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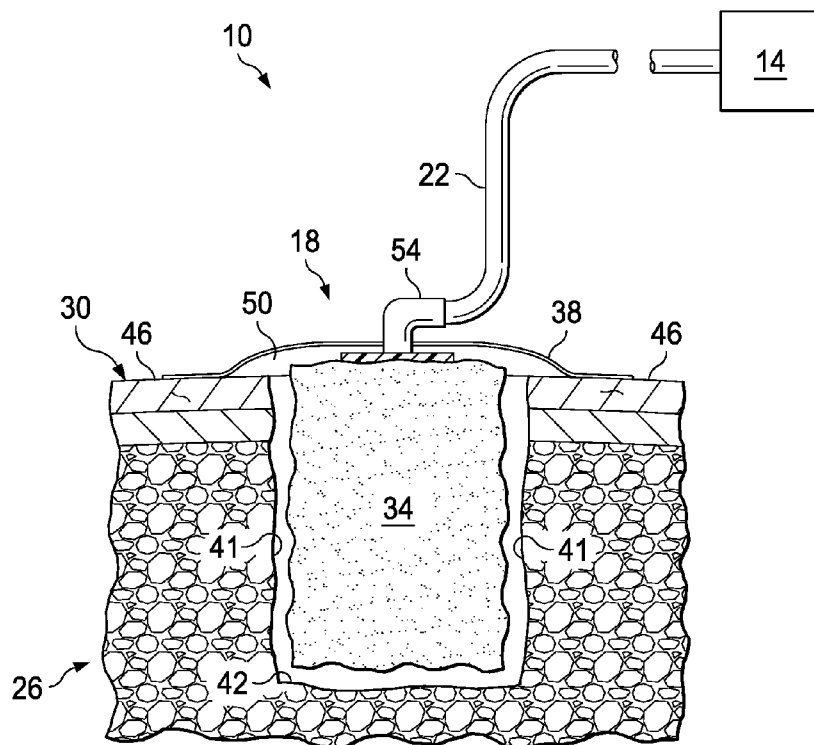
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[Continued on next page]

(54) Title: FOAM STRUCTURE WOUND INSERTS FOR DIRECTIONAL GRANULATION



(57) Abstract: A wound treatment system comprises a wound-treatment apparatus and a wound dressing coupled to the apparatus. The wound dressing includes a foam structure wound insert having pores with a greater cross-sectional area when viewed from a first direction and a smaller cross-sectional area when viewed from an orthogonal direction. Methods for making such wound inserts may include compressing foam structure material having pores with a substantially uniform cross-sectional area. Methods for treating a wound using a wound insert.



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## **FOAM STRUCTURE WOUND INSERTS FOR DIRECTIONAL GRANULATION**

### **CROSS-REFERENCE TO RELATED APPLICATION**

**[0001]** This application claims priority to U.S. Provisional Patent Application No. 61/594,018 filed February 2, 2012, entitled FOAM WOUND INSERTS FOR DIRECTIONAL GRANULATION, the disclosure of which is hereby incorporated by reference in its entirety.

### **TECHNICAL FILED**

**[0002]** The present disclosure relates generally to healing of wounds and wound-treatment therapies. More particularly, but not by way of limitation, the present disclosure relates to fluid-instillation and negative-pressure wound therapies.

### **BACKGROUND INFORMATION**

**[0003]** Clinical studies and practice have shown that providing a reduced pressure in proximity to a tissue site augments and accelerates the growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but application of reduced pressure has been particularly successful in treating wounds. This treatment (frequently referred to in the medical community as “negative pressure wound therapy,” “reduced pressure therapy,” or “vacuum therapy”) provides a number of benefits, including faster healing and increased formulation of granulation tissue.

**[0004]** Typically, reduced pressure is applied to tissue through a wound insert (e.g., a porous pad or other manifold device). The wound insert typically contains cells or pores that are capable of distributing reduced pressure to the tissue and channeling fluids that are drawn from the tissue. The wound insert can be incorporated into a wound dressing having other components that facilitate treatment, such as, for example, a drape (e.g., adhesive surgical drape).

## SUMMARY OF ILLUSTRATIVE EMBODIMENTS

**[0005]** The present disclosure includes embodiments of wound inserts with pores configured to promote directional granulation during negative pressure therapy.

**[0006]** An exemplary embodiment of a wound insert for use with a wound dressing, wherein the wound insert comprises a foam structure having a first surface, a second surface generally parallel to the first surface, and a third surface extending between the first surface and the second surface. The wound insert further comprises a plurality of pores distributed through the foam structure in an open-cell relation forming flow channels for receiving and distributing fluid to a wound. Each pore of the plurality of pores has a first cross-sectional area parallel to the first surface and a second cross-sectional area perpendicular to the first surface wherein the first cross-sectional area of most of the pores is greater than the second cross-sectional area of the pores. The second surface is adapted to receive fluids from a source of fluid and the first surface is adapted to be disposed proximate the wound for distributing fluids to the wound. The first cross-sectional area may have an average diameter greater than or equal to about 2.0 mm. The second cross-sectional area may have an average minor axis less than or equal to about 0.5 mm.

**[0007]** Certain embodiments include a wound insert for use with a wound dressing, where the wound insert comprises a first surface, a second surface, a third surface extending between the first and second surfaces, and a plurality of pores distributed through the wound insert. The pores comprise an average cross-sectional area that is greater when viewed from a direction perpendicular to the first surface than the average cross-sectional area of the pores when viewed from a direction perpendicular to the third surface. In particular embodiments, the third surface is substantially perpendicular to the first and second surfaces. In specific embodiments, the wound insert is substantially rectangular in shape.

**[0008]** In certain embodiments, the first surface comprises a plurality of channels, and in specific embodiments the channels are approximately 1.0 mm wide. In particular embodiments, the wound insert is configured to be inserted into a wound such that the first surface is proximal to a lower portion of the wound that is distal from an epidermis. In particular embodiments, the foam structure comprises a hydrophilic foam structure.

**[0009]** Certain embodiments comprise a wound insert for use with a wound dressing, where the wound insert comprises a first surface and a plurality of pores, where a majority of

the pores of the wound insert comprise a maximum cross-sectional area that is greater when viewed from a direction perpendicular to the first surface than when viewed from a direction parallel to the first surface. In particular embodiments, substantially all of the pores of the wound insert comprise a cross-sectional area that is greater when viewed from a direction perpendicular to the first surface than when viewed from a direction parallel to the first surface.

**[0010]** In particular embodiments, a majority of the pores of the wound insert comprise a substantially circular cross-section when viewed from a direction perpendicular to the first surface and a substantially oval cross-section when viewed from a direction parallel to the first surface. In certain embodiments, the majority of the pores of the wound insert comprise a substantially circular cross-section with a diameter greater than approximately 1.0 mm when viewed from a direction perpendicular to the first surface and a substantially oval cross-section with a minor axis less than approximately 0.5 mm when viewed from a direction parallel to the first surface.

**[0011]** Particular embodiments include a wound-treatment method comprising: positioning a wound insert on a wound of a patient, where the wound insert comprises a first surface having a plurality of pores with a first average cross-sectional area, and a second surface having a plurality of pores with a second average cross-sectional area that is less than the first average cross-sectional area; orienting the wound insert such that the first surface is proximal a bottom surface of the wound; and coupling a drape to skin adjacent the wound such that the drape covers the wound insert to form a space between the drape and the wound.

**[0012]** Specific embodiments also include applying negative pressure to the wound through the wound dressing. In certain embodiments, applying negative pressure comprises activating a vacuum source that is coupled to the wound dressing. Particular embodiments also include delivering a fluid to the wound through the wound dressing. In certain embodiments, delivering a fluid comprises activating a fluid source that is coupled to the wound dressing.

