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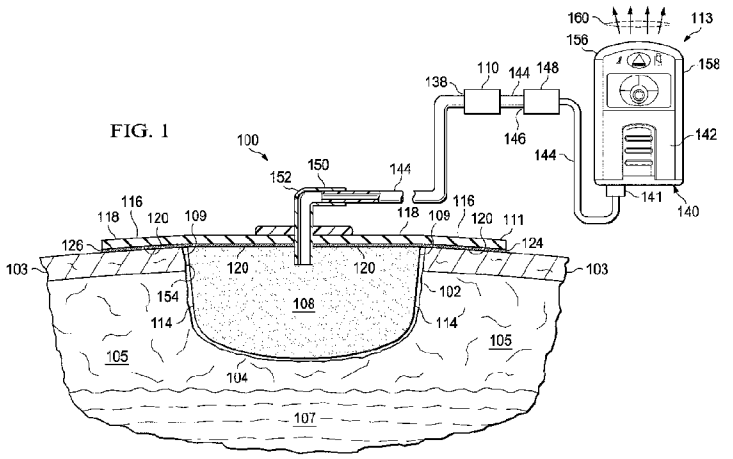
(54) Title: REDUCED-PRESSURE SOURCES, SYSTEMS, AND METHODS EMPLOYING A POLYMERIC, POROUS, HYDROPHOBIC MATERIAL

FIG. 1




(57) Abstract: Reduced-pressure sources, systems, and methods involve using a vacuum pump that is disposed within a sealed space to produce reduced pressure. The exhaust from the vacuum pump is exhausted from the sealed space through pores in an enclosure member that is made of a polymeric, porous, hydrophobic material. Other devices, systems, and methods are disclosed.

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# TITLE OF THE INVENTION

## REDUCED-PRESSURE SOURCES, SYSTEMS, AND METHODS EMPLOYING A POLYMERIC, POROUS, HYDROPHOBIC MATERIAL

### 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 61/359,205, entitled "Evaporative Body Fluid Containers and Methods," filed 28 June 2010, which is incorporated herein by reference for all purposes; U.S. Provisional Patent Application serial number 61/325,115, entitled "Reduced-Pressure Sources, Systems, and Methods Employing A Polymeric, Porous, Hydrophobic Material," filed 16 April 2010, which is incorporated herein by reference for all purposes; and U.S. Provisional Patent Application serial number 61/359,181, entitled "Dressings and Methods For Treating a Tissue Site On A Patient," filed 28 June 2010, which is incorporated herein by reference for all purposes.

### BACKGROUND

**[0002]** The present disclosure relates generally to reduced-pressure medical treatment systems and, more particularly, but not by way of limitation, to reduced-pressure sources, systems, and methods.

**[0003]** Clinical studies and practice have shown that providing a reduced pressure in proximity to a tissue site augments and accelerates the growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but application of reduced pressure has been particularly successful in treating wounds. This treatment (frequently referred to in the medical community as "negative pressure wound therapy," "reduced pressure therapy," or "vacuum therapy") provides a number of benefits, which may include faster healing and increased formulation of granulation tissue. Typically, reduced pressure is applied to tissue through a porous pad or other manifold device. The porous pad distributes reduced pressure to the tissue and channels fluids that are drawn from the tissue.

**[0003a]** Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

**[0003b]** It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

SUMMARY

**[0003c]** According to a first aspect, the present invention provides a reduced-pressure source for use with a reduced-pressure system for treating a tissue site on a patient, the reduced-pressure source comprising:

a pump housing forming a sealed space having a positive-pressure chamber and a reduced-pressure chamber, wherein an enclosure member forms at least a portion of the positive-pressure chamber;

a vacuum pump disposed within the sealed space, the vacuum pump having a reduced-pressure outlet fluidly coupled to the reduced-pressure chamber and an exhaust outlet fluidly coupled to the positive-pressure chamber; and

wherein the enclosure member comprises a polymeric, porous, hydrophobic material for preventing ingress of liquid and allowing the exhaust gas to exit the positive-pressure chamber under pressure.

**[0003d]** According to a second aspect, the present invention provides a system for treating a tissue site on a patient with reduced pressure, the system comprising:

a treatment manifold for placing proximate to the tissue site for distributing reduced pressure to the tissue site;

a reduced-pressure source fluidly coupled to the treatment manifold for providing reduced pressure to the treatment manifold;

a sealing member for forming a fluid seal over the tissue site; and

wherein the reduced-pressure source comprises:

a pump housing forming a sealed space, wherein an enclosure member forms at least a portion of the pump housing,

a vacuum pump disposed in the sealed space,

a reduced-pressure outlet fluidly coupled to the vacuum pump and configured to discharge reduced pressure out of the vacuum pump to a reduced-pressure chamber,

an exhaust outlet fluidly coupled to the vacuum pump and configured to discharge an exhaust gas from the vacuum pump to the sealed space, and

wherein the enclosure member comprises a polymeric, porous, hydrophobic material and is configured so that the exhaust gas exits the sealed space through the enclosure member under pressure.

**[0003e]** According to a third aspect, the present invention provides a method of treating a tissue site with reduced pressure, the method comprising:

forming a sealed space configured to block the passage of liquids, wherein at least a portion of the sealed space is formed by an enclosure member comprising a polymeric, porous, hydrophobic material;

disposing a vacuum pump within the sealed space, wherein the vacuum pump includes a reduced-pressure outlet and an exhaust outlet;

discharging a reduced pressure out of the vacuum pump to a reduced-pressure chamber;

discharging an exhaust gas from the vacuum pump through the exhaust outlet to the sealed space;

exhausting the exhaust gas from the sealed space through the enclosure member without a vent aperture; and

delivering the reduced pressure to the tissue site.

**[0003f]** According to a fourth aspect, the present invention provides a method of manufacturing a reduced-pressure sourcye for use with a reduced-pressure system for treating a tissue site on a patient, the method comprising:

forming a pump housing that forms a sealed space, wherein forming the pump housing includes forming an enclosure member that comprises at least a portion of the pump housing;

disposing a vacuum pump within the sealed space, wherein the vacuum pump includes a reduced-pressure outlet fluidly coupled to the vacuum pump for delivering reduced pressure and an exhaust outlet fluidly coupled to the vacuum pump for delivering an exhaust gas from the vacuum pump to the sealed space; and

wherein the enclosure member comprises a polymeric, porous, hydrophobic material that is operable to prevent ingress of liquid and to allow the exhaust gas to exit the sealed space under pressure.

**[0003g]** According to a fifth aspect, the present invention provides a method for treating a tissue site on a patient, the method comprising:

disposing a treatment manifold proximate to the tissue site;

disposing an absorbent layer over the treatment manifold for receiving fluids from the tissue site;

fluidly coupling a micro-pump to the absorbent layer;

covering the treatment manifold, absorbent layer, and micro-pump with an enclosing cover to form a sealed space;

wherein the micro-pump includes an exhaust outlet and is for generating reduced pressure and an exhaust that exits an exhaust outlet of the micro-pump;

wherein at least a portion of the enclosing cover is formed from a polymeric, porous, hydrophobic material and is operable to prevent ingress of liquid and to allow the exhaust to egress the sealed space;

activating the micro-pump to produce reduced pressure and the exhaust; and

wherein the exhaust from the micro-pump exits the sealed space through the enclosing cover.

