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(71) Applicant (for all designated States except US): **KCI LICENSING, INC.** [US/US]; Legal Department - Intellectual Property, P.O. Box 659508, San Antonio, TX 78265-9508 (US).

## (72) Inventors; and

(75) Inventors/Applicants (for US only): **TOUT, Aidan, Marcus** [GB/GB]; 9 Collingwood Close, Alderbury, Wiltshire SP5 3FE (GB). **LOCKE, Christopher, Brian** [GB/GB]; 6 Bosworth Mews, Bournemouth, Dorset BH9 3SD (GB).

(74) Agents: **WELCH, Gerald, T.** et al.; SNR Denton US LLP, P.O. Box 061080, Wacker Drive Station, Willis Tower, Chicago, IL 60606 (US).

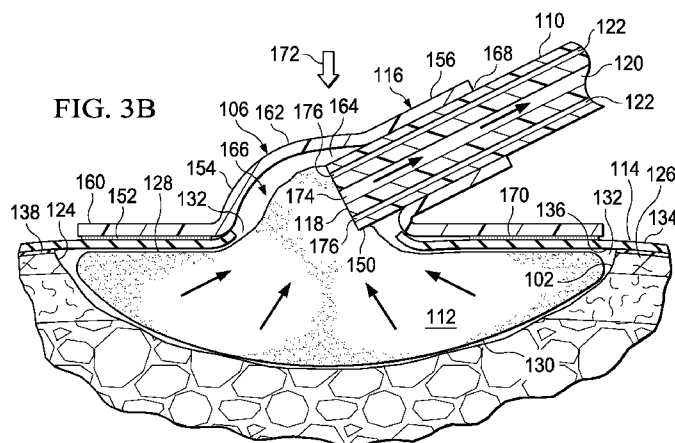
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(57) Abstract: Systems and methods for a reduced-pressure interface for connecting a multi-lumen conduit to a distribution manifold. The interface includes a housing having a flange portion and a cavity wall portion. The cavity wall portion forms a cavity having a tissue-facing cavity opening. The interface further includes an attachment device, a conduit port, and a multi-lumen conduit. The attachment device is coupled to a tissue-facing side of the flange portion for coupling the housing to a sealing member. The conduit includes a distal end and a proximal end whereby the distal end extends through a conduit aperture and past the cavity wall portion into the cavity. The conduit further includes a primary lumen and a plurality of sensing lumens. The primary lumen and the plurality of sensing lumens extend from the proximal end of the conduit to the distal end. The conduit is adapted to contact the distribution manifold.



**SYSTEMS AND METHODS FOR TREATING A TISSUE SITE WITH REDUCED  
PRESSURE INVOLVING A REDUCED-PRESSURE INTERFACE HAVING A  
MULTI-LUMEN CONDUIT FOR CONTACTING A MANIFOLD**

5

**RELATED APPLICATIONS**

[0001] The present invention claims the benefit, under 35 USC § 119(e), of the filing of U.S. Provisional Patent Application serial number 61/511,827, entitled “Systems and Methods for Treating a Tissue Site with Reduced Pressure Involving a Reduced-Pressure Interface having a Multi-Lumen Conduit for Contacting a Manifold,” filed July 26, 2011, and  
10 U.S. Provisional Patent Application serial number 61/511,840, entitled “Systems and Methods for Treating a Tissue Site with Reduced Pressure Involving a Reduced-Pressure Interface having a Cutting Element,” filed July 26, 2011, which is incorporated herein by reference for all purposes.

**BACKGROUND**

15 [0002] The present disclosure relates generally to medical treatment systems and, more particularly, but not by way of limitation, to systems, methods, and apparatuses for treating a tissue site with reduced pressure involving a reduced-pressure interface having a multi-lumen conduit for contacting a manifold.

[0003] Clinical studies and practice have shown that providing a reduced pressure in  
20 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, which may include faster healing and  
25 increased formulation of granulation tissue. Typically, reduced pressure is applied to tissue through a manifold device, such as a porous pad. The porous pad contains cells or pores that distribute reduced pressure to the tissue and channel fluids that are drawn from the tissue.

## SUMMARY

[0004] According to an illustrative embodiment a reduced-pressure interface for connecting a multi-lumen conduit to a distribution manifold is presented. The reduced-pressure interface includes a multi-lumen conduit that abuts, at least in part, a distribution manifold. The distribution manifold contacts at least some distal apertures that open into sensing lumens in the multi-lumen conduit. The distribution manifold may thereby protect those openings from liquids entering that might block the sensing lumens.

[0005] According to another illustrative embodiment, a system for treating a tissue site on a patient with reduced pressure includes a distribution manifold for placing proximate to the tissue site, a sealing member for covering the distribution manifold and a portion of intact epidermis of the patient to form a sealed space, a reduced-pressure interface for providing reduced pressure through the sealing member to the distribution manifold, a reduced-pressure source, and a multi-lumen conduit for fluidly coupling the reduced-pressure source to the reduced-pressure interface. The reduced-pressure interface includes a housing having a cavity wall portion. The cavity wall portion forms a cavity having a tissue-facing cavity opening. The reduced-pressure interface further includes an attachment device coupled to the housing for coupling the housing to the sealing member, a conduit port coupled to the cavity wall and having a conduit aperture, and a multi-lumen conduit. The multi-lumen conduit has a distal end and a proximal end. The distal end of the multi-lumen conduit extends through the conduit aperture into the cavity. The multi-lumen conduit further includes at least one primary lumen for delivering reduced pressure and a plurality of sensing lumens. The primary lumen and the plurality of sensing lumens extend from the distal end of the multi-lumen conduit towards the proximal end of the multi-lumen conduit. The plurality of sensing lumens have a corresponding plurality of distal openings at the distal end of the multi-lumen conduit. At least one of the plurality of distal openings of the plurality of sensing lumens contacts the distribution manifold.

[0006] The reduced-pressure interface allows the sensing lumens not to become blocked. This is because the distribution manifold is against at least one of the distal apertures and helps protect the sensing lumen from liquid entry. The reduced-pressure interface may also avoid spraying or an aerosol effect of liquids from the tissue site that might otherwise enter a sensing lumen.

[0007] According to another illustrative embodiment, a method for treating a tissue site on a patient with reduced pressure includes disposing a distribution manifold proximate to

the tissue site and covering the distribution manifold and a portion of intact epidermis of the patient with a sealing member to form a sealed space in which the distribution manifold is disposed. The sealing member has a first side and a second, tissue-facing side. The method further includes providing a reduced-pressure source, providing a multi-lumen conduit having a distal end and a proximal end. The multi-lumen conduit includes a plurality of sensing lumens and at least one primary lumen. The method further includes fluidly coupling a distal end of the multi-lumen conduit to the sealed space and disposing at least one distal opening of a plurality of distal openings of the plurality of sensing lumens in contact with the distribution manifold. The method also includes delivering reduced pressure to the multi-lumen conduit.

**[0008]** According to another illustrative embodiment, a reduced-pressure connection for providing reduced pressure to a tissue site in a sealed space formed by a sealing member includes a distribution manifold for placing proximate to the tissue site and a multi-lumen conduit. The distribution manifold includes a foam member. The multi-lumen conduit has a plurality of sensing lumens and at least one primary lumen. A plurality of distal opening are associated with the plurality of sensing lumens on a distal end of the multi-lumen conduit. The distal end of the multi-lumen conduit is in direct contact with the distribution manifold such that at least one of the plurality of distal apertures abuts the distribution manifold.

**[0009]** According to another illustrative embodiment, a reduced pressure treatment system for treating a wound on a patient with reduced pressure includes a manifold for positioning adjacent to the wound, a drape for covering the manifold and a portion of intact epidermis of the patient to form a sealed space, a reduced-pressure interface for providing reduced pressure through the drape to the manifold, a reduced-pressure source, and a first conduit and a second conduit for fluidly coupling the reduced-pressure source to the reduced-pressure interface. The reduced-pressure interface includes a housing having a cavity wall portion that forms a cavity having a tissue-facing cavity opening, an attachment device coupled to the housing for coupling the housing to the drape, a conduit port coupled to the cavity wall and having a conduit aperture, and the first conduit and the second conduit. The first conduit and the second conduit have a distal end and a proximal end, such that the distal end extends through the conduit aperture into the cavity. The first conduit further includes at least one primary lumen for delivering reduced pressure such that the primary lumen extends from the distal end to the proximal end of the first conduit. The second conduit further includes a plurality of sensing lumens extending from the distal end to the proximal end of the second conduit. The plurality of sensing lumens have a corresponding plurality of distal

openings at the distal end of the second conduit, and at least one of the plurality of distal openings of the plurality of sensing lumens contacts the manifold.

[0010] According to yet another illustrative embodiment, a method for treating a wound on a patient with reduced pressure includes positioning a manifold adjacent to the wound and covering the manifold and a portion of intact epidermis of the patient with a drape to form a sealed space. The drape has a first side and a second, tissue-facing side. The method further includes providing a reduced-pressure source and providing a first conduit and a second conduit. The first conduit and the second conduit have a distal end and a proximal end. The second conduit further includes a plurality of sensing lumens. The first conduit further includes at least one reduced-pressure lumen. The method further includes fluidly coupling the distal end of the first conduit and the second conduit to the drape, disposing at least one distal opening of a plurality of distal openings of the plurality of sensing lumens in contact with the manifold, and delivering reduced pressure to the first conduit.

[0011] According to another illustrative embodiment, a reduced-pressure connection for providing reduced pressure to a wound in a sealed space formed by a drape includes a manifold for placing proximate to the wound. The manifold includes a foam member. The connection further includes a first conduit having at least one primary lumen such that the first conduit has a distal end and a second conduit having a plurality of sensing lumens such that a plurality of distal opening are associated with the plurality of sensing lumens on a distal end of the second conduit. The distal end of the first and second conduits are in direct contact with the manifold such that at least one of the plurality of distal apertures abuts the manifold.

[0012] Other features and advantages of the illustrative embodiments will become apparent with reference to the drawings and detailed description that follow.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0013] FIGURE 1 is a schematic perspective view of an illustrative embodiment of a system for treating a tissue site with reduced pressure;

5 [0014] FIGURE 2 is a schematic, cross-sectional view of an illustrative embodiment of a multi-lumen conduit of the system shown in FIGURE 1 taken along line 2-2;

[0015] FIGURE 3A is a schematic, cross-sectional view of an illustrative embodiment of a reduced-pressure interface having a multi-lumen conduit extending into a cavity of the reduced-pressure interface;

10 [0016] FIGURE 3B is a schematic, cross-sectional view of the reduced-pressure interface of FIGURE 3A under reduced pressure with a distribution manifold contacting the multi-lumen conduit;

[0017] FIGURE 4 is a schematic, top perspective view of another illustrative embodiment of a reduced-pressure interface having a multi-lumen conduit extending into a cavity of the reduced-pressure interface;

15 [0018] FIGURE 5A is a schematic, cross-sectional view of the reduced-pressure interface of FIGURE 4 as applied to a tissue site;

[0019] FIGURE 5B is a schematic, cross-sectional view of the reduced-pressure interface of FIGURE 5A under reduced pressure such that the distribution manifold contacts the multi-lumen conduit;

20 [0020] FIGURE 6 is a schematic, cross-sectional view of one illustrative embodiment of a reduced-pressure interface having a cutting element for use as part of a system for treating a tissue site with reduced pressure;

25 [0021] FIGURE 7A is a schematic, cross-sectional view of the reduced-pressure interface of FIGURE 6 under reduced pressure but prior to the cutting element perforating a sealing member;

[0022] FIGURE 7B is another schematic, cross-sectional view of the reduced-pressure interface of FIGURE 6 under reduced pressure after the cutting member has perforated the sealing member;

30 [0023] FIGURE 7C is another schematic, cross-sectional view of the reduced-pressure interface of FIGURE 6 under reduced pressure after the cutting member has perforated the sealing member and the cutting element has been removed;

[0024] FIGURE 8 is a schematic, cross-sectional view of another illustrative embodiment of a reduced-pressure interface having a cutting element for use as part of a system for treating a tissue site with reduced pressure;

5 [0025] FIGURE 9A is a schematic, cross-sectional view of the reduced-pressure interface of FIGURE 8 being applied on a patient, but prior to reduced pressure being supplied;

[0026] FIGURE 9B is a schematic, cross-sectional view of the reduced-pressure interface of FIGURE 8 under reduced pressure prior to the cutting element perforating a sealing member; and

10 [0027] FIGURE 9C is a schematic, cross-sectional view of the reduced-pressure interface of FIGURE 8 under reduced pressure after the cutting member has perforated the sealing member and the cutting element has been removed.

### DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0028] In the following detailed description of the illustrative embodiments, reference is made to the accompanying drawings that form a part hereof. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is understood that other embodiments may be utilized and that logical, structural, mechanical, electrical, and chemical changes may be made without departing from the spirit or scope of the invention. To avoid detail not necessary to enable those skilled in the art to practice the embodiments described herein, the description may omit certain information known to those skilled in the art. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the illustrative embodiments are defined only by the appended claims. Unless otherwise indicated, as used herein, “or” does not require mutual exclusivity.

[0029] The term “reduced pressure” as used herein generally refers to a pressure less than the ambient pressure at a tissue site that is being subjected to treatment. In most cases, this reduced pressure will be less than the atmospheric pressure at which the patient is located. Alternatively, the reduced pressure may be less than a hydrostatic pressure associated with tissue at the tissue site. Unless otherwise indicated, quantitative values of pressure stated herein are gauge pressures. Reference to increases in reduced pressure typically refer to a decrease in absolute pressure, and decreases in reduced pressure typically refer to an increase in absolute pressure.

