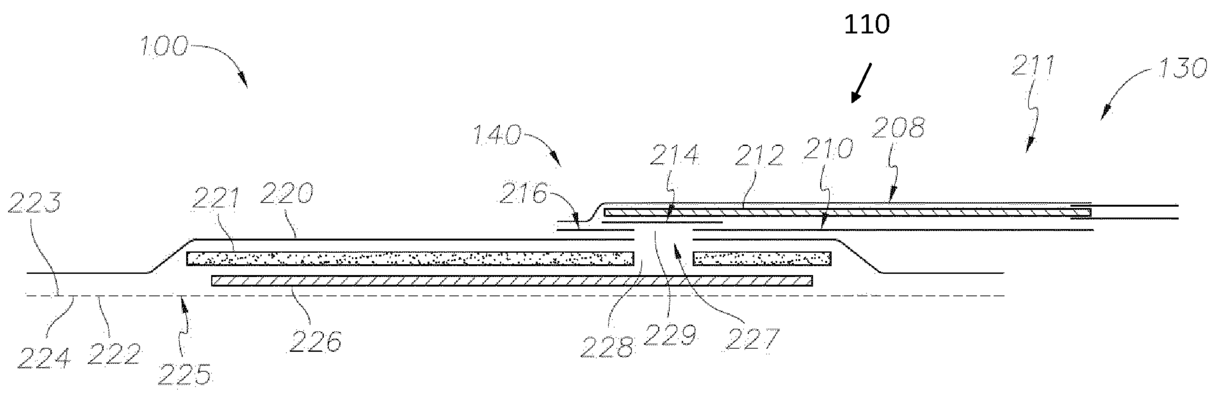

100
110
211
130
140
214
212
210
208
216
223
221
220
224
222
225
226
228
229
227

FIGURE 5A

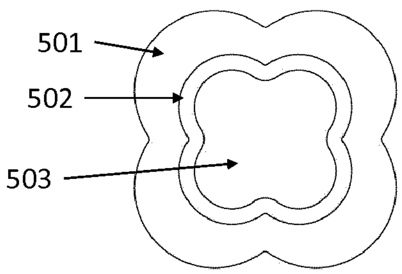
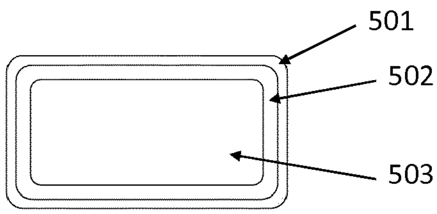