**[0003h]** According to a sixth aspect, the present invention provides a dressing for treating a tissue site on a patient with reduced pressure, the dressing comprising:

a treatment manifold for placing proximate to the tissue site;

an absorbent layer for receiving and retaining fluids from the tissue site;

a micro-pump having an exhaust outlet, the micro-pump for generating reduced pressure and an exhaust that exits the exhaust outlet;

an enclosing cover covering the treatment manifold, the absorbent layer, and the micro-pump to form a sealed space that is liquid-tight, the sealed space having a first portion and a second portion;

wherein in the exhaust outlet of the micro-pump is fluidly coupled to the first portion of the sealed space to provide exhaust to the first portion of the sealed space and the micro-pump is fluidly coupled to the second portion of the sealed space to provide reduced pressure to the second portion of the sealed space; and

wherein at least a portion of the enclosing cover is formed from a polymeric, porous, hydrophobic material and is configured to allow the exhaust to egress the sealed space under pressure.

**[0003i]** Unless the context clearly requires otherwise, throughout the description and the claims, the words "comprise", "comprising", and the like are to be construed in an

inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

**[0004]** According to an illustrative embodiment, a reduced-pressure source for use with a reduced-pressure system for treating a tissue site on a patient includes an enclosure member forming, at least in part, a sealed space and a vacuum pump disposed within the sealed space. The reduced-pressure source also includes a reduced-pressure outlet fluidly coupled to the vacuum pump for delivering reduced pressure and includes an exhaust outlet fluidly coupled to the vacuum pump for delivering an exhaust gas from the vacuum pump to the sealed space. The enclosure member comprises a polymeric, porous, hydrophobic material for allowing the exhaust gas to exit the sealed space.

**[0005]** According to another illustrative embodiment, a system for treating a tissue site on a patient with reduced pressure includes a treatment manifold for placing proximate to the tissue site for distributing reduced pressure to the tissue site, a reduced-pressure source fluidly coupled to the treatment manifold for providing reduced pressure to the treatment manifold, and a sealing member for forming a fluid seal over the tissue site. The reduced-pressure source includes an enclosure member forming, at least in part, a sealed space, and includes a vacuum pump disposed in the sealed space. The reduced-pressure source also includes a reduced-pressure outlet fluidly coupled to the vacuum pump for delivering reduced pressure and an exhaust outlet fluidly coupled to the vacuum pump for delivering an exhaust gas from the vacuum pump to the sealed space. The enclosure member comprises a polymeric, porous, hydrophobic material for allowing the exhaust gas to exit the sealed space.

**[0006]** According to another illustrative embodiment, a method of generating reduced pressure for use with a reduced-pressure system for treating a tissue site on a patient includes forming a sealed space and disposing a vacuum pump within the sealed space. At least a portion of the sealed space is formed by an enclosure member comprising a polymeric, porous, hydrophobic material. The vacuum pump includes a reduced-pressure outlet and an exhaust outlet. The enclosure member allows the exhaust gas to exit the sealed space. The method further includes exhausting the exhaust gas substantially from the sealed space through the enclosure member and delivering the reduced pressure to a desired location.

**[0007]** According to another illustrative embodiment, a method of manufacturing a reduced-pressure source for use with a reduced-pressure system for treating a tissue site on a patient includes forming an enclosure member for enclosing, at least in part, a sealed space and disposing a vacuum pump within the sealed space. The vacuum pump includes a reduced-pressure outlet fluidly coupled to the vacuum pump for delivering reduced pressure and an exhaust outlet fluidly coupled to the vacuum pump for delivering an exhaust gas from the vacuum pump to the sealed space. The step of forming an enclosure member includes forming an enclosure member from a polymeric, porous, hydrophobic material that allows the exhaust gas to exit the sealed space.

**[0008]** According to another illustrative embodiment, a dressing for treating a tissue site on a patient with reduced pressure includes a treatment manifold for placing proximate to the tissue site, an absorbent layer for receiving and retaining fluids from the tissue site, and a micro-pump having an exhaust outlet. The micro-pump generates reduced pressure and an exhaust that exits the exhaust outlet. The dressing further includes an enclosing cover for covering treatment manifold, the absorbent layer, and the micro-pump. The enclosing cover forms a sealed space. At least a portion of the enclosing cover is formed from a polymeric, porous, hydrophobic material that allows the exhaust to egress the sealed space.

**[0009]** According to another illustrative embodiment, a method for treating a tissue site on a patient includes disposing a treatment manifold proximate to the tissue site, disposing an absorbent layer over the treatment manifold for receiving fluids from the tissue site, and fluidly coupling a micro-pump to the absorbent layer. The method further includes covering the treatment manifold, absorbent layer, and micro-pump with an enclosing cover to form a sealed space. The sealed space has a first portion and a second portion. The micro-pump includes an exhaust outlet and a reduced-pressure outlet. The first portion of the sealed space is fluidly coupled to the micro-pump and receives exhaust from the exhaust outlet. The second portion of the sealed space is fluidly coupled to the micro-pump and receives reduced pressure. At least a portion of the enclosing cover is formed from a polymeric, porous, hydrophobic material that allows the exhaust to egress the first portion of the sealed space. The method also includes activating the micro-pump to produce reduced pressure and an exhaust and allowing the exhaust from the micro-pump to exit the sealed space through the enclosing cover.

**[0010]** 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

**[0011]** FIGURE 1 is a schematic diagram with a portion shown in cross section of an illustrative embodiment of a reduced-pressure treatment system employing a reduced-pressure source;

**[0012]** FIGURE 2 is a schematic, perspective view showing a back side of an illustrative embodiment of the reduced-pressure source of FIGURE 1;

**[0013]** FIGURE 3 is a schematic diagram of an illustrative embodiment of a reduced-pressure source;

**[0014]** FIGURE 4 is a schematic, front view of an illustrative embodiment of a reduced-pressure source;

**[0015]** FIGURE 5 is a schematic, perspective view of another illustrative embodiment of a reduced-pressure source shown as part of a dressing; and

**[0016]** FIGURE 6 is a schematic cross sectional view of a portion of the reduced-pressure source of FIGURE 5.

## DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

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

**[0018]** According to an illustrative embodiment, a reduced-pressure source 140, 240, 340, 440 is provided that is substantially liquid-tight such that liquids on an exterior of the reduced-pressure source 140, 240, 340, 440 cannot enter the reduced-pressure source 140, 240, 340, 440, but gases or vapors can exit the reduced-pressure source 140, 240, 340, 440. In this way, a user may engage in activities involving liquids, e.g., a shower or sweat-producing exercise, without the potential for liquids to enter the reduced-pressure source 140, 240, 340, 440.

**[0019]** Referring now to the drawings and primarily to FIGURE 1, an illustrative embodiment of a reduced-pressure treatment system 100 for treating a tissue site 104, such as a wound 102, is presented. The wound 102 may be centered in a wound bed. The wound 102 may be through or involve epidermis 103, dermis 105, and subcutaneous tissue 107. The reduced-pressure treatment system 100 may also be used at other tissue sites. 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, vascular tissue, connective tissue, cartilage, tendons, ligaments, or any other tissue. Unless otherwise indicated, as used herein, "or" does not require mutual exclusivity.