**[0013]** Particular embodiments also include a method of making a wound insert, comprising: applying a compressive force to foam structure comprising a plurality of pores, where the compressive force is applied in a first direction against a first surface; creating a reduced pore size on a second surface of the foam structure, where the second surface is substantially parallel to the first direction; and removing the compressive force from the foam

structure, where the reduced pore size on the second surface of the foam structure is maintained after the compressive force is removed.

**[0014]** In specific embodiments, the first surface comprises a pore size greater than the reduced pore size on the second surface after the compressive force is removed. In particular embodiments, the compressive force compresses the foam structure at a ratio greater than or equal to approximately 5:1. In certain embodiments, the compressive force is applied with a heated plate. In particular embodiments, the heated plate forms a film-like structure on the first surface of the foam structure and further comprising removing the film-like structure from the first surface of the foam structure.

**[0015]** Details associated with the exemplary embodiments described above and any other exemplary embodiments are presented below.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The following drawings illustrate by way of example and not limitation. For the sake of brevity and clarity, every feature of a given structure is not always labeled in every figure in which that structure appears. Identical reference numbers do not necessarily indicate an identical structure. Rather, the same reference number may be used to indicate a similar feature or a feature with similar functionality, as may non-identical reference numbers.

[0017] **FIG. 1** depicts a side view of one embodiment of the present wound dressings having one of the present wound inserts and coupled to a wound site and to a wound treatment apparatus.

[0018] **FIG. 2** depicts an enlarged side view of the wound insert of **FIG. 1** disposed at the wound site.

[0019] **FIG. 3** depicts a schematic block diagram of one embodiment of a wound treatment apparatus that can comprise and/or be coupled to and/or be used with the present wound dressings and/or wound inserts.

[0020] **FIG. 4** depicts a perspective view of an embodiment of a foam structure component having an open-cell structure.

[0021] **FIG. 5** depicts a perspective view of an embodiment of a compressed foam structure component having an open-cell structure.

[0022] **FIG. 6A** depicts a perspective view of a first exemplary embodiment of a wound insert severed from the foam structure component of **FIG. 5**.

[0023] **FIG. 6B** depicts a photograph that is a perspective view of a second exemplary embodiment of a wound insert similar to the wound insert of **FIG. 6A**.

[0024] **FIG. 7** depicts a photograph of a first surface of the wound insert of **FIG. 6B**.

[0025] **FIGS. 8** depicts a photograph of a second surface of the wound insert of **FIG. 6B**.

[0026] **FIG. 9** depicts a perspective view of a second exemplary embodiment of a wound insert.

## DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0027] The term “coupled” is defined as connected, although not necessarily directly, and not necessarily mechanically; two items that are “coupled” may be integral with each other. The terms “a” and “an” are defined as one or more unless this disclosure explicitly requires otherwise. The terms “substantially,” “approximately,” and “about” are defined as largely but not necessarily wholly what is specified, as understood by a person of ordinary skill in the art.

[0028] The terms “comprise” (and any form of comprise, such as “comprises” and “comprising”), “have” (and any form of have, such as “has” and “having”), “include” (and any form of include, such as “includes” and “including”) and “contain” (and any form of contain, such as “contains” and “containing”) are open-ended linking verbs. As a result, a method that “comprises,” “has,” “includes” or “contains” one or more steps possesses those one or more steps, but is not limited to possessing only those one or more steps. Likewise, a wound dressing that “comprises,” “has,” “includes” or “contains” one or more elements possesses those one or more elements, but is not limited to possessing only those elements. For example, in a wound dressing that comprises a wound insert and a drape, the wound dressing includes the specified elements but is not limited to having only those elements. For example, such a wound dressing could also include a connection pad configured to be coupled to a wound-treatment apparatus.

[0029] Further, a device or structure that is configured in a certain way is configured in at least that way, but it can also be configured in other ways than those specifically described.

[0030] Referring now to the drawings, and more particularly to FIG. 1, shown therein is an exemplary embodiment of a wound treatment system 10. In the embodiment shown, system 10 comprises a wound-treatment apparatus 14, and a wound dressing 18 coupled to apparatus 14 by a conduit 22. As shown, dressing 18 is configured to be coupled to (and is shown coupled to) a wound 26 of a patient’s epidermis 30. In this embodiment, wound 26 comprises a bottom wound surface 42 and side wound surfaces 41. In the embodiment shown, dressing 18 comprises a wound insert 34 and a drape 38. As shown, wound insert 34 is configured to be positioned (and is shown positioned) on wound 26 (e.g., on or adjacent to bottom wound surface 42), and/or drape 38 is configured to be coupled to (and is shown coupled to) skin 46 of the patient adjacent to wound 26 such that drape 38 covers wound insert



34 and wound 26, and forms a space 50 between drape 38 and wound 26 (e.g., wound surface 42).

**[0031]** Apparatus 14 can comprise, for example, a vacuum source configured to be actuated for applying negative pressure (e.g., via conduit 22) to wound dressing 18, a fluid source configured to be actuated for delivering (e.g., via conduit 22) a fluid (e.g., an installation fluid such as a medicinal fluid, antibacterial fluid, irrigation fluid, and or the like) to wound dressing 18. System 10 can be implemented and/or actuated and/or coupled to patient 30 in any of various configurations and/or methods similar to those described in the prior art. For example, various wound therapy systems and components are commercially available through and/or from KCI USA, Inc. of San Antonio, Texas, U.S.A., and/or its subsidiary and related companies (collectively, "KCI").

**[0032]** Conduit 22 can comprise a single lumen conduit (e.g., switched between a vacuum source and/or a fluid source and apparatus 14), or can comprise multiple single-lumen conduits or a multi-lumen conduit such that, for example, fluid can be delivered and/or negative pressure can be applied to wound dressing 18 individually and/or simultaneously. Additionally, conduit 22 can comprise, for example, a first lumen for the application of negative pressure and/or fluid delivery, and at least one additional lumen for coupling to pressure sensor(s) to sense pressure or negative pressure between drape 38 and surface 42. In some embodiments, conduit 22 can comprise multiple lumens (e.g., as in a single conduit with a central lumen for application of negative pressure and/or fluid delivery, and one or more peripheral lumens disposed adjacent or around the central lumen such that the peripheral lumens can be coupled to a pressure sensor to sense a pressure or negative pressure between drape 38 and surface 42 (e.g. in space 50). The lumens may be arranged with a central lumen and other lumens disposed radially around the central lumen, or in other suitable arrangements. The lumens may also be provided in separate conduits. In the embodiment shown, system 10 further comprises a wound dressing connection pad 54 configured to be coupled (and is shown coupled) to conduit 22. One example of a suitable connection pad 54 is the "V.A.C. T.R.A.C.<sup>®</sup> Pad," commercially available from KCI. One example of a suitable drape 38 includes the "V.A.C.<sup>®</sup> Drape" commercially available from KCI.

**[0033]** Referring now to FIG. 2, a side view of a wound insert 34 is shown. Wound insert 34 has an upper side 100, a lower side 104, lateral sides 108, 112 and interior volume 116. Although only one side is shown of wound insert 34, it will be understood by those of

ordinary skill in the art that wound insert 34 includes a three-dimensional rectangular volume having a depth extending perpendicular to the side shown. In other embodiments, wound insert 34 can have any suitable shape, such as, for example, a round cylindrical shape, a fanciful shape, or may be trimmed to fit an irregular shape of a wound (e.g., 26 and/or wound surface 42). Wound insert 34 can comprise foam structure, such as, for example, open-celled foam structure (which may also be reticulated).

**[0034]** Embodiments of the present wound treatment methods may be better understood with reference to FIG. 3, which depicts a schematic block diagram of one embodiment of system 10. In the embodiment shown, wound dressing 18 is coupled to apparatus 14, and apparatus 14 comprises a vacuum source 200 (e.g., a vacuum pump and/or the like) coupled to a canister 204 (e.g., configured to receive bodily fluids and or the like from wound dressing 18) by way of a conduit 208. In the embodiment shown, apparatus 14 further comprises: a pressure sensor 212 having a first pressure transducer 216 coupled to conduit 208 by way of conduit 220 and/or tee-fitting 224, and a second pressure transducer 228 coupled to canister 204 and/or wound dressing 18 by way of conduit 232. Pressure sensor 212 is configured to sense the negative pressure in wound dressing 18, and/or any of the various lumens (e.g., within conduits) coupled to wound dressing 18, pressure sensor 212, and/or vacuum source 200.