[0030] Referring now to the drawings and initially to FIGURES 1-3B, a system 100 for treating a tissue site 102 on a patient 104 with reduced pressure is presented. The system 100 includes a reduced-pressure dressing 106 for disposing proximate the tissue site 102. The system includes a reduced-pressure interface 116 that fluidly couples a multi-lumen conduit 110 to a distribution manifold 112. The reduced-pressure interface 116 may allow for an easily manufactured connection that allows at least one of a plurality of sensing lumens 122 within the multi-lumen conduit 110 to remain open or unblocked during operation. During operation, the sensing lumens 122 may remain unblocked by a distal end 118 of the multi-lumen conduit 110 being against (or abutting) or embedded in the distribution manifold 112 such that at least one distal aperture on the distal end 118 of the multi-lumen conduit 110 is in contact with the distribution manifold 112. This in turn avoids an open area where liquids may spray, foam, or otherwise travel towards the distal apertures and also offers a filter member in front of the distal apertures.



[0031] The system 100 also includes a reduced-pressure treatment unit 108 fluidly connected to the reduced-pressure dressing 106 through the multi-lumen conduit 110 for applying reduced pressure to the tissue site 102. The reduced-pressure dressing 106 further includes the distribution manifold 112, a sealing member 114, and the reduced-pressure interface 116. The reduced-pressure interface 116 is adapted to connect to the multi-lumen conduit 110. The multi-lumen conduit 110 has the distal end 118 and includes at least one primary lumen 120 and the sensing lumens 122. While usually there will be only one primary lumen 120, there could be additional larger lumens for transporting the reduced pressure to the tissue site 102 and concomitantly removing any fluids. The distal end 118 of the multi-lumen conduit 110 is adapted to extend into the reduced-pressure interface 116 and, at least partially, contact the distribution manifold 112. The multi-lumen conduit 110 may either abut or be embedded within the distribution manifold 112.

[0032] Extending the multi-lumen conduit 110 into the reduced-pressure interface 116 to promote contact between the distal end 118 of the multi-lumen conduit 110 and the distribution manifold 112 may, in addition to those previously mentioned, provide a number of benefits. The benefits may include ease of application, reduction of error when forming a seal between the multi-lumen conduit 110 and the distribution manifold 112, and reduction in instances of sensing lumen occlusion when fluid is removed from the tissue site 102. Instances where the sensing lumens 122 become occluded may disconnect the system's 100 ability to monitor levels of reduced pressure, and thus, control the reduced pressure at the tissue site 102.

[0033] Fluid removed from the tissue site 102 will follow the path of least resistance which preferentially is the primary lumen 120. When the primary lumen 120 and at least one of the sensing lumens 122 are not in direct contact with the manifold, the fluid may splash, foam, or otherwise fail to smoothly transition into the primary lumen 120. When the fluid splashes or foams, the fluid may enter the sensing lumens 122 occluding the sensing lumens 122. Should all of the sensing lumens 122 become occluded, the sensing lumens 122 are effectively disabled from sensing the reduced pressure levels at the tissue site 102. When the primary lumen 120 and at least one of the sensing lumens 122 are in contact with the distribution manifold 112, the fluid withdrawn from the tissue site 102 tends to bypass entering the sensing lumens 122 contacting the distribution manifold 112 and flow into the primary lumen 120. The distribution manifold 112 may further provide a barrier between the primary lumen 120 and the at least one of the plurality of sensing lumens 122 contacting the distribution manifold 112. Additionally, having the multi-lumen conduit 110 in direct contact

with the distribution manifold 112 may help ensure that there is a constant low velocity liquid flow into the multi-lumen conduit 110 which may minimize the instance of aerosolized particles being deposited around the at least one sensing lumen 122 contacting the distribution manifold 112 and may also provide a filter to liquids entering the at least one sensing lumen 122.

[0034] In prior reduced pressure treatment systems using a reduced pressure interface and a multi-lumen conduit, the reduced pressure interfaces have been designed to remove the sensory lumens from direct contact with the distribution manifold to inhibit fluid from occluding the sensory lumens. However, testing has shown that removing the sensory lumens from contacting the distribution manifold creates splashing and foaming that may occlude the sensory lumens undermining the purpose of removing the sensory lumens from contacting the distribution manifold.

[0035] The system 100 may be used with various different types of tissue sites 102. The tissue site 102 may be a wound 124 or wound cavity. As shown in at least FIGURES 3A-3B, the tissue site 102 or the wound 124, may be through an epidermis 126 and into a subcutaneous tissue or any other tissue. The tissue site 102 may be the bodily tissue of any human, animal, or other organism, including bone tissue, adipose tissue, muscle tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, ligaments, body cavity or any other tissue. Treatment of the tissue site 102 may include removal of fluids, e.g., exudate or ascites.

[0036] Referring still to FIGURES 1-3B, the distribution manifold 112 is proximate the tissue site 102 and has a first side 128 and a second, tissue-facing side 130. The term “distribution 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 102. The distribution manifold 112 typically includes a plurality of flow channels or pathways that distribute fluids provided to and removed from the tissue site 102 around the distribution manifold 112. In one illustrative embodiment, the flow channels or pathways are interconnected to improve distribution of fluids provided or removed from the tissue site 102. The distribution manifold 112 may be a biocompatible material that is capable of being placed in contact with the tissue site 102 and distributing reduced pressure to the tissue site 102. Examples of the distribution manifold 112 may include, without limitation, devices that have structural elements arranged to form flow channels, such as, for example, cellular foam, open-cell foam, porous tissue collections, liquids, gels, and foams that include, or cure to include, flow channels. The distribution manifold 112 may be porous and may be

made from foam, gauze, felted mat, or any other material suited to a particular biological application. In one embodiment, the distribution manifold 112 is a porous foam and includes a plurality of interconnected cells or pores that act as flow channels. The porous foam may be a polyurethane, open-cell, reticulated foam such as GranuFoam® material manufactured by Kinetic Concepts, Incorporated of San Antonio, Texas. In some situations, the distribution manifold 112 may also be used to distribute fluids such as medications, antibacterials, growth factors, and various solutions to the tissue site 102. Other layers may be included in or on the distribution manifold 112, such as absorptive materials, wicking materials, hydrophobic materials, and hydrophilic materials.

[0037] In one illustrative embodiment, the distribution manifold 112 may be constructed from bioresorbable materials that do not have to be removed from a patient's body following use of the system 100. Suitable bioresorbable materials may include, without limitation, a polymeric blend of polylactic acid (PLA) and polyglycolic acid (PGA). The polymeric blend may also include without limitation polycarbonates, polyfumarates, and caprolactones. The distribution manifold 112 may further serve as a scaffold for new cell-growth, or a scaffold material may be used in conjunction with the distribution manifold 112 to promote cell-growth. A scaffold is a substance or structure used to enhance or promote the growth of cells or formation of tissue, such as a three-dimensional porous structure that provides a template for cell growth. Illustrative examples of scaffold materials include calcium phosphate, collagen, PLA/PGA, coral hydroxy apatites, carbonates, or processed allograft materials.

[0038] The distribution manifold 112 may be covered by the sealing member 114, which may also be referred to as a drape. The sealing member 114 forms a sealed space 132 over the tissue site 102. The sealing member 114 has a first side 134, and a second, tissue-facing side 136. The sealing member 114 may be any material that provides a fluid seal. "Fluid seal," or "seal," means a seal adequate to maintain reduced pressure at a desired site given the particular reduced-pressure source or subsystem involved. The sealing member 114 may, for example, be an impermeable or semi-permeable, elastomeric material. "Elastomeric" means having the properties of an elastomer. Elastomer generally refers to a polymeric material that has rubber-like properties. More specifically, most elastomers have ultimate elongations greater than 100% and a significant amount of resilience. The resilience of a material refers to the material's ability to recover from an elastic deformation. Elastomers that are relatively less resilient may also be used as these elastomers are more likely to tear when faced with the cutting element. Examples of elastomers may include, but are not limited to,

natural rubbers, polyisoprene, styrene butadiene rubber, chloroprene rubber, polybutadiene, nitrile rubber, butyl rubber, ethylene propylene rubber, ethylene propylene diene monomer, chlorosulfonated polyethylene, polysulfide rubber, polyurethane (PU), EVA film, co-polyester, and silicones. Additional, specific examples of dressing sealing member materials include a silicone drape, 3M Tegaderm® drape, polyurethane (PU) drape such as one available from Avery Dennison Corporation of Pasadena, California. An additional, specific non-limiting example of a dressing sealing member material includes a 30µm matt polyurethane film such as the Inspire™ 2317 manufactured by Exopack™ Advanced Coatings of Matthews, North Carolina. The sealing member 114 may be preformed with an aperture or other means to transmit fluid from the distribution manifold to the reduced-pressure treatment unit 108. Alternatively, a healthcare provider may cut the sealing member to form an aperture or a cutting element attached to a reduced-pressure interface may be used to form an aperture.

[0039] An attachment device 138 may be used to hold the sealing member 114 against a portion of the patient's intact epidermis 126 or another layer, such as a gasket or additional sealing member. The attachment device 138 may take numerous forms. For example, the attachment device 138 may be a medically acceptable adhesive, such as a pressure-sensitive adhesive, that extends about a periphery or all of the sealing member 114. The attachment device 138 may also be a sealing ring or other device. The attachment device 138 is disposed on the second, tissue-facing side 136 of the sealing member 114. Before use, the attachment device 138 may be covered by a release liner (not shown).

[0040] The reduced-pressure interface 116 may be positioned adjacent to or coupled to the sealing member 114 to provide fluid access to the distribution manifold 112. Another attachment device 152 similar to the attachment device 138 may be used to hold the reduced-pressure interface 116 against the sealing member 114. The multi-lumen conduit 110 fluidly couples the reduced-pressure treatment unit 108 and the reduced-pressure interface 116. The reduced-pressure interface 116 allows the reduced pressure to be delivered to the tissue site 102. 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 (-667 Pa) and -500 mm Hg (-66.7 kPa) and more typically between -75 mm Hg (-9.9 kPa) and -300 mm Hg (-39.9 kPa). For example, and not by way of limitation, the pressure may be -12, -12.5, -13, -14, -14.5, -15, -15.5, -16, -16.5, -17, -17.5, -18, -18.5, -19, -19.5, -20, -20.5, -21, -21.5, -22, -22.5, -23, -23.5, -24, -24.5, -25, -25.5, -26, -26.5 kPa or another pressure.

[0041] As shown, the multi-lumen conduit 110 includes the primary lumen 120 and the plurality of sensing lumens 122. In one illustrative embodiment, the primary lumen 120 is a

central lumen 140 and the plurality of sensing lumens 122 are peripheral lumens 142. The primary lumen 120 and the plurality of sensing lumens 122 are adapted to maintain fluid isolation between the primary lumen 120 and the plurality of sensing lumens 122 as the multi-lumen conduit 110 transports fluids from the reduced-pressure interface 116 to the reduced-pressure treatment unit 108. Liquids or exudates communicated from the distribution manifold 112 through the primary lumen 120 are removed from the multi-lumen conduit 110 and retained within a liquid-collection chamber (not explicitly shown) in fluid communication with the reduced-pressure treatment unit 108. The plurality of sensing lumens 122 fluidly communicates reduced pressure representative of the tissue site 102 to an instrumentation unit 144.

[0042] The reduced-pressure treatment unit 108 may include a liquid-collection chamber, or a collection canister, and the instrumentation unit 144 in fluid communication with a reduced-pressure source 146. The instrumentation unit 144 may include a microprocessor 148 adapted to process pressure signals received by the multi-lumen conduit 110, monitor the pressure signals, and issue alerts according to a pre-determined pressure configuration.

[0043] In an illustrative embodiment, the reduced-pressure source 146 is an electrically-driven vacuum pump. In another implementation, the reduced-pressure source 146 may instead be a manually-actuated or manually-charged pump that does not require electrical power. The reduced-pressure source 146 instead may be any other type of reduced pressure pump, or alternatively a wall suction port such as those available in hospitals and other medical facilities. The reduced-pressure source 146 may be housed within or used in conjunction with the reduced-pressure treatment unit 108, which may also include the instrumentation unit 144. The instrumentation unit 144 may include sensors, processing units, alarm indicators, memory, databases, software, display units, and user interfaces that further facilitate the application of reduced pressure treatment to the tissue site 102.

[0044] In one example, pressure-detection sensors (not shown) located in the instrumentation unit 144 may be disposed at or near the reduced-pressure source 146. The pressure-detection sensors may receive pressure data, or a pressure signal, from the reduced-pressure interface 116 via at least one of the plurality of sensing lumens 122 that is dedicated to delivering reduced pressure data to the pressure-detection sensors. The pressure signal or data may be representative of a pressure at a distal end 150 of any one of the plurality of sensing lumens 122. The pressure-detection sensors may communicate with a processing unit

that monitors and controls the reduced pressure that is delivered by the reduced-pressure source 146.

[0045] Referring now primarily to FIGURE 3A-3B, an illustrative embodiment of the reduced pressure interface 116 is presented in more detail. The reduced-pressure interface 116 includes a housing 154, a conduit port 156 coupled to the housing 154, the attachment device 152 for coupling the reduced-pressure interface 116 to the sealing member 114, and the multi-lumen conduit 110.

[0046] The housing 154 may have a flange portion 160 and a cavity wall portion 162. The cavity wall portion 162 forms a cavity 164 having a tissue-facing cavity opening 166.