**[0020]** The reduced-pressure treatment system 100 includes a treatment manifold 108. In addition, the reduced-pressure treatment system 100 includes a sealing member 111 and a reduced-pressure subsystem 113. The reduced-pressure subsystem 113 includes a reduced-pressure source 140 that is sealed to prevent liquid ingress and yet allows gas—typically air—to be vented without an aperture (i.e., a macroscopic aperture) as will be described further below.

**[0021]** In one illustrative embodiment, the treatment manifold 108 is made from a porous and permeable foam or foam-like material and, more particularly, a reticulated, open-cell polyurethane or polyether foam that allows good permeability of wound fluids while under a reduced pressure. One such foam material that has been used is the VAC® GranuFoam® Dressing available from Kinetic Concepts, Inc. (KCI) of San Antonio, Texas. Any material or combination of materials may be used for the manifold material provided that the manifold material is adapted to distribute the reduced pressure. 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 a tissue site. A manifold typically includes a plurality of flow channels or pathways. The plurality of flow channels may be interconnected to improve distribution of fluids provided to and removed from the area of tissue around the manifold. Examples of manifolds may include, without limitation, devices that have structural elements arranged to form flow channels, cellular foam, such as open-cell foam, porous tissue collections, and liquids, gels, and foams that include or cure to include flow channels.

**[0022]** The sealing member 111 covers the treatment manifold 108 and extends past a peripheral edge 114 of the treatment manifold 108 to form a sealing-member extension 116. The sealing-member extension 116 has a first side 118 and a second, patient-facing side 120. The sealing-member extension 116 may be sealed against epidermis 103 or against a gasket or drape by sealing apparatus 124, such as a pressure-sensitive adhesive 126. The sealing apparatus 124 may take numerous forms, such as an adhesive sealing tape, or drape tape or strip; double-side drape tape; pressure-sensitive adhesive 126; paste; hydrocolloid; hydrogel; or other sealing means. If a tape is used, the tape may be formed of the same material as the sealing member 111 with a pre-applied, pressure-sensitive adhesive. The pressure-sensitive adhesive 126 may be applied on the second, patient-facing side 120 of the sealing-member extension 116. The pressure-sensitive adhesive 126 provides a substantial fluid seal between the sealing member 111 and the epidermis 103, which, as used herein, is also deemed to include a gasket or drape against the epidermis 103. Before the sealing member 111 is secured to the epidermis 103, removable strips covering the pressure-sensitive adhesive 126 may be removed. As used herein, "fluid seal" means a seal adequate to maintain reduced pressure at a desired site given the particular reduced-pressure source or subsystem involved.

**[0023]** The sealing member 111 may be an elastomeric material or any material or substance that provides a fluid seal. "Elastomeric" means having the properties of an

elastomer and generally refers to a polymeric material that has rubber-like properties. More specifically, most elastomers have an ultimate elongation greater than 100% and a significant amount of resilience. The resilience of a material refers to the material's ability to recover from an elastic deformation. Examples of elastomers may include, but are not limited to, natural rubbers, polyisoprene, styrene butadiene rubber, chloroprene rubber, polybutadiene, nitrile rubber, butyl rubber, ethylene propylene rubber, ethylene propylene diene monomer, chlorosulfonated polyethylene, polysulfide rubber, polyurethane, EVA film, co-polyester, and silicones. Further still, sealing member materials may include a silicone drape, 3M Tegaderm® drape, acrylic drape such as one available from Avery Dennison.

**[0024]** The reduced-pressure subsystem 113 includes the reduced-pressure source 140, which may take many different forms. The reduced-pressure source 140 provides reduced pressure as a part of the reduced-pressure treatment system 100. As used herein, "reduced pressure" generally refers to a pressure less than the ambient pressure at a tissue site 104 that is being subjected to treatment. In most cases, this reduced pressure will be less than the atmospheric pressure at which the patient is located. Alternatively, the reduced pressure may be less than a hydrostatic pressure at a tissue site. Reduced pressure may initially generate fluid flow in the treatment manifold 108, a reduced-pressure delivery conduit 144, and adjacent to 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. Unless otherwise indicated, values of pressure stated herein are gauge pressures.

**[0025]** The reduced pressure delivered may be constant or varied (patterned or random) and may be delivered continuously or intermittently. Consistent with the use herein, an increase in reduced pressure or vacuum pressure typically refers to a reduction in absolute pressure.

**[0026]** The reduced-pressure source 140 is shown having a reservoir region 142, or canister region. An interposed membrane filter, such as hydrophobic or oleophobic filter, may be interspersed between the reduced-pressure delivery conduit 144, or tubing, and the reduced-pressure source 140. A portion 146 of the reduced-pressure delivery conduit 144 may have one or more devices, such as a representative device 148. The representative device 148 may be, for example, a fluid reservoir to hold exudates and other fluids removed, a pressure-feedback device, a volume detection system, a blood detection system, an infection detection system, a flow monitoring system, or a temperature monitoring system. Multiple

representative devices 148 may be included in series or parallel. For example, a second representative device 110 may be included on a portion 138 of the reduced-pressure delivery conduit 144. Some of these devices may be formed integrally with the reduced-pressure source 140. For example, a reduced-pressure port 141 on reduced-pressure source 140 may include a filter member that includes one or more filters, e.g., an odor filter.

**[0027]** The reduced-pressure source 140 may be any device for supplying a reduced pressure, such as a portable therapy unit, a stationary therapy unit, or other device. 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.

**[0028]** The reduced pressure developed by reduced-pressure source 140 is delivered through the reduced-pressure delivery conduit 144 to a reduced-pressure interface 150, which may include an elbow port 152. In one illustrative embodiment, the elbow port 152 is a TRAC® technology port available from Kinetic Concepts, Inc. of San Antonio, Texas. The reduced-pressure interface 150 allows the reduced pressure to be delivered through the sealing member 111 to the treatment manifold 108, as well as to a sealed space 154, or sealed treatment space, in which the treatment manifold 108 is located. In this illustrative embodiment, the reduced-pressure interface 150 extends through the sealing member 111 and into the treatment manifold 108.

**[0029]** In operation according to one illustrative embodiment, the treatment manifold 108 is placed adjacent the tissue site 104, e.g., in the wound bed on wound 102, with a portion near a wound edge 109. The sealing member 111 is placed over the tissue site 104 and the treatment manifold 108 and at least partially against epidermis 103 (or gasket or drape) to form a fluid seal and the sealed space 154. If not already installed, the reduced-pressure interface 150 is installed. The reduced-pressure delivery conduit 144 is fluidly coupled to the reduced-pressure interface 150 and the reduced-pressure source 140 whereby reduced pressure may be provided to the treatment manifold 108. The reduced-pressure source 140 may be activated to begin the delivery of reduced pressure to the treatment manifold 108 in the sealed space 154.

**[0030]** Referring now primarily to FIGURES 1 and 2, the reduced-pressure source 140 is water proof or water resistant and uses a sealed space (not explicitly shown). The sealed space may be formed by two chambers or areas: one for positive pressure and one for reduced pressure. The reduced pressure chamber may be one or more conduits in the first chamber (e.g., conduits 268, 244 in FIG. 3). The sealed space is formed within a pump housing 156. The pump housing 156 is formed by or includes an enclosure member 158. The enclosure member 158 is formed from a polymeric, porous, hydrophobic material. The pump housing 156 may be formed completely using the enclosure member 158 or the enclosure member 158 may form only a portion of the pump housing 156.

