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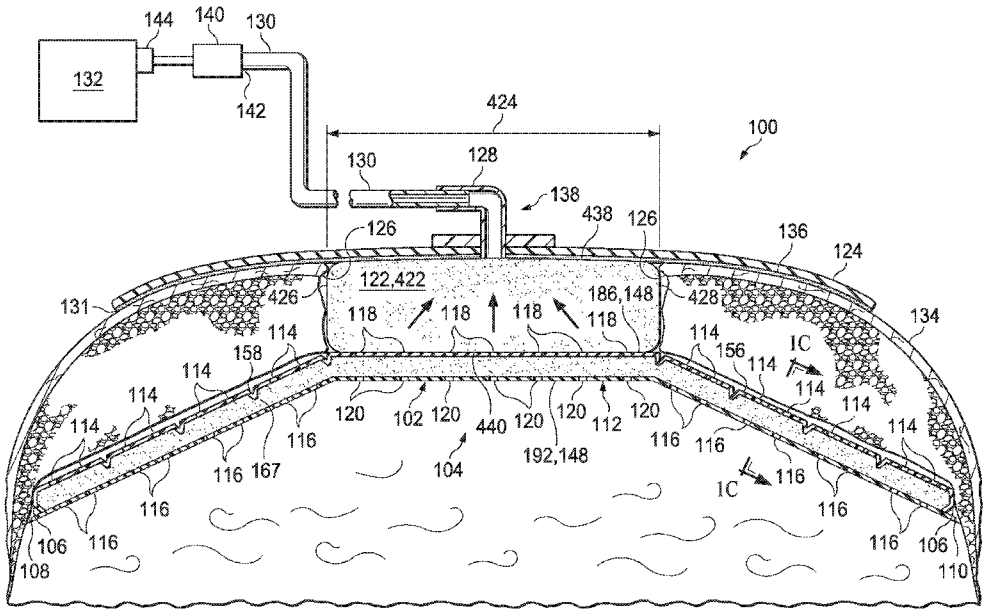

FIG. 1A

(57) Abstract: In some examples, a lateral force manifold may be configured to distribute reduced pressure relative to a tissue site and to provide a lateral contractive force relative to the tissue site. The example lateral force manifold may include a plurality of first contractive portions and a plurality of second contractive portions positioned across a lateral width of the lateral force manifold and configured to provide a differential amount of contraction in the lateral force manifold across the lateral width. Other apparatus, dressings, systems, and methods are disclosed.

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DRESSING INCLUDING DIFFERENTIAL LATERAL CONTRACTION CAPABILITY

RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Provisional Patent Application No. 62/866,952, entitled "Dressing Including Differential Lateral Contraction Capability," filed June 26, 2019, which is incorporated herein by reference for all purposes.

TECHNICAL FIELD

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

BACKGROUND

[0003] Clinical studies and practice have shown that reducing pressure in proximity to a tissue site can augment and accelerate growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but have proven particularly advantageous for treating wounds. Regardless of the etiology of a wound, whether trauma, surgery, or another cause, proper care of a wound is important to the outcome. Treatment of wounds or other tissue with reduced pressure may be commonly referred to as "negative-pressure therapy," but is also known by other names, including "negative-pressure wound therapy," "reduced-pressure therapy," "vacuum therapy," and "vacuum-assisted closure," for example. Negative-pressure therapy may provide a number of benefits, including migration of epithelial and subcutaneous tissues, improved blood flow, and micro-deformation of tissue at a wound site. Together, these benefits can increase development of granulation tissue and reduce healing times. While the clinical benefits of negative-pressure therapy are widely known, the cost and complexity of negative-pressure therapy can be a limiting factor in its application, and the development and operation of negative-pressure systems, components, and processes continues to present significant challenges to manufacturers, healthcare providers, and patients.

SUMMARY

[0004] Shortcomings with certain aspects of tissue treatment dressings, systems, and methods are addressed as shown and described in a variety of illustrative, non-limiting example embodiments herein.

[0005] In some example embodiments, a system for treating a tissue site may include a treatment manifold, a non-adherent drape, a lateral force manifold, and a sealing member. The treatment manifold may include a connection manifold member and a plurality of leg manifold members extending from the connection manifold member. The non-adherent drape may surround the treatment manifold. The lateral force manifold may be configured to be positioned proximate to and in fluid communication with the treatment manifold through the non-adherent drape. The lateral force manifold may include a lateral width extending from a first edge to an opposite second edge. Further, the lateral force manifold may include at least one first contractive portion and at least one second contractive portion. The at least one first contractive portion may be configured to contract a first amount under a reduced pressure. The at least one second contractive portion may be configured to contract a second amount under the reduced pressure. The second amount of contraction may be less than the first amount, and the first contractive portion may be positioned next to the second contractive portion along the lateral width. The sealing member may be configured to provide a pneumatic seal relative to the tissue site.

[0006] In some example embodiments, a lateral force manifold may be configured to distribute reduced pressure relative to a tissue site. The example lateral force manifold may include a lateral width extending from a first edge to an opposite second edge. Further, the example lateral force manifold may include a plurality of first contractive portions and a plurality of second contractive portions. The plurality of first contractive portions may include a first density, and the plurality of second contractive portions may include a second density. The second density may be greater than the first density, and the first contractive portions and the second contractive portions may alternate along the lateral width.

[0007] Other aspects, features, and advantages of the illustrative example embodiments will become apparent with reference to the drawings and detailed description that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIGURE 1A is a schematic diagram, with a portion in cross-section, of an illustrative example embodiment of an open-cavity, reduced-pressure treatment device and system;

[0009] FIGURE 1B is a schematic cross-section of a portion of the example treatment device of FIGURE 1A;

[0010] FIGURE 1C is a schematic cross-section of a portion of the example treatment device of FIGURE 1A taken along line 1C-1C;

[0011] FIGURE 1D is a schematic cross-section of a portion of the example system of FIGURE 1A;

[0012] FIGURE 2 is a schematic, perspective view of the example open-cavity, reduced-pressure treatment device of FIGURES 1A-1D;

[0013] FIGURE 3A is a schematic, plan view of another illustrative example embodiment of an open-cavity, reduced-pressure treatment device;

[0014] FIGURE 3B is a schematic, plan view of a portion of the example treatment device of FIGURE 3A;

[0015] FIGURE 3C is a schematic cross-section of a portion of the example treatment device of FIGURE 3B taken along line 3C-3C;

[0016] FIGURE 4A is a perspective view of an illustrative example embodiment of a lateral force manifold according to this disclosure;

[0017] FIGURE 4B is a perspective view of another illustrative example embodiment of a lateral force manifold according to this disclosure;

[0018] FIGURE 5A is a side view of an illustrative example embodiment of a porous material before felting to form a portion of an illustrative lateral force manifold;

[0019] FIGURE 5B is a side view of a portion of an illustrative example lateral force manifold after felting the porous material of FIGURE 5A;

[0020] FIGURE 6A is a side view of an illustrative example embodiment of a porous material before felting to form a portion of another illustrative lateral force manifold; and

[0021] FIGURE 6B is a side view of another illustrative example lateral force manifold after felting the porous material of FIGURE 6A.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0022] The following description of example embodiments enables a person skilled in the art to make and use the subject matter set forth in the appended claims. Certain details already known in the art may be omitted. Therefore, the following detailed description is illustrative and non-limiting.

[0023] Referring to FIGURES 1A-1D, an illustrative embodiment of an open-cavity, reduced-pressure system 100 and a treatment device 102 is presented. The open-cavity reduced-pressure system 100 and the treatment device 102 are for treating a tissue site 104 of a patient. The tissue site 104 may be the bodily tissue of any human, animal, or other organism, including bone tissue, adipose tissue, muscle tissue, dermal tissue, tissue, connective tissue, cartilage, tendons, ligaments, or any other tissue. In this illustrative embodiment, the tissue site 104 includes tissue in a body cavity, and in particular the abdominal cavity, and includes the abdominal contents or tissue that is proximate the abdominal cavity. Treatment of the tissue site 104 may include removal of fluids, *e.g.*, exudate or ascites, protection of the abdominal cavity, or reduced-pressure therapy.

[0024] As shown, the treatment device 102 is disposed within the abdominal cavity of the patient to treat the tissue site 104. The treatment device 102 includes a plurality of encapsulated leg members 106 that are supported by the abdominal contents, which make up a surface on which the plurality of leg members 106 are placed. One or more of the plurality of encapsulated leg members 106 may be placed in or proximate to a first paracolic gutter 108, and one or more of the plurality of encapsulated leg members 106 may be placed in or proximate to a second paracolic gutter 110. The plurality of encapsulated leg members 106 is coupled to a central connection member 112, and there is fluid communication between the plurality of encapsulated leg members 106 and the central connection member 112. The plurality of encapsulated leg members 106 and/or the central connection member 112 may be formed with fenestrations 114, 116, 118, 120 that allow fluids in the abdominal cavity to pass through. The fenestrations 114, 116, 118, 120 may take any shape, *e.g.*, circular apertures, rectangular openings, polygons, etc., but are presented in this illustrative embodiment as slits, or linear cuts. One or more fenestrations 114, 116, 118, 120 might be omitted in alternative embodiments.

[0025] A manifold 122, or manifold pad, distributes reduced pressure to the treatment device 102. A sealing member 124 provides a pneumatic seal over body-cavity opening 126. One or more skin closure devices may be placed on a patient's epidermis 134. Reduced

pressure is delivered to the manifold 122 through a reduced-pressure interface 128, which is coupled to a reduced-pressure delivery conduit 130. A reduced-pressure source 132 delivers reduced pressure to the reduced-pressure delivery conduit 130.

[0026] The reduced pressure may be applied to the tissue site 104 to help promote removal of ascites, exudates, or other fluids from the tissue site 104. In some instances, reduced pressure may be applied to stimulate the growth of additional tissue. In some instances, only fluid removal may be desired. In the case of a wound at the tissue site 104, the growth of granulation tissue, removal of exudates, or removal of bacteria may help to promote healing of the wound. In the situation of a non-wounded or non-defective tissue, reduced pressure may be used in some instances to promote the growth of tissue that may be harvested and transplanted to another tissue site.

[0027] As used herein, "reduced pressure" generally refers to a pressure less than the ambient pressure at a tissue site being subjected to treatment. Typically, this reduced pressure will be less than the atmospheric pressure. The reduced pressure may also be less than a hydrostatic pressure at a tissue site. Unless otherwise indicated, values of pressure stated herein are gauge pressures. While the amount and nature of reduced pressure applied to a tissue site will typically vary according to the application, the reduced pressure will typically be between -5 mm Hg and -500 mm Hg, and more typically in a therapeutic range between -100 mm Hg and -200 mm Hg.

[0028] The reduced pressure delivered may be constant, varied, patterned, or random, and may be delivered continuously or intermittently. Although the terms "vacuum" and "negative pressure" may be used to describe the pressure applied to the tissue site, the actual pressure applied to the tissue site may be more than the pressure normally associated with a complete vacuum. Consistent with the use herein, an increase in reduced pressure corresponds to a reduction in pressure (more negative relative to ambient pressure) and a decrease in reduced pressure corresponds to an increase in pressure (less negative relative to ambient pressure).

[0029] Reduced pressure may initially generate fluid flow in the manifold 122, the reduced-pressure conduit 130, and proximate the tissue site 104. As the hydrostatic pressure around the tissue site 104 approaches the desired reduced pressure, the flow may subside, and the reduced pressure may be maintained.

[0030] The manifold 122 is proximate the central connection member 112. The manifold 122 may take many forms. The term "manifold" as used herein generally refers to a

substance or structure that is provided to assist in applying reduced pressure to, delivering fluids to, or removing fluids from the tissue site 104. The manifold 122 typically includes a plurality of flow channels or pathways that distribute the fluids provided to and removed from the tissue site 104 around the manifold 122 and through the central connection member 112. In one illustrative embodiment, the flow channels or pathways are interconnected to improve distribution of fluids provided or removed from the tissue site 104. The manifold 122 may be a biocompatible material that is capable of being placed in contact with the tissue site 104 and distributing reduced pressure to the tissue site 104.

[0031] Examples of suitable materials for the manifold 122 may include, without limitation, devices that have structural elements arranged to form flow channels, cellular foam, such as open-cell foam, porous tissue collections, liquids, gels and foams that include or cure to include flow channels. The manifold 122 may be porous and may be made from foam, gauze, felted mat, silicone, polyvinyl alcohol, or any other material suited to a particular biological application. In one embodiment, the manifold 122 is a porous foam and includes a plurality of interconnected cells or pores that act as pathways or flow channels. The porous foam may be a polyurethane or polyether, open-cell, reticulated foam, such as GRANUFOAM™ material available from Kinetic Concepts, Incorporated in San Antonio, Texas. Other embodiments might include "closed cells." These closed-cell portions of the manifold may contain a plurality of cells, the majority of which are not fluidly connected to adjacent cells. The closed cells may be selectively disposed in the manifold 122 to prevent transmission of fluids through perimeter surfaces of the manifold 122. In some situations, the manifold 122 may also be used to distribute fluids such as medications, antibacterials, growth factors, and various solutions to the tissue site 104. Other layers may be included in or on the manifold 122, such as absorptive materials, wicking materials, hydrophobic materials, and hydrophilic materials.