The conduit port 156 is coupled to or formed as part of the cavity wall portion 162 of the housing 154. The conduit port 156 includes a conduit aperture 168 whereby the conduit port 156 is adapted to receive the multi-lumen conduit 110. The attachment device 152 may be coupled to a tissue-facing side 170 of the flange portion 160 for coupling the housing 154 to the first side 134 of the sealing member 114. The housing 154 is made of a semi-rigid material that is capable of collapsing under a force such as a driving force 172. In a non-limiting example, the reduced-pressure interface 116, and thus the housing 154, may be made from a plasticized polyvinyl chloride (PVC), polyurethane, cyclic olefin copolymer elastomer, thermoplastic elastomer, poly acrylic, silicone polymer, and polyether block amide copolymer.

[0047] The multi-lumen conduit 110 includes the distal end 118 and a proximal end 158. The distal end 118 extends through the conduit aperture 168 and past the cavity wall portion 162 into the cavity 164. In one specific, non-limiting embodiment, the distal end 118 extends past the cavity wall portion 162 up to 5 mm. It should be understood, however, that the distal end 118 may extend past the cavity wall portion 162 beyond 5 mm. The extent to which the distal end 118 extends past the cavity wall portion 162 may be determined based on the housing's 154 ability to collapse under the driving force 172. The proximal end 158 of the multi-lumen conduit 110 connects to the reduced-pressure treatment unit 108. In one embodiment, the multi-lumen conduit 110 is connected to the conduit port 156. The multi-lumen conduit 110 may be connected to the conduit port 156 by a weld or adhesive. While the multi-lumen conduit 110 is shown as extending past the cavity wall portion 162, the multi-lumen conduit 110 may be flush with the cavity wall portion 162 (not shown). The multi-lumen conduit 110 is adapted for at least a portion of the distal end 118 of the multi-lumen conduit 110 to contact the distribution manifold 112 during reduced pressure therapy. In one embodiment, a distal aperture 174 of the primary lumen 120 and a distal aperture 176 of at

least one of the plurality of sensing lumens 122 is adapted to contact the distribution manifold 112.

**[0048]** In operation, a method for treating the tissue site 102 on the patient 104 with reduced pressure includes disposing the distribution manifold 112 proximate to the tissue site 102. The distribution manifold 112 and the portion of intact epidermis 126 of the patient 104 is covered with the sealing member 114 to form the sealed space 132 in which the distribution manifold 112 is disposed. The sealing member 114 has the first side 134 and the second, tissue-facing side 136. The reduced-pressure interface 116 is coupled proximate the first side 134 of the sealing member 114. The multi-lumen conduit 110 couples the reduced-pressure interface 116 to the reduced-pressure source 146. The reduced-pressure interface 116 includes the housing 154 having the flange portion 160 and the cavity wall portion 162, such that the cavity wall portion 162 forms the cavity 164 having the tissue-facing cavity opening 166. The attachment device 138 coupled to the tissue-facing side 170 of the flange portion 160 of the housing 154 connects the housing 154 to the sealing member 114. The reduced-pressure interface 116 further includes the conduit port 156 coupled to the cavity wall portion 162 having the conduit aperture 168 for receiving and coupling to the multi-lumen conduit 110. The multi-lumen conduit 110 includes the distal end 118 and the proximal end 158. The distal end 118 extends through the conduit aperture 168 and past the cavity wall portion 162 into the cavity 164. The multi-lumen conduit 110 further includes the primary lumen 120 for delivering reduced pressure and the plurality of sensing lumens 122. The primary lumen 120 and the plurality of sensing lumens 122 extend from the proximal end 158 of the multi-lumen conduit 110 to the distal end 118. At least a portion of the distal end 118 of the multi-lumen conduit 110 is positioned in contact with the distribution manifold 112.

**[0049]** The multi-lumen conduit 110 is connected to the conduit port 156. In one embodiment, the multi-lumen conduit 110 is welded to the conduit port 156 prior to packaging. In another embodiment, the multi-lumen conduit 110 is attached to the conduit port 156 by an adhesive.

**[0050]** An aperture is formed in the sealing member 114 for providing fluid communication between the housing 154 and the distribution manifold 112. The aperture may be preformed, formed by a healthcare provider, or formed by a cutting element on the reduced-pressure interface 116.

**[0051]** The step of coupling the reduced-pressure interface 116 proximate to the first side 134 of the sealing member 114 may include using the attachment device 152 of the

reduced-pressure interface 116 to adhere the reduced-pressure interface 116 to the sealing member 114.

**[0052]** The step of positioning at least a portion of the distal end 118 of the multi-lumen conduit 110 in contact with the distribution manifold 112 may further include  
5 positioning the distal aperture 174 of the primary lumen 120 and the distal aperture 176 of at least one of the plurality of sensing lumens 122 in contact with the distribution manifold 112. In one embodiment, the distal aperture 176 of the at least one of the plurality of sensing lumens 122 is positioned below the distal aperture 174 of the primary lumen 120 relative to the distribution manifold 112.

10 **[0053]** In another embodiment, the step of positioning the at least the portion of the distal end 118 of the multi-lumen conduit 110 in contact with the distribution manifold 112 further includes applying the driving force 172 to the reduced-pressure interface 116 of sufficient strength to cause the at least the portion of the distal end 118 of the multi-lumen conduit 110 to contact the distribution manifold 112. The driving force 172 may push the  
15 multi-lumen conduit 110 into the distribution manifold 112. In one embodiment the driving force 172 may pull the distribution manifold 112 into the multi-lumen conduit 110. In yet another embodiment, the driving force 172 may both push the multi-lumen conduit 110 into the distribution manifold 112 while pulling the distribution manifold 112 into the multi-lumen conduit 110.

20 **[0054]** The step of positioning the at least the portion of the distal end 118 of the multi-lumen conduit 110 in contact with the distribution manifold 112 may further comprise applying a reduced pressure.

**[0055]** In one embodiment, the step of positioning the at least the portion of the distal end 118 of the multi-lumen conduit 110 in contact with the distribution manifold 112 further  
25 comprises applying reduced pressure through the reduced-pressure interface 116 to create sufficient reduced pressure in the cavity 164 to pull a portion of the distribution manifold 112 into the cavity 164 such that the distribution manifold 112 abuts the distal aperture 174 of the primary lumen 120.

30 **[0056]** In another embodiment, the step of positioning the at least the portion of the distal end 118 of the multi-lumen conduit 110 in contact with the distribution manifold 112 further comprises the step of applying reduced pressure through the reduced-pressure interface 116 to create sufficient reduced pressure in the cavity 164 to push the housing 154 towards the distribution manifold 112 such that the distal aperture 174 of the primary lumen 120 and the



distal aperture 176 of the at least one of the sensory lumens 122 abuts the distribution manifold 112.

[0057] In yet another embodiment, the step of positioning the at least the portion of the distal end 118 of the multi-lumen conduit 110 in contact with the distribution manifold 112 further comprises manually applying the driving force 172 to an exterior of the reduced-pressure interface 116.

[0058] In one embodiment, the step of applying the driving force 172 to the reduced-pressure interface 116 comprising applying reduced pressure to the cavity 164 less than the threshold pressure ( $P_t$ ) such that the wall portion collapses driving the multi-lumen conduit 110 into the distribution manifold 112.

[0059] Referring now primarily to FIGURES 4-5B, another illustrative embodiment of a reduced-pressure interface 216 is presented. The reduced-pressure interface 216 is analogous in many respects to the reduced-pressure interface of FIGURES 3A-3B. The reduced-pressure interface 216 includes a housing 254 that may have a flange portion 260 and a cavity wall portion 262. The flange portion 260 may be coupled to the sealing member 114 by the attachment device 152. The cavity wall portion 262 is collapsible under reduced pressure. In one embodiment, the cavity wall portion 262 is collapsible under manual pressure. The cavity wall portion 262 may include a bellows configuration 290 for permitting the cavity wall portion 262 to collapse when a cavity 264 pressure ( $P_c$ ) inside the cavity 264 is less than a threshold pressure ( $P_t$ ) on an absolute pressure side.

[0060] The reduced-pressure interface 216 may further include a conduit adapter 292 for receiving the multi-lumen conduit 110 to provide fluid communication between the reduced-pressure treatment unit 108 and the tissue site 102. The conduit adapter 292 includes an adapter flange 294. The adapter flange 294 is positioned on an exterior 284 of the cavity wall portion 262. In a specific, non-limiting example, the conduit adapter 292 and the adapter flange 294 may be formed from materials to include plasticized polyvinyl chloride (PVC), polyurethane, cyclic olefin copolymer elastomer, thermoplastic elastomer, poly acrylic, silicone polymer, and polyether block amide copolymer.

[0061] The multi-lumen conduit 110 is connected to the conduit adapter 292. In a specific, non-limiting embodiment, the multi-lumen conduit 110 may be connected to the conduit adapter 292 by a weld or an adhesive. The multi-lumen conduit 110 extends beyond the conduit adapter 292 into the cavity 264. The reduced-pressure interface 216 is configured to position the distal end 118 of the multi-lumen conduit 110 in contact with the distribution manifold 112.

[0062] In one embodiment, reduced pressure applied through the reduced-pressure interface 216 may create sufficient reduced pressure in the cavity 264 to pull a portion of the distribution manifold 112 into the cavity 264 and abut the primary lumen 120 of the multi-lumen conduit 110. In another embodiment, the distribution manifold 112 may be partially pulled into the primary lumen 120. The distribution manifold 112 abuts the distal end 118 of the multi-lumen conduit 110 including the distal aperture 176 of the at least one of the plurality of sensing lumens 122. Allowing the distribution manifold 112 to completely abut the distal end 118 of the multi-lumen conduit 110 may help ensure fluid isolation between each of the lumens in the multi-lumen conduit 110.

[0063] Referring now primarily to FIGURES 6-7C, another illustrative embodiment of a reduced-pressure interface 316 is presented. The reduced-pressure interface 316 is analogous in many respects to the reduced-pressure interface of FIGURES 3A-3B. The reduced-pressure interface 316 includes a housing 354, a conduit port 356 coupled to the housing 354, and the attachment device 152 for coupling the reduced-pressure interface 316 to the sealing member 114. The reduced-pressure interface 316 further includes a cutting element 317.

[0064] The housing 354 may have a flange portion 360 and a cavity wall portion 362. The cavity wall portion 362 forms a cavity 364 having a tissue-facing cavity opening 366. The conduit port 356 is coupled to or formed as part of the cavity wall portion 362 of the housing 354. The conduit port 356 includes a conduit aperture 368 whereby the conduit port 356 is adapted to receive the multi-lumen conduit 110. The attachment device 152 may be coupled to a tissue-facing side 370 of the flange portion 360 for coupling the housing 354 to the first side 134 of the sealing member 114. The housing 354 is made of a semi-rigid material that is capable of collapsing under a force such as the driving force 172. In a non-limiting example, the reduced-pressure interface 316, and thus the housing 354, may be made from a plasticized polyvinyl chloride (PVC), polyurethane, cyclic olefin copolymer elastomer, thermoplastic elastomer, poly acrylic, silicone polymer, and polyether block amide copolymer.

[0065] The cutting element 317 may be at least temporarily coupled to the housing 354 proximate to the tissue-facing cavity opening 366. The cutting element 317 is adapted to form an aperture 319 in the sealing member 114 when the cutting element 317 is driven into the sealing member 114 with the driving force 172. The driving force 172 may also cause the cutting element 317 to penetrate or cut a portion of the distribution manifold 112.

[0066] The cutting element 317 may have a piercing length ( $L_p$ ). The distribution manifold 112 may have a thickness greater than  $T$  when subject to reduced pressure such that

the piercing length ( $L_p$ ) of the cutting element 317 is less than the thickness  $T$ , i.e.,  $L_p < T$ . One benefit of the piercing length ( $L_p$ ) being less than the thickness,  $T$ , of the distribution manifold 112 under reduced pressure is that the cutting element 317 cannot completely cut through the distribution manifold 112 and reach the tissue site 102.

5           **[0067]** As previously mentioned, the cutting element 317 may be only temporarily coupled to the housing 354. In one embodiment, the cutting element 317 may be removed by a care giver. In another embodiment, the cutting element 317 may be formed from a liquid soluble material such as a water soluble material adapted to allow the cutting element 317 to dissolve. For example, the water soluble material may include at least one of the following:

10 Polyvinyl alcohol (PVOH), polyvinyl pyrrolidone, hydroxyl and carboxyl modified cellulose, hydroxyl and carboxyl modified acrylics, starch, sugars (sucrose, glucose, fructose), weak acids (tartaric, citric, malic), salts (sodium chloride, sodium carbonate, sodium bicarbonate), polyethylene oxide (PEO), polyethylene glycol (PEG). The cutting element 317 may dissolve as liquids are removed from the tissue site 102. Reduced pressure is applied to the reduced-

15 pressure interface 316 after perforating the sealing member 114 typically causing liquids to be removed from the tissue site 102. After a sufficient amount of time, liquids removed from the tissue site 102 cause the cutting element 317 to substantially dissolve. The cutting element 317 may dissolve within 2 minutes, 5 minutes, 10 minutes, or another time period. As the cutting element 317 is dissolved the cutting element 317 is removed by the multi-lumen

20 conduit 110 with liquids from the tissue site 102. A liquid, e.g., saline solution, may also be introduced through the multi-lumen conduit 110, or otherwise, to dissolve the cutting element 317.

**[0068]** As shown in FIGURE 7C, once the cutting element 317 has substantially dissolved, reduced pressure applied through the reduced-pressure interface 316 creates

25 sufficient reduced pressure in the cavity 364 to pull a portion of the distribution manifold 112 into the cavity 364 such that the distribution manifold 112 abuts a distal end 118 of the multi-lumen conduit 110 to include the distal aperture 176 of the at least one of the plurality of sensing lumens 122. Allowing the distribution manifold 112 to completely abut the distal end 118 of the multi-lumen conduit 110 may help ensure fluid isolation between each of the

30 lumens in the multi-lumen conduit 110.