**[0031]** A vacuum pump (not shown) is disposed within the sealed space. The polymeric, porous, hydrophobic material allows an exhaust gas from the vacuum pump within the sealed space to exit when under pressure while not allowing the ingress of fluids. The polymeric, porous, hydrophobic material allows the exhaust gas to exit without requiring a vent aperture, but instead uses pores and the properties of the material. The exhaust gas exiting the enclosure member 158 is represented by arrows 160. The sealed space also functions to make the reduced-pressure source 140 operate with a lower decibel level from a perspective of outside the pump housing 156. The vacuum pump may have a conduit associated with the vacuum pump that delivers reduced pressure from the vacuum pump through the sealed space to a reduced-pressure outlet (not shown) that is fluidly coupled to the reduced-pressure port 141.

**[0032]** The polymeric, porous, hydrophobic material may be any polymeric material that allows the exhaust gas to exit through the material and keeps fluids from entering the sealed space. The polymeric, porous, hydrophobic material is porous so in the first instance it will allow the passage of gas through its pores. The hydrophobic nature of the polymer, however, will block the passage of essentially aqueous liquids through the pores due to surface tension effects.

**[0033]** There is a relationship that describes the pressure required to push a liquid of a certain surface tension through an orifice, of a given pore size, of a material of a given surface energy (this pressure is sometimes called the "breakthrough pressure"). For example, to create a given breakthrough pressure for water passing through a pore could be achieved with a large pore low surface energy material, or a small pore high surface energy material. The following equation may be used to describe the relationship: $P = -2 \sigma \cos \theta r$, where P = breakthrough pressure; $\theta$ = contact angle between liquid and pore material (is a function of the surface energy of the contact surface and surface tension of the contacting liquid); $\sigma$ = surface tension of the contacting liquid; and r = radius of the pore. In an embodiment, the breakthrough pressure is such that liquids do not break through for the pressure range involved. Thus, gas may exit, but liquids do not.

**[0034]** In on embodiment, the polymeric, porous, hydrophobic material is formed from a hydrophobic sintered polymer that is porous and gas permeable. Most polymers that can be made into a particulate may be used, e.g., polyolefins such as polyethylene, and polypropylene, polyamines, polyethylene vinyl acetate, polyvinyl chloride, styrenics (e.g., polystyrnene and copolymers including styrene acrylics), or polytetrafluoroethylene. The polymeric, porous, hydrophobic material may be a hydrophobic, spun-bonded high-density polyethylene fibers or material, such as a TYVEK® material form E.I. Du Pont De Nemours and Company Corporation of Wilmington, Delaware.

**[0035]** The polymeric, porous, hydrophobic material may also be formed with hydrophobic bonded, porous fibers. The polymeric, porous, hydrophobic material may also be formed by starting with a hydrophilic material and treating the material, e.g., with a plasma treatment, to make the material hydrophobic. Also, a hard polymer may be used that is caused to be porous by drilling micro-apertures (1 micron or sub micron), such as with a laser. If not already hydrophobic, the drilled polymer may be treated with a plasma. In addition, an odor-absorbing material may be added to the polymeric, porous, hydrophobic material to help remove odors as the exhaust gas exits. The odor-absorbing material may be, for example, charcoal, clays such as bentonite clay, porous silicas, zeolites, and aluminas, or substrates and supports that contains charcoal or activated carbon, for example polymeric meshes and membranes. Other substances may be added such as anti-microbials, silver, or dyes.

**[0036]** The pump housing 156 may be formed completely by injection, or transfer, or compression, or rotational molding, or thermoforming (vacuum forming) using the polymeric, porous, hydrophobic material. In another embodiment, the pump housing 156 may be formed

with a first portion, or enclosure member 158, formed from the polymeric, porous, hydrophobic material and a second portion formed from a polymer or other material having greater rigidity than the polymeric, porous, hydrophobic material. As will be described further below, the pump housing 156 may also be a dressing covering in some embodiments. The pump housing 156 may be made to be flexible and translucent if desired. The translucent portion allows visual feedback on what is occurring in the sealed space. A liquid-sensitive dye may be associated with the pump housing 156 by either including it in the polymeric, porous, hydrophobic material or coating the polymeric, porous, hydrophobic material. The liquid-sensitive dye changes color upon becoming wet and thus serves as a leak indicator.

**[0037]** While FIGURES 1 and 2 show the polymeric, porous, hydrophobic material utilized as an enclosure member 158 on a pump housing 156, it should be understood that the enclosure member 158 may be used as the pump housing 156, a vent panel, or a dressing cover depending on the desired application. With the reduced-pressure source 140, which is portable in the illustrative embodiment shown in FIGURE 1, the sealed space is substantially liquid-tight and, thus, the wearer may engage in activities subject to fluids on the exterior, e.g., taking a shower, without fluids entering the reduced-pressure source 140.

**[0038]** Referring now primarily to FIGURE 3, a schematic diagram of a reduced-pressure source 240 is presented that has a portion removed to allow components in a sealed space 262 to be visible. The reduced-pressure source 240 has a pump housing 256. The pump housing 256 may be formed totally or in part by an enclosure member 258. The pump housing 256 forms the sealed space 262. Accordingly, the sealed space 262 may be formed in part or totally by the enclosure member 258. The sealed space 262 is sealed to prevent or inhibit the ingress of liquids, such as water, and also inhibits the entry of particulates, such as dust.

**[0039]** A vacuum pump 264, which may include any device for generating a reduced pressure, is disposed within the sealed space 262. The vacuum pump 264 has a reduced-pressure outlet 266 that is fluidly coupled to the vacuum pump 264 and that discharges reduced pressure 269 out of the vacuum pump 264. In this embodiment, the reduced-pressure outlet 266 is fluidly coupled to a transport conduit 268, which is a second chamber. The transport conduit 268 delivers the reduced pressure to a canister 270. The canister 270 is for receiving and retaining fluids, such as exudates. The canister 270 is fluidly coupled to a reduced-pressure delivery conduit 244. The vacuum pump 264 also has an exhaust outlet 272 that discharges exhaust 274, or exhaust gas 274, from the vacuum pump 264. The reduced-

pressure delivery conduit 244 delivers reduced pressure 269 to another location, such as a tissue site, and typically receives fluids 276.

**[0040]** The exhaust 274 is delivered into the sealed space 262. As the exhaust gas 274 increases the pressure within the sealed space 262, the exhaust gas 274 is moved through the enclosure member 258 as suggested by arrows 260 without a vent aperture. The enclosure member 258 is made from the same materials and in the same various ways as the enclosure member 158 in FIGURES 1-2. Thus, the exhaust 274 exits through pores in the enclosure member 258.

**[0041]** Referring now primarily to FIGURE 4, another illustrative embodiment of a reduced-pressure source 340 is presented. The reduced-pressure source 340 is analogous in most respects to the reduced-pressure source 240 of FIGURE 3, and to show corresponding parts, the reference numerals have been indexed by 100. Thus, the reduced-pressure source 340 has a pump housing 356 that forms a sealed space (not explicitly shown) in which a vacuum pump (not shown) is disposed.