[0032] A material with a higher or lower density than GRANUFOAM™ material may be desirable depending on the application. Among the many possible materials, the following may be used: GRANUFOAM™ material, FOAMEX™ technical foam, a molded bed of nails structures, a patterned grid material such as those manufactured by Sercol Industrial Fabrics, 3D textiles such as those manufactured by Baltex of Derby, United Kingdom, a gauze, a flexible channel-containing member, a graft, or similar materials. In some instances, ionic silver may be added to the manifold 122 by, for example, a micro

bonding process. Other substances, such as anti-microbial agents, may be added to the manifold 122 as well.

[0033] The sealing member 124 is configured to be placed over the body-cavity opening 126 and may be formed from any material capable of providing a pneumatic seal or fluid seal adequate for the open-cavity, reduced-pressure system 100 to hold a reduced pressure at the tissue site 104. The sealing member 124 may be a cover that is used to secure the manifold 122 on the central connection member 112. The sealing member 124 may be impermeable or semi-permeable. The sealing member 124 is capable of maintaining reduced pressure at the tissue site 104 after installation of the sealing member 124 over the body-cavity opening 126. The sealing member 124 may be a flexible over-drape or film formed from a silicone-based compound, acrylic, hydrogel or hydrogel-forming material, or any other biocompatible material that includes the impermeability or permeability characteristics as desired for applying reduced pressure to the tissue site 104.

[0034] More specifically, the sealing member 124 may comprise, for example, one or more of the following materials: hydrophilic polyurethane; cellulosics; hydrophilic polyamides; polyvinyl alcohol; polyvinyl pyrrolidone; hydrophilic acrylics; hydrophilic silicone elastomers; an INSPIRE 2301 material from Expopack Advanced Coatings of Wrexham, United Kingdom having, for example, an MVTR (inverted cup technique) of 14400 g/m2/24 hours and a thickness of about 30 microns; a thin, uncoated polymer drape; natural rubbers; polyisoprene; styrene butadiene rubber; chloroprene rubber; polybutadiene; nitrile rubber; butyl rubber; ethylene propylene rubber; ethylene propylene diene monomer; chlorosulfonated polyethylene; polysulfide rubber; polyurethane (PU); EVA film; co-polyester; silicones; a silicone drape; a TEGADERM™ drape available from 3M; a polyurethane (PU) drape such as one available from Avery Dennison Corporation of Pasadena, California; polyether block polyamide copolymer (PEBAX), for example, from Arkema, France; EXPOPACK 2327; or other appropriate material.

[0035] Further, the sealing member 124 may be vapor permeable and/or liquid impermeable, thereby allowing vapor and inhibiting liquids from exiting a sealed space between the sealing member 124 and the tissue site 104. In some embodiments, the sealing member 124 may be a flexible, breathable film, membrane, or sheet having a high moisture vapor transfer rate (MVTR) of, for example, at least about 300g/m2 per 24 hours. In other embodiments, a low or no vapor transfer drape might be used. The sealing member 124 may comprise a range of medically suitable films having a thickness up to about 50 microns (μm).

[0036] The sealing member 124 may further include an attachment means 131 to secure the sealing member 124 to the patient's epidermis 134. The attachment means 131 may take many forms; for example, an adhesive layer 136 may be positioned along a perimeter of the sealing member 124 or any portion of the sealing member 124 to provide, directly or indirectly, the pneumatic seal with the patient's epidermis 134. The adhesive layer 136 might also be pre-applied to the sealing member 124 and covered with a releasable backing, or member (not shown), that is removed at the time of application.

[0037] The reduced-pressure interface 128 may be, as one example, a port or connector 138, which permits the passage of fluid from the manifold 122 to the reduced-pressure delivery conduit 130 and vice versa. For example, fluid collected from the tissue site 104 using the manifold 122 and the treatment device 102 may enter the reduced-pressure delivery conduit 130 via the connector 138. In another embodiment, the open-cavity, reduced-pressure system 100 may omit the connector 138 and the reduced-pressure delivery conduit 130 may be inserted directly into the sealing member 124 and into the manifold 122. The reduced-pressure delivery conduit 130 may be a medical conduit or tubing or any other means for transportating a reduced pressure and fluid. The reduced-pressure delivery conduit 130 may be a multi-lumen member for readily delivering reduced pressure and removing fluids. In one embodiment, the reduced-pressure delivery conduit 130 is a two-lumen conduit with one lumen for reduced pressure and liquid transport and one lumen for communicating pressure to a pressure sensor.

[0038] Reduced pressure is generated and supplied to the reduced-pressure delivery conduit 130 by the reduced-pressure source 132. A wide range of reduced pressures may be generated or supplied by the reduced-pressure source 132. In one embodiment, the range may include -50 to -300 mm Hg, and in another embodiment, the range may include -100 mm Hg to -200 mm Hg. In one illustrative embodiment, the reduced-pressure source 132 includes preset selectors for -100 mm Hg, -125 mm Hg, and -150 mm Hg. The reduced-pressure source 132 may also include a number of alarms, such as a blockage alarm, a leakage alarm, or a battery-low alarm.

[0039] The reduced-pressure source 132 may be any suitable device for providing reduced pressure, such as, for example, a vacuum pump, wall suction, hand pump, manual pump, electronic pump, micro-pump, piezoelectric pump, diaphragm pump, a portable source, wall source, a unit for abdominal cavities, or other source. The reduced-pressure source 132 may include control circuitry and sensors, such as a pressure sensor, that may be

configured to monitor reduced pressure at the tissue site 104. The reduced-pressure source 132 may also be configured to control the amount of reduced pressure from the reduced-pressure source 132 being applied to the tissue site 104 according to a user input and a reduced-pressure feedback signal received from the tissue site 104. The reduced-pressure source 132 may selectively deliver a constant pressure, varied pressure, intermittent pressure, or continuous pressure. The fluid removed from the cavity through the reduced-pressure delivery conduit 130 could be as much as 5 liters or more per day.

[0040] A number of different devices, *e.g.*, device 140, may be added to a medial portion 142 of the reduced-pressure delivery conduit 130. For example, the device 140 might be a fluid reservoir, or canister collection member, a pressure-feedback device, a volume detection system, a blood detection system, an infection detection system, a filter, a port with a filter, a flow monitoring system, a temperature monitoring system, etc. Multiple devices 140 might be included. Some of these devices, *e.g.*, the fluid collection member, may be formed integral to the reduced-pressure source 132. For example, a reduced-pressure port 144 on the reduced-pressure source 132 may include a filter member (not shown) that includes one or more filters and may include a hydrophobic filter that prevents liquid from entering an interior space of the reduced-pressure source 132.

[0041] Referring now to FIGURES 1A, 1C, and 2, the treatment device 102 can include a non-adherent drape 148. The non-adherent drape 148 may be formed of a non-adherent material that inhibits tissue adhesion to the non-adherent drape 148. In one embodiment, the non-adherent drape 148 is formed from a breathable polyurethane film. The non-adherent drape 148 can include a plurality of openings, apertures, or fenestrations 150. The fenestrations can take a variety of shapes, such as circular openings, rectangular openings, polygon-shaped openings, etc., but are shown in FIGURE 2 as slits, or linear cuts. Depending on the particular application of device 102, the desired fluid flow and/or pressure delivery, or other system parameters, the fenestrations can have different sizes.

[0042] Referring to FIGURES 1A, 1D, and 2, the treatment device 102 includes the central connection member 112 to which the plurality of encapsulated leg members 106 are coupled. The central connection member 112 includes a connection manifold member 154 that is encapsulated by a first connection encapsulation member 186, which may be referred to as a first non-adherent drape 186, and a second connection encapsulation member 192, which may be referred to as a second non-adherent drape 192. A portion of the central connection member 112 can fluidly couple at leg coupling areas 152 to permit fluid

communication between the central connection member 112 and the plurality of encapsulated leg members 106. The first and the second connection encapsulation member or non-adherent drape 186, 192 may be defined by a single piece of material or, as illustrated, more than one sheet of material. For example, the non-adherent drape 148 may be used as a single sheet or may include the first non-adherent drape 186 and the second non-adherent drape 192.

[0043] The central connection member 112, as discussed above, can fluidly communicate with manifold 122. In one aspect, fenestrations 118, similar to the fenestrations discussed above, can permit fluid communication. Additionally, or alternatively, a portion or portions of the first connection encapsulation member or non-adherent drape 186 can be exposed to manifold 122.

[0044] Referring again to FIGURES 1A-1D, each of the plurality of encapsulated leg members 106 can include a leg manifold member 160, which may be a single manifold member that runs between leg modules 156 and/or central connection member 112, or individual manifold components. The leg manifold member 160 is disposed within an interior portion 162 of each of the encapsulated leg members 106. Each leg manifold member 160 has a first side 164 and a second, inward-facing (patient-facing) side 166.

[0045] In some embodiments, the connection manifold member 154 and one or more of the leg manifold members 160 extending from the connection manifold member 154 may form a treatment manifold 167. The treatment manifold 167 including the leg manifold members 160 and the connection manifold member 154 may comprise or be formed of a foam or a manifold material similar or analogous to the manifold materials described herein for the manifold 122.

[0046] The non-adherent drape 148 may surround the treatment manifold 167. For example, the non-adherent drape 148 may be coupled around the leg manifold members 160 and the connection manifold member 154 to provide the plurality of encapsulated leg members 106 in fluid communication with the central connection member 112. In some embodiments, the non-adherent drape 148 may include the first non-adherent drape 186 and the second non-adherent drape 192 and the treatment manifold 167 may be positioned as a layer between the first non-adherent drape 186 and the second non-adherent drape 192. The first non-adherent drape 186 may be coupled to the second non-adherent drape 192 to provide the plurality of encapsulated leg members 106 in fluid communication with the central connection member 112.

[0047] In one embodiment, one or more of the plurality of leg manifold members 160 can have different material properties or structures. For example, different flow rates may be desired in different encapsulated leg members 106. In one aspect, different manifold materials or manifold properties, different manifold sizes, manifold compression, the use flow restricting material structures, and/or or valves can provide different flow rates of fluid through the encapsulated leg members and/or central connection member.

[0048] In one aspect, a first leg encapsulating member 168, which can be formed with fenestrations 114, is disposed on the first side 164 of the leg manifold member 160. A second leg encapsulating member 170, which can include fenestrations 116, is disposed on the second, inward-facing side 166 of the leg manifold member 160. The first leg encapsulating member 168 and the second leg encapsulating member 170 may be a portion of the non-adherent drape 148. In some embodiments, the first leg encapsulating member 168 may be a portion of the first non-adherent drape 186 and the second leg encapsulating member 170 may be a portion of the second non-adherent drape 192. In some embodiments, the encapsulated leg members 106 can be mated with one another, for example, via the drape 148. In some embodiments, the encapsulated leg members 106 can be independently movable with respect to one another with the exception of their proximal end adjacent to the central connection member 112. For example, the encapsulated leg members 106 need not be connected to one another. In another embodiment, a portion of the material connecting the encapsulated leg members 106, *e.g.*, the non-adherent drape 148 between adjacent encapsulated leg members 106, is expandable (*e.g.*, a stretchable, flexible, deformable, and/or elastic material) and permits movement of individual encapsulated leg members 106 relative to one another.

[0049] As shown in the longitudinal cross section of FIGURE 1B by arrows 172, fluid can flow from leg modules 156 towards the central connection member 112. As shown by arrows 174, the fluid is able to enter fenestrations 114 and 116 and flow into the leg manifold member 160 and then flow toward the central connection member 112 as represented by arrows 172.

[0050] In plan view, the encapsulated leg members 106 may take a number of different shapes, such as elongate shapes, rectangular, elliptical, etc. In one aspect, the encapsulated leg members 106 may include leg modules 156. Adjacent leg modules 156 are fluidly coupled to each other and have a manipulation zone 158 between them. In one aspect, the manipulation zone includes a weakened or perforated area to facilitate sizing of the

device. For example, a clinician can cut through a leg module to size the device. By pulling on the partially cut leg module the manifold can be torn away at the next manipulation zone. In one aspect, the recessed shape of the manipulation zone 158 can inhibit accidental removal of additional leg modules. Additionally, or alternatively, the outer portion of the leg modules can be fixed to the device to inhibit unwanted manifold removal.

[0051] The encapsulated leg members 106 may also have various dimensions. If the longer dimension, *e.g.*, lengthwise or longitudinal dimension, of the encapsulated leg 106 is L_1 and the width is w_1, then the aspect ratio is given by L_1/w_1. The aspect ratio may be 8.0, 7.0, 6.0, 5.0, 4.0, 3.0, 2.0 or any number in between. Moreover, other aspect ratios are possible. Generally, the width w_1 of the encapsulated leg member will be greater than a width w_2 of the central connection member 112, *i.e.*, $w_2 > w_1$. For example, in one illustrative embodiment, the encapsulated leg members 106 are approximately 270 mm long, 60 mm wide (w_1), and 10 mm thick, and the central connection member has a width parallel to the first width (w_1) of about 130 mm (w_2). Thus, in that illustrative example, the aspect ratio of the encapsulated leg 106 is approximately (270/60) or 4.5. In this same illustrative embodiment, the manipulation zones 158 have a width of about 10 mm.

