

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
28 July 2011 (28.07.2011)

PCT

(10) International Publication Number
WO 2011/090996 A2

(51) International Patent Classification:

A61M 39/24 (2006.01) **A61L 15/40** (2006.01)
A61M 1/00 (2006.01) **A61M 27/00** (2006.01)
A61F 13/00 (2006.01)

(21) International Application Number:

PCT/US2011/021665

(22) International Filing Date:

19 January 2011 (19.01.2011)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/296,822 20 January 2010 (20.01.2010) US

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

(72) Inventors; and

(75) Inventors/Applicants (for US only): **PERKINS, Joanna** [US/US]; P.O. Box 659508, San Antonio, TX 78265 (US). **SLACK, Paul** [CA/US]; P.O. Box 659508, San Antonio, TX 78265 (US). **HIGLEY, Kevin** [US/US]; P.O. Box 659508, San Antonio, TX 78265 (US). **KNOWLES, Kenneth** [US/US]; P.O. Box 659508, San Antonio, TX 78265 (US). **TOUT, Aiden** [GB/GB]; P.O. Box 659508, San Antonio, TX 78265 (US).

(74) Agent: **ROBINSON, Eagle, H.**; Fulbright & Jaworski L.L.P., 600 Congress Ave., Suite 2400, Austin, TX 78701 (US).

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

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report (Rule 48.2(g))

(54) Title: LEAK-RESISTANT BANDAGE SYSTEMS AND METHODS WITH HYDROPHILIC FOAM WOUND INSERT FOR FLUID-INSTILLATION AND/OR NEGATIVE-PRESSURE WOUND THERAPIES

(57) Abstract: Wound treatment systems and methods (e.g., having hydrophilic wound inserts), such as for negative-pressure and/or fluid-installation wound therapies. Some embodiments include a check-valve assembly between a wound dressing and a vacuum source.



WO 2011/090996 A2

DESCRIPTION

LEAK-RESISTANT BANDAGE SYSTEMS AND METHODS WITH HYDROPHILIC FOAM WOUND INSERT FOR FLUID-INSTILLATION AND/OR NEGATIVE- PRESSURE WOUND THERAPIES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application No. 61/296,822, filed January 20, 2010, which is incorporated herein in its entirety.

BACKGROUND

1. Field of the Invention

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

2. Background Information

[0003] Clinical studies and practice have shown that providing a reduced pressure in proximity to a tissue site augments and accelerates the growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but application of reduced pressure has been particularly successful in treating wounds. This treatment (frequently referred to in the medical community as "negative pressure wound therapy," "reduced pressure therapy," or "vacuum therapy") provides a number of benefits, including faster healing and increased formulation of granulation tissue. Typically, reduced pressure is applied to tissue through a wound insert (e.g., a porous pad or other manifold device). The wound insert typically contains cells or pores that are capable of distributing reduced pressure to the tissue and channeling fluids that are drawn from the tissue. The wound insert can be incorporated into a wound dressing having other components that facilitate treatment, such as, for example, a drape (e.g., adhesive surgical drape). Instillation of fluids (e.g., irrigation fluids and/or medicaments) may be used in conjunction with negative pressure wound therapy to promote healing and/or improve efficacy.

[0004] While NPWT has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable, some difficulty remains. With current negative-pressure and/or fluid-instillation systems, leaks may occur at the dressing site due to the presence of fluid (e.g., instillation fluids, body fluids, etc.) and/or due to such fluids

being forced to the perimeter of a wound insert (e.g., a foam wound insert). Such fluids may interact with the adhesive between the drape and adjacent healthy skin, and can lead to failure and leakage, thus requiring removal of a wound dressing and application of a new dressing. Such removal and re-application can be detrimental to a patient as the wound is exposed to external atmosphere (e.g., bacteria, contaminants, and the like). Further, fluid forced to the edges of wound can pool and/or macerate/damage the periwound skin and/or intact skin.

SUMMARY

[0005] The present disclosure includes embodiments of methods of forming a wound insert, wound-treatment methods, wound dressings, and wound-treatment systems.

[0006] Some embodiments of the present check-valve assemblies comprise: a housing defining a first connection, a second connection, a first passageway between the first and second connections, and a second passageway between the first and second connections that is distinct from the first passageway; a check valve disposed in the first passageway and configured to: permit fluid to pass through the check valve assembly from the first connection to the second connection if the pressure at the second connection is less than the pressure at the first connection; and substantially prevent fluid from passing through the check valve from the second connection to the first connection if the pressure at the second connection is greater than the pressure at the first connection. In some embodiments, the check valve comprises a duckbill valve. In some embodiments, the check valve comprises a ball valve. In some embodiments, the first connection comprises a multi-lumen connection having a first lumen in communication with the first passageway, and a second lumen in communication with the second passageway, and where the second connection comprises a multi-lumen connection having a first lumen in communication with the first passageway, and a second lumen in communication with the second passageway. In some embodiments, the second lumen of the first connection is an annular lumen disposed around the first lumen of the first connection, and where the second lumen of the second connection is an annular lumen disposed around the first lumen of the second connection.