**[0042]** In this embodiment, a portion of the pump housing 356 is an enclosure member 358 that comprises a vent panel 378, which is gas permeable. The other portions of the pump housing 356 may not be gas permeable. The vent panel 378 is made of the same type of materials as and may be regarded as an enclosure member (e.g., enclosure member 158 of FIGURE 1). The vent panel 378 is adapted to allow the exhaust gas 360 to exit the sealed space without allowing liquids to enter and without requiring a vent aperture. The size of the vent panel 378 is dependent on the desired gas flow rate across the vent panel 378. Reduced pressure 369 is delivered through a reduced-pressure delivery conduit 344. Fluids 376 may also be received by the reduced-pressure delivery conduit 344.

**[0043]** In forming the vent panel 378 and pump housing 356, a laminate member of the polymeric, porous, hydrophobic material is formed into the vent panel 378. The vent panel 378 may then be overmolded to form the pump housing 356. This creates the vent panel 378 for allowing exhaust gases to exit the sealed space. The size of the vent panel will be determined by the need for an adequate flow rate of the exhaust gas from the sealed space.

**[0044]** According to one illustrative embodiment, the pump housing 356 and vent panel 378 are formed by starting with a filter block, or a laminate of filter material, and then overmolding, i.e., molding around the filter block in an injection molding process. Alternatively, the filter block or laminate may be bonded in place using a liquid or pressure sensitive sheet adhesive or otherwise attached.

**[0045]** Referring now primarily to FIGURES 5-6, another illustrative embodiment of a reduced-pressure source 440 is presented. The reduced-pressure source 440 is incorporated into a dressing 401 that is placed on a tissue site 404, such as a wound 402. The dressing 401 includes a treatment manifold 408 and a sealing layer 415. A micro-pump 464 is included to provide reduced pressure 469 to the treatment manifold 408 and to the tissue site 404.

**[0046]** The micro-pump 464 may include a piezoelectric disc pump, a diaphragm pump, a piston pump, a peristaltic pump, or other means of creating reduced pressure in a small space. The dressing 401 may also include a number of layers. For example, the dressing 401 may include an absorbent layer 471 that delivers or helps deliver reduced pressure and receives and retains fluids and may include a liquid-air separator 473 that is positioned between the absorbent layer 471 and the micro-pump 464 to inhibit liquid from entering the micro-pump 464. A diverter layer 475 may be disposed between the absorbent layer 471 and the micro-pump 464 that may include apertures (not shown) for transmitting reduced pressure from the micro-pump 464 to the absorbent layer 471. The micro-pump 464 may also include one or more batteries and controls (not shown).

**[0047]** The sealing member 411 may be deployed over a portion of the micro-pump 464, the sealing layer 415, and a portion of the patient's epidermis 403. The sealing member 411 may have a central aperture 417 over a portion of the micro-pump 464. An enclosing cover 458, which may be flexible or semi-flexible as with other members, is disposed over the central aperture 417 and a portion of the sealing member 411 to created a sealed space 462. The sealed space 462 may have two portions: a first portion 491 above (for the orientation shown) the micro-pump 464 and a second portion 493 below (for the orientation shown) the micro-pump 464. The first portion 491 is fluidly coupled to the micro-pump 464 and receives exhaust from an exhaust outlet 495 of the micro-pump 464. The second portion 493 is also fluidly coupled to the micro-pump 464 and receives reduced pressure from the micro-pump 464. At least a portion of the enclosing cover 458 is formed from a polymeric, porous, hydrophobic material that allows the exhaust to egress the first portion of the sealed space 462. That is, the enclosing cover 458, or at least a portion of the enclosing cover 458, is formed from the same materials as the previously-mentioned enclosure members 158, 258, 358, i.e., a polymeric, porous, hydrophobic material.

**[0048]** The central aperture 417 allows exhaust 474 from an exhaust outlet 472, which is on the surface of the micro-pump 464 in this embodiment, to exit the sealing member 411 and impinge upon the enclosing cover 458. As pressure rises, the exhaust gas 474 exits

through the polymeric, porous, hydrophobic material of the enclosure member 458. Fluids removed by the micro-pump 464 may be stored in the absorbent layer 471 of the dressing 401. In another embodiment, the enclosure member 458 may only comprise a portion of a cover over the absorbent layer 471 and the micro-pump 464, and in this embodiment, the enclosure member 458 covers at least the central aperture 417. In an alternative embodiment, the sealing member 411 may comprise the enclosure member 458.

**[0049]** Although the present invention and its advantages have been disclosed in the context of certain illustrative 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.

**[0050]** 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.

**[0051]** The steps of the methods described herein may be carried out in any suitable order, or simultaneously where appropriate.

**[0052]** 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.

**[0053]** It will be understood that the above description of preferred embodiments is given by way of example only and that various modifications may be made by those skilled in the art. The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments of the invention. Although various embodiments of the invention have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of the claims.

2011239545 02 Nov 2015

**CLAIMS**

We claim:

Claim 1. A reduced-pressure source for use with a reduced-pressure system for treating a tissue site on a patient, the reduced-pressure source comprising:

a pump housing forming a sealed space having a positive-pressure chamber and a reduced-pressure chamber, wherein an enclosure member forms at least a portion of the positive-pressure chamber;

a vacuum pump disposed within the sealed space, the vacuum pump having a reduced-pressure outlet fluidly coupled to the reduced-pressure chamber and an exhaust outlet fluidly coupled to the positive-pressure chamber; and

wherein the enclosure member comprises a polymeric, porous, hydrophobic material for preventing ingress of liquid and allowing the exhaust gas to exit the positive-pressure chamber under pressure.

Claim 2. The reduced-pressure source of claim 1, wherein the polymeric, porous, hydrophobic material comprises a hydrophobic sintered polymer.

Claim 3. The reduced-pressure source of claim 1, wherein the polymeric, porous, hydrophobic material comprises a hydrophobic spun-bonded material.

Claim 4. The reduced-pressure source of claim 1, wherein the polymeric, porous, hydrophobic material comprises hydrophobic bonded, porous fibers.

Claim 5. The reduced-pressure source of claim 1, wherein the polymeric, porous, hydrophobic material comprises a polyolefin material.

Claim 6. The reduced-pressure source of any one of the preceding claims, wherein the enclosure member comprises an injection molded member.

Claim 7. The reduced-pressure source of any one of the preceding claims, further comprises a liquid-sensitive dye associated with the enclosure member and adapted to change colors upon becoming wet.

Claim 8. The reduced-pressure source of any one of the preceding claims, wherein the enclosure member is translucent.

Claim 9. The reduced-pressure source of any one of the preceding claims, wherein the enclosure member comprises the complete pump housing.

Claim 10. The reduced-pressure source of any one of claims 1-8, wherein the enclosure member comprises a vent panel on the pump housing.

Claim 11. The reduced-pressure source of any one of the preceding claims, wherein the enclosure member comprises a dressing covering and the vacuum pump comprises a micro-pump disposed between the dressing covering and the patient.

Claim 12. The reduced-pressure source of any one of the preceding claims, wherein the polymeric, porous, hydrophobic material comprises an odor-absorbing material.