[0052] Referring to FIGURE 1C, a lateral cross section of a portion of the encapsulated leg member 106 is presented. As before, it can be seen that the first side 164 of the leg manifold member 160 is covered with the first leg encapsulating member 168, and that the second, inward-facing side 166 of the leg manifold member 160 is covered by the second leg encapsulating member 170, which in this instance is a portion of the non-adherent drape 148. Thus, in this illustrative embodiment, the fenestrations 116 may be some of the plurality of fenestrations 150 in the non-adherent drape 148. In this illustrative embodiment, peripheral edges 176 of the leg manifold member 160 are also covered by a portion of the first leg encapsulating member 168. The peripheral edges 176 include a first lateral edge 177 and a second lateral edge 179. The first leg encapsulating member 168 covers the first side 164 and the peripheral edges 176 and extends onto a first surface 178 of the non-adherent drape 148 and forms extensions 180. The extensions 180 have been coupled to the second leg encapsulating member 170 by welds 182. The first leg encapsulating member 168 may, however, be coupled to the second leg encapsulating member 170 using any known technique, including welding (*e.g.*, ultrasonic or RF welding), bonding, adhesives, cements, etc.

[0053] In some embodiments, at least a portion of a longitudinal length of at least one of the encapsulated leg members 106 is configured to contact the tissue site 104. Further, in some embodiments, the fenestrations 116 may be positioned along the longitudinal length of at least one of the encapsulated leg members 160.

[0054] Referring again to FIGURE 1D and FIGURE 2, the central connection member 112 includes the connection manifold member 154 that is encapsulated within the first connection encapsulation member 186, which has fenestrations 118. The first connection encapsulation member 186 is disposed on a first side 188 of the connection manifold member 154. The second connection encapsulation member 192 is disposed on a second, inward-facing side 190 of the connection manifold member 154. The second connection encapsulation member 192 is formed with fenestrations 120. The first connection encapsulation member 186 has a peripheral zone or edge 194 as shown in FIGURE 2. In a similar fashion, the second connection encapsulation member 192 has a peripheral zone or edge (not explicitly shown) that lines up with the peripheral edge 194. The peripheral edge 194 of the first connection encapsulation member 186 is coupled to peripheral edge of the second connection encapsulation member 192, except at the leg coupling areas 152 in order to allow fluid within the plurality of encapsulated leg members 106 to flow into the connection manifold member 154 as suggested by arrows 196 in FIGURE 1D. Fluid may also enter directly into the connection manifold member 154 by flowing through fenestrations 120 as suggested by arrows 198. The manifold 122 is disposed proximate to the first connection encapsulation member 186, and when a reduced pressure is applied to the manifold 122, the reduced pressure causes fluid to flow from the connection manifold member 154 through fenestrations 118 and into the manifold 122 as suggested by arrows 200. The fluid continues to flow in the direction of the reduced-pressure interface 128 through which the fluid is removed to the reduced-pressure delivery conduit 130.

[0055] Referring to FIGURES 1A-1D and 2, in operation, the illustrative open-cavity, reduced-pressure system 100 may be used by first sizing the treatment device 102 as will be explained further below in connection with FIGURE 3A. The non-adherent drape 148 with the plurality of encapsulated leg members 106 is disposed within the abdominal cavity through the body-cavity opening 126 and is distributed against the abdominal contents; this may include placing at least one encapsulated leg member 106 in or proximate the first paracolic gutter 108, the second paracolic gutter 110, or behind the liver, etc. Once the treatment device 102 has been distributed, the manifold 122 is placed adjacent a first side 184

of the first connection encapsulation member 186. The sealing member 124 may then be applied over the body-cavity opening 126 to provide a pneumatic seal over the body-cavity opening 126.

[0056] In addition to the sealing member 124, the body-cavity opening 126 may be further closed or reinforced using mechanical closing means, *e.g.*, staples, or using a reduced-pressure closure system. The sealing member 124 may be applied in a number of ways, but according to one illustrative embodiment, the releasable backing member that is on the adhesive layer 136 of the sealing member 124 is removed and then the sealing member 124 is placed against the patient's epidermis 134 about the body-cavity opening 126. The reduced-pressure interface 128, such as port 138, is then coupled or attached to the sealing member 124 such that reduced pressure can be delivered by the interface 128, through the sealing member 124, and to the manifold 122 and the central connection member 154. The reduced-pressure delivery conduit 130 is fluidly coupled to the reduced-pressure interface 128 and to the reduced-pressure port 144 on the reduced-pressure source 132.

[0057] The reduced-pressure source 132 is activated and thereby provides reduced pressure into the reduced-pressure delivery conduit 130, which delivers the reduced pressure to the reduced-pressure interface 128 and into the manifold 122 and the central connection member 154. The manifold 122 distributes the reduced pressure and draws fluid through fenestrations 118 from the connection manifold member 154. The connection manifold member 154 draws fluid from the abdominal cavity through fenestrations 120 and pulls fluid from the plurality of encapsulated leg members 106 as suggested by arrows 196. Fluid from the abdominal cavity flows into the plurality of encapsulated leg members 106 through fenestrations 114 on the first leg encapsulating member 168 and through fenestrations 116 on the second leg encapsulating member 170 and then flows through the leg as suggested by arrows 172 towards the connection manifold member 154. The fluid then flows through the manifold 122, the reduced-pressure interface 128, and into the reduced-pressure delivery conduit 130.

[0058] Referring now to FIGURES 3A-3C, another illustrative embodiment of an open-cavity, reduced-pressure treatment device 302 is presented. The open-cavity, reduced-pressure treatment device 302 is analogous in most respects to the treatment device 102 of FIGURES 1A-1D. The open-cavity, reduced-pressure treatment device 302 has a non-adherent drape 304, a plurality of encapsulated leg members 306, and a central connection member 308. In this particular illustrative embodiment, the non-adherent drape 304 is

formed generally with an oval or arcuate shape. The non-adherent drape 304 is formed with a plurality of fenestrations 305. The non-adherent drape 304 forms the second leg encapsulating member (see by analogy second leg encapsulating member 170 in FIGURE 1B) and the second connection encapsulation member (see by analogy 192 in FIGURE 1D). As such, the plurality of fenestrations 305 serves as flow channels for the plurality of encapsulated leg members 306 and the central connection member 308 on the second, inward-facing side. The non-adherent drape 304 could also be used on the first side of the plurality of encapsulated leg members 306 and the central connection member 308.

[0059] Each of the encapsulated leg members 306 may be formed with a plurality of leg modules 310 with manipulation zones 312 between the plurality of leg modules 310. As with the manipulation zone 158 in FIGURES 1A-D, the manipulation zones 312 facilitate movement of the plurality of encapsulated leg members 306 within the body cavity and provide an easier location at which to cut the plurality of encapsulated leg members 306 when the open-cavity, reduced-pressure treatment device 302 is being sized for a particular application. In this regard, visual indicia 314 may be added on the non-adherent drape 304 to help the healthcare provider know where to cut the non-adherent drape 304 for different sizes of application within the cavity. The visual indicia 314 may comprise cut lines, or graduations, that preferably run through the manipulation zones 312. The manipulation zones 312 provide a convenient and easy location for cutting the open-cavity, reduced-pressure treatment device 302.

[0060] Referring to FIGURE 3C, a lateral cross section of a portion of an encapsulated leg member 306 is presented. The plurality of encapsulated leg members 306 are formed with a leg manifold member 318 having a first side 320 and a second, inward-facing (patient-facing) side 322. A first leg encapsulating member 324 covers the first side 320 of the leg manifold member 318 and covers a lateral zone or edge 326 of the leg manifold member 318. The second, inward-facing side 322 of the leg manifold member 318 is covered by a second leg encapsulating member 328, which in this embodiment is a portion of the non-adherent drape 304. The first leg encapsulating member 324 is coupled to the second leg encapsulating member 328 by any means known in the art, such as by welding (*e.g.*, ultrasonic or RF), bonding, adhesives, cements, etc. In this illustrative embodiment, the first leg encapsulating member 324 and the second leg encapsulating member 328 are coupled by a weld 330. Referring to FIGURE 3B, the weld 330 is shown along the perimeter of the plurality of leg modules 310.

[0061] Referring again to FIGURE 3A, the central connection member 308 is formed analogously to the central connection member 112 in FIGURE 2. A first connection encapsulation member 334 and a second connection encapsulation member of the central connection member 308 are coupled along a peripheral edge 332 using a weld 333 or another coupling technique, such as those previously mentioned. The peripheral edge 332 is not sealed, however, proximate each of the encapsulated leg members 306 in order to provide a channel for fluid to flow from the plurality of encapsulated leg members 306 into the central connection member 308.

[0062] According to one illustrative approach to constructing the open-cavity, reduced-pressure treatment device 302, the non-adherent drape 304, which is already formed with the plurality of fenestrations 305 and that has visual indicia 314 is provided. The leg manifold member 318 is disposed adjacent the non-adherent drape 304. The central connection manifold 308 is disposed adjacent to the leg manifold member 318 or may be formed integral with leg manifold member 318. The first connection encapsulation member 334 is placed on the central connection member 308, and the first leg encapsulating member 324 is placed over the leg manifold member 318. The first connection encapsulation member 334 and the first leg encapsulating member 324 may be formed from an integral sheet. Next, the welds 330 and 333 are applied.

[0063] In an alternative embodiment for manufacturing an open-cavity, reduced-pressure treatment device, a first non-adherent drape 304, which includes fenestrations, may be provided and the leg manifold member 318 and the central connection manifold 308 disposed on the first non-adherent drape 304. A second non-adherent drape, which has fenestrations, is placed over the first non-adherent drape 304, the leg manifold member 318, and the central connection manifold 308. Next, a plurality of welds (*e.g.*, thermal or RF or another coupling techniques used) are made, such as with the welds 330. The first non-adherent drape 304 and the second non-adherent drape may be cut to size before or after assembly. By using two drapes, the first non-adherent drape 304 and the second non-adherent drape may provide better distribution of reduced pressure and may ease the manufacturing process.

[0064] The fenestrations may be formed before or after assembly. The perimeter of the first non-adherent drape 304 and the second non-adherent drape may be welded. Other points may be welded between the drapes to form a single unit. In another alternative embodiment, the drapes may initially be placed and welded without fenestrations, and then

fenestrations added to the drapes so that the fenestrations align. The fenestrations might also be formed using an electrical member that cuts and seals at the same time to form aligned, "button hole" fenestrations through the two drapes.

[0065] Referring to FIGURES. 1A, 1D, 4A, and 4B, in some example embodiments, the manifold 122 may be a lateral force manifold 422. The lateral force manifold 422 may be configured to distribute reduced pressure relative to the tissue 104 and other components of the system 100, such as, for example, the treatment device 102 or the treatment manifold 167. As such, the lateral force manifold 422 may be positioned proximate to and in fluid communication with the treatment device 102 or the treatment manifold 167. In some examples, the lateral force manifold 422 may be in fluid communication with the treatment manifold 167 through the non-adherent drape 148, or a portion of the non-adherent drape 148, such as the first non-adherent drape 186. Further, in some examples, the lateral force manifold 422 may be configured to be positioned in direct contact with the non-adherent drape 148 or the first non-adherent drape 186. Further, in some examples, the lateral force manifold 422 may be positioned proximate to and in fluid communication with the connection manifold member 154 or the central connection member 112. The sealing member 124 may be configured to cover the treatment manifold 167 and the lateral force manifold 422 at the tissue site 104.

[0066] Referring to FIGURES 1A and 4A-4B, in some example embodiments, the lateral force manifold 422 may include a lateral width 424 extending from a first edge 426 to an opposite second edge 428 of the lateral force manifold 422. The lateral width 424 may be configured to extend across the body-cavity opening 126 at the tissue site 104. Further, the lateral force manifold 422 may include a longitudinal length 430 extending from a first end 432 to an opposite second end 434 of the lateral force manifold 422. The longitudinal length 430 may be greater than the lateral width 424 and perpendicular to the lateral width 424 of the lateral force manifold 422. The longitudinal length 430 may be configured to be positioned along a closure line that may be formed by opposing sides of the body-cavity opening 126, such as, for example, an incision or a line of staples or sutures, etc. Further, the lateral force manifold 422 may include a thickness 436 extending from a first side 438 to an opposite second side 440 of the lateral force manifold 422. The thickness 436 of the lateral force manifold 422 may be perpendicular to both the lateral width 424 and the longitudinal length 430 of the lateral force manifold 422. The first side 438 of the lateral force manifold 422 may be configured to face outward from or away from the tissue site 104 and, for

example, the treatment device 102, the treatment manifold 167, or portions thereof. Further, the second side 440 of the lateral force manifold 422 may be configured to face the tissue site 104 and, for example, the treatment device 102, the treatment manifold 167, or portions thereof. The first side 438 may mirror the second side 440 of the lateral force manifold 422, and thus, both the first side 438 and the second side 440 may include the same features described herein.