**[0069]** In operation, a caregiver may treat the tissue site 102 on the patient 104 with a method that includes disposing the distribution manifold 112 proximate to the tissue site 102. The distribution manifold 112 and the portion of intact epidermis 126 of the patient 104 is covered with the sealing member 114 to form the sealed space 132 in which the distribution

manifold 112 is disposed. The reduced-pressure interface 316 is coupled to the sealing member 114. The multi-lumen conduit 110 is fluidly coupled on one end to the reduced-pressure source 146 and on the opposing end to the reduced-pressure interface 316. The driving force 172 is then applied to the reduced-pressure interface 316 with sufficient strength to cause the cutting element 317 to perforate (e.g., pierce, tear, cut or otherwise create the aperture 319) the sealing member 114.

**[0070]** Referring now primarily to FIGURES 8-9C, another illustrative embodiment of a reduced-pressure interface 416 is presented. The reduced-pressure interface 416 is analogous in many respects to the reduced-pressure interface 316 of FIGURES 5A and 5B.

The reduced-pressure interface 416 includes a housing 454 and a cutting element 417. The housing 454 may have a flange portion 460 and a cavity wall portion 462. The flange portion 460 may be coupled to the sealing member 114 by the attachment device 152. The cavity wall portion 462 is collapsible under reduced pressure. The cavity wall portion 462 may include a bellows configuration 490 for permitting the cavity wall portion 462 to collapse when a cavity pressure ( $P_c$ ) inside a cavity 464 is less than a threshold pressure ( $P_t$ ) on an absolute pressure side.

**[0071]** The reduced-pressure interface 416 may further include a conduit adapter 492 for receiving the multi-lumen conduit 110 to provide fluid communication between the reduced-pressure treatment unit 108 and the tissue site 102. The conduit adapter 492 includes an adapter flange 494. The adapter flange 494 is positioned on an exterior 484 of the cavity wall portion 462. In a specific, non-limiting example, the conduit adapter 492 and the adapter flange 494 may be formed from materials to include plasticized polyvinyl chloride (PVC), polyurethane, cyclic olefin copolymer elastomer, thermoplastic elastomer, poly acrylic, silicone polymer, and polyether block amide copolymer.

**[0072]** The multi-lumen conduit 110 is connected to the conduit adapter 492. In a specific, non-limiting embodiment, the multi-lumen conduit 110 may be connected to the conduit adapter 492 by a weld or an adhesive. The multi-lumen conduit 110 extends beyond the conduit adapter 492 into the cavity 464. The reduced-pressure interface 416 is configured to position the distal end 118 of the multi-lumen conduit 110 in contact with the distribution manifold 112.

**[0073]** The cutting element 417 may be at least temporarily coupled to the conduit adapter 492. The cutting element 417 is configured to make orthogonal cuts in the sealing member 114 when the housing 454 is compressed with the driving force 172 thereby impacting the cutting element 417. The cutting element 417 is thus driven into the sealing

member 114. The driving force 172 may be manually applied to the exterior 484 of the reduced-pressure interface 416 causing the housing 454 to collapse and thereby driving or pushing the cutting element 417 into the sealing member 114. In another embodiment, the driving force 172 is applied by applying reduced pressure to the cavity 464 such that the cavity pressure ( $P_c$ ) in the cavity 464 is less than a threshold pressure ( $P_t$ ). When the cavity pressure ( $P_c$ ) in the cavity 464 is less than the threshold pressure ( $P_t$ ), the cavity wall portion 462 collapses and impacts the cutting element 417. With continued reduced pressure, a portion of the cutting element 417 is driven through the sealing member 114. The threshold pressure ( $P_t$ ) is at least in part dependent on the type and thickness of material used for the housing 454. In the event reduced pressure is applied to the cavity 464, a tensile force 473 may be applied to the sealing member 114 causing the sealing member 114 to be pulled into the cavity 464. This movement helps the cutting element 417 to be driven into the sealing member 114.

[0074] In one embodiment, the cutting element 417 may be formed from a liquid soluble material such as a water soluble material adapted to allow the cutting element 417 to dissolve. The water soluble material may include at least one of the following: Polyvinyl alcohol (PVOH), polyvinyl pyrrolidone, hydroxyl and carboxyl modified cellulose, hydroxyl and carboxyl modified acrylics, starch, sugars (sucrose, glucose, fructose), weak acids (tartaric, citric, malic), salts (sodium chloride, sodium carbonate, sodium bicarbonate), polyethylene oxide (PEO), polyethylene glycol (PEG). The cutting element 417 may dissolve as liquids are removed from the tissue site 102. Reduced pressure is applied to the reduced-pressure interface 416 typically causing liquids to be removed from the tissue site 102. After a sufficient amount of time, liquids removed from the tissue site 102 may cause the cutting element 417 to substantially dissolve. As the cutting element 417 is dissolved, the cutting element 417 is removed by the multi-lumen conduit 110 with the liquids from the tissue site 102. While the cutting element 417 may be dissolvable, it is worth noting that the conduit adapter 492 and the adapter flange 494 do not dissolve.

[0075] Once the cutting element 417 has substantially dissolved, reduced pressure applied through the reduced-pressure interface 416 may be of sufficient reduced pressure in the cavity 464 to pull a portion of the distribution manifold 112 into the cavity 464 and into contact with the primary lumen 120 of the multi-lumen conduit 110. The distribution manifold 112 abuts the distal end 118 of the multi-lumen conduit 110 including the distal aperture 176 of the at least one of the plurality of sensing lumens 122. Allowing the distribution manifold 112 to completely abut the distal end 118 of the multi-lumen conduit 110 may help ensure fluid isolation between each of the lumens in the multi-lumen conduit 110.

[0076] Although the present invention and its advantages have been disclosed in the context of certain illustrative, non-limiting embodiments, it should be understood that various changes, substitutions, permutations, and alterations can be made without departing from the scope of the invention as defined by the appended claims. It will be appreciated that any  
5 feature that is described in connection to any one embodiment may also be applicable to any other embodiment.

[0077] 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.

10 [0078] The steps of the methods described herein may be carried out in any suitable order, or simultaneously where appropriate.

[0079] 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.

15 [0080] It will be understood that the above description of preferred embodiments is given by way of example only and that various modifications may be made by those skilled in the art. The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments of the invention. Although various embodiments of the invention have been described above with a certain degree of particularity, or with  
20 reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of the claims.

**CLAIMS**

We claim:

1. A system for treating a tissue site on a patient with reduced pressure, the system comprising:
  - 5 a distribution manifold for placing proximate to the tissue site;
  - a sealing member for covering the distribution manifold and a portion of intact epidermis of the patient to form a sealed space;
  - a reduced-pressure interface for providing reduced pressure through the sealing member to the distribution manifold;
  - 10 a reduced-pressure source;
  - a multi-lumen conduit for fluidly coupling the reduced-pressure source to the reduced-pressure interface; and
  - wherein the reduced-pressure interface comprises:
    - a housing having a cavity wall portion,
    - 15 wherein the cavity wall portion forms a cavity having a tissue-facing cavity opening,
    - an attachment device coupled to the housing for coupling the housing to the sealing member,
    - a conduit port coupled to the cavity wall and having a conduit aperture,
    - 20 and
    - the multi-lumen conduit, wherein:
      - the multi-lumen conduit has a distal end and a proximal end,
      - the distal end extends through the conduit aperture into the cavity,
      - the multi-lumen conduit further comprises at least one primary
      - 25 lumen for delivering reduced pressure and a plurality of sensing lumens,
      - the primary lumen and the plurality of sensing lumens extending from the distal end of the multi-lumen conduit towards the proximal end of the multi-lumen conduit, and
      - 30 wherein the plurality of sensing lumens have a corresponding plurality of distal openings at the distal end of the multi-lumen conduit; and

wherein at least one of the plurality of distal openings of the plurality of sensing lumens contacts the distribution manifold.

2. The system of claim 1, wherein the multi-lumen conduit is connected to the conduit port.
3. The system of claim 1, wherein the primary lumen comprises a central lumen and the plurality of sensing lumens comprise peripheral lumens.
4. The system of claim 1, wherein a distal end of the primary lumen and a distal end of at least one of the plurality of sensing lumens contact the distribution manifold.
5. The system of claim 1, wherein the reduced-pressure interface is fluidly coupled to the distribution manifold through an aperture in the sealing member.
6. The system of claim 1, wherein the attachment device is an adhesive.
7. The system of claim 1, wherein the housing is made of a semi-rigid material that collapses when exposed to a pressure ( $P_c$ ) in the cavity that is less than a threshold pressure ( $P_t$ ).
8. The system of claim 1, further comprising an instrumentation unit fluidly coupled to at least one of the plurality of sensing lumens, wherein the instrumentation unit includes a pressure sensor and a microprocessor, wherein the microprocessor is configured to process a pressure signal from the pressure sensor.
9. The system of claim 1, further comprising:
  - a cutting element at least temporarily coupled to the housing proximate to the tissue-facing cavity opening, the cutting element adapted to form an aperture in the sealing member when the cutting element is driven into the sealing member with a driving force; andwherein the multi-lumen conduit is connected to the conduit port.



10. The system of claim 9, wherein the cutting element is formed from a water soluble material.
11. The system of claim 9, wherein the distribution manifold has a thickness greater than T when under the influence of reduced pressure at an operating level, wherein the cutting element has a piercing length ( $L_p$ ), wherein  $L_p < T$ , and wherein the cutting element creates an aperture in the distribution manifold.
12. The system of claim 1, further comprising:  
a cutting element at least temporarily coupled to the housing,  
wherein the cutting element further comprises a conduit adapter connected to the conduit port for receiving the multi-lumen conduit, the conduit adapter having an adapter flange on an exterior of the cavity wall and having a tube extension sized and configured to mate with the conduit aperture and receive the multi-lumen conduit, wherein the cutting element further comprises a base member and a stylus member, and wherein the base member is coupled to the tube extension.
13. The system of claim 12, wherein the cutting element is formed from a water soluble material.
14. The system of claim 12, wherein the distribution manifold has a thickness greater than T when under the influence of reduced pressure at an operating level, wherein the cutting element has a piercing length ( $L_p$ ), wherein  $L_p < T$ , and wherein the cutting element penetrates a portion of the distribution manifold when placed under reduced pressure at an operation level.

15. A method for treating a tissue site on a patient with reduced pressure, the method comprising:

disposing a distribution manifold proximate to the tissue site;  
covering the distribution manifold and a portion of intact epidermis of the patient  
5 with a sealing member to form a sealed space in which the distribution manifold is disposed, wherein the sealing member has a first side and a second, tissue-facing side;

providing a reduced-pressure source;

providing a multi-lumen conduit having a distal end and a proximal end, wherein  
10 the multi-lumen conduit comprises a plurality of sensing lumens and at least one primary lumen;

fluidly coupling the distal end of the multi-lumen conduit to the sealed space;

disposing at least one distal opening of a plurality of distal openings of the plurality  
of sensing lumens in contact with the distribution manifold; and

15 delivering reduced pressure to the multi-lumen conduit.

16. The method of claim 15, wherein the step of fluidly coupling a distal end of the multi-lumen conduit to the sealed space comprises:

coupling a reduced-pressure interface to the sealing member, wherein the reduced-pressure interface comprises:

20 a housing having a cavity wall portion,  
wherein the cavity wall portion forms a cavity having a tissue-facing cavity opening,

an attachment device coupled to the housing for coupling the housing to the sealing member, and

25 a conduit port formed in the cavity wall and having a conduit aperture; and  
extending the multi-lumen conduit through the conduit port.

17. The method of claim 15, wherein the primary lumen comprises a central lumen and the plurality of sensing lumens comprise peripheral lumens.
18. The method of claim 16, wherein the multi-lumen conduit is connected to the conduit port.
19. The method of claim 15, wherein the sealing member includes an aperture for providing  
5 fluid communication between the housing and the distribution manifold.
20. The method of claim 16, wherein the step of coupling the reduced-pressure interface comprises coupling the reduced-pressure interface proximate to the first side of the sealing member using the attachment device of the reduced-pressure interface to adhere the reduced-pressure interface to the sealing member.
- 10 21. The method of claim 16, wherein the step of disposing at least one distal opening of a plurality of distal openings of the plurality of sensing lumens in contact with the distribution comprises applying a driving force to the reduced-pressure interface of sufficient strength to cause at least one distal opening of the plurality of distal openings to be in contact with the distribution manifold.
- 15 22. The method of claim 16, wherein the step of disposing at least one distal opening of a plurality of distal openings of the plurality of sensing lumens in contact with the distribution manifold comprises applying reduced pressure through the reduced-pressure interface sufficiently into the cavity to pull a portion of the distribution manifold into the cavity such that the distribution manifold contacts at least one distal opening of the plurality  
20 of sensing lumens.
23. The method of claim 16, wherein the step of disposing at least one distal opening of a plurality of distal openings of the plurality of sensing lumens in contact with the distribution manifold comprises applying reduced pressure through the reduced-pressure interface sufficiently into the cavity to pull a portion of the distribution manifold into the  
25 cavity such that the distribution manifold contacts at least one distal opening of the plurality of sensing lumens and the primary lumen.