Claim 13. A system for treating a tissue site on a patient with reduced pressure, the system comprising:

a treatment manifold for placing proximate to the tissue site for distributing reduced pressure to the tissue site;

a reduced-pressure source fluidly coupled to the treatment manifold for providing reduced pressure to the treatment manifold;

a sealing member for forming a fluid seal over the tissue site; and

wherein the reduced-pressure source comprises:

a pump housing forming a sealed space, wherein an enclosure member forms at least a portion of the pump housing,

a vacuum pump disposed in the sealed space,

a reduced-pressure outlet fluidly coupled to the vacuum pump and configured to discharge reduced pressure out of the vacuum pump to a reduced-pressure chamber,

an exhaust outlet fluidly coupled to the vacuum pump and configured to discharge an exhaust gas from the vacuum pump to the sealed space, and

wherein the enclosure member comprises a polymeric, porous, hydrophobic material and is configured so that the exhaust gas exits the sealed space through the enclosure member under pressure.

Claim 14. The system of claim 13, wherein the polymeric, porous, hydrophobic material comprises a hydrophobic sintered polymer.

Claim 15. The system of claim 13, wherein the polymeric, porous, hydrophobic material comprises a hydrophobic spun-bonded material.

Claim 16. The system of claim 13, wherein the polymeric, porous, hydrophobic material comprises hydrophobic bonded, porous fibers.

Claim 17. The system of claim 13, wherein the polymeric, porous, hydrophobic material comprises a polyolefin material.

Claim 18. The system of any one of claims 13-17, wherein the enclosure member comprises an injection molded member.

Claim 19. The system of any one of claims 13-18, further comprises a liquid-sensitive dye associated with the enclosure member and adapted to change colors upon becoming wet.

Claim 20. The system of any one of claims 13-19, wherein the enclosure member is translucent.

Claim 21. The system of any one of claims 13-20, wherein the enclosure member comprises the complete pump housing.

Claim 22. The system of any one of claims 13-20, wherein the enclosure member comprises a vent panel on the pump housing.

Claim 23. The system of any one of claims 13-22, wherein the enclosure member comprises a dressing covering and the vacuum pump comprises a micro-pump disposed between the dressing covering and the patient.

Claim 24. The system of any one of claims 13-23, wherein the polymeric, porous, hydrophobic material comprises an odor-absorbing material.

Claim 25. A method of treating a tissue site with reduced pressure, the method comprising:

forming a sealed space configured to block the passage of liquids, wherein at least a portion of the sealed space is formed by an enclosure member comprising a polymeric, porous, hydrophobic material;

disposing a vacuum pump within the sealed space, wherein the vacuum pump includes a reduced-pressure outlet and an exhaust outlet;

discharging a reduced pressure out of the vacuum pump to a reduced-pressure chamber;

discharging an exhaust gas from the vacuum pump through the exhaust outlet to the sealed space;

exhausting the exhaust gas from the sealed space through the enclosure member without a vent aperture; and

delivering the reduced pressure to the tissue site.

Claim 26. The method of claim 25, wherein the polymeric, porous, hydrophobic material comprises a hydrophobic sintered polymer.

Claim 27. The method of claim 25, wherein the polymeric, porous, hydrophobic material comprises a hydrophobic spun-bonded material.

Claim 28. The method of claim 25, wherein the polymeric, porous, hydrophobic material comprises hydrophobic bonded, porous fibers.

Claim 29. The method of claim 25, wherein the polymeric, porous, hydrophobic material comprises a polyolefin material.

Claim 30. The method of claim 25, wherein the polymeric, porous, hydrophobic material comprises a hydrophobic sintered polymer and a liquid-sensitive dye associated with the enclosure member that is adapted to change colors upon becoming wet.

Claim 31. The method of any one of claims 25-30, wherein the enclosure member comprises the complete pump housing.

Claim 32. The method of any one of claims 25-30, wherein the enclosure member comprises a vent panel on the pump housing.

Claim 33. The method of any one of claims 25-32, wherein the enclosure member comprises a dressing covering and the vacuum pump comprises a micro-pump disposed between the dressing covering and the patient.

Claim 34. The method of any one of claims 25-33, wherein the polymeric, porous, hydrophobic material comprises an odor-absorbing material.

Claim 35. A method of manufacturing a reduced-pressure source for use with a reduced-

pressure system for treating a tissue site on a patient, the method comprising:

forming a pump housing that forms a sealed space, wherein forming the pump housing includes forming an enclosure member that comprises at least a portion of the pump housing;

disposing a vacuum pump within the sealed space, wherein the vacuum pump includes a reduced-pressure outlet fluidly coupled to the vacuum pump for delivering reduced pressure and an exhaust outlet fluidly coupled to the vacuum pump for delivering an exhaust gas from the vacuum pump to the sealed space; and

wherein the enclosure member comprises a polymeric, porous, hydrophobic material that is operable to prevent ingress of liquid and to allow the exhaust gas to exit the sealed space under pressure.

Claim 36. The method of claim 35, wherein the step of forming the pump housing comprises injection molding the enclosure member.

Claim 37. The method of claim 35 or claim 36, wherein the step of forming an enclosure member comprises forming a laminate member and overmolding around the laminate member to form the enclosure member.

Claim 38. The method of claim 35 or claim 36, wherein the step of forming an enclosure member comprises forming a polymer member and forming pores therethrough.

Claim 39. The method of claim 35 or claim 36, wherein the step of forming an enclosure member comprises injection molding a first portion enclosure member from the polymeric, porous, hydrophobic material and injection molding a second portion from a material more rigid than the polymeric, porous, hydrophobic material.

Claim 40. A method for treating a tissue site on a patient, the method comprising:

disposing a treatment manifold proximate to the tissue site;

disposing an absorbent layer over the treatment manifold for receiving fluids from the tissue site;

fluidly coupling a micro-pump to the absorbent layer;

covering the treatment manifold, absorbent layer, and micro-pump with an enclosing cover to form a sealed space;

wherein the micro-pump includes an exhaust outlet and is for generating reduced

pressure and an exhaust that exits an exhaust outlet of the micro-pump;

wherein at least a portion of the enclosing cover is formed from a polymeric, porous, hydrophobic material and is operable to prevent ingress of liquid and to allow the exhaust to egress the sealed space;

activating the micro-pump to produce reduced pressure and the exhaust; and

wherein the exhaust from the micro-pump exits the sealed space through the enclosing cover.

Claim 41. The method of claim 40, wherein the polymeric, porous, hydrophobic material comprises a hydrophobic sintered material.

Claim 42. The method of claim 40, wherein the polymeric, porous, hydrophobic material comprises a hydrophobic spun-bonded material.

Claim 43. The method of claim 40, wherein the polymeric, porous, hydrophobic material comprises hydrophobic bonded, porous fibers.

Claim 44. The method of claim 40, wherein the polymeric, porous, hydrophobic material comprises a polyolefin material.

Claim 45. The method of any one of claims 40-44, further comprising a liquid-gas separator and a diverter layer.

Claim 46. The method of any one of claims 40-44, further comprising a liquid-gas separator for preventing liquids from the tissue site from reaching the micro-pump, a diverter layer for distributing reduced pressure from the micro-pump, a sealing layer for placing proximate to the tissue site outboard of the treatment manifold, and a sealing member for disposing over at least a portion of the enclosing cover.