**[0035]** In the embodiment shown, apparatus 14 further comprises a pressure release valve 236 coupled to conduit 232. Further, in the embodiment shown, canister 204 and vacuum source 200 are coupled to wound dressing 18 by way of conduit 240; and/or canister 204 can comprise a filter 244 at or near an outlet of canister 204 to prevent liquid or solid particles from entering conduit 208. Filter 244 can comprise, for example, a bacterial filter that is hydrophobic and/or lipophobic such that aqueous and/or oily liquids will bead on the surface of the filter. Apparatus 14 is typically configured such that, during operation, vacuum source 200 will provide sufficient airflow through a filter 244 that the pressure drop across filter 244 is not substantial (e.g., such that the pressure drop will not substantially interfere with the application of negative pressure from wound dressing 18 from vacuum source 200).

**[0036]** In the embodiment shown, apparatus 14 further comprises a fluid source 248 coupled to wound dressing 18 by way of a conduit 252 that is coupled to conduit 240 such as, for example, by way of a tee- or other suitable fitting 256. In some embodiments, tee fitting 256 can comprise a switch valve and/or the like such that communication can be selectively

permitted between wound dressing 18 and vacuum source 200, or between wound dressing 18 and fluid source 248. In some embodiments apparatus 14 comprises only one of vacuum source 200 and fluid source 248. In embodiments of apparatus 14 that comprise only fluid source 248, canister 204 and/or pressure sensor 212 can also be omitted. In various embodiments, such as the one shown, conduit 232 and/or conduit 240 and/or conduit 252 can be combined and/or comprised in a single multi-lumen conduit, such as is described above with reference to FIG. 1. In some embodiments, fluid source 248 is coupled directly to wound dressing 18 (e.g., conduit 252 is coupled one end to wound dressing 18, such as via connection pad 54, and conduit 252 is coupled on the other end to fluid source 248; and conduit 252 is not coupled to tee fitting 256).

**[0037]** In various embodiments, such as the one shown in FIG. 3, apparatus 14 can be configured such that as soon as liquid in the canister reaches a level where filter 244 is occluded, a much-increased negative (or subatmospheric) pressure occurs in conduit 208 and is sensed by transducer 216. Transducer 216 can be connected to circuitry that interprets such a pressure change as a filled canister and signals this by means of a message on an LCD and/or buzzer that canister 204 requires emptying and/or replacement, and/or that automatically shuts off or disables vacuum source 200.

**[0038]** Apparatus 14 can also be configured to apply negative (or subatmospheric) pressure (e.g., continuously, intermittently, and/or periodically) to the wound site, and/or such that pressure relief valve 236 enables pressure at the wound site to be brought to atmospheric pressure rapidly. Thus, if apparatus 14 is programmed, for example, to relieve pressure at ten-minute intervals, at these intervals pressure relief valve 236 can open for a specified period, allow the pressure to equalize at the wound site, and then close to restore the negative pressure. It will be appreciated that when constant negative pressure is being applied to the wound site, valve 236 remains closed to prevent leakage to or from the atmosphere. In this state, it is possible to maintain negative pressure at the wound site without running and/or operating pump 200 continuously, but only from time to time or periodically, to maintain a desired level of negative pressure (i.e. a desired pressure below atmospheric pressure), which is sensed by transducer 216. This saves power and enables the appliance to operate for long periods on its battery power supply.

**[0039]** Referring now to FIGS. 4-9, various views are shown of several embodiments of the present wound inserts and components used to form such inserts. FIG. 4 depicts a

perspective view of a foam structure component or foam structure 300 that includes a plurality of pores 310 that may be substantially spherical and uniform in size. The foam structure 300 has an open-cell structure so that a substantial number of the pores 310 are interconnected to form flow channels through which negative pressure may be applied to the wound. Foam structure 300 comprises a first surface 320 and a substantially parallel second surface 330, as well as a plurality of surfaces 340 extending between first and second surfaces 320, 330. As illustrated in this view, pores 310 comprise a cross-section that is substantially similar in size and shape, regardless of which direction foam structure 300 is viewed from. For example, if viewed in the direction indicated by arrow 325 (*e.g.*, perpendicular to first surface 320) pores 310 comprise a cross-section that is substantially spherical and similar in size. If viewed from a direction parallel to first surface 320 (and perpendicular to arrow 325 and one of surfaces 340 as indicated by arrow 326), pores 310 also comprise a cross section that is generally equivalent in size and shape to the cross-section viewed in the direction of arrow 325.

**[0040]** Referring now to FIG. 5, a perspective view of foam structure 400 is shown comprising a plurality of pores 410 that are not substantially similar in size when viewed from different directions. Foam structure 400 comprises a first surface 420 and a substantially parallel second surface 430 as well as a plurality of surfaces 440 extending between first and second surfaces 420, 430. As illustrated in this view, pores 410 comprise a cross-section that is substantially circular and similar in size and shape when viewed in the direction indicated by arrow 425 (*e.g.*, perpendicular to first surface 420). However, if viewed from a direction parallel to first surface 420 (and perpendicular to arrow 425 and one of surfaces 440 as indicated by arrow 426), pores 410 comprise a cross-section that is substantially oval rather than circular in shape (and smaller than the cross-section when viewed in the direction indicated by arrow 425). Pores 410 therefore comprise a cross-sectional area that is greater when viewed from a direction perpendicular to the first surface 420 (arrow 425) than when viewed from a direction parallel to the first surface 420 (arrow 426). To describe this in other words, the pores 410 have a first cross-sectional area parallel to the first surface 420 that on average is greater than a second cross-sectional area perpendicular to the first surface 420.

**[0041]** As described above, the foam structure 300 has an open-cell structure so that a substantial number of pores for 10 are interconnected to form flow channels through which fluids such as, for example, negative pressure or liquids may be applied to the wound. Consequently, when such fluids are applied to the foam structure 400, airflow through the

foam structure 400 via the flow channels formed by the pores 410 is greater in the direction perpendicular to the first surface 420 (arrow 425) than in the direction parallel to the first surface 420 (arrow 426). The reduction of airflow through the flow channels in a direction parallel to the first surface 420 is partially caused as a result of the pores 410 being compressed or flattened in the direction perpendicular to the first surface 420. The reduction in airflow via flow channels having this smaller cross-section formed by a series of pores 410 in a direction parallel to the first surface 420 can inhibit granulation of the surface of a wound adjacent the third surface 440.

**[0042]** While pores 410 are shown in FIG. 5 to be identical in size and shape when viewed from a particular direction, it is understood that the pores 410 may vary in size and shape and not be uniform throughout the foam structure 400 as will be illustrated in more detail below. However, for purposes of illustration, the pores 410 in this exemplary embodiment comprise a substantially circular cross-section with a diameter greater than or equal to approximately 1.0 mm when viewed from a direction perpendicular to first surface 420 (arrow 425). In other exemplary embodiments, pores 410 may comprise a substantially circular cross-section with a diameter greater than or equal to approximately 2.0 mm when viewed from a direction perpendicular (arrow 425) to first surface 420. In other exemplary embodiments, pores 410 may also comprise a substantially oval cross-section with a minor axis less than or equal to approximately 0.5 mm when viewed from a direction parallel to first surface 420 (arrow 426).