24. The method of claim 16, wherein the step of disposing at least one distal opening of a plurality of distal openings of the plurality of sensing lumens in contact with the distribution manifold comprises the step of applying reduced pressure through the reduced-pressure interface to create sufficient reduced pressure in the cavity to push the housing  
5 towards the distribution manifold such that a distal aperture of the primary lumen and at least one of the distal apertures of the sensory lumens abuts the distribution manifold.
25. The method of claim 16, wherein the step of disposing at least one distal opening of a plurality of distal openings of the plurality of sensing lumens in contact with the distribution manifold comprises manually applying a driving force to an exterior of the  
10 reduced-pressure interface.
26. The method of claim 16, wherein the housing is formed of a semi-rigid material that collapses when under reduced pressure less than a threshold pressure ( $P_t$ ), and wherein the step of disposing at least one distal opening of a plurality of distal openings of the plurality of sensing lumens in contact with the distribution manifold comprises the step of applying  
15 a driving force to the reduced-pressure interface comprising applying reduced pressure to the cavity less than the threshold pressure ( $P_t$ ) such that the wall portion collapse driving the multi-lumen conduit into the distribution manifold.
27. The method of claim 16, wherein the reduced-pressure interface further comprises a cutting member at least temporarily coupled to the housing proximate to the tissue-facing  
20 cavity opening.
28. The method of claim 27, further comprising the following steps:  
driving the cutting member through the sealing member to create an aperture in the sealing member;  
removing fluid from the tissue site whereby the fluid dissolves the cutting member  
25 causing the distal end of the multi-lumen conduit to contact the distribution manifold through the aperture in the sealing member.
29. A reduced-pressure connection for providing reduced pressure to a tissue site in a sealed space formed by a sealing member, the reduced-pressure connection comprising:  
a distribution manifold for placing proximate to the tissue site, wherein the  
30 distribution manifold comprises a foam member;

a multi-lumen conduit having a plurality of sensing lumens and at least one primary lumen, wherein a plurality of distal opening are associated with the plurality of sensing lumens on a distal end of the multi-lumen conduit; and  
5 wherein the distal end of the multi-lumen conduit is in direct contact with the distribution manifold such that at least one of the plurality of distal apertures abuts the distribution manifold.

30. The reduced-pressure connection of claim 29, wherein the distal end of the multi-lumen conduit is in direct contact with the distribution manifold such that a majority of the plurality of distal apertures abut the distribution manifold.

31. A reduced pressure treatment system for treating a wound on a patient with reduced pressure, the system comprising:

a foam manifold for positioning proximate to the wound;

a drape for covering the manifold and a portion of epidermis of the patient to form a sealed space;

a reduced-pressure interface for providing reduced pressure through the drape to the manifold;

a reduced-pressure source;

a first conduit for fluidly coupling the reduced-pressure source to the reduced-pressure interface;

a second conduit having at least one sensing lumen and having a distal opening and a proximal opening;

wherein the reduced-pressure interface comprises:

a housing having a cavity wall portion that forms a cavity having a tissue-facing cavity opening,

an attachment device coupled to the housing for coupling the housing to the drape,

a conduit port coupled to the cavity wall and having a conduit aperture for receiving the first conduit;

wherein the first conduit and the second conduit each have a distal end and a proximal end;

wherein the distal end of the first conduit extends through the conduit aperture into the cavity, the first conduit comprises at least one primary lumen for

delivering reduced pressure, the primary lumen extends from the distal end

to the proximal end of the first conduit; and

the sensing lumen extends from the distal end to the proximal end of the second

conduit, and wherein the sensing lumen has a distal opening that contacts the manifold.

32. A method for treating a wound on a patient with reduced pressure, the method comprising:
- positioning a manifold adjacent to the wound;
  - covering the manifold and a portion of intact epidermis of the patient with a drape  
to form a sealed space, wherein the drape has a first side and a second,  
5 tissue-facing side;
  - providing a reduced-pressure source;
  - providing a first conduit and a second conduit, each having a distal end and a  
proximal end, wherein the second conduit comprises a plurality of sensing  
lumens and the first conduit comprises at least one reduced-pressure lumen;
  - 10 fluidly coupling the distal end of the first conduit to the sealed space;
  - fluidly coupling the distal end of the second conduit to the sealed space;
  - disposing at least one distal opening of a plurality of distal openings of the plurality  
of sensing lumens in contact with the manifold; and
  - delivering reduced pressure to the first conduit.

33. A reduced-pressure connection for providing reduced pressure to a wound in a sealed space formed by a drape, the reduced-pressure connection comprising:
- a manifold for placing proximate to the wound, wherein the manifold comprises a foam member;
  - 5 a first conduit having at least one primary lumen, wherein the first conduit has a distal end;
  - a second conduit having a plurality of sensing lumens, wherein a plurality of distal openings are associated with the plurality of sensing lumens on a distal end of the second conduit; and
  - 10 wherein the distal end of the first and second conduits are in direct contact with the manifold such that at least one of the plurality of distal apertures abuts the manifold.
34. The devices, systems, and methods described and disclosed herein.