[0067] Referring to FIGURES 4A-4B, in some example embodiments, the lateral force manifold 422 may include at least one first contractive portion 442 and at least one second contractive portion 444. The at least one first contractive portion 442 may be configured to contract a first amount under a reduced pressure, such as a reduced pressure generated by the reduced-pressure source 132. Further, the at least one second contractive portion 444 may be configured to contract a second amount under the same level of reduced pressure from the reduced-pressure source 132. The second amount of contraction in the second contractive portion 444 may be less than the first amount of contraction in the first contractive portion 442.

[0068] In some example embodiments, the first contractive portion 442 may be positioned next to the second contractive portion 444 along the lateral width 424. Further, in some examples, the second contractive portion 444 may substantially or entirely surround the first contractive portion 442.

[0069] In some example embodiments, the at least one first contractive portion 442 may be a plurality of first contractive portions 442, and the at least one second contractive portion 444 may be a plurality of second contractive portions 444. In some examples, one or more of the first contractive portions 442 may be positioned between the second contractive portions 444 along the lateral width 424. Further, in some examples, the first contractive portions 442 and the second contractive portions 444 may alternate along the lateral width 424.

[0070] In some example embodiments, the first contractive portions 442 and the second contractive portions 444 of the lateral force manifold 422 may be configured in an alternating pattern as shown in FIGURES 4A-4B, which may also be substantially concentric. The alternating pattern may be discontinuous as shown in FIGURE 4A or continuous as shown in FIGURE 4B.

[0071] For example, referring to FIGURE 4A, the lateral force manifold 422 may be a lateral force manifold 422a. The lateral force manifold 422a may include the first

contractive portions 442 and the second contractive portions 444 positioned in an arcuate shape 446. As shown in FIGURE 4A, the first contractive portions 442 may alternate with the second contractive portions 444 along the arcuate shape 446 and along the lateral width 424. The arcuate shape 446 may also be concentric as shown in FIGURE 4A.

[0072] Further, in some examples, the lateral force manifold 422 may be a lateral force manifold 422b as shown in FIGURE 4B. The lateral force manifold 422b may include the first contractive portions 442 and the second contractive portions 444 configured in substantially concentric and alternating rings 448. The rings 448 formed by the first contractive portions 442 and the second contractive portions 444 may each be continuous along the path of the ring 448. However, the alternating configuration of the rings 448 may cause the first contractive portions 442 and the second contractive portions 444 to alternate relative to each other along the lateral width 424.

[0073] Referring to FIGURES 5A-6B, in some example embodiments, the at least one first contractive portion 442 and the at least one second contractive portion 444 may each include or be formed of a porous material 450 including an initial thickness 451 and pores 452 defining a porosity. In some examples, the porous material 450 of the second contractive portion 444 may have a higher density than the porous material 450 of the first contractive portion 442.

[0074] In some examples, the pores 452 in the first contractive portion 442 may be pores 452a, and the pores 452 in the second contractive portion 444 may be pores 452b. The pores 452b in the second contractive portion 444 may have an average size that is smaller than an average size of the pores 452a in the first contractive portion 442. Further, the porosity, void fraction, or empty void space of the first contractive portion 442 may be higher than a porosity, void fraction, or empty void space of the second contractive portion 444.

[0075] Further, the first contractive portion 442 may have a first thickness 454 and the second contractive portion 444 may have a second thickness 456. In some examples, the first thickness 454 may be greater than the second thickness 456 as shown in FIGURE 5B. In other examples, the first thickness 454 may be the same or substantially the same as the second thickness 456 as shown in FIGURE 6B.

[0076] Further, the first contractive portion 442 and the second contractive portion 444 may have different compression force deflection properties. For example, a first compression force required to compress the first contractive portion 442 by a target amount may be less than a second compression force required to compress the second contractive

portion 444 by the same target amount. In some example embodiments, the first compression force required to compress the first contractive portion 442 by 25 percent of its original or relaxed thickness may be between 0.1 pounds per square inch (psi) to 0.6 psi, and the second compression force required to compress the second contractive portion 444 by 25 percent of its original or relaxed thickness may be between 0.7 psi to 4.5 psi.

[0077] In some example embodiments, the at least one first contractive portion 442 and the at least one second contractive portion 444 may each include for be formed of a foam similar or analogous to the foam materials described herein for the manifold 122. In some examples, the foam of the second contractive portion 444 may have a higher density than the foam of the first contractive portion 442. Further, in some examples, the second contractive portion 444 may include or be formed of a felted foam or a compressed foam.

[0078] As described herein, the terms "felting" or "felted" may refer to a porous material, such as the porous material 450, that has been treated or modified to impart a desired property to the porous material 450. For example, the porous material 450 may be a foam treated or modified to have a desired porosity or density. Felting may be performed by any known methods, which may include applying heat and pressure to a porous material or foam material. Such methods may include compressing the porous material 450 between one or more heated platens or dies (not shown) for a specified period of time and at a specified temperature. The direction of compression may be along the initial thickness 451 of the porous material 450 as shown in FIGURES 5A and 6A. In some examples, the initial thickness 451 may be between about 0.2 centimeters to about 6 centimeters.

[0079] The period of time of compression may range from 10 minutes up to 24 hours, though the time period may be more or less depending on the specific type of porous material used. Further, in some examples, the temperature may range between 120°C to 260°C. Generally, the lower the temperature of the platen, the longer a porous material must be held in compression. After the specified time period has elapsed, the pressure and heat will form a felted structure or surface on or through the porous material 450 or a portion of the porous material 450. The felted structure may be comparatively smoother than any unfinished or non-felted surface or portion of the porous material 450. Further, the pores in the felted structure may be smaller than the pores throughout any unfinished or non-felted surface or portion of the porous material 450. In some examples, the felted structure may be applied to all surfaces or portions of the porous material 450. Further, in some examples, the felted

structure may extend into or through an entire thickness of the porous material 450 such that the all of the porous material 450 is felted.

[0080] Felting may be expressed as a ratio of the uncompressed thickness or the initial thickness 451 of the porous material 450 to the compressed or final thickness of the porous material 450 after the felting process has taken place. For example, a felting ratio of 1:3 compresses the porous material 450 to one-third of the uncompressed or the initial thickness 451 of the porous material 450. A felting ratio of 1:7 compresses the porous material 450 to one-seventh of the uncompressed or the initial thickness 451 of the porous material 450. In some embodiments, the compressed thickness of the porous material 450 may be less than one-tenth, one-ninth, one-eighth, one-seventh, one-sixth, one-fifth, one-fourth, one-third, or one-half of the uncompressed or the initial thickness 451 of the porous material 450. In some examples, the porous material 450 of the second contractive portion 444 may be felted to a felting compression ratio of 1.5 times to 10 times compared to the first contractive portion 442 or the initial thickness 451 of the porous material 450. The 1.5 times compression ratio may be expressed as 1:1.5 and the 10 times compression ratio may be expressed as 1:10.

[0081] Referring to a cross-section of the porous material 450 shown in FIGURE 5A, in some examples, the initial thickness 451 may be substantially constant across the cross-section of the porous material 450. Referring to FIGURE 6A, in other examples, the porous material 450 may include more than one thickness, or a variable thickness, across the cross-section of the porous material 450. For example, in FIGURE 6A, the initial thickness 451 of the porous material 450 may be an initial thickness 451a and the porous material 450 may additionally include an initial thickness 451b that is greater than the initial thickness 451a.

[0082] In some examples, the porous material 450 shown in FIGURE 5A may be treated, modified, or felted to produce the first contractive portion 442 having the first thickness 454 and the second contractive portion 444 having the second thickness 456 that is less than the first thickness 454 as shown in FIGURE 5B. In the example of FIGURE 5B, the first thickness 454 of the first contractive portion 442 may be the same or substantially the same as the initial thickness 451 of the porous material 450, while the second thickness 456 of the second contractive portion 444 may be less than the initial thickness 451 after compression of the porous material 450.

[0083] In other examples, the porous material 450 shown in FIGURE 6A may be treated, modified, or felted to produce the first contractive portion 442 having the first

thickness 454 and the second contractive portion 444 having the second thickness 456 that is the same or substantially the same as the first thickness 454. In the example of FIGURE 6B, both the first thickness 454 of the first contractive portion 442 and the second thickness 456 of the second contractive portion 444 may be the same or substantially the same as the initial thickness 451 after compression of the porous material 450. The use of the variable initial thickness 451a and 451b in the porous material 450 prior to compression is a non-limiting example of how the first contractive portion 442 and the second contractive portion 444 can be finished or manufactured to have the same or different thicknesses.

[0084] The varying amounts of contraction between the at least one first contractive portion 442 and the at least one second contractive portion 444 and the alternating positioning of the first contractive portion 442 relative to the second contractive portion 444 across the lateral width 424 of the lateral force manifold 422 may allow the lateral force manifold 422 to exhibit additional compression in a lateral direction across the body-cavity opening 126 while under reduced pressure. For example, the increased empty void space or porosity associated with the less dense first contractive portion 442 may provide increased movement or contraction as the voids and pores have more space to collapse under reduced pressure compared to the second contractive portion 444.

[0085] Another illustrative embodiment for using an open-cavity, reduced-pressure treatment device or system according to this disclosure will now be presented. The system is particularly suitable for temporary bridging of abdominal wall openings where primary closure may not be readily possible and or repeat abdominal entries are necessary. The illustrative system described here may be used with open abdominal wounds, with exposed viscera, including but not limited to abdominal compartment syndrome. Before applying the system, typically hemostasis should be achieved.

[0086] In deploying the open-cavity, reduced-pressure treatment system, the reduced-pressure treatment device preferably covers all exposed viscera and preferably separates completely the viscera from contact with the abdominal wall. For example, the lower surface of the reduced pressure treatment device, such as drape 148, can be sized and shaped to permit coverage. The reduced-pressure treatment device may be placed over the omentum or exposed internal organs, and carefully tucked between the abdominal wall and internal organs. In doing so, the healthcare provider may use the reduced-pressure treatment device to completely separate the abdominal wall from the internal organs.

[0087] To prepare for deployment of the system, any sharp edges or bone fragments are eliminated from wound area or covered. The abdominal wound is irrigated and the periwound area cleaned. The periwound tissue at the epidermis is typically dried before further application.

[0088] The reduced-pressure treatment device is then sized by determining the appropriate size and cutting. The reduced-pressure treatment device is initially unfolded in a sterile field. Either side of the reduced-pressure treatment device may be placed on the omentum or viscera. The reduced-pressure treatment device is gently placed over the open abdominal cavity. The orientation of the reduced-pressure treatment device for the specific application is determined. If the reduced-pressure treatment device will be placed around tubes, drains or the falciform ligament, the reduced-pressure device is cut only between the plurality of encapsulated leg members. The reduced-pressure treatment device is placed in the proper orientation before cutting.

[0089] The reduced-pressure treatment device is then folded to size and used that way or may be cut. The healthcare provider holds the reduced-pressure treatment device by the edge and slightly lifts the reduced-pressure treatment device. The reduced-pressure treatment device is slowly lowered into the paracolic gutter with one hand and the other hand is used to gently and evenly work the reduced-pressure treatment device down. The healthcare provider folds any excess portions of the reduced-pressure treatment device up and over onto itself. The healthcare provider continues to place the reduced-pressure treatment device between abdominal wall and internal organs throughout the abdominal compartment. The healthcare provider preferably provides full coverage of all viscera. The reduced-pressure treatment device may then be cut as needed for sizing outside of the wound.

[0090] To size the device, the reduced-pressure treatment device can be cut through center of one of the large manifold squares, or leg modules, using sterile scissors. In this illustrative embodiment, the cut is not made through the manipulation zone, but through the leg module. The healthcare provider then pinches the remaining half of the foam square, or leg module, and the adjacent, inboard manipulation zone through the encapsulating member with one hand and pulls the manifold material. The manifold material in the leg module and the manipulation zone will separate at the next square, or leg module. This will ensure that edges of the reduced-pressure treatment device cover the otherwise exposed manifold edge. The manifold material, *e.g.*, foam, preferably does not contact organs.

[0091] The manifold that is to be placed on top of the central connection member is next prepared. In this embodiment, the manifold may be a perforated foam manifold that has perforations to help tear the manifold to the desired size. The manifold preferably fits directly over the reduced-pressure treatment device while still being in contact with wound edges. The manifold should not contact intact skin. Two or more manifolds may be used in some instances. Then, the sized manifold is gently placed into the wound cavity over the reduced-pressure treatment device. The healthcare provider preferably takes care to avoid the manifold going below the level of the abdominal incision or wound.

[0092] A drape, or over-drape, is then applied. To apply the drape, a backing is removed from an adhesive layer on one side of the drape and the drape is applied. The drape covers the manifold and a portion of intact epidermis. Preferably the drape covers at least an 8-10 centimeter border of intact periwound tissue. Additional drape material may be added to seal any difficult areas.