**[0043]** In particular embodiments, foam structure 400 may be formed by modifying foam structure with substantially spherical pores (including *e.g.*, foam structure 300 illustrated in FIG. 4). For example, foam structure 300 may be heat compressed or felted in the depth direction of arrow 325 to create a reduced pore size on foam structure surfaces substantially parallel to the direction of compression. In certain exemplary embodiments, foam structure 300 may be compressed at a ratio greater than or equal to approximately 5:1 (*e.g.*, overall the dimension of foam structure 300 parallel to direction 325 is reduced by a factor of 5). In certain exemplary embodiments, foam structure 300 may be compressed at a ratio greater than or equal to approximately 6:1, 7:1, 8:1, 9:1 or 10:1. In still other exemplary embodiments, foam structure 300 may be compressed at a ratio less than or equal to approximately 5:1. In other specific embodiments, heated plates can be used to compress foam structure 400 to create the pore geometry illustrated in FIG. 5. In such embodiments, the outer layer of pores

that contacts the heated plates may form a film-like structure with closed pores which can be removed prior to use at the wound site.

**[0044]** As shown in FIGS. 4 and 5, the reduction in size between pores 310 and 410 can be achieved by the flattening of individual pores as suggested above, in which the pores undergo a shape change from substantially spherical shape to a more elliptical shape (*e.g.*, substantially circular in cross-section when viewed from one direction and substantially oval in cross section when viewed from a direction perpendicular to the first direction). As indicated above, the flattening of the individual pores 410 in a direction perpendicular to the first surface 420 reduces airflow through the flow channels in a direction parallel to the first surface 420.

**[0045]** In exemplary embodiments, a foam structure component similar to foam structure 400 may be further separated into multiple sections to form multiple wound inserts. For example, the foam structure 400 may be sliced along dashed line 428 to form a separate wound insert such as, for example, wound insert 500 shown in the perspective view of FIG. 6A. Wound insert 500 can be suitable for use in deep, narrow wounds as discussed more fully below. Wound insert 500 comprises a first surface 520 and a substantially parallel second surface 530 as well as a plurality of surfaces 540 extending between first and second surfaces 520, 530. Wound insert 500 further comprises a plurality of pores 510 distributed throughout wound insert 500. as illustrated in this view, pores 510 comprise a cross-section that is substantially circular and similar in size and shape when viewed in the direction indicated by arrow 525 (*e.g.*, perpendicular to first surface 520). However, if viewed from a direction parallel to first surface 520 (and perpendicular to arrow 525 and one of the surfaces 540 as indicated by arrow 526), pores 510 comprise a cross-section that is substantially oval rather than circular in shape (and smaller than the cross-section when viewed in the direction indicated by arrow 525). Thus, pores 510 comprise a cross-sectional area that is greater when viewed from a direction perpendicular to the first surface 520 (arrow 525) than when viewed from a direction parallel to the first surface 520 (arrow 526).

**[0046]** FIG. 6B depicts a photograph that is a perspective view of a second exemplary embodiment of a wound insert similar to the wound insert of FIG. 6A. The wound insert 500 is a schematic view showing that the pores 510 have substantially uniform cross-section, *i.e.*, circular when viewed in the perpendicular direction and oval when viewed in the parallel direction. However, the cells 610 of the wound insert 600 are not uniform in shape when

viewing the first surface 620 from a direction perpendicular to the first surface 620 (See FIG. 7) as illustrated by arrow 625 and when viewing the surface 640 from a direction parallel to the first surface 620 (See FIG. 8) as illustrated by arrow 626.

[0047] FIG. 7 provides a more detailed view of pores 610 when viewed perpendicular to first surface 620, while FIG. 8 provides a more detailed view of pores 610 when viewed parallel to first surface 620 (and perpendicular to a surface 640). As illustrated in FIGS. 7 and 8, pores 610 comprise a cross-sectional area that is greater when viewed from a direction perpendicular to first surface 620 (*e.g.*, in FIG. 7) than when viewed from a direction parallel to first surface 620 (*e.g.*, in FIG. 8). Thus, pores 610 comprise a cross-sectional area that is greater when viewed from a direction perpendicular to the first surface 620 (arrow 525) than when viewed from a direction parallel to the first surface 620 (arrow 526) where they appear to be flattened as illustrated in FIG. 8 as a result of the original foam structure component such as, for example, foam structure 400 being compressed to form the wound insert 600.

[0048] During use, wound inserts 500, 600 can promote directional granulation in a wound surface as described above. For example, when negative pressure is applied to the foam structure 500, 600, airflow through the foam structure via the flow channels formed by the pores 510, 610 is greater in the direction perpendicular to the first surface 520, 620 than in the direction parallel to the first surface. More specifically, wound inserts 500, 600 can promote granulation in a wound surface proximal to first surfaces 520, 620 which can be located near the bottom of a wound (*e.g.* similar to a wound surface 42 in FIG. 1). The larger cross-sectional area of the pores 510, 610 at first surfaces 520, 620 can promote granulation, while the smaller cross-sectional area of the pores 510, 610 on the side surfaces 540, 640 between first surfaces 520, 620 and second surfaces 530, 630 can inhibit granulation (*e.g.* on side wound surfaces 41 in FIG. 1). Minimizing granulation between the side surfaces 540, 640 and the side surfaces of an incision, for example, can facilitate removal of wound inserts 500, 600 from the incision so that the removal of wound inserts 500, 600 is less painful for a patient.

[0049] Particularly in deep, narrow wounds, granulation of side walls in the wound can lead to premature closing of the wound and the formation of undesirable voids within the wound. In addition, side wall granulation in such wounds can make removal of the wound insert difficult and painful for the patient. In certain instances, portions of a wound insert or dressing unlike the embodiments described above can be torn from the main body of the

wound insert during removal as a result of too much granulation by the sidewalls of the wound. Consequently, those granulized portions might accidentally be left in the wound causing infection and other problems.

**[0050]** A wound insert configured similar to wound inserts 500, 600 can address these issues by promoting wound healing at the bottom of the wound while inhibiting wound healing at the sides of the wound. In certain embodiments, wound inserts 500, 600 may comprise indicia 550 providing instructions on the proper direction of insertion into a wound as shown in FIG. 6A. Indicia 550 may comprise an arrow and/or surface labels as shown to provide a user instructions on the proper orientation of the wound insert so that first surfaces 520, 620 are proximal to the lower portion of the wound distal from the epidermis.

**[0051]** In exemplary embodiments, a user may cut or trim wound inserts 500, 600 to a desired size or shape and retain the geometric properties that promote directional granulation. In other exemplary embodiments, a wound insert may have other shapes or features that promote directional granulation. Referring to FIG. 9, for example, foam structure structure 400 is generally equivalent to that illustrated in FIG. 5 (and like reference numbers are provided in FIG. 9 for reference to features described in the embodiment of FIG. 5). The embodiment of FIG. 9, however, also includes channels 450 in surface 430 to enhance granulation. In specific embodiments, channels 450 may comprise a width W equivalent to approximately 1 mm. Channels 450 may be created during manufacturing by forming foam structure structure 400 in a mold that comprises recessed channels or raised portions (including for example, rods or pins). In certain embodiments, foam structure 400 may be perforated prior to the compression or felting process in order to promote the formation of channels 450.

**[0052]** Exemplary embodiments of manufacturing wound inserts according to the present disclosure can also comprise cooling the foam structure (e.g., after heating the foam structure structure) such that the compressed portion of the foam structure remains substantially compressed at room temperature (e.g., at a temperature of 72 degrees Fahrenheit) in the absence of a compressive force. In other embodiments, cooling the foam structure includes cooling a coating that has been applied to the foam structure such that the compressed portion remains substantially compressed in the absence of a compressive force at a temperature or temperature range equal to, less than, greater than, or between any of 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, and/or 150 degrees Fahrenheit.



[0053] The various illustrative embodiments of devices, systems, and methods described herein are not intended to be limited to the particular embodiments disclosed. Rather, they include any modifications and alternative features that may fall within the scope of the claims.

[0054] It will be understood that the benefits and advantages described above may relate to one embodiment or may relate to several embodiments. It will further be understood that reference to 'an' item refers to one or more of those items, unless otherwise specified.