FIGURE 5B



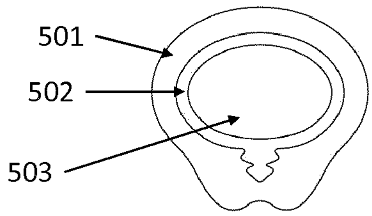


FIGURE 5C

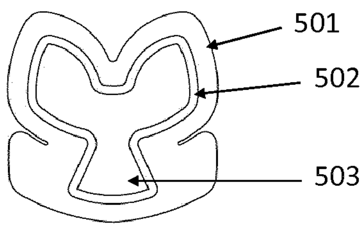


FIGURE 5D

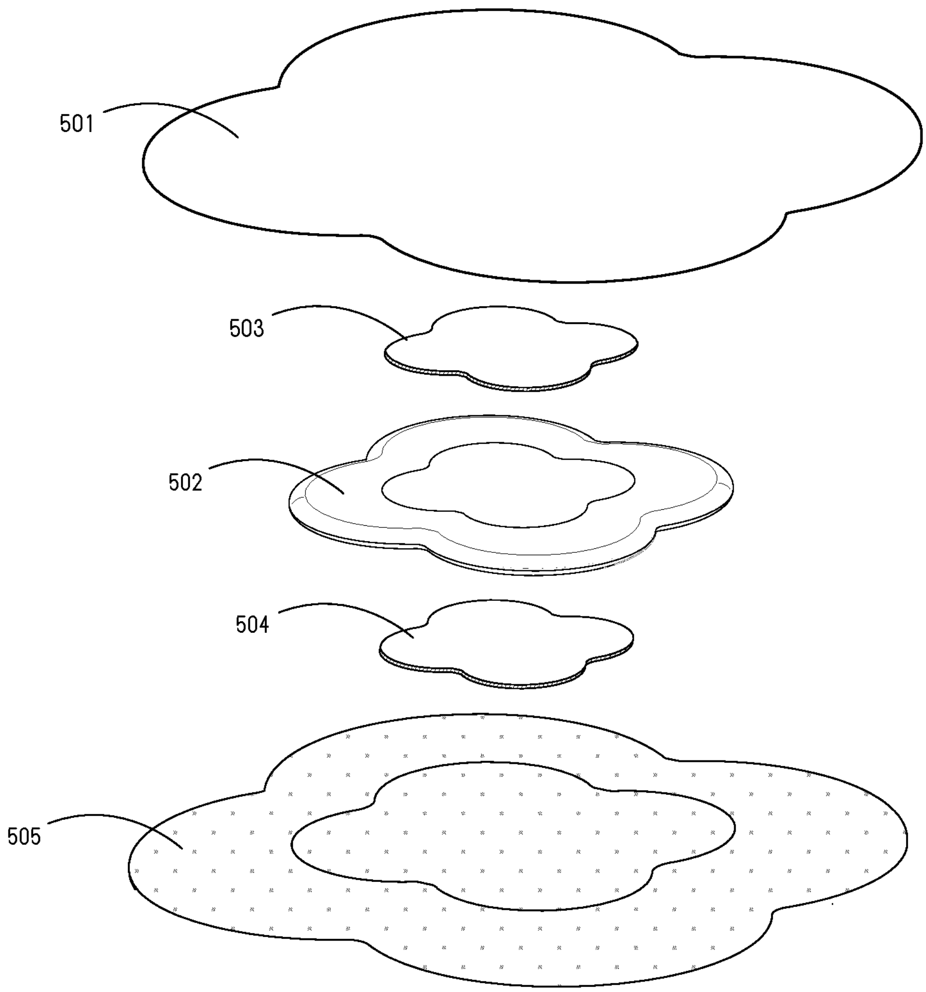