[0093] The reduced-pressure interface, or interface pad, is then added. The healthcare provider chooses an application site. The site is chosen to optimize fluid flow as well as to facilitate easy tubing positioning. The healthcare provider pinches the drape and cuts a 2.5 cm hole (preferably not a slit) through the drape. The interface pad, which has a central disc and a surrounding outer adhesive skirt, is applied. The interface pad is applied by removing backing layers on an inward-facing surface of the interface pad to expose an adhesive. The interface pad opening in the central disc is placed directly over the hole in the drape. Pressure is gently applied on the central disc and the outer skirt to ensure complete adhesion of the interface pad. One or more stabilization layers may then be removed from a first side of the skirt. The system is now ready for the application of reduced pressure.

[0094] The appended claims set forth novel and inventive aspects of the subject matter in this disclosure. While shown in several illustrative embodiments, a person having ordinary skill in the art will recognize that the systems, apparatuses, and methods described herein are susceptible to various changes and modifications. Features may be emphasized in some example embodiments while being omitted in others, but a person of skill in the art will appreciate that features described in the context of one example embodiment may be readily applicable to other example embodiments. Further, certain features, elements, or aspects may be omitted from this disclosure if not necessary to distinguish the novel and inventive features from what is already known to a person having ordinary skill in the art. Features, elements, and aspects described herein may also be combined or replaced by alternative

features serving the same, equivalent, or similar purpose without departing from the scope of the invention defined by the appended claims. Moreover, descriptions of various alternatives using terms such as “or” do not require mutual exclusivity unless clearly required by the context, and the indefinite articles "a" or "an" do not limit the subject to a single instance unless clearly required by the context.

CLAIMS

We claim:

1. A system for treating a tissue site, comprising:
    a treatment manifold including a connection manifold member and a plurality of leg manifold members extending from the connection manifold member;
    a non-adherent drape surrounding the treatment manifold;
    a lateral force manifold configured to be positioned proximate to and in fluid communication with the treatment manifold through the non-adherent drape, the lateral force manifold comprising:
        a lateral width extending from a first edge to an opposite second edge,
        at least one first contractive portion configured to contract a first amount under a reduced pressure, and
        at least one second contractive portion configured to contract a second amount under the reduced pressure, wherein second amount of contraction is less than the first amount, and wherein the first contractive portion is positioned next to the second contractive portion along the lateral width; and
    a sealing member configured to provide a pneumatic seal relative to the tissue site.

2. The system of claim 1, wherein the leg manifold members and the connection manifold member comprise a foam.

3. The system of claim 1, wherein the non-adherent drape is coupled around the leg manifold members and the connection manifold member to provide a plurality of encapsulated leg members in fluid communication with a central connection member.

4. The system of claim 3, wherein at least a portion of a longitudinal length of at least one of the encapsulated leg members is configured to contact the tissue site.

5. The system of claim 3, further comprising a plurality of fenestrations positioned along a longitudinal length of at least one of the encapsulated leg members.

6. The system of claim 1, wherein the non-adherent drape comprises a first non-adherent drape and a second non-adherent drape, and wherein the treatment manifold is positioned as a layer between the first non-adherent drape and the second non-adherent drape.

7. The system of claim 6, wherein the first non-adherent drape is coupled to the second non-adherent drape to provide a plurality of encapsulated leg members in fluid communication with a central connection member.

8. The system of claim 1, wherein the lateral force manifold is configured to distribute reduced pressure to the treatment manifold.

9. The system of claim 1, wherein the first contractive portion and the second contractive portion of the lateral force manifold each comprise foam.

10. The system of claim 1, wherein the lateral force manifold is configured to be positioned in direct contact with the non-adherent drape proximate to the connection manifold member.

11. The system of claim 1, wherein the non-adherent drape is coupled around the leg manifold members and the connection manifold member to provide a plurality of encapsulated leg members in fluid communication with a central connection member, and wherein the lateral force manifold is configured to be positioned proximate to and in fluid communication with the central connection member.

12. The system of claim 1, wherein the sealing member is configured to cover the treatment manifold and the lateral force manifold at the tissue site.

13. The system of claim 1, further comprising a reduced-pressure delivery conduit and a reduced pressure source, the reduced-pressure delivery conduit configured to provide reduced pressure from the reduced-pressure source to the central connection member.

14. The system of claim 13, further comprising a reduced-pressure interface configured to be coupled to the sealing member and to fluidly couple the reduced-pressure delivery conduit to the central connection member.

15. The system of claim 1, wherein the second contractive portion surrounds the first contractive portion.

16. The system of claim 1, wherein first contractive portion and the second contractive portion each include a porous material, and wherein the second contractive portion has a higher density than the first contractive portion.

17. The system of claim 1, wherein the first contractive portion and the second contractive portion each include pores, and wherein the pores in the second contractive portion are smaller than the pores in the first contractive portion.

18. The system of claim 1, wherein the first contractive portion and the second contractive portion each comprise a foam, and wherein the foam of the second contractive portion has a higher density than the foam of the first contractive portion.

19. The system of claim 1, wherein the second contractive portion comprises a felted foam.

20. The system of claim 1, wherein the first contractive portion and the second contractive portion each comprise a foam, and wherein the foam of the second contractive portion is felted to a felting compression ratio of 1.5 times to 10 times compared to the first contractive portion.

21. The system of claim 1, wherein a first compression force required to compress the first contractive portion by 25 percent is between 0.1 psi to 0.6 psi and a second compression force required to compress the second contractive portion by 25 percent is between 0.7 psi to 4.5 psi.

22. The system of claim 1, wherein the first contractive portion has a first thickness and the second contractive portion has a second thickness, and wherein the first thickness is greater than the second thickness.

23. The system of claim 1, wherein the at least one first contractive portion is a plurality of first contractive portions and the at least one second contractive portion is a plurality of second contractive portions, wherein one or more of the first contractive portions are positioned between the second contractive portions along the lateral width.

24. The system of claim 1, wherein the at least one first contractive portion is a plurality of first contractive portions and the at least one second contractive portion is a plurality of second contractive portions, and wherein the first contractive portions and the second contractive portions alternate along the lateral width.

25. The system of claim 1, wherein the at least one first contractive portion is a plurality of first contractive portions and the at least one second contractive portion is a plurality of second contractive portions, and wherein the first contractive portions and the second contractive portions are configured in substantially concentric and alternating rings.

26. The system of claim 1, wherein the at least one first contractive portion is a plurality of first contractive portions and the at least one second contractive portion is a plurality of second contractive portions, and wherein the first contractive portions and the second contractive portions are configured in a substantially concentric and alternating pattern.

27. The system of claim 26, wherein the substantially concentric and alternating pattern is continuous or discontinuous.

28. The system of claim 1, wherein the lateral force manifold further comprises a longitudinal length perpendicular to the lateral width and extending from a first end to an opposite second end, and a thickness perpendicular to both the lateral width and the longitudinal length and extending from a first side to an opposite second side that is configured to face the tissue site, and wherein the longitudinal length is greater than the lateral width.

29. The system of claim 28, wherein the lateral width is configured to extend across a body-cavity opening at the tissue site.

30. The system of claim 28, wherein the first side of the lateral force manifold is configured to face outward from the tissue site and the second side is configured to face toward the treatment manifold.

31. A lateral force manifold configured to distribute reduced pressure relative to a tissue site, the lateral force manifold comprising:

a lateral width extending from a first edge to an opposite second edge;

a plurality of first contractive portions including a first density; and

a plurality of second contractive portions including a second density that is greater than the first density, wherein the first contractive portions and the second contractive portions alternate along the lateral width.

32. The lateral force manifold of claim 31, wherein first contractive portions are configured to contract a first amount under a reduced pressure and the second contractive portions are configured to contract a second amount under the reduced pressure, and wherein the second amount of contraction is less than the first amount of contraction.

33. The lateral force manifold of claim 31, wherein the first contractive portions and the second contractive portions of the lateral force manifold each comprise foam.

34. The lateral force manifold of claim 31, wherein the first contractive portions and the second contractive portions each include pores, and wherein the pores in the second contractive portions have a smaller average size than the pores in the first contractive portions.

35. The lateral force manifold of claim 31, wherein the second contractive portions comprise a felted foam.

36. The lateral force manifold of claim 31, wherein the first contractive portions and the second contractive portions each comprise a foam, and wherein the foam of the second contractive portions are felted to a felting compression ratio of 1.5 times to 10 times compared to the first contractive portions.

37. The lateral force manifold of claim 31, wherein a first compression force required to compress the first contractive portions by 25 percent is between 0.1 psi to 0.6 psi and a second compression force required to compress the second contractive portions by 25 percent is between 0.7 psi to 4.5 psi.

38. The lateral force manifold of claim 31, wherein the lateral force manifold further comprises a longitudinal length perpendicular to the lateral width and extending from a first end to an opposite second end, and a thickness perpendicular to both the lateral width and the longitudinal length and extending from a first side to an opposite second side that is configured to face the tissue site, and wherein the longitudinal length is greater than the lateral width.

39. The lateral force manifold of claim 38, wherein the lateral width is configured to extend across an incision at the tissue site.

40. The apparatus, systems, and methods as shown and described herein.

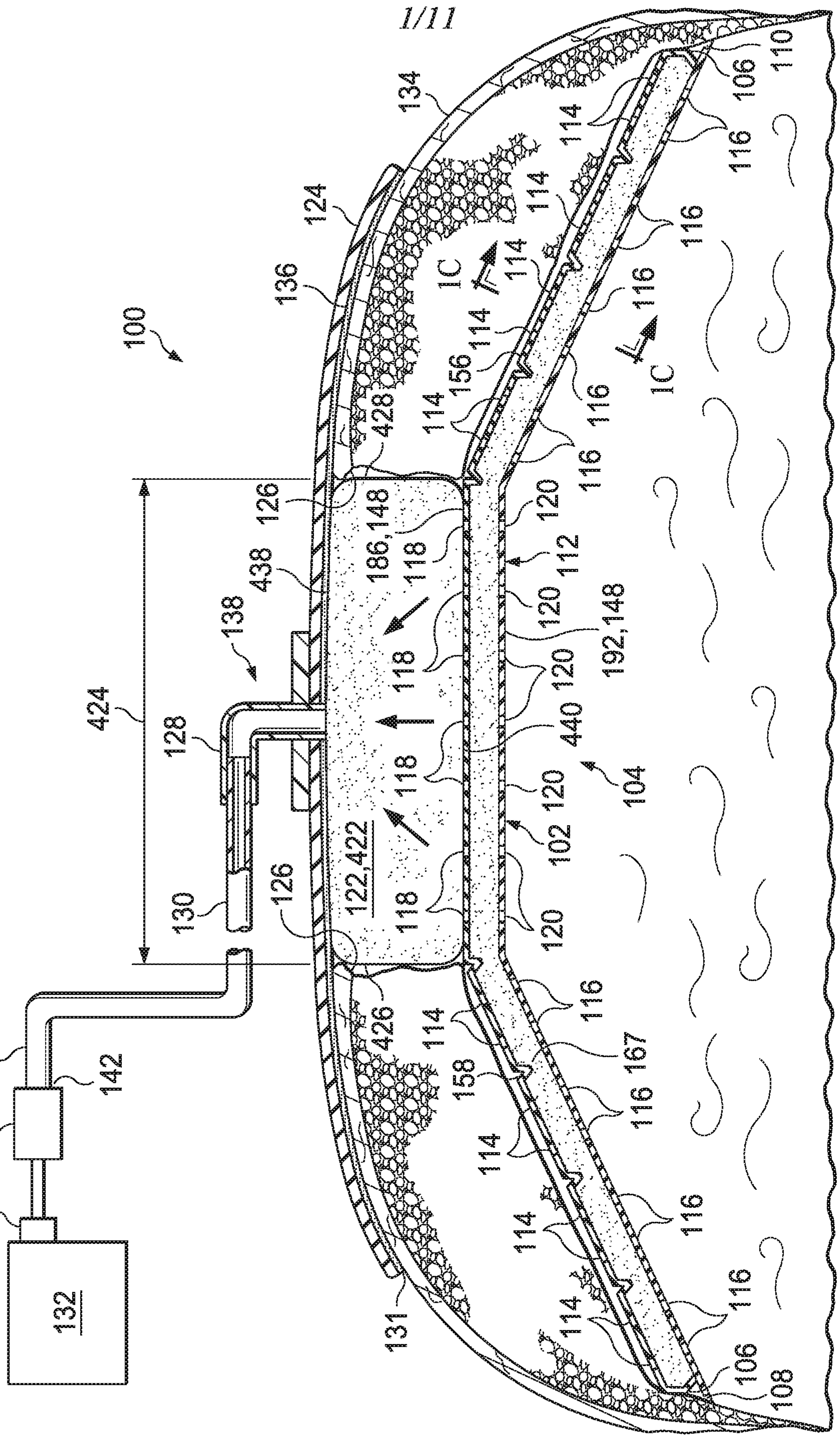
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FIG. 1A