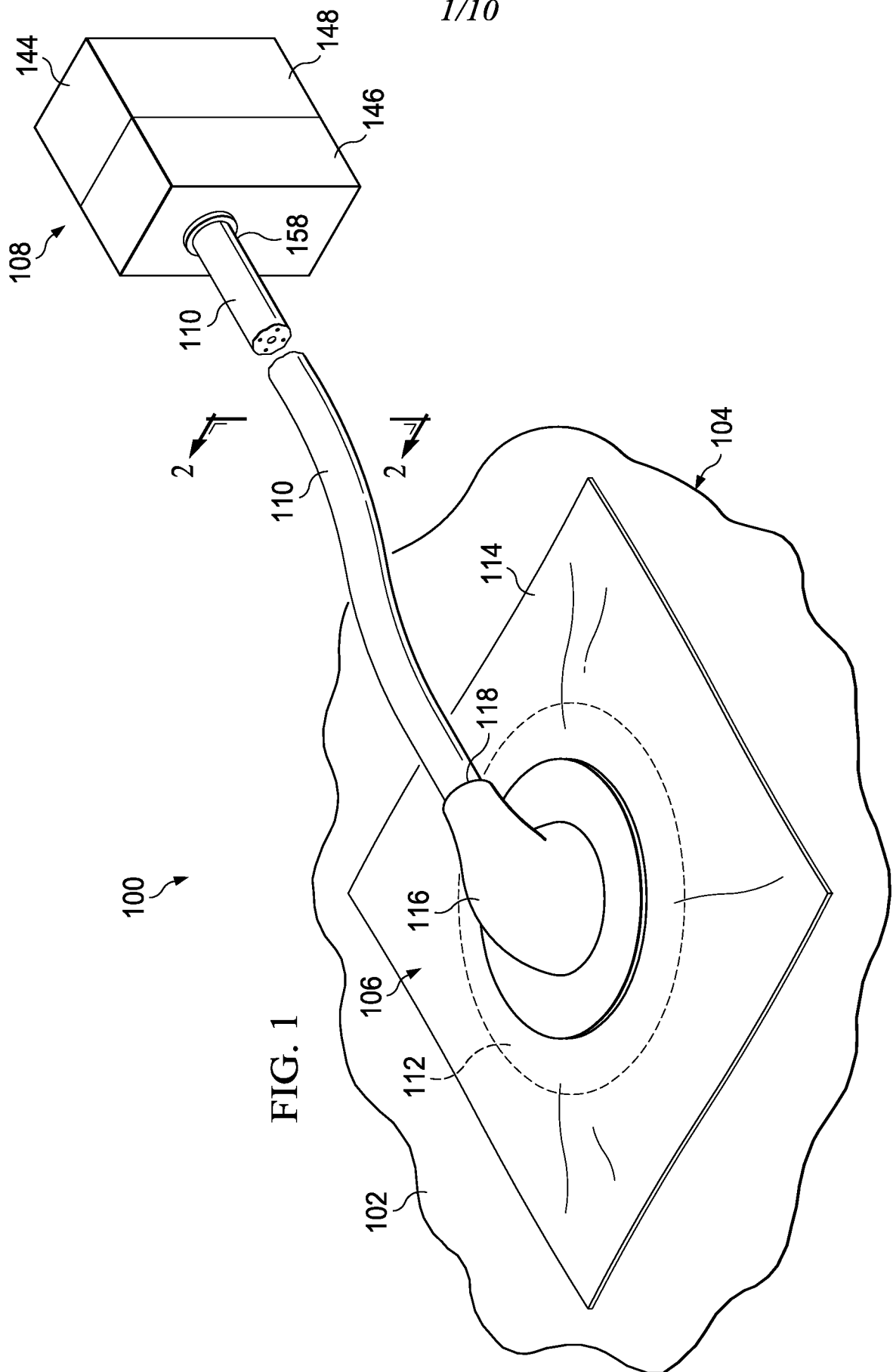


FIG. 2

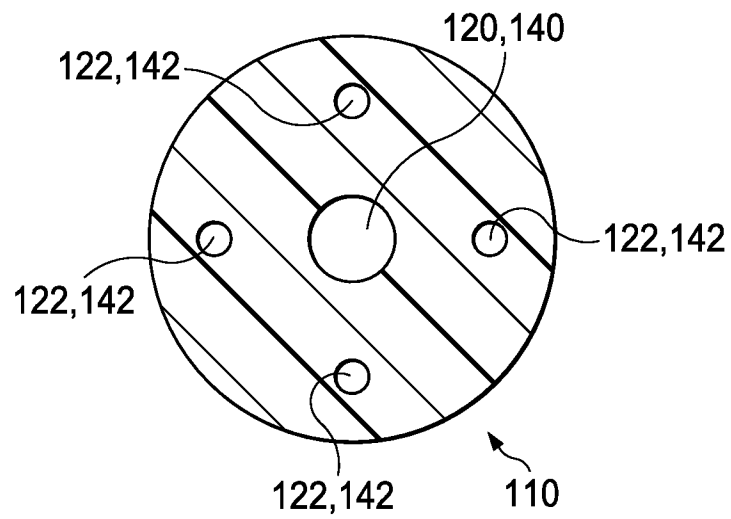
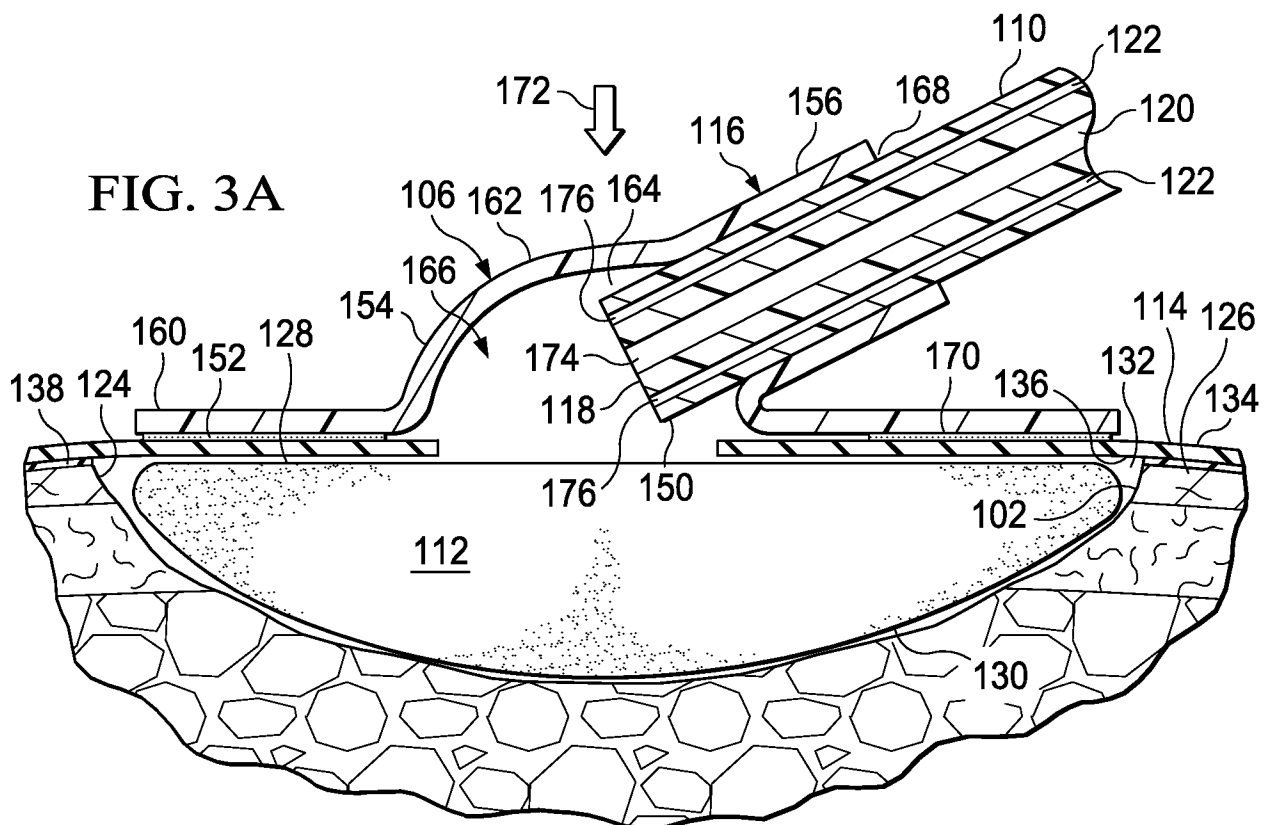
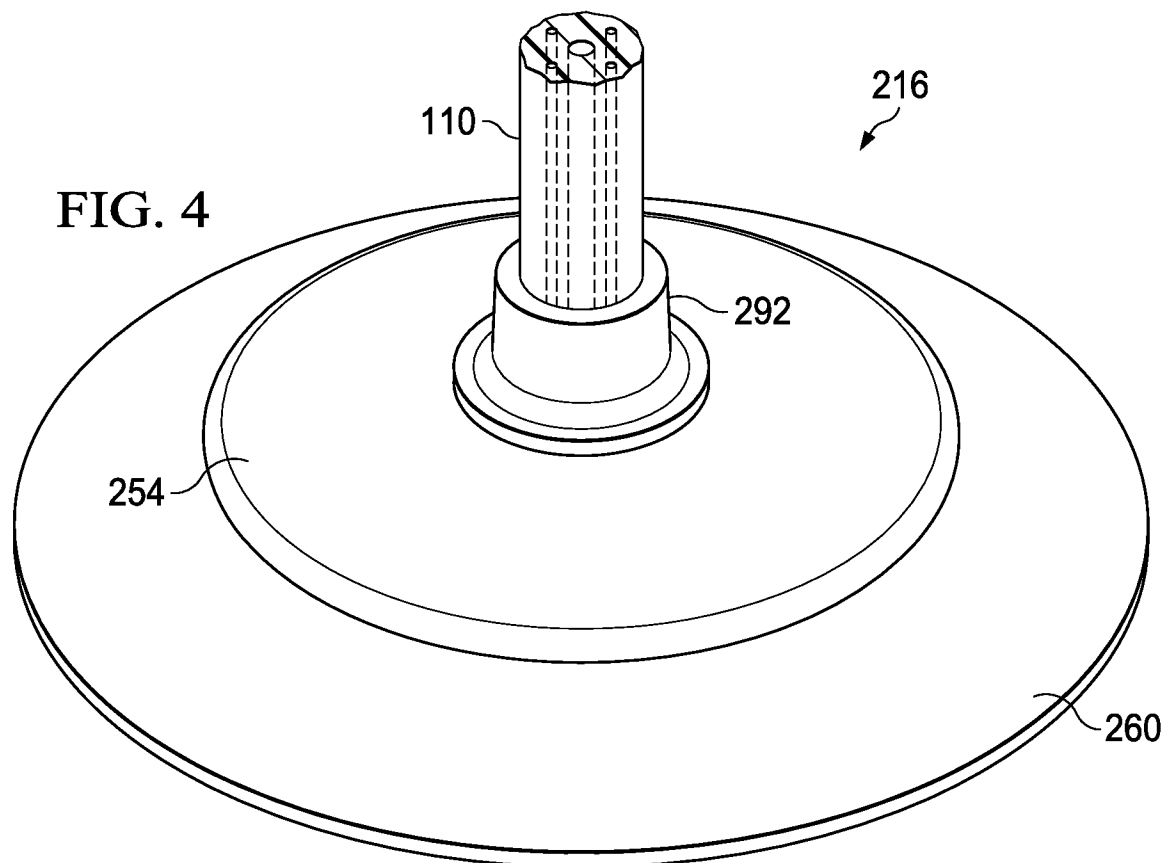
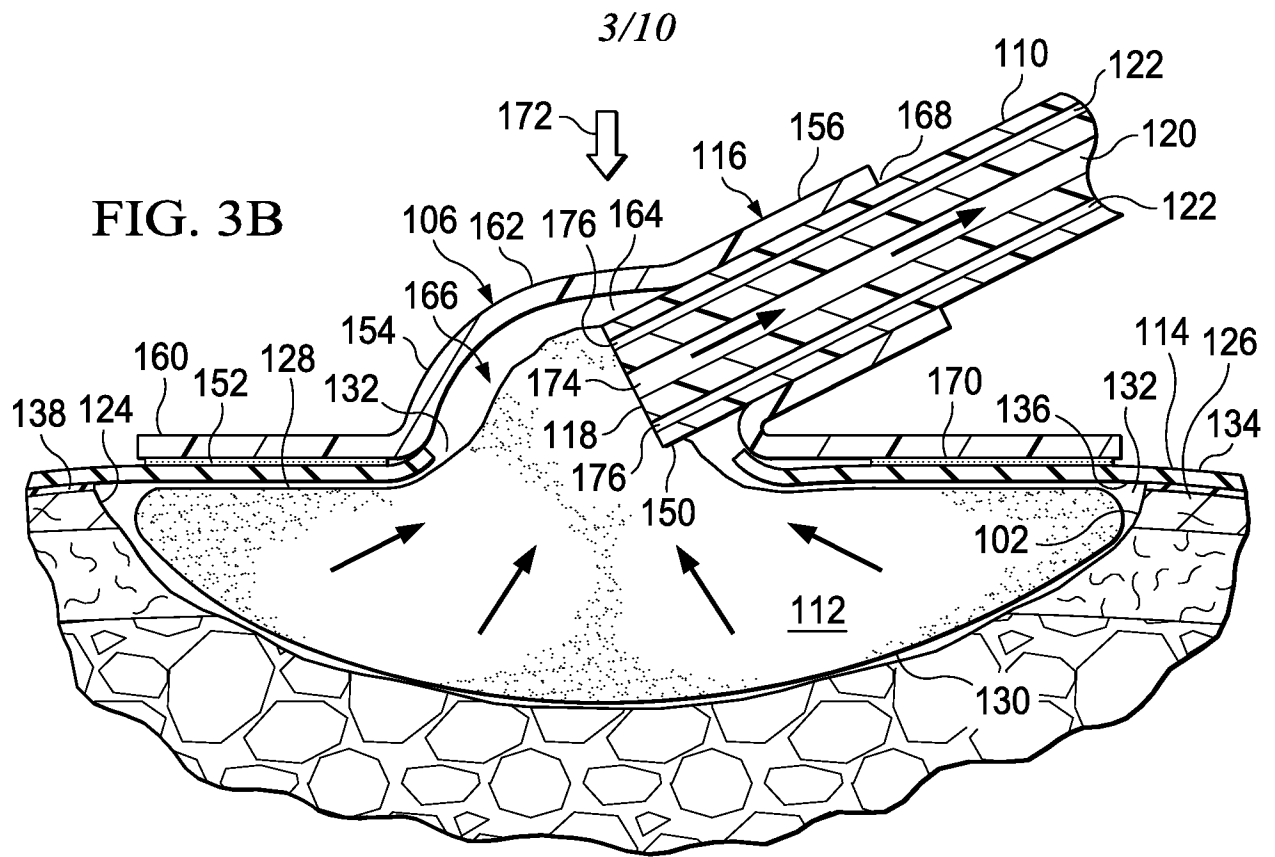


FIG. 3A





4/10

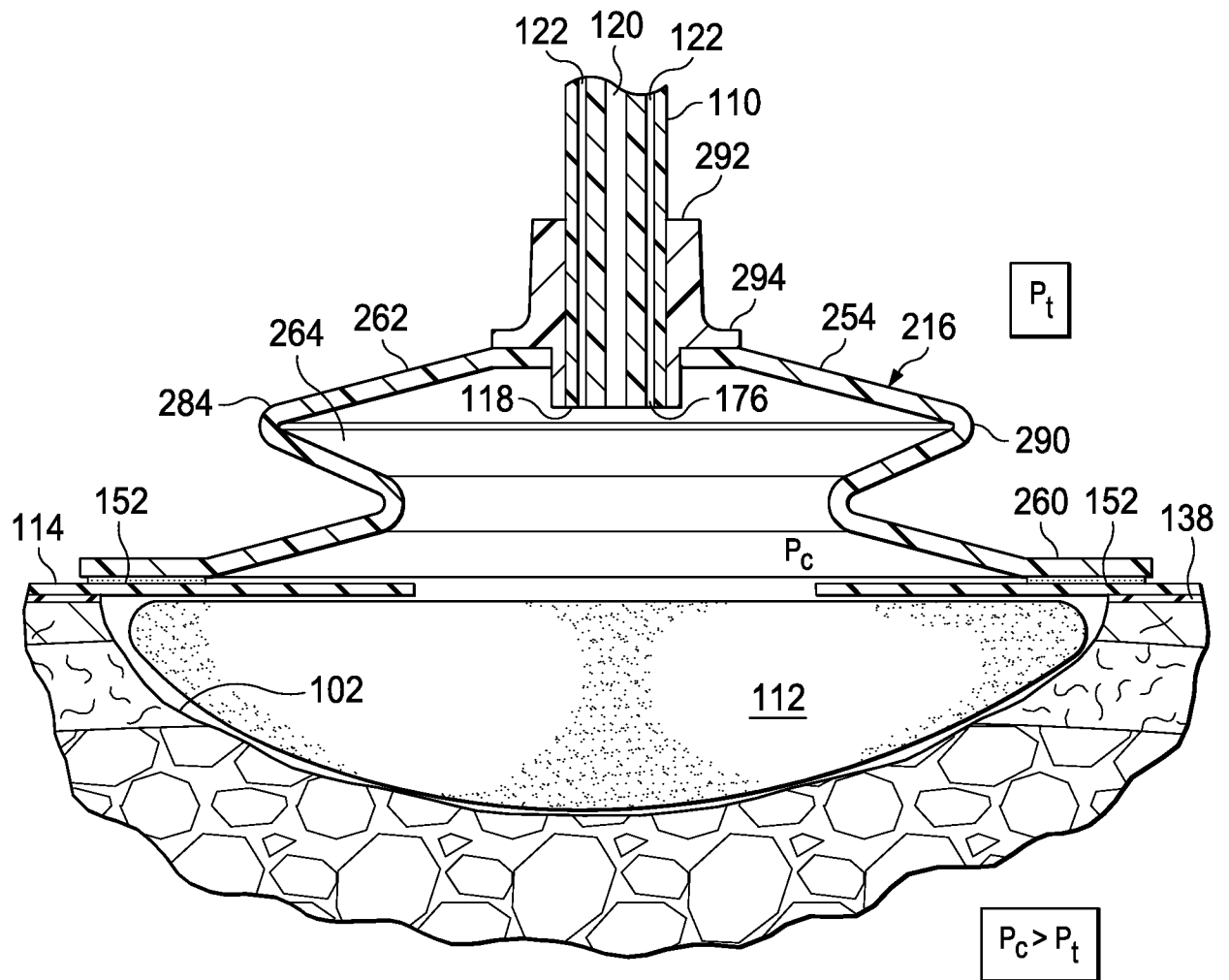


FIG. 5A

*5/10*

FIG. 5B

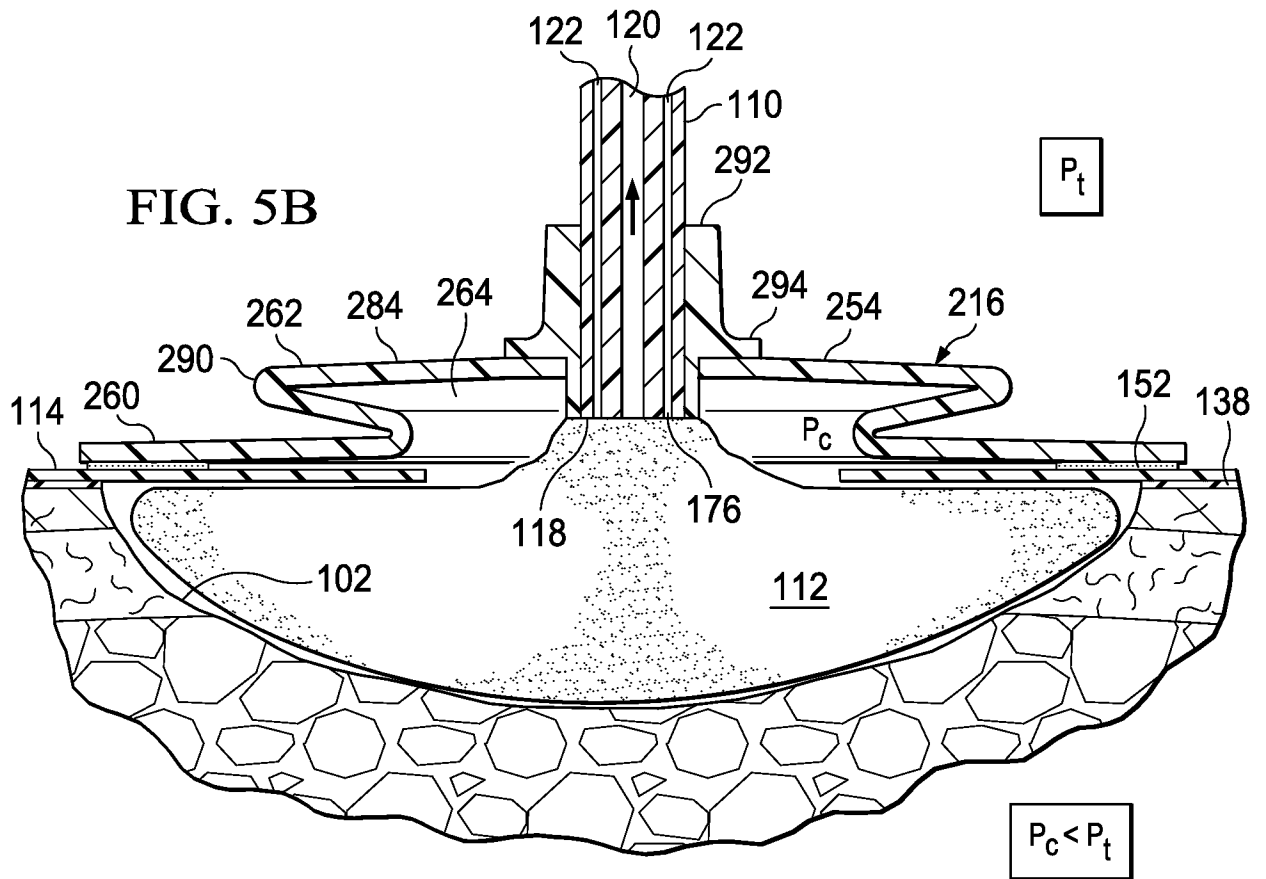
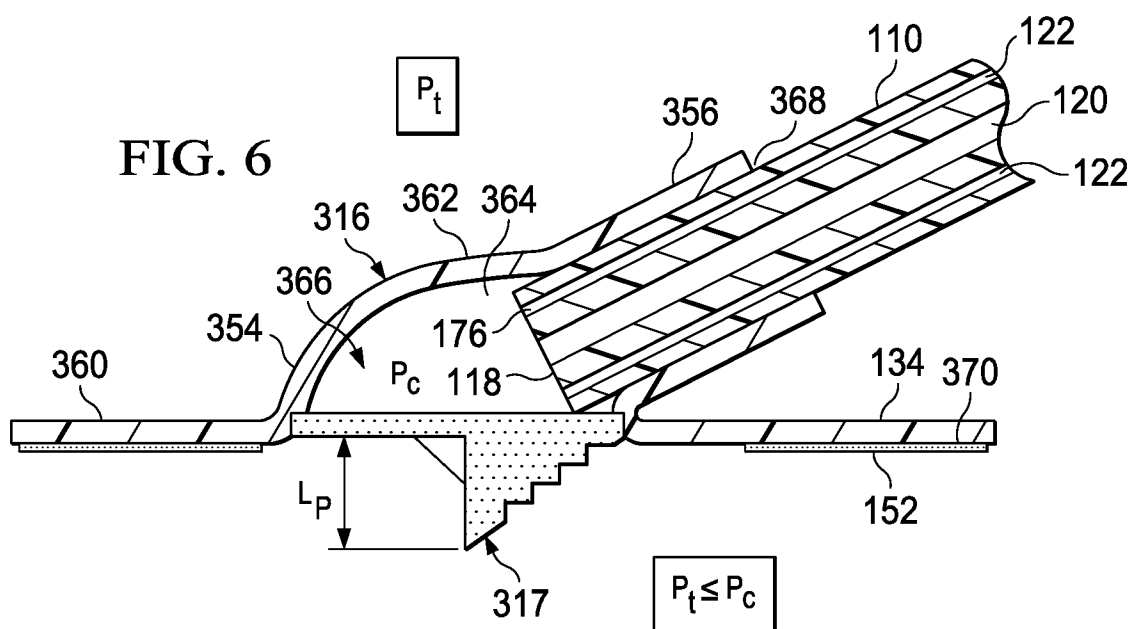