Claim 47. A dressing for treating a tissue site on a patient with reduced pressure, the dressing comprising:

a treatment manifold for placing proximate to the tissue site;

an absorbent layer for receiving and retaining fluids from the tissue site;

a micro-pump having an exhaust outlet, the micro-pump for generating reduced pressure and an exhaust that exits the exhaust outlet;

an enclosing cover covering the treatment manifold, the absorbent layer, and the

micro-pump to form a sealed space that is liquid-tight, the sealed space having a first portion and a second portion;

wherein in the exhaust outlet of the micro-pump is fluidly coupled to the first portion of the sealed space to provide exhaust to the first portion of the sealed space and the micro-pump is fluidly coupled to the second portion of the sealed space to provide reduced pressure to the second portion of the sealed space; and

wherein at least a portion of the enclosing cover is formed from a polymeric, porous, hydrophobic material and is configured to allow the exhaust to egress the sealed space under pressure.

Claim 48. The dressing of claim 47, wherein the polymeric, porous, hydrophobic material comprises a hydrophobic sintered material.

Claim 49. The dressing of claim 47, wherein the polymeric, porous, hydrophobic material comprises a hydrophobic spun-bonded material.

Claim 50. The dressing of claim 47, wherein the polymeric, porous, hydrophobic material comprises hydrophobic bonded, porous fibers.

Claim 51. The dressing of claim 47, wherein the polymeric, porous, hydrophobic material comprises a polyolefin material.

Claim 52. The dressing of any one of claims 47-51, further comprising a liquid-gas separator and a diverter layer.

Claim 53. The dressing of any of claims 47-51, further comprising a liquid-gas separator for preventing liquids from the tissue site from reaching the micro-pump, a diverter layer for distributing reduced pressure from the micro-pump, a sealing layer for placing proximate to the tissue site outboard of the treatment manifold, and a sealing member for disposing over at least a portion of the enclosing cover.

Claim 54. A reduced-pressure source manufactured by the method of any one of claims 35-39.

Claim 55. Use of a reduced-pressure source according to any one of claims 1-12, a system according to any one of claims 13-24, or a dressing according to any one of claims 47-53 for treating a tissue site on a patient.

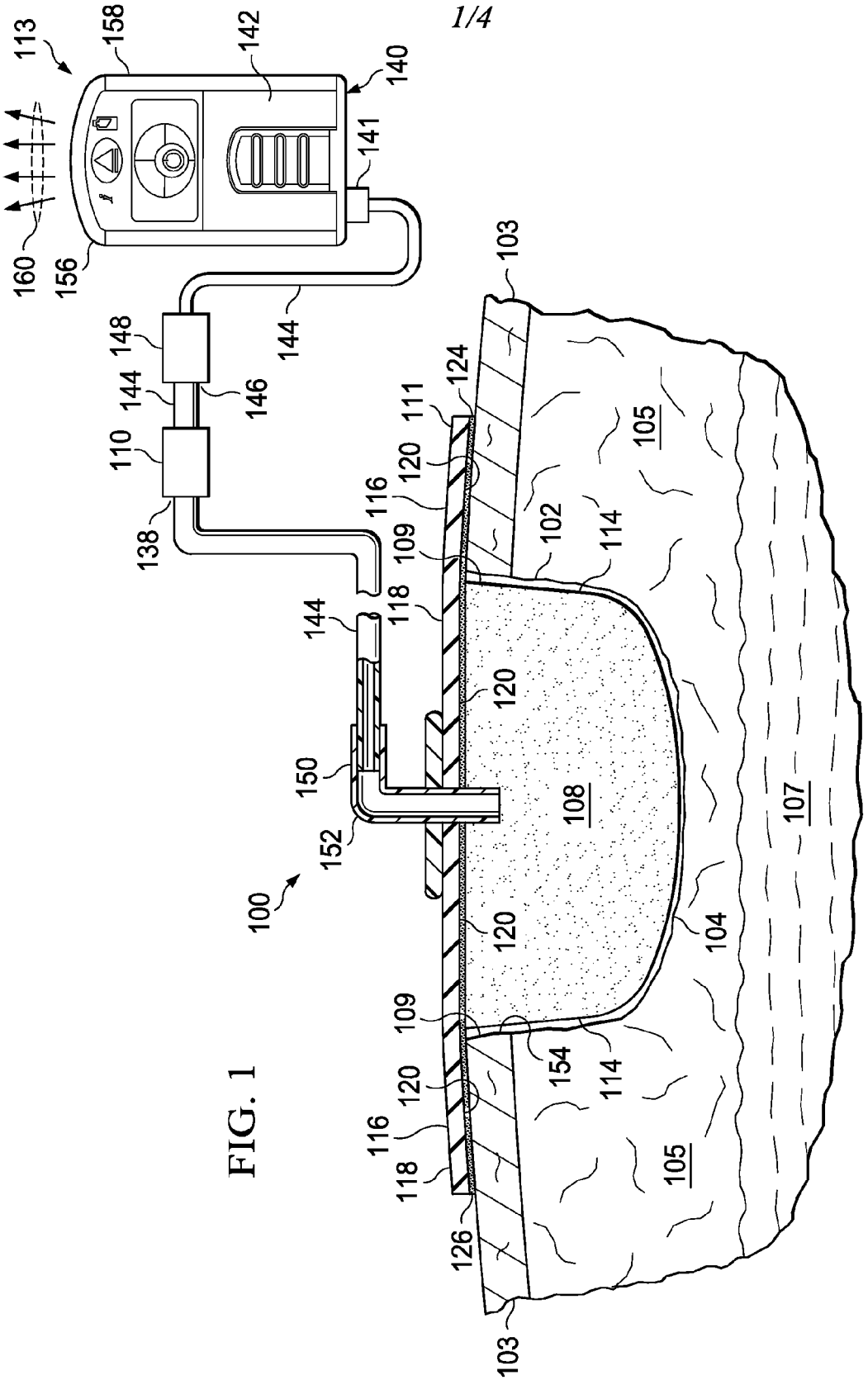
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FIG. 1