[0055] The steps of the methods described herein may be carried out in any suitable order, or simultaneously where appropriate, and may be accomplished by embodiments other than those described herein that are covered by the method claims.

[0056] Where appropriate, aspects of any of the examples described above may be combined with aspects of any of the other examples described to form further examples having comparable or different properties and addressing the same or different problems.

[0057] It will be understood that the above description of preferred embodiments is given by way of example only and that various modifications may be made by those skilled in the art. The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments. Although various embodiments have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of this invention.

## CLAIMS

1. A wound insert for use with a wound dressing, the wound insert comprising:  
a foam structure having a first surface, a second surface generally parallel to the first surface, and a third surface extending between the first surface and the second surface; and  
a plurality of pores distributed through the foam structure in an open-cell relation forming flow channels for receiving and distributing fluid to a wound, each pore of the plurality of pores having a first cross-sectional area parallel to the first surface and a second cross-sectional area perpendicular to the first surface wherein the first cross-sectional area of most of the pores is greater than the second cross-sectional area of the pores.
2. The wound insert of claim 1 wherein the third surface is substantially perpendicular to the first and second surfaces.
3. The wound insert of claim 1 wherein the wound insert is substantially rectangular in shape.
4. The wound insert of claim 1 wherein the first surface comprises a plurality of channels.
5. The wound insert of claim 4 wherein the channels are approximately 1.0 mm wide.
6. The wound insert of claim 1 wherein the second surface is adapted to receive fluids from a source of fluid and the first surface is adapted to be disposed proximate the wound for distributing the fluids to the wound.
7. The wound insert of claim 1 further comprising indicia positioned on the third surface indicating the correct orientation of the wound insert within the wound.

8. The wound insert of claim 1, where the foam structure comprises hydrophilic foam.
9. The wound insert of claim 1, wherein the first cross-sectional area has an average diameter greater than or equal to about 2.0 mm.
10. The wound insert of claim 1, wherein the second cross-sectional area has an average minor axis less than or equal to about 0.5 mm.
11. A wound insert for use with a wound dressing, the wound insert comprising:  
a foam structure having a first surface and a second surface generally parallel to the first surface; and  
a plurality of pores distributed through the foam structure and formed having an open-cell relation including flow channels for receiving and distributing fluid to a wound, wherein flow channels formed by pores extending in a direction perpendicular to the first surface have a greater cross-section than the flow channels formed by pores extending in a direction parallel to the first surface.
12. The wound insert of claim 11, wherein a majority of the pores of the plurality of pores comprise a first cross-sectional area when viewed from a direction perpendicular to the first surface that is greater than a second cross-sectional when viewed from a direction parallel to the first surface.

13. A wound-treatment method comprising:  
positioning a wound insert on a wound of a patient, the wound insert comprising:  
a first surface having a plurality of pores with a first average cross-sectional area;  
a second surface having a plurality of pores with a second average cross-sectional area that is less than the first average cross-sectional area;  
orienting the wound insert such that the first surface is proximal a bottom surface of the wound; and  
coupling a drape to skin adjacent the wound such that the drape covers the wound insert and the wound, and forms a space between the drape and the wound.
14. The method of claim 13, further comprising:  
applying negative pressure to the wound through the wound dressing.
15. The method of claim 14, where applying negative pressure comprises activating a vacuum source that is coupled to the wound dressing.
16. The method of claim 13, further comprising:  
delivering a fluid to the wound through the wound dressing.
17. The method of claim 16, where delivering a fluid comprises activating a fluid source that is coupled to the wound dressing.
18. A method of making a wound insert, comprising:  
applying a compressive force to foam structure comprising a plurality of pores,  
wherein the compressive force is applied in a first direction against a first surface;  
creating a reduced pore size on a second surface of the foam structure, wherein the second surface is substantially parallel to the first direction; and  
removing the compressive force from the foam structure, wherein the reduced pore size on the second surface of the foam structure is maintained after the compressive force is removed.

19. The method of claim 18 wherein the first surface comprises a pore size greater than the reduced pore size on the second surface after the compressive force is removed.
20. The method of claim 18 wherein the compressive force compresses the foam structure at a ratio greater than or equal to approximately 5:1.
21. The method of claim 18 wherein the compressive force is applied with a heated plate.
22. The method of claim 21 wherein the heated plate forms a film-like structure on the first surface of the foam structure and further comprising removing the film-like structure from the first surface of the foam structure.