FIG. 6



*6/10*

FIG. 7A

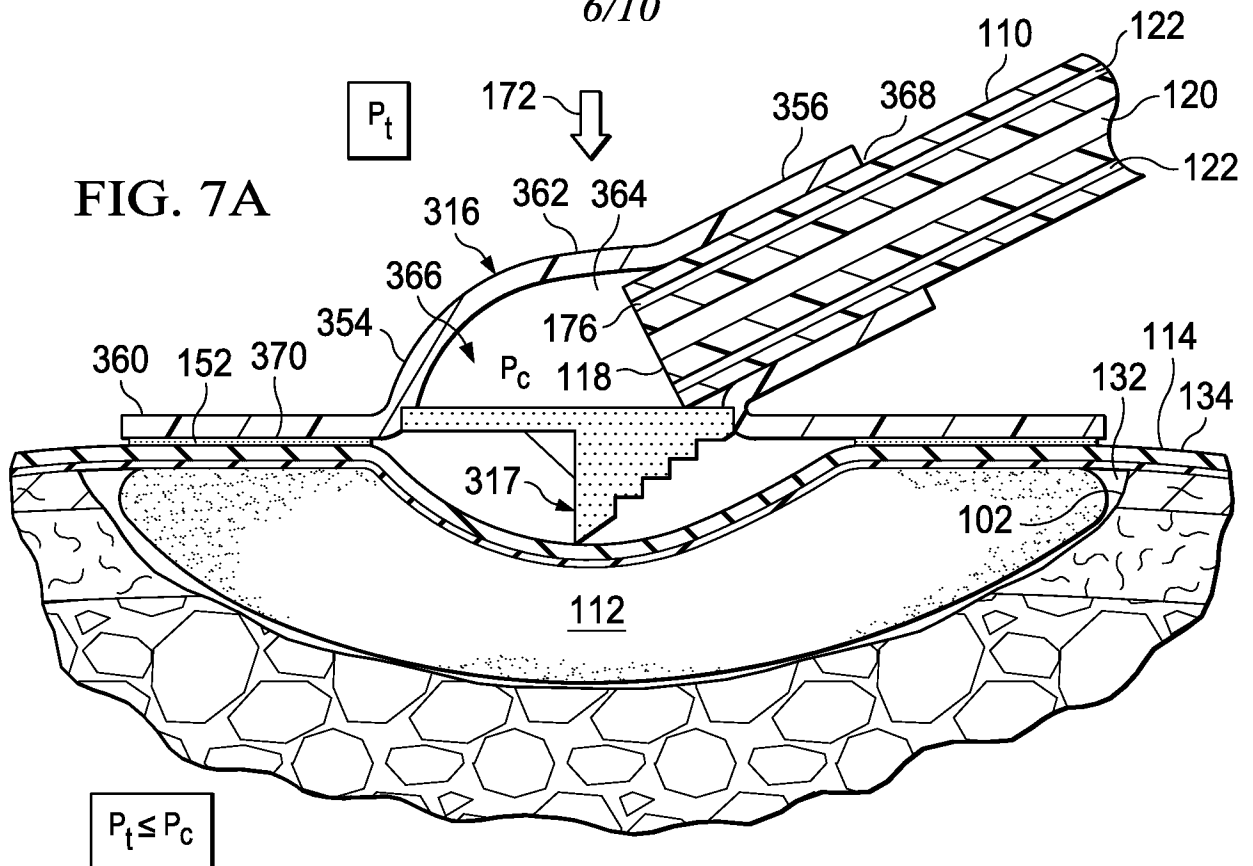
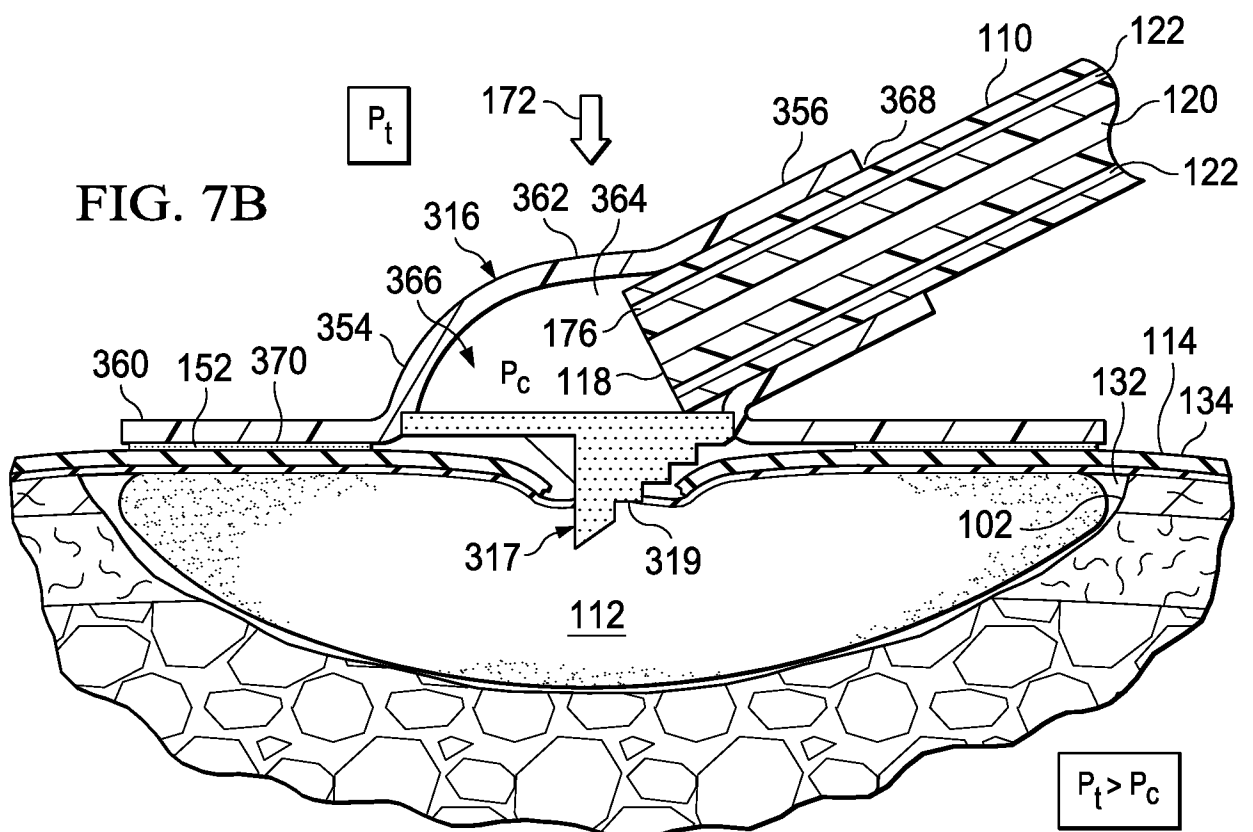


FIG. 7B



7/10

FIG. 7C

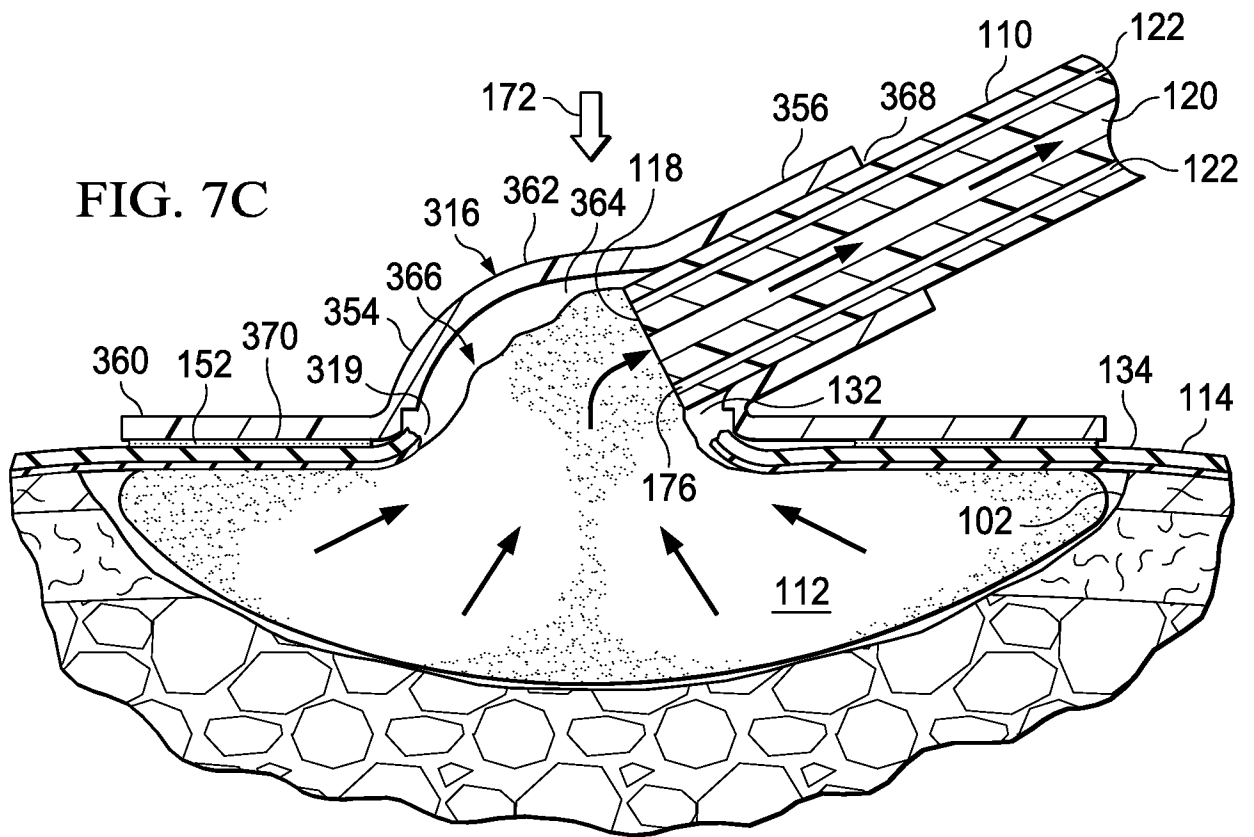
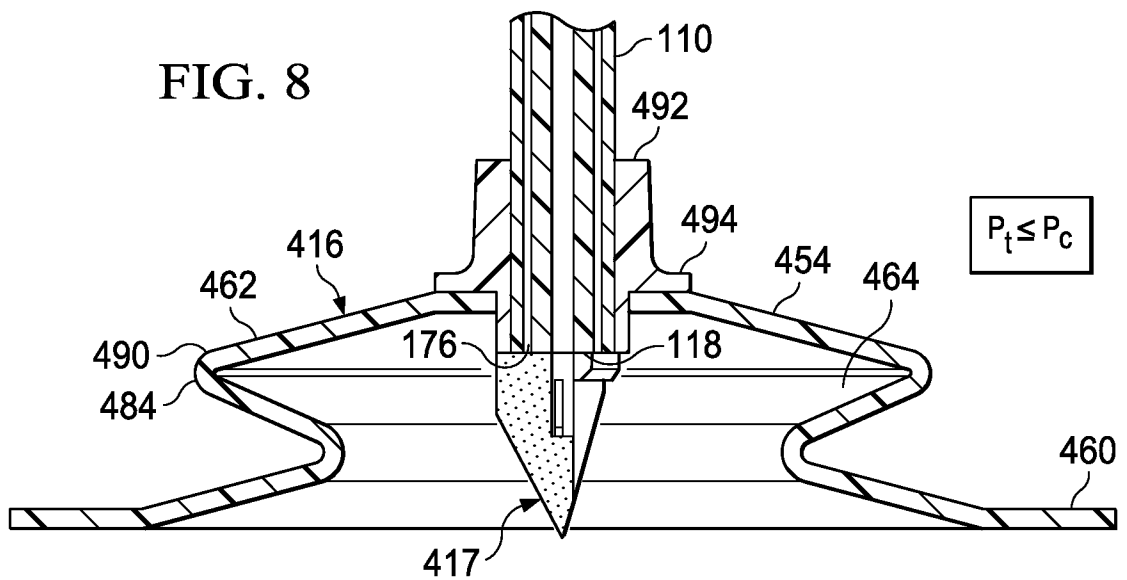