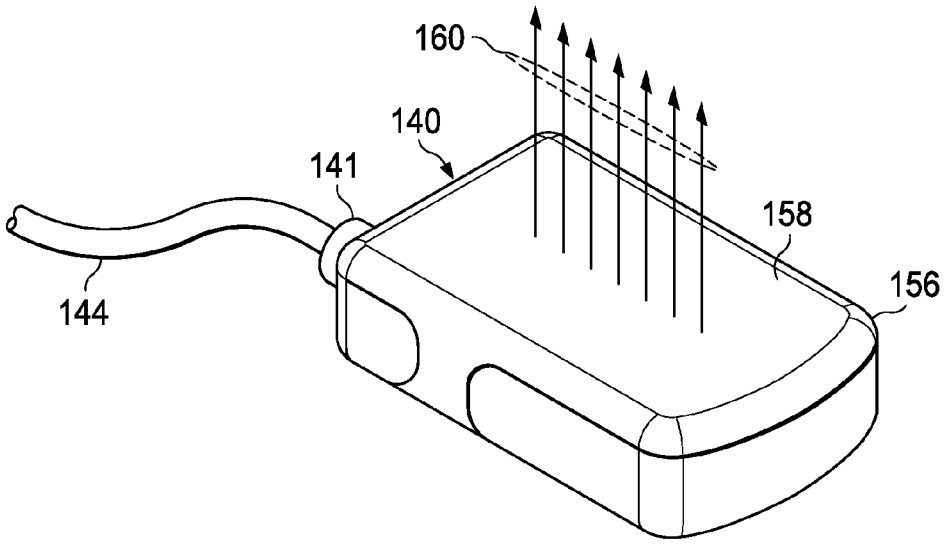


FIG. 2

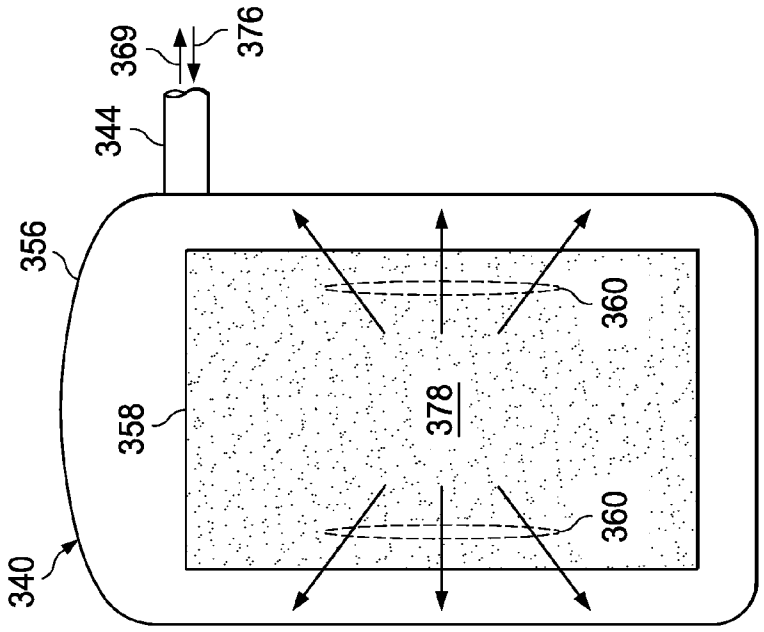
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FIG. 4

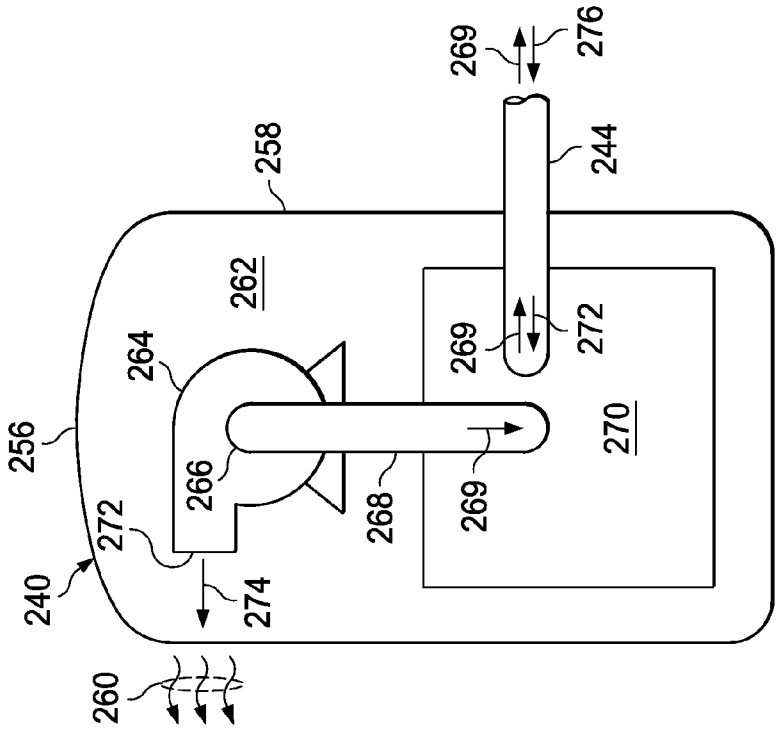
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FIG. 3

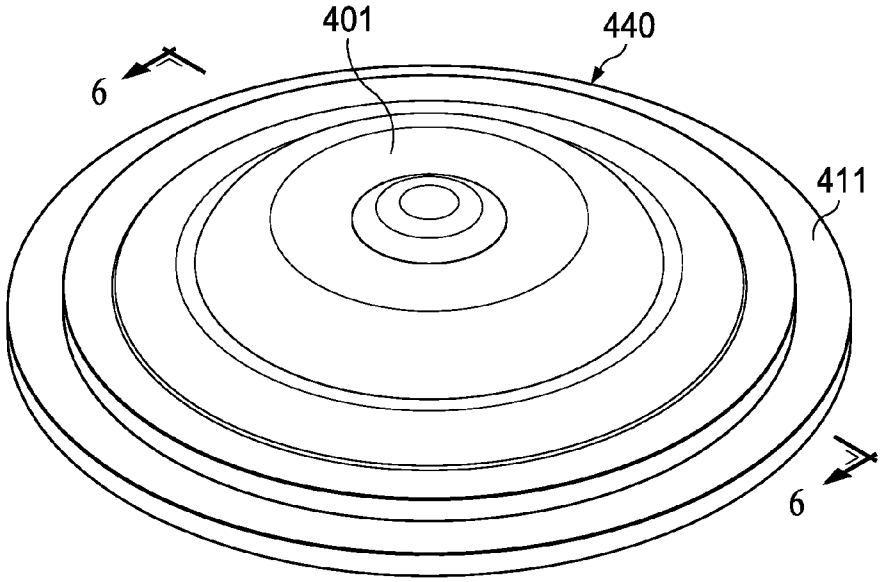
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FIG. 5

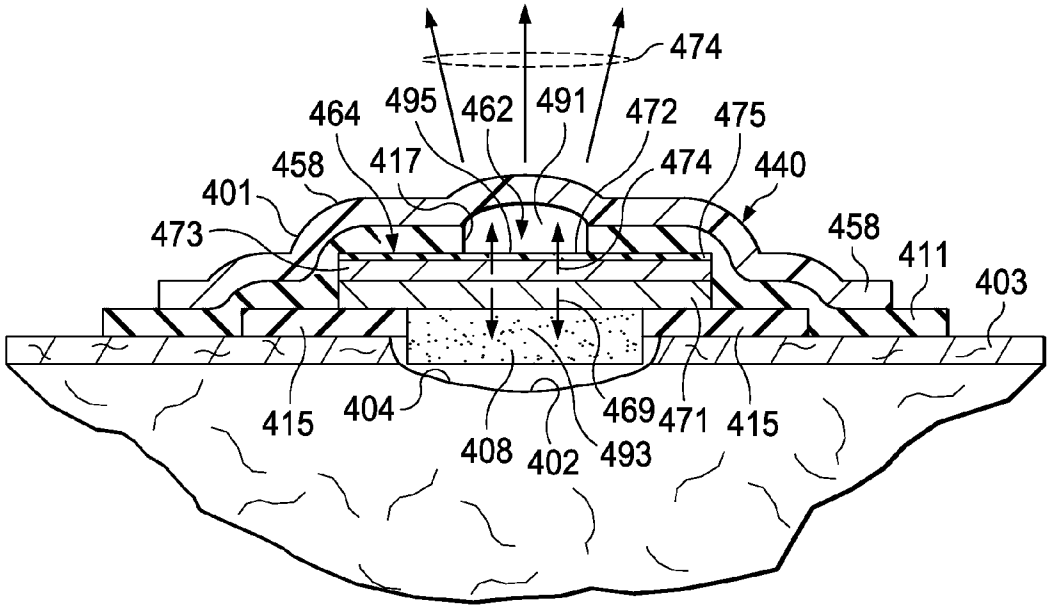
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FIG. 6