FIGURE 5E

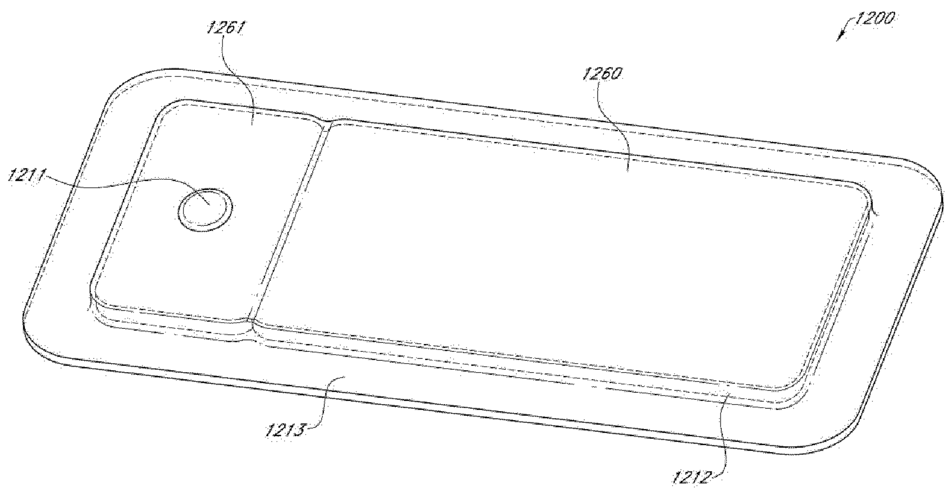


FIGURE 6A

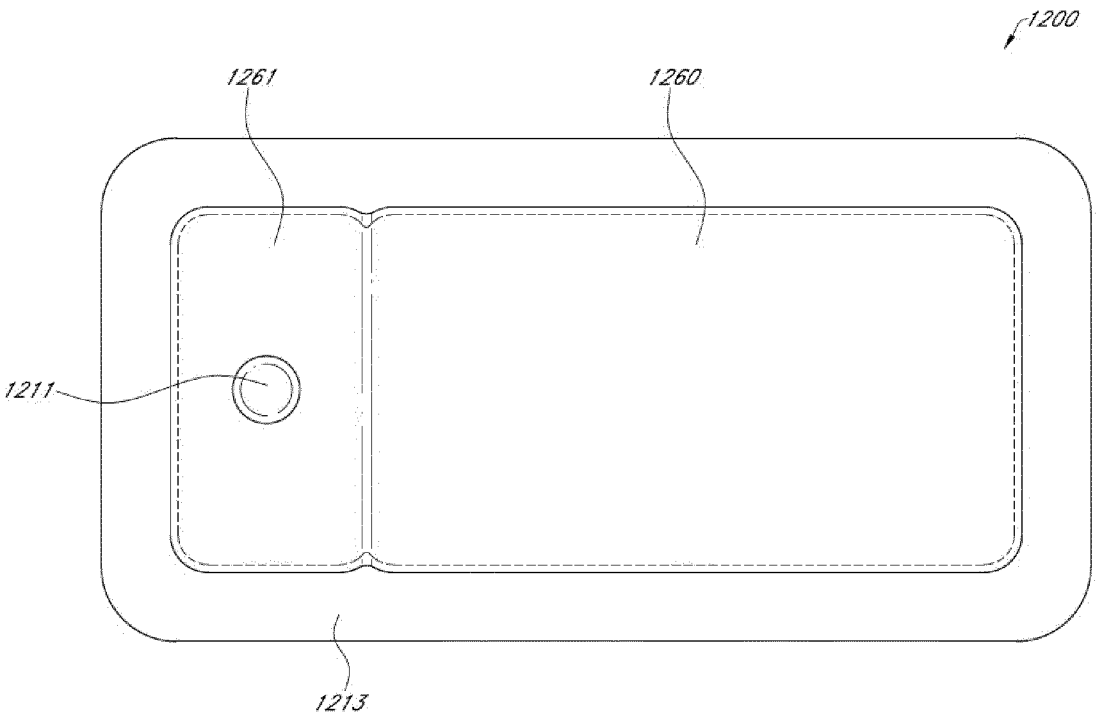


FIGURE 6B

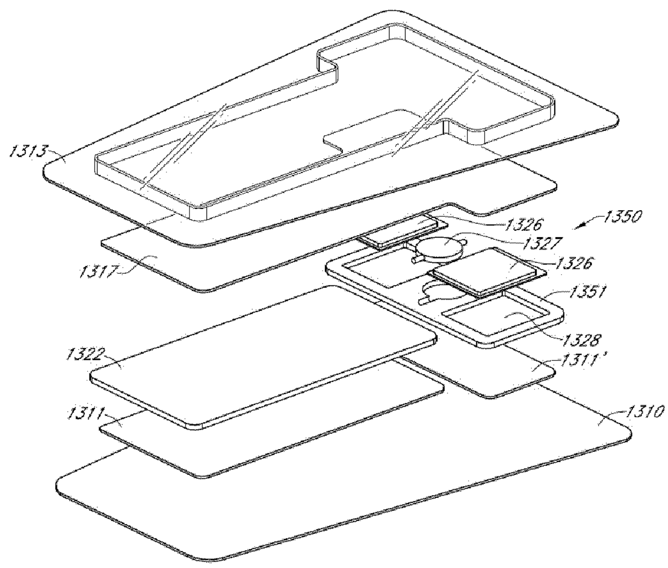