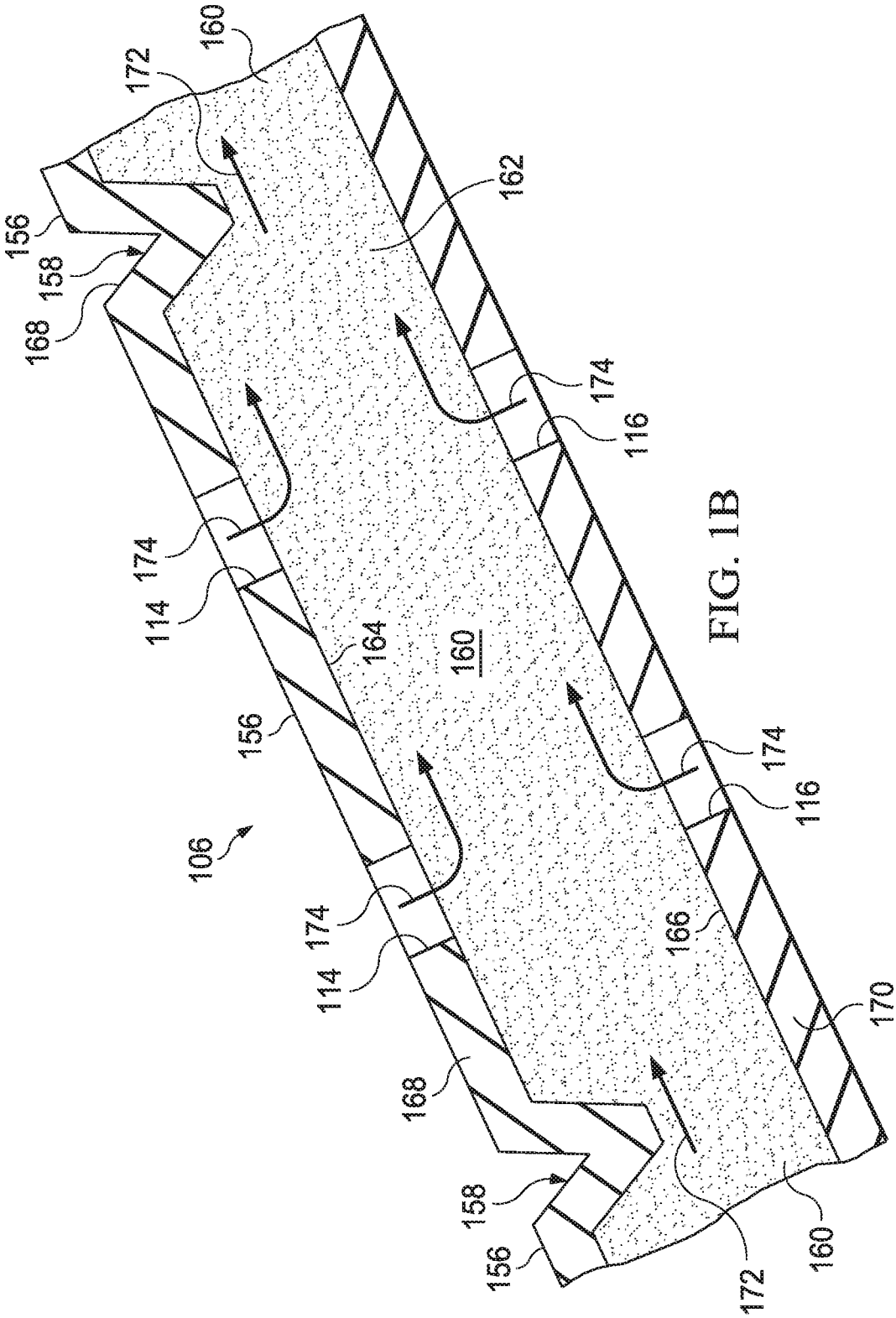

FIG. 1B

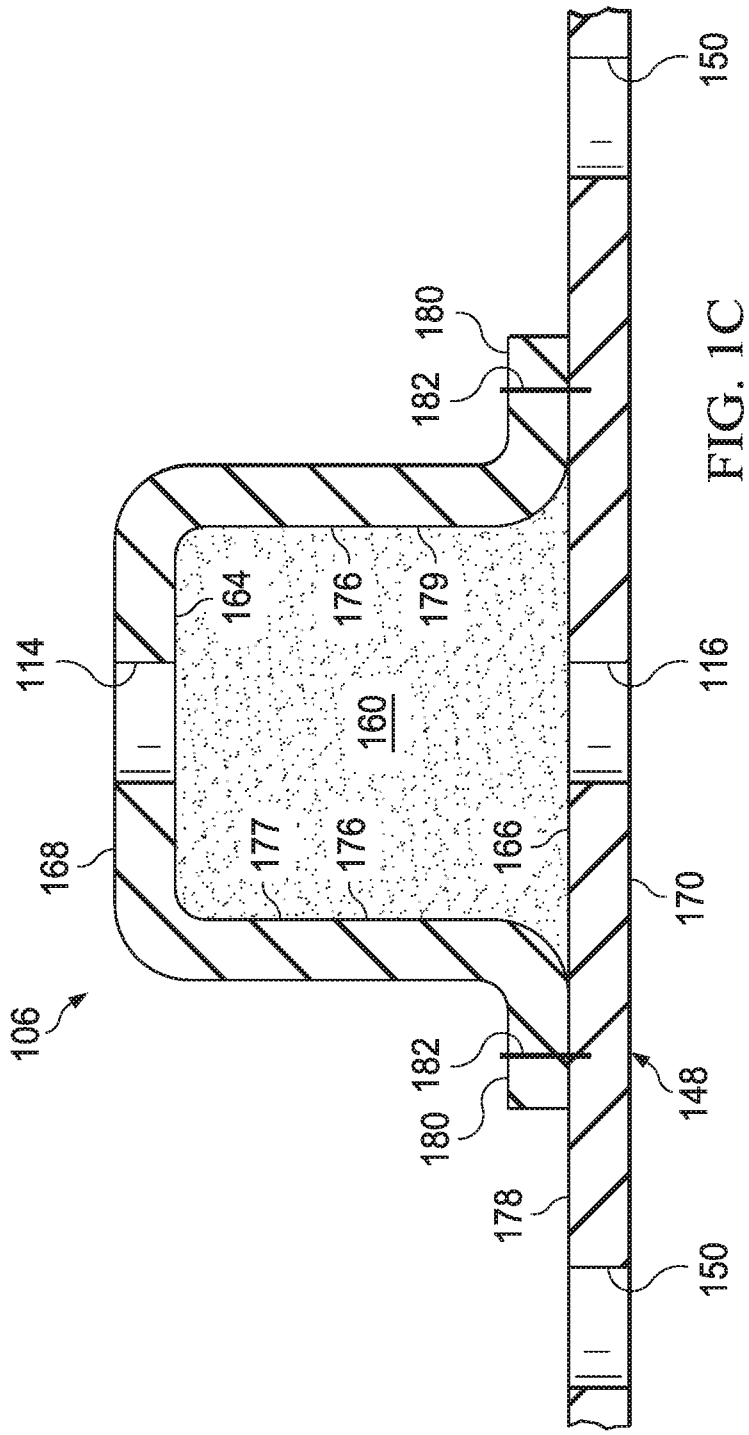
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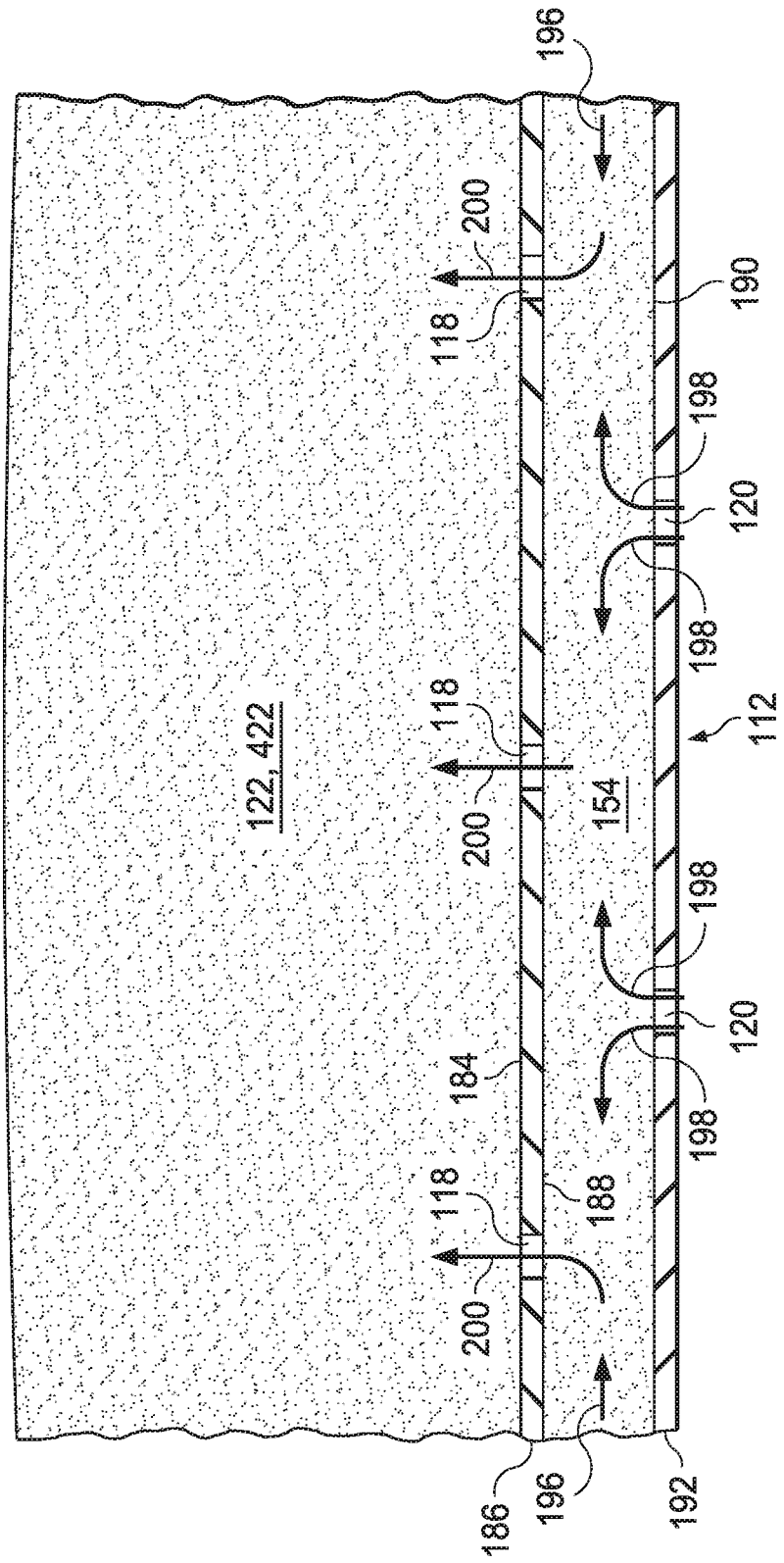
FIG. 1C

FIG. 1D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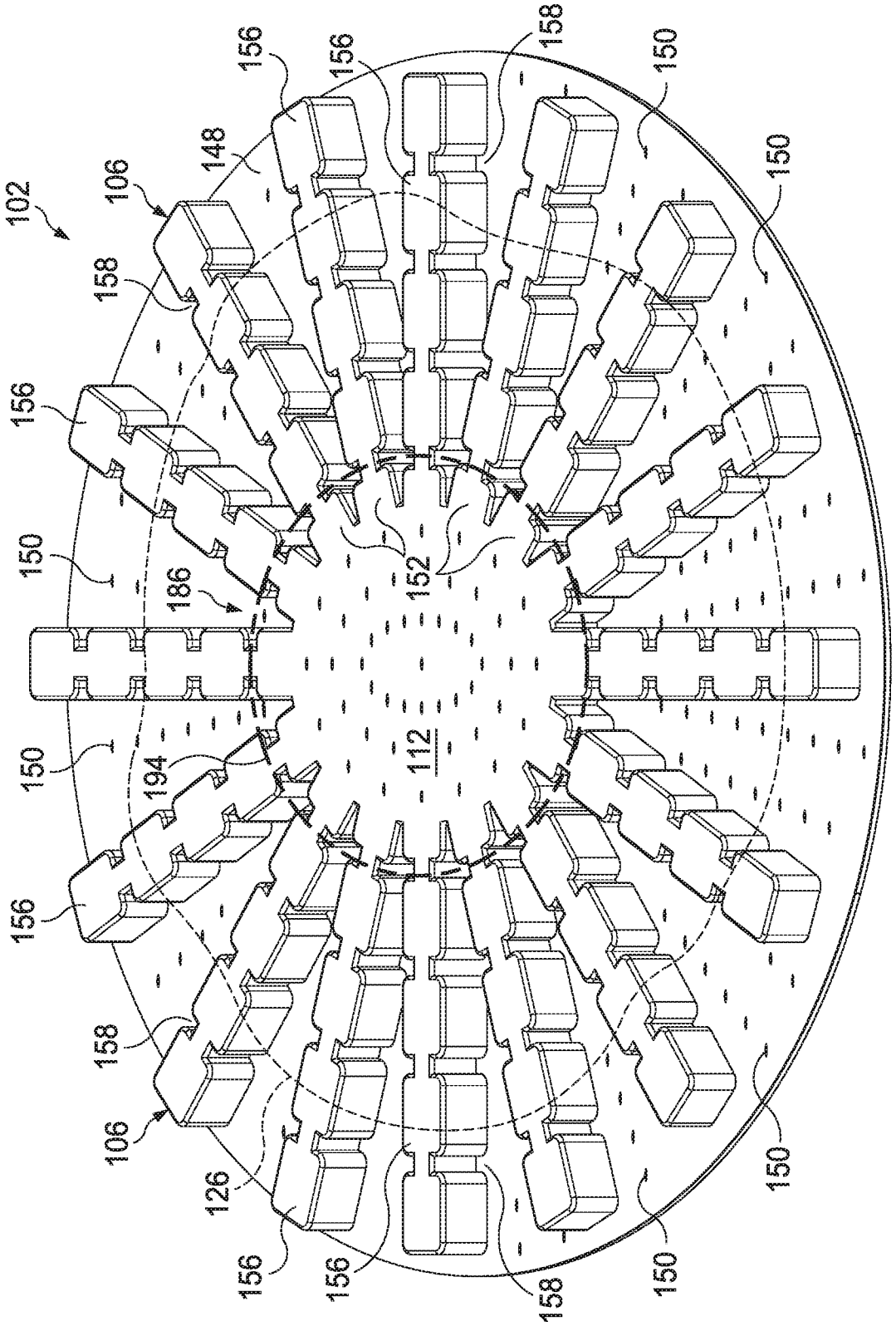