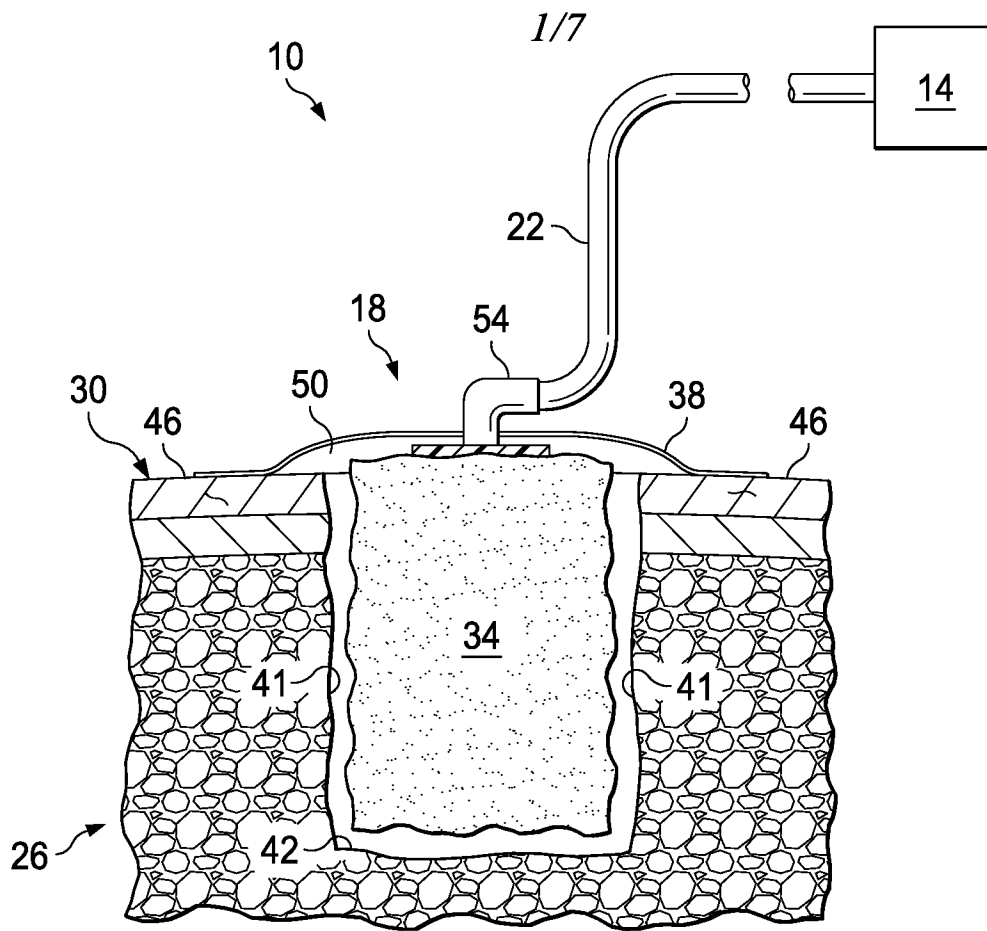


FIG. 1

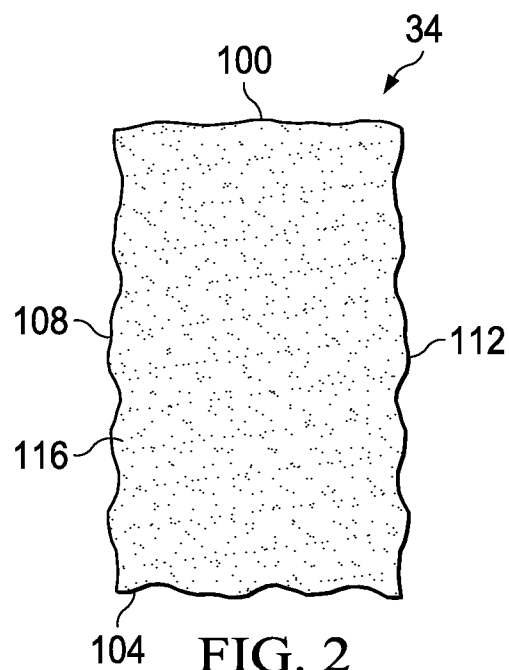
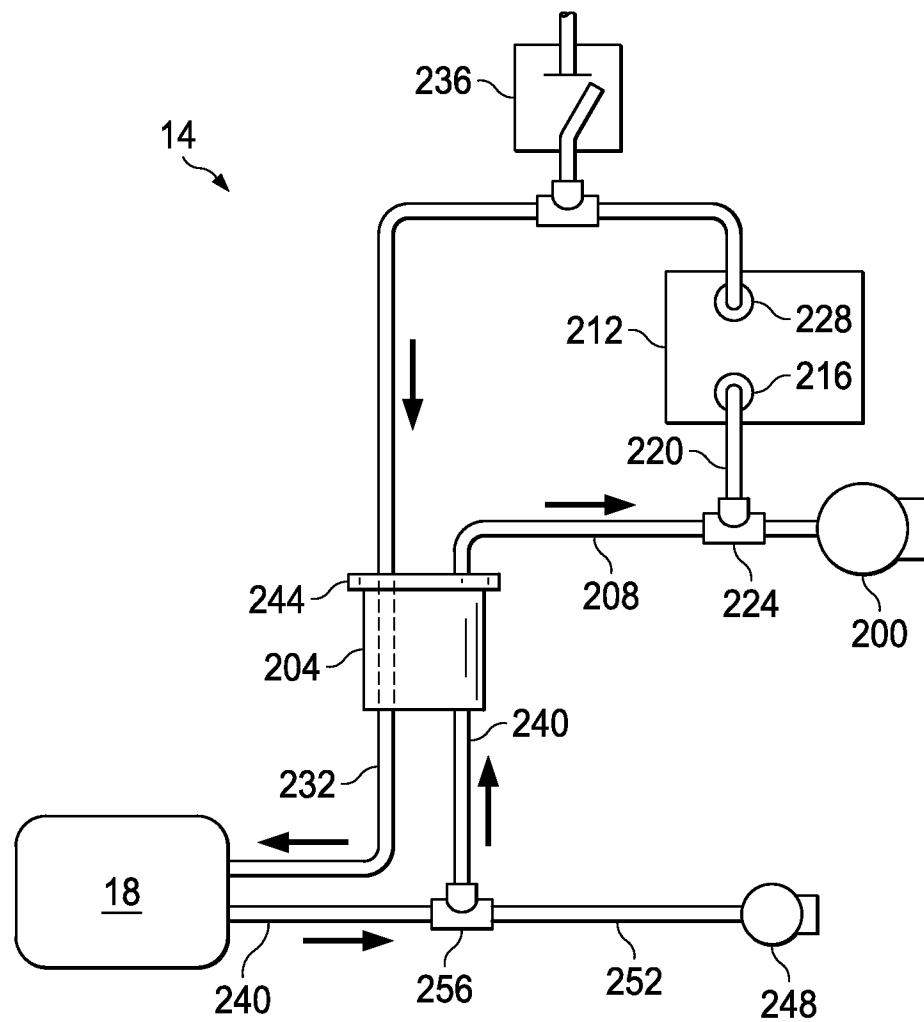
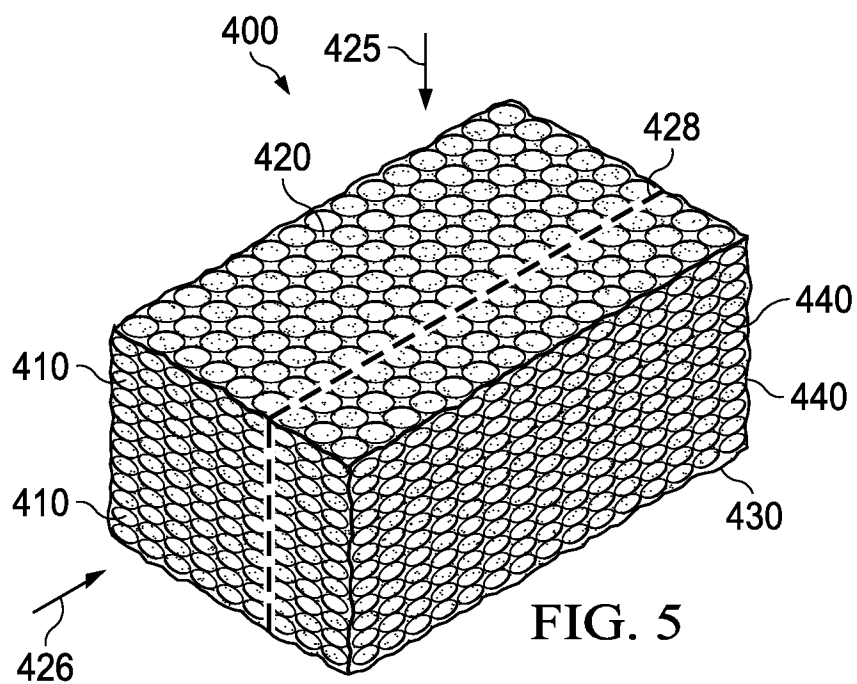
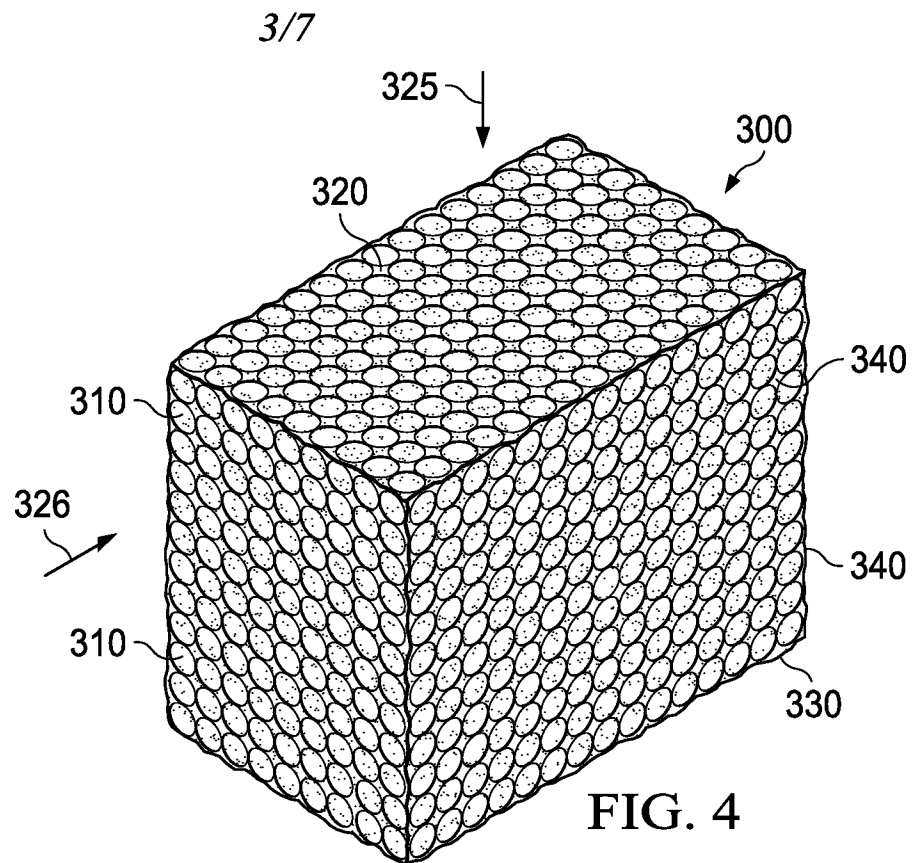