FIGURE 6C

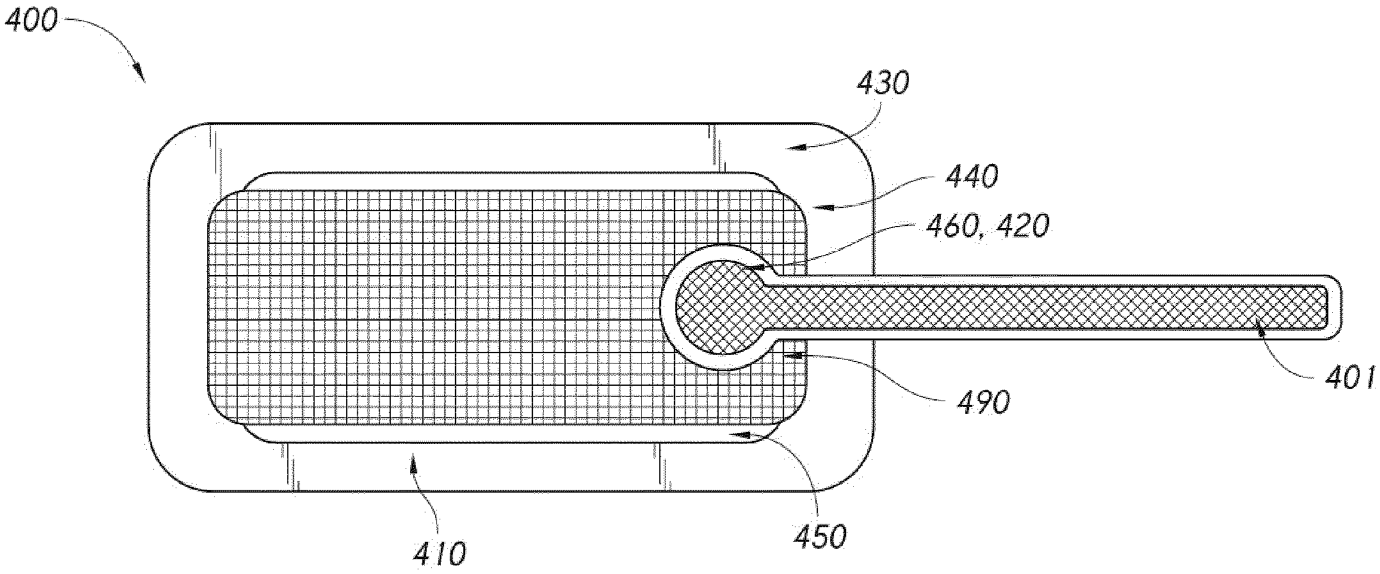


FIGURE 7A

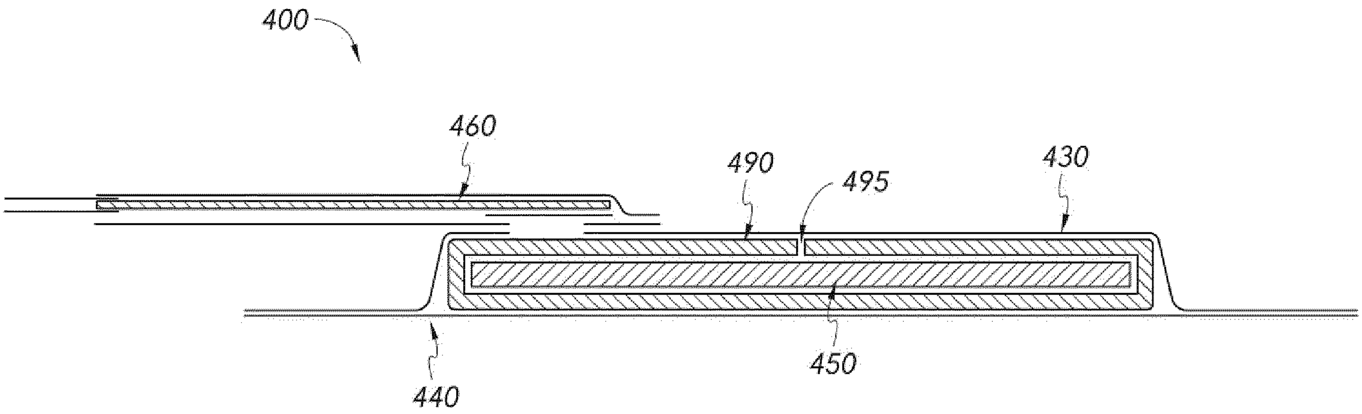


FIGURE 7B

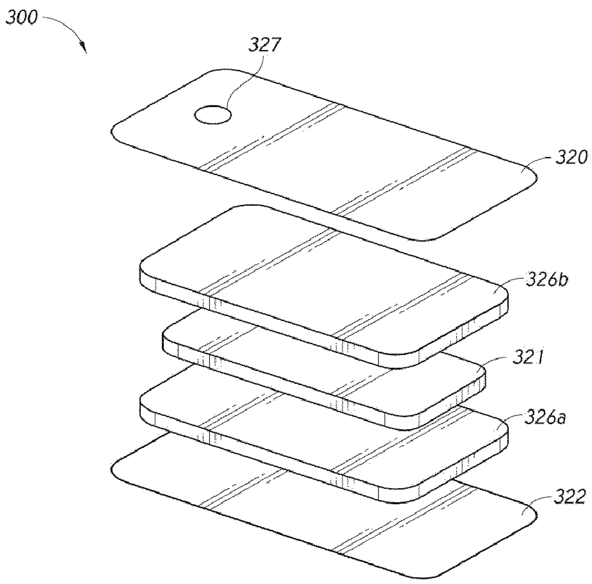


FIGURE 7C