FIG. 8



8/10

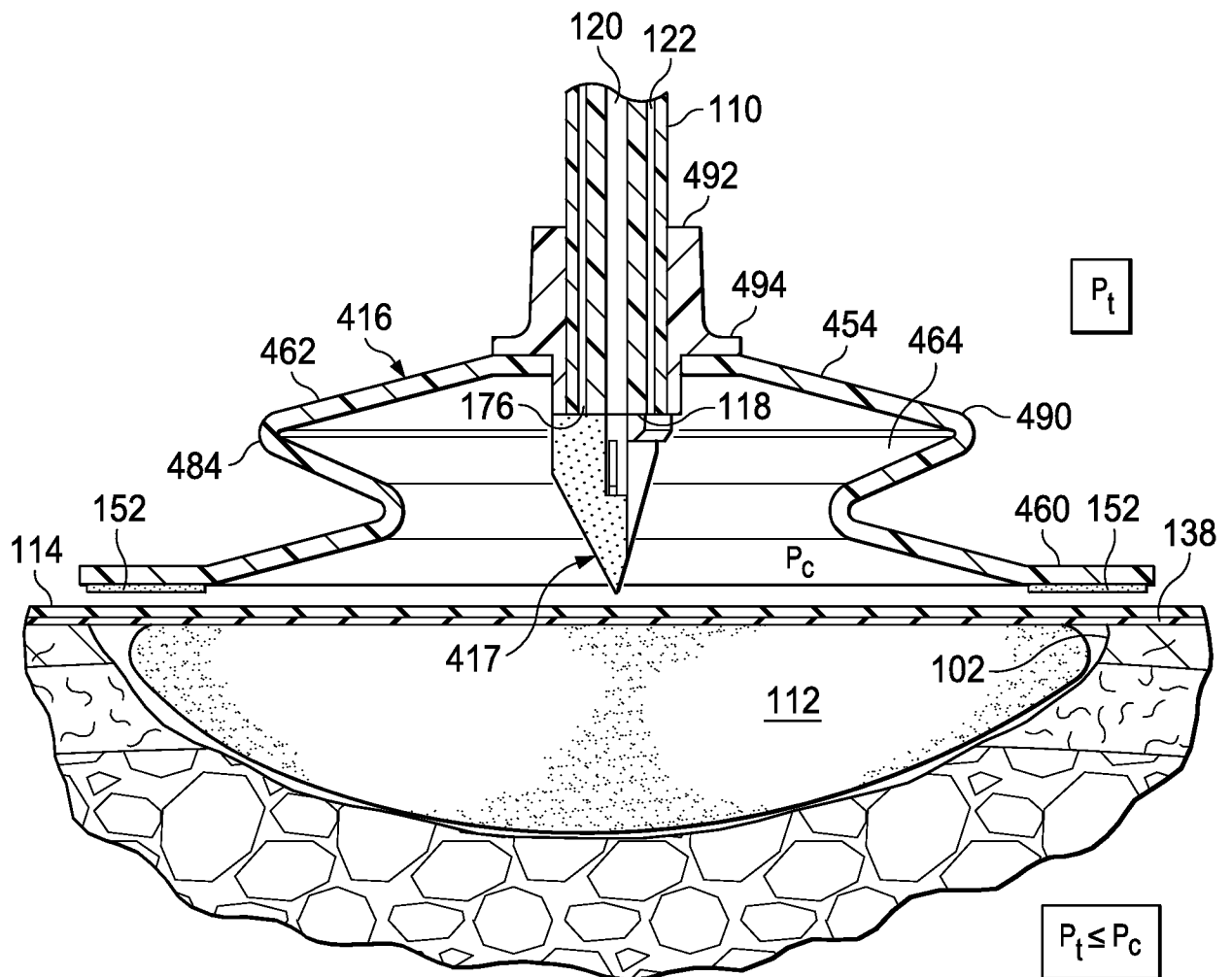


FIG. 9A



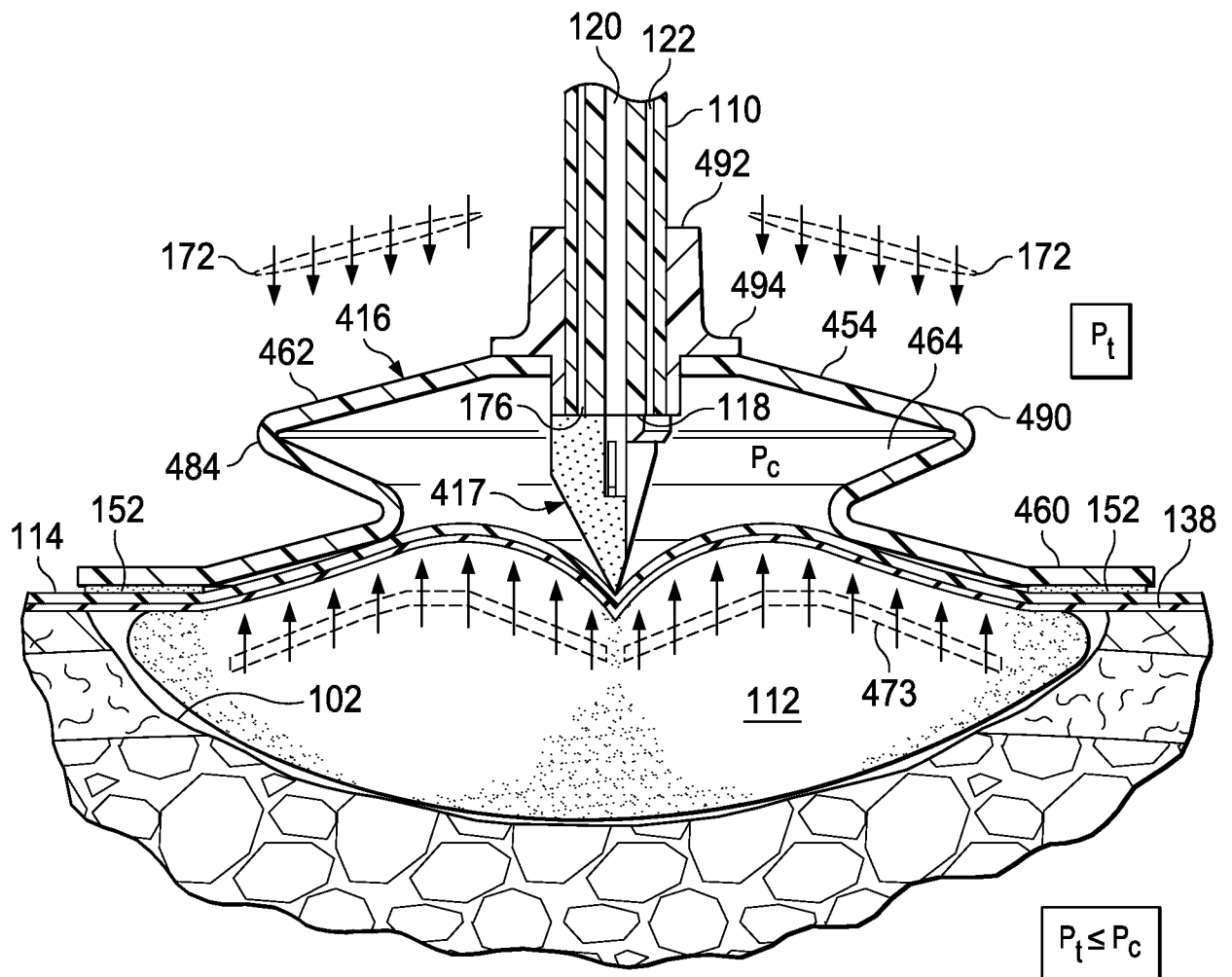


FIG. 9B

10/10

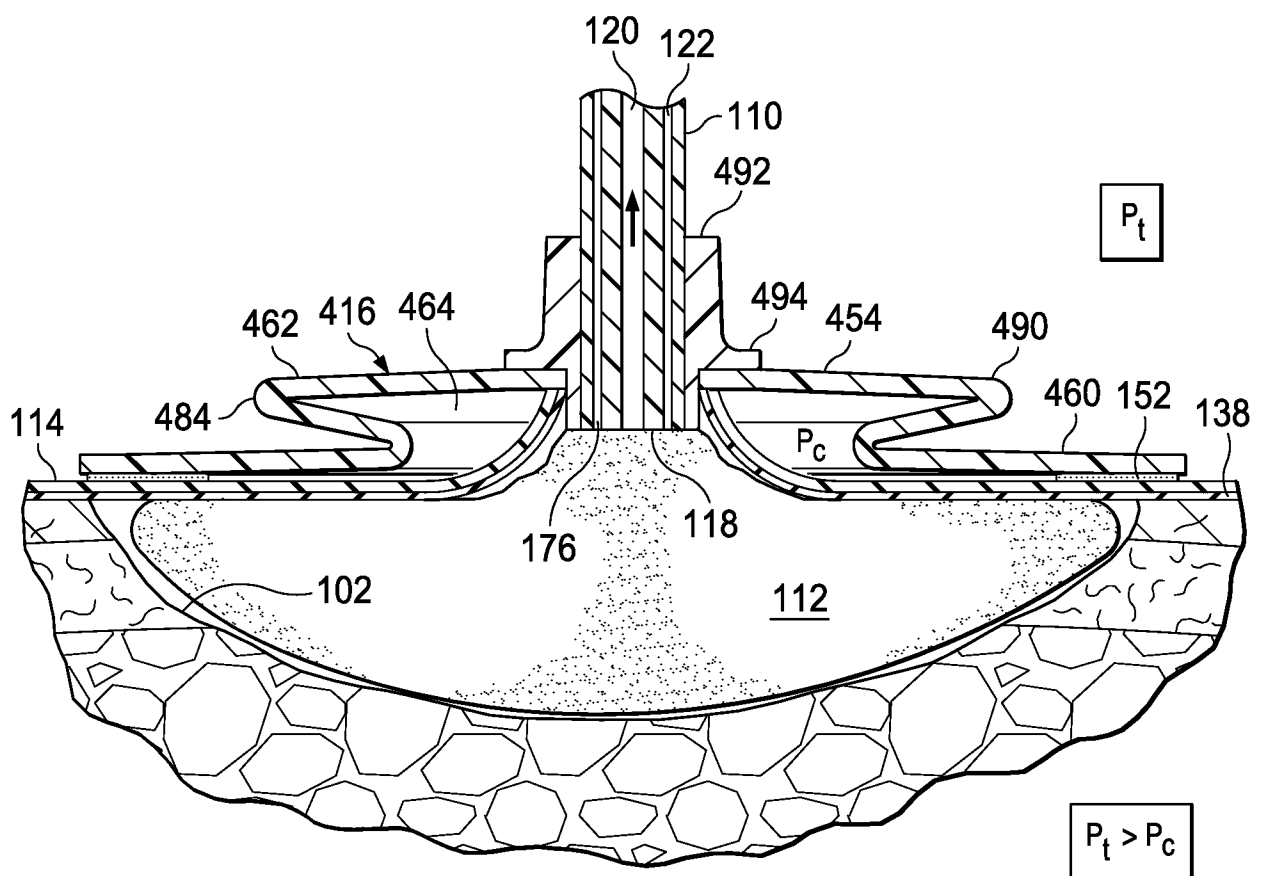


FIG. 9C

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2012/047733

A. CLASSIFICATION OF SUBJECT MATTER  
INV. 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)  
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	US 2009/270820 A1 (JOHNSON ROYCE W [US] ET AL) 29 October 2009 (2009-10-29) paragraphs [0078], [0079], [0090], [0091], [0094] - [0096], [0100], [0105], [0106]; figures 11f, 12a-e, 13ab -----	1-14, 29-31, 33
A	WO 03/073970 A1 (HILL ROM SERVICES INC [US]; LOCKWOOD JEFFREY S [US]; PETROSENKO ROBERT) 12 September 2003 (2003-09-12) page 13, line 14 - line 21; figure 7 -----	9



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

19 October 2012

Date of mailing of the international search report

26/10/2012

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040,  
Fax: (+31-70) 340-3016

Authorized officer

Lakkis, Angeliki

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2012/047733

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP 1487389 A1	22-12-2004
		US 2005085795 A1	21-04-2005
		WO 03073970 A1	12-09-2003
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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2012/047733

### 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.: 15-28, 32  
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.: 34  
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.1

Claims Nos.: 15-28, 32

Claims 15-28, 32: Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy and/or surgery. Reason: presence of a surgical/therapeutical step: "delivering reduced pressure to the multi-lumen conduit or to the first conduit and thus to a tissue site or wound of a patient.

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Continuation of Box II.2

Claims Nos.: 34

Claim 34: According to Rule 6.2(a) PCT claims shall not, except where absolutely necessary, rely, in respect of the technical features of the invention, on references to the description or drawings. However, in the present case, it is apparently possible to define the subject-matter claimed in technical terms. Consequently, claim 34 has 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 Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.