FIG. 2

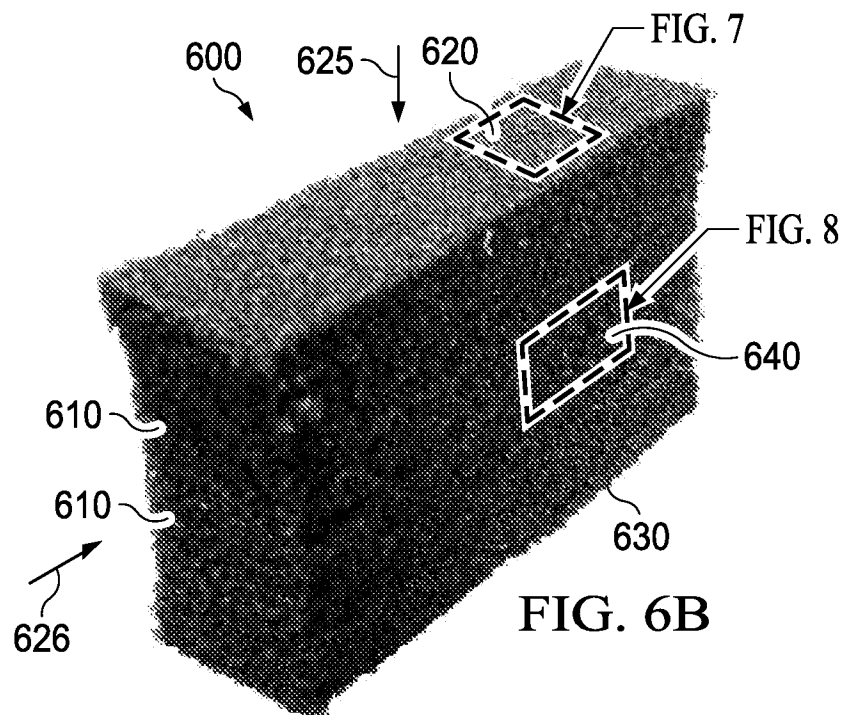
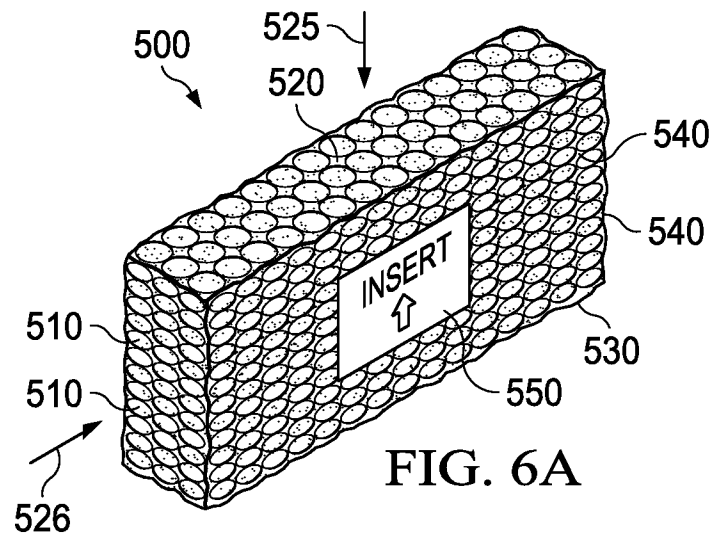
FIG. 3







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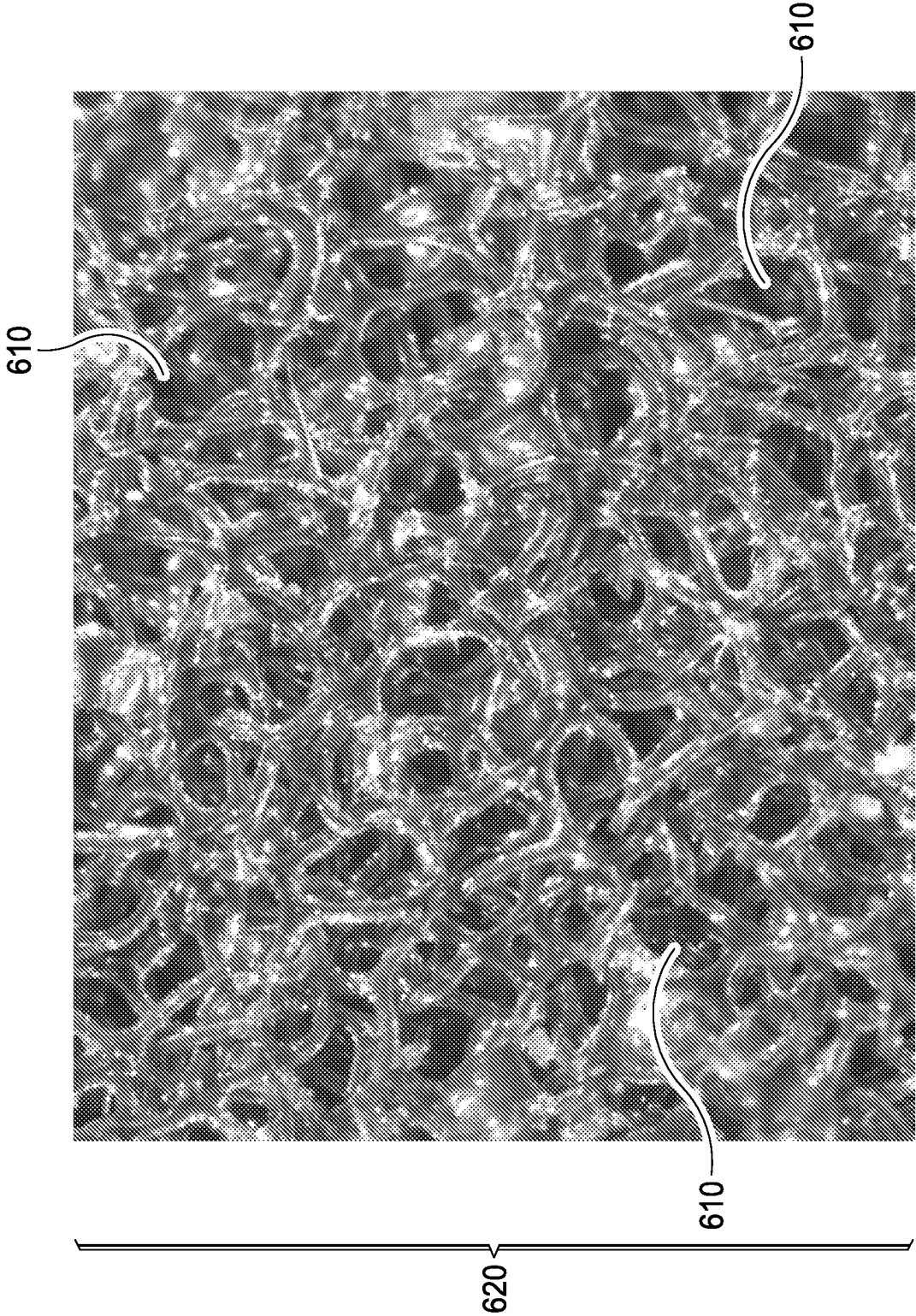