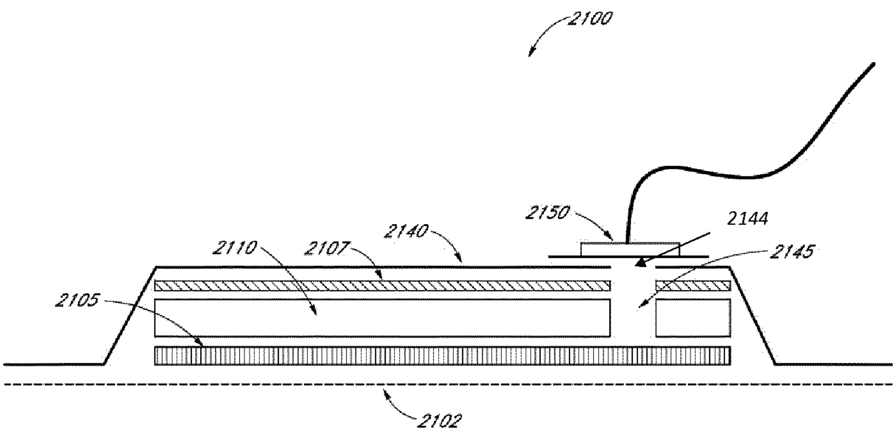


FIGURE 8A

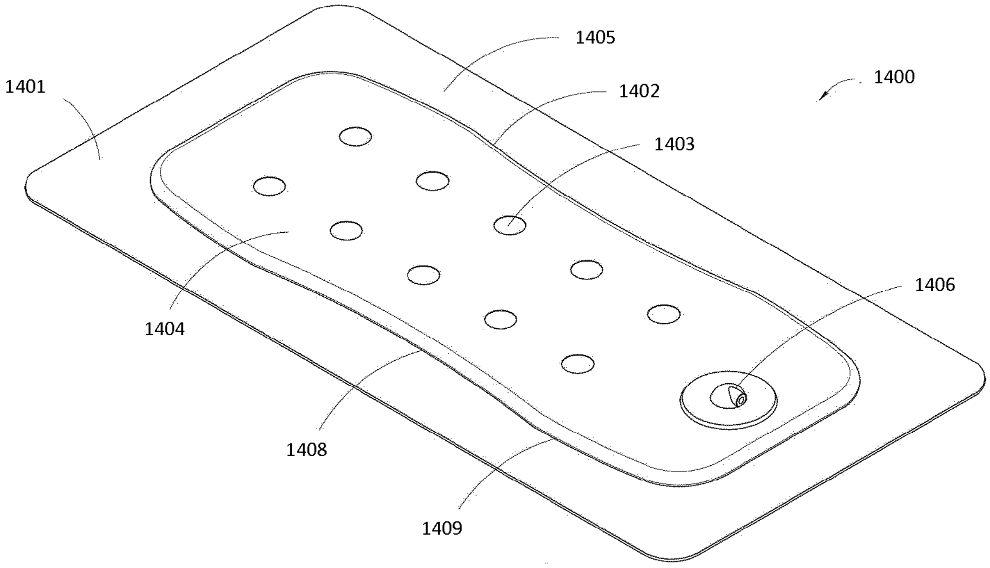


FIGURE 8B

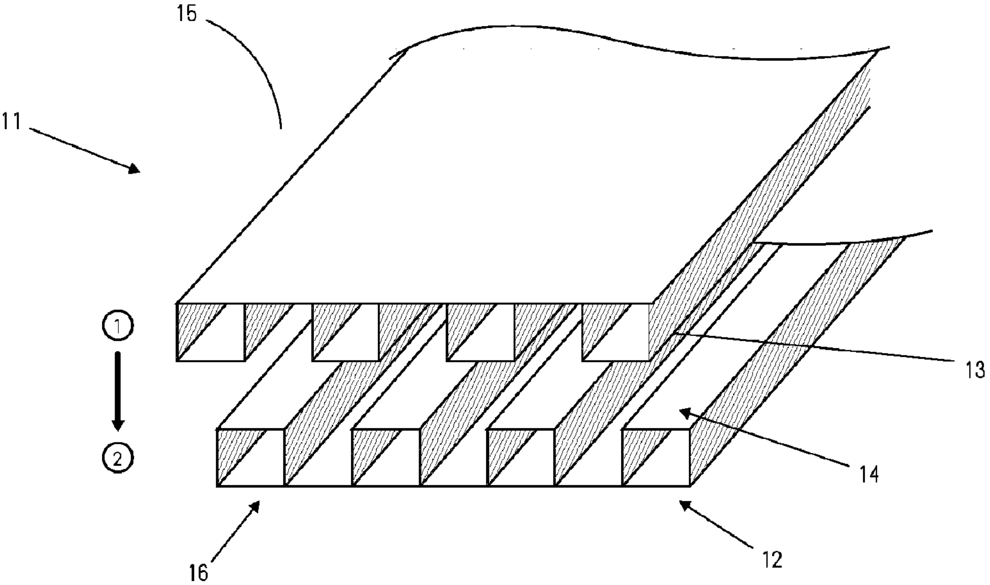


FIGURE 2B