FIG. 2

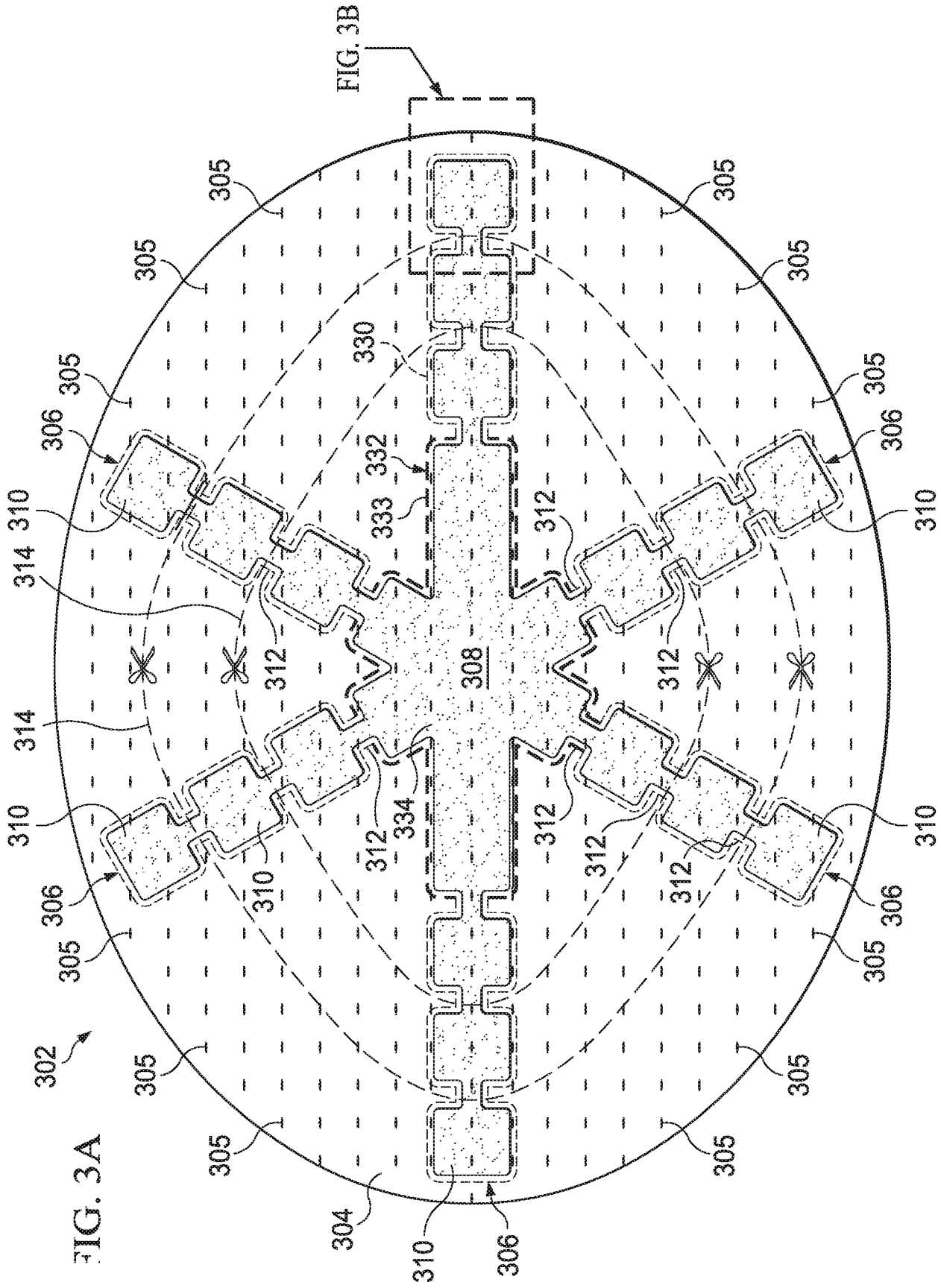

FIG. 3A

FIG. 3B

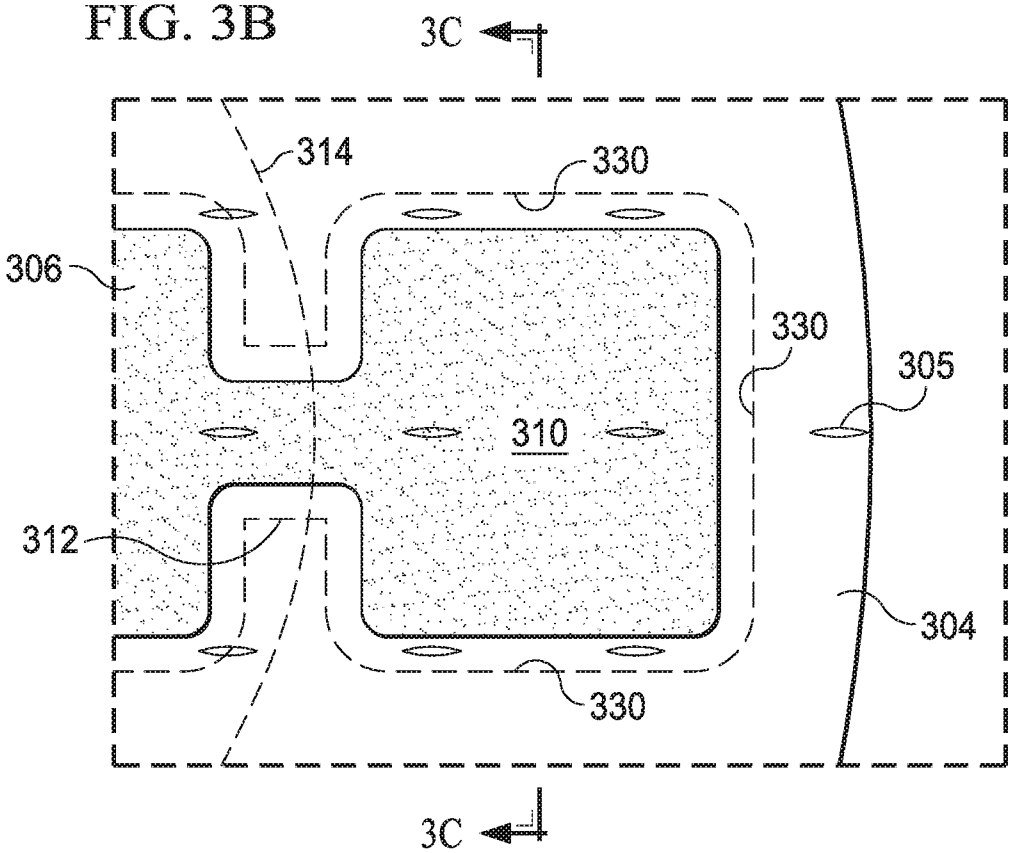
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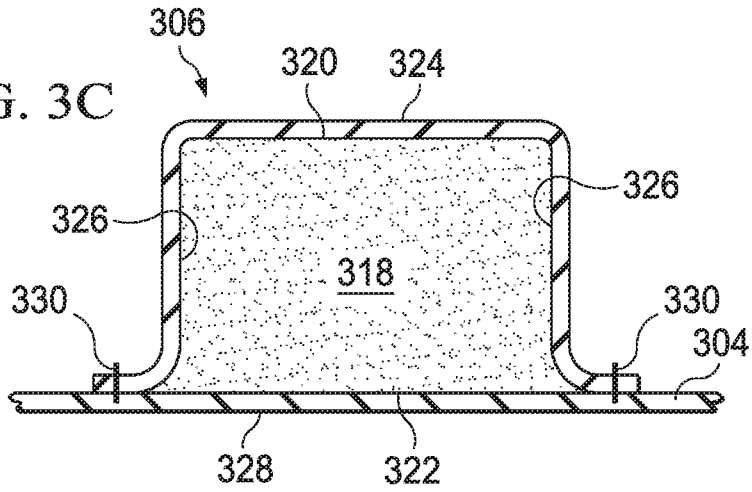
FIG. 3C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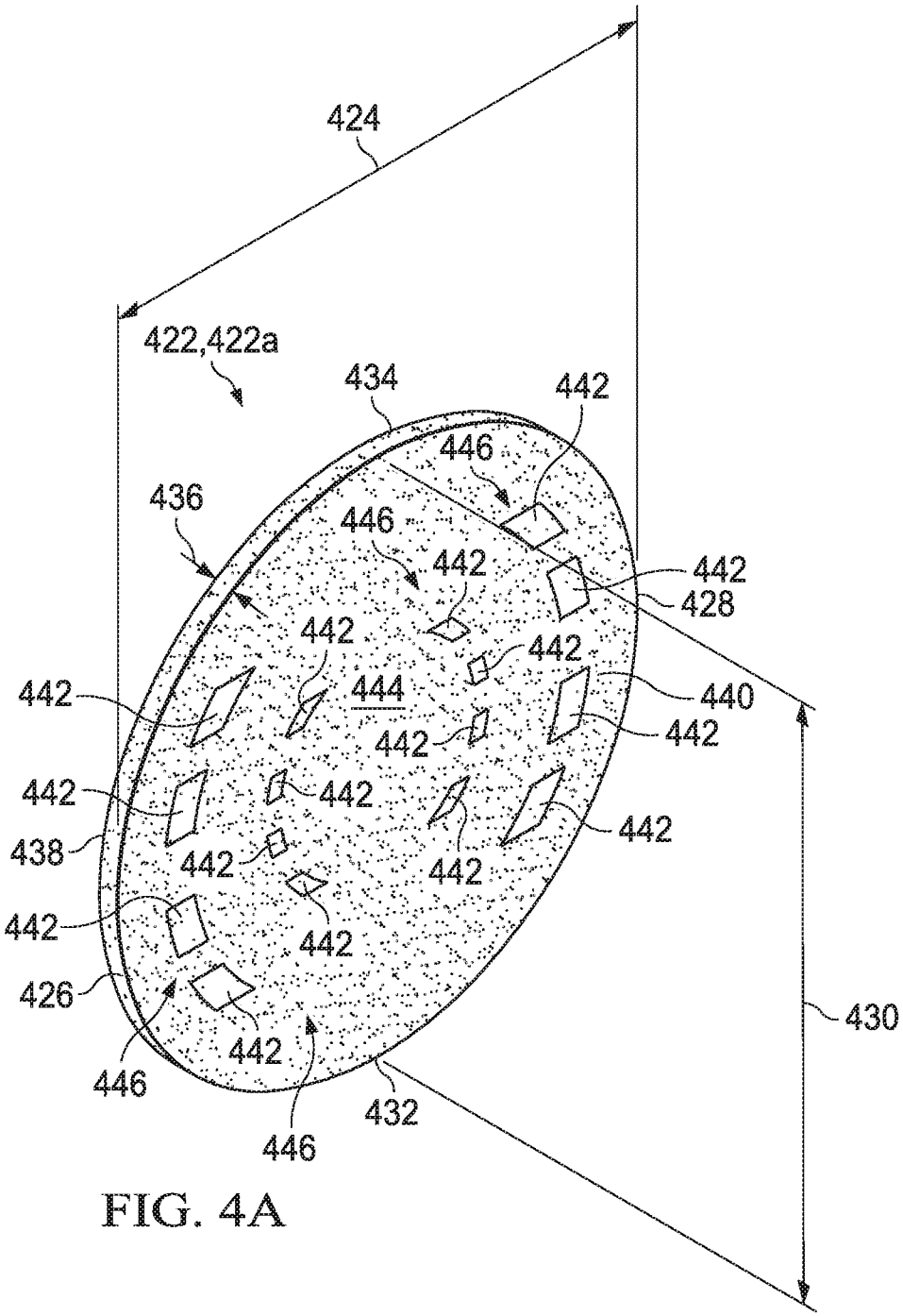
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FIG. 4A