FIG. 7

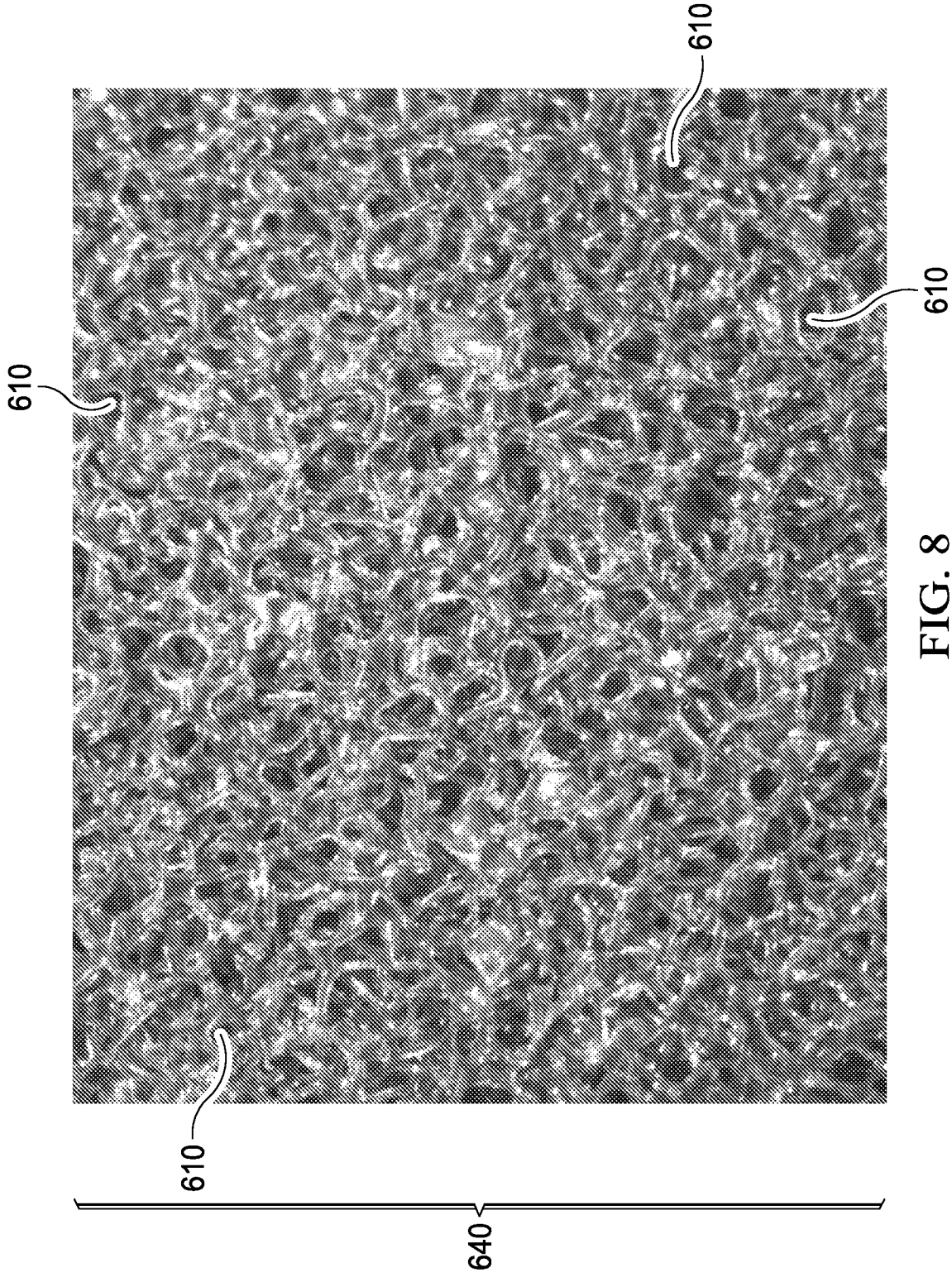
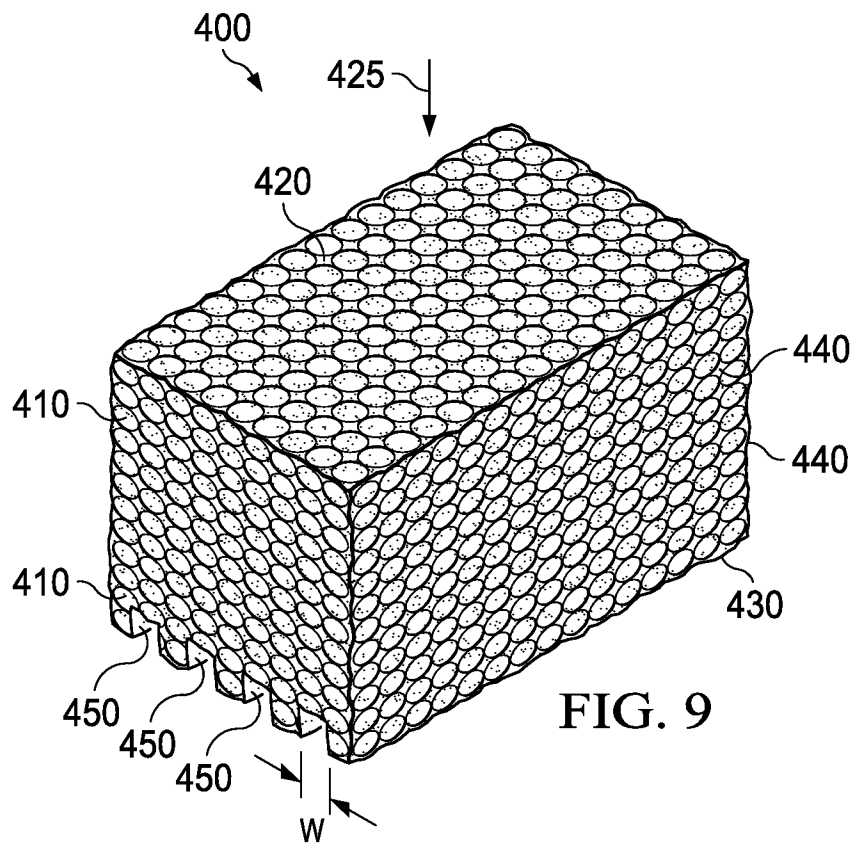


FIG. 8

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# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2013/024194

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F13/00 A61L15/42 B29C44/56  
ADD.

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

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F A61L B29C

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/021622 A2 (DOW GLOBAL TECHNOLOGIES INC [US]; STRANDBURG GARY M [US]; VANSUMEREN M) 10 March 2005 (2005-03-10) page 3, line 24 page 19, line 3 - page 22, line 2; claims 5-7, searching-14, 22-23, 28, 34; examples 3,7; table 4 page 22, lines 20-23 page 24, lines 1-14	1-12, 18-22
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

\* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

10 April 2013

Date of mailing of the international search report

17/04/2013

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
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Fax: (+31-70) 340-3016

Authorized officer

Joly, Florence

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2013/024194

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 747 420 A1 (ALBANY INT RESEARCH [US]) 11 December 1996 (1996-12-11) page 3, lines 39-43 page 4, lines 48-52 page 5, lines 1-4; figures 1-28; examples 4, 6-7 -----	1-4,6,8, 11,12

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2013/024194

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 13-17  
because they relate to subject matter not required to be searched by this Authority, namely:  
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2013/024194

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**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box II.1

Claims Nos.: 13-17

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 13 -17 :

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

The claims 13 is :

A wound-treatment method comprising: positioning a wound insert on a wound of a patient, the wound insert comprising: a first surface having a plurality of pores with a first average cross-sectional area; a second surface having a plurality of pores with a second average cross-sectional area that is less than the first average cross-sectional area; orienting the wound insert such that the first surface is proximal a bottom surface of the wound; and coupling a drape to skin adjacent the wound such that the drape covers the wound insert and the wound, and forms a space between the drape and the wound. The subject matter of claim 13 is considered as a method of treatment of the human or animal body by therapy. Therefore the subject matter of claims 13 and of its dependent claims 14-17 is considered by this Authority to be covered by the provisions of Rule 39(iv) PCT and article 17(2)(a)(i) PCT. Consequently no international search will be carried out on the subject-matter of claims 13 -17. The subject-matter of claims 13 -17 is considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT and article 34(4)(a)(i) PCT. Consequently no opinion will be formulated on the subject matter of claims 13 and 14.