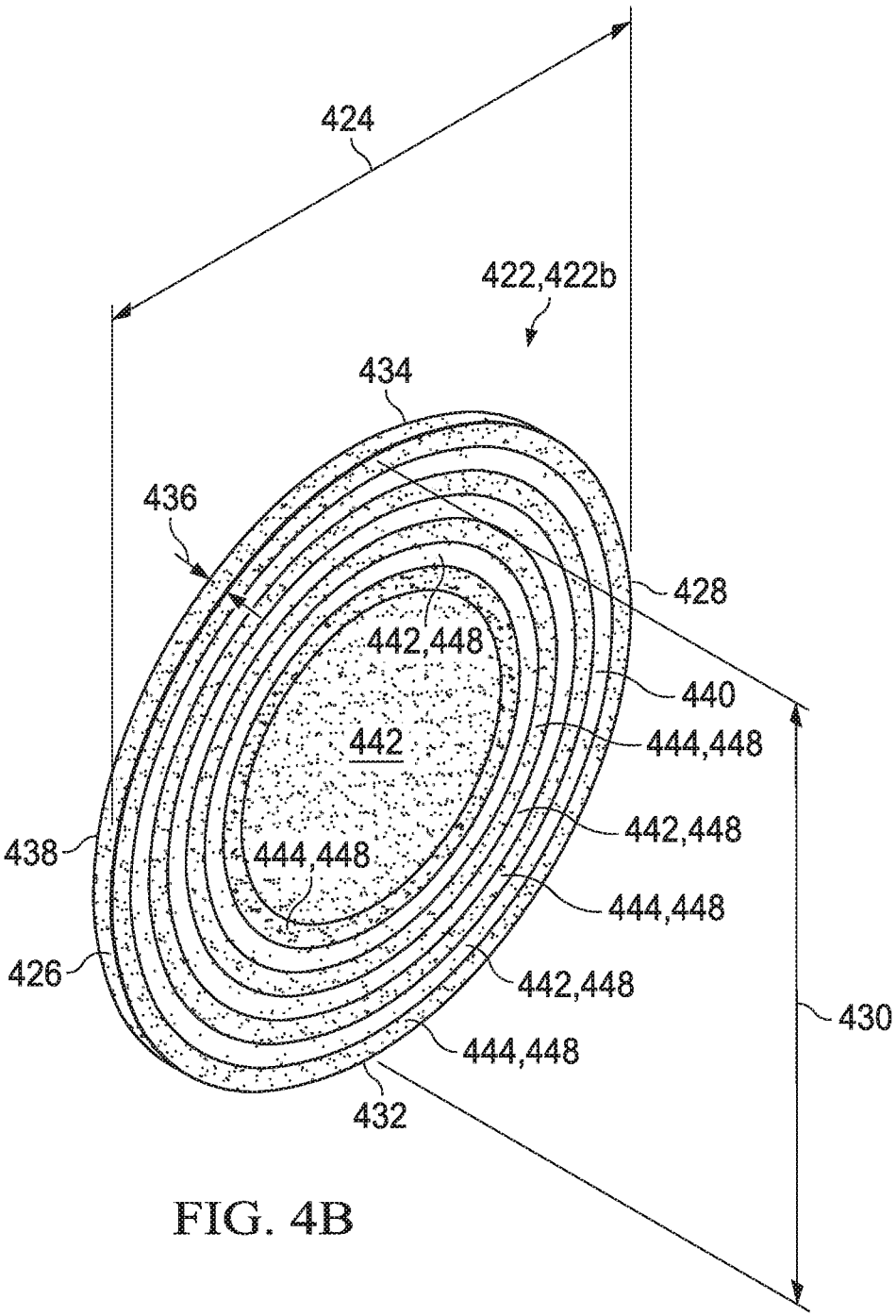
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FIG. 4B

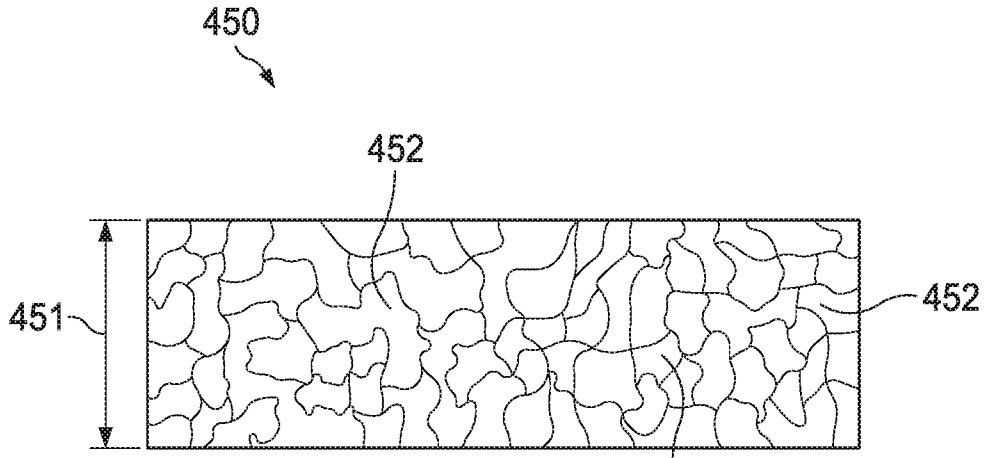
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FIG. 5A

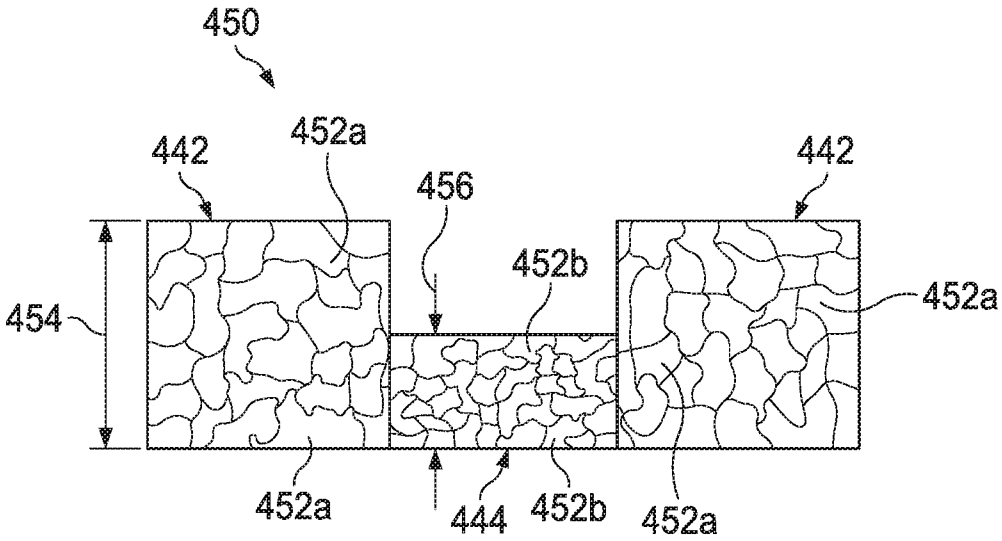
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FIG. 5B

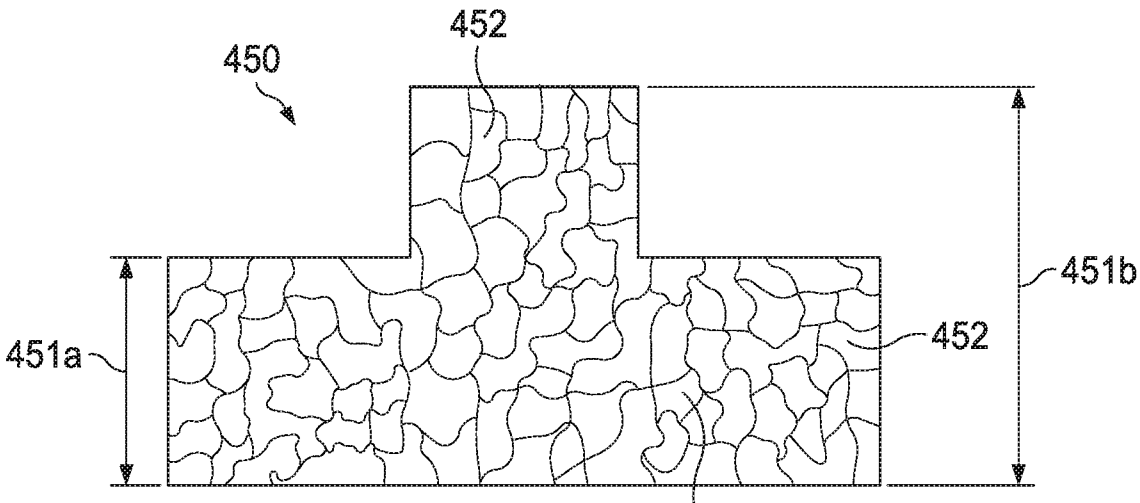
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FIG. 6A

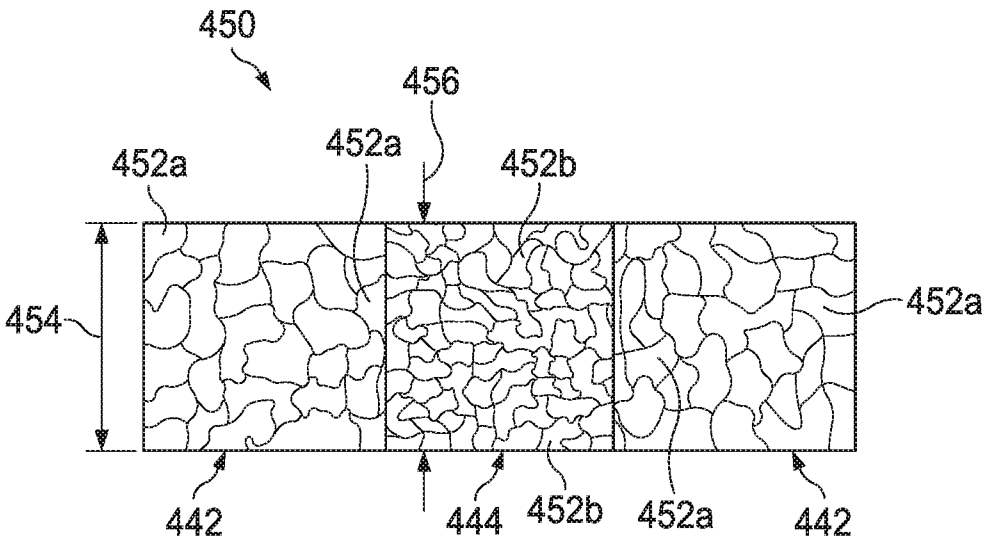
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FIG. 6B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/034263

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/00 A61F13/02 A61F13/14 A61M1/00
ADD.

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where 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,P	WO 2020/014178 A1 (KCI LICENSING INC [US]) 16 January 2020 (2020-01-16)	1-8, 10-15, 19, 23-32, 35,38,39
A,P	paragraph [0025] - paragraph [0051]; figures 1-4	9,16-18, 20-22, 33,34, 36,37

X,P	WO 2019/152422 A1 (KCI LICENSING INC [US]) 8 August 2019 (2019-08-08)	31-39
A,P	paragraph [0051] - paragraph [0057]; figures 4-7	1-30

	-/--	

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

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier 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	Date of mailing of the international search report
21 July 2020	29/07/2020

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/034263

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2015/172104 A1 (KCI LICENSING INC [US]) 12 November 2015 (2015-11-12)	31-39
A	paragraph [0059] - paragraph [0061] paragraph [00102]; claim 1; figures 1, 15	1-30

X	WO 2013/175309 A1 (SMITH & NEPHEW [GB]) 28 November 2013 (2013-11-28)	31-39
Y	paragraph [0030] - paragraph [0040] paragraph [0062] - paragraph [0064]; figures 1, 2B-2E	1-30

Y	WO 2010/051068 A1 (KCI LICENSING INC [US]; HARDMAN IAN JAMES [GB] ET AL.) 6 May 2010 (2010-05-06)	1-30
A	claims 1-30; figures 1-5	31-39

Y	WO 2011/130551 A1 (KCI LICENSING INC [US]; LOCKE CHRISTOPHER BRIAN [GB] ET AL.) 20 October 2011 (2011-10-20)	1-30
A	figures 1-3	31-39

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/034263

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.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 40
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 40

Claim 40 is an omnibus type claim and has therefore not been searched.

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2020/034263

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International application No
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