[0007] Some embodiments of the present wound-treatment systems comprise: a fluid source configured to be coupled to a wound dressing such that the fluid source is actuatable to deliver a fluid to the wound dressing; a check-valve assembly configured to be coupled to a wound dressing; a vacuum source configured to be coupled to the check-valve assembly such that the vacuum source is actuatable to apply negative pressure to a wound dressing through the check-valve assembly; where the system is configured such that (e.g., if a wound dressing

is coupled to the fluid source, the vacuum source, and the check-valve assembly, and the wound dressing is coupled to skin adjacent a wound of a patient such that the wound dressing covers the wound to form a substantially enclosed space adjacent the wound) the check-valve assembly: substantially prevents fluid flow through the check-valve assembly toward the wound dressing.. In some embodiments, the system can be configured such that the check-valve assembly substantially prevents pressure in the space adjacent the wound from exceeding atmospheric pressure. Some embodiments further comprise: a wound dressing that comprises: a wound insert; and a drape configured to be coupled to skin adjacent a wound of a patient such that the drape covers the wound insert and the wound to form a space between the drape and the wound; In some embodiments, the wound insert comprises an open-celled hydrophilic foam. In some embodiments, the wound insert comprises a hydrophobic foam coated with a hydrophilic coating.

[0008] In some embodiments, the check-valve assembly comprises: a housing defining a first connection configured to be coupled to the wound dressing, a second connection configured to be coupled to the vacuum source, a first passageway between the first and second connections, and a second passageway between the first and second connections; a check valve disposed in the first passageway and configured to: permit fluid to pass through the check valve from the first connection to the second connection when the pressure at the second connection is less than the pressure at the first connection; and substantially prevent fluid from passing through the check valve from the second connection to the first connection when the pressure at the second connection is greater than the pressure at the first connection.

[0009] Some embodiments of the present wound-treatment methods comprise: applying negative pressure through a check-valve assembly and wound dressing to a wound of a patient, the wound dressing coupled to skin adjacent the wound such that the wound dressing covers the wound to form a substantially enclosed space adjacent the wound; and delivering a fluid to the wound dressing; where the check-valve assembly is configured to: substantially prevent backflow of fluids through the check-valve assembly, and substantially prevent pressure in the space between the drape and the wound from exceeding atmospheric pressure. In some embodiments, the wound dressing comprises: a wound insert; and a drape coupled to skin adjacent the wound such that the drape covers the wound insert and the wound to form the substantially enclosed space between the drape and the wound.

[0010] In some embodiments, delivering a fluid comprises activating a fluid source that is coupled to the wound dressing. In some embodiments, applying negative pressure

comprises activating a vacuum source that is coupled to the wound dressing. In some embodiments, the wound insert comprises hydrophilic foam. In some embodiments, the wound insert comprises a hydrophobic foam coated with a hydrophilic coating. In some embodiments, the check-valve assembly comprises: a housing defining a first connection
5 configured to be coupled to the wound dressing, a second connection configured to be coupled to the vacuum source, a first passageway between the first and second connections, and a second passageway between the first and second connections; a check valve disposed in the first passageway and configured to: permit fluid to pass through the check valve from the first connection to the second connection when the pressure at the second connection is less than
10 the pressure at the first connection; and substantially prevent fluid from passing through the check valve from the second connection to the first connection when the pressure at the second connection is greater than the pressure at the first connection.

[0011] Some embodiments of the present wound-treatment methods comprise: coupling a wound dressing to skin adjacent a wound of a patient such that the wound dressing
15 covers the wound to form a substantially enclosed space adjacent the wound; coupling the wound dressing to a fluid source such that the fluid source is actuatable to deliver fluid to the wound dressing; coupling the wound dressing to a check-valve assembly and a vacuum source such that the check-valve assembly: substantially prevents backflow of fluids through the check-valve assembly. Some embodiments comprise configuring the system such that the
20 check-valve assembly also substantially prevents pressure in the space adjacent the wound from exceeding atmospheric pressure. In some embodiments, the wound dressing comprises: a wound insert comprising an open-celled foam configured to exhibit hydrophilic properties; and a drape; and where coupling the wound dressing comprises: positioning the wound insert on the wound; and coupling the drape to skin adjacent the wound such that the drape covers
25 the wound insert and the wound, and forms a space between the drape and the wound. Some embodiments further comprise: applying a negative pressure to the wound through the check-valve assembly and the wound dressing; and delivering a fluid to the wound through the wound dressing. In some embodiments, the wound insert comprises hydrophilic foam. In some embodiments, the wound insert comprises a hydrophobic foam coated with a
30 hydrophilic coating.

[0012] Any embodiment of any of the present systems and/or methods can consist of or consist essentially of - rather than comprise/include/contain/have - any of the described steps, elements, and/or features. Thus, in any of the claims, the term "consisting of" or "consisting essentially of" can be substituted for any of the open-ended linking verbs recited

above, in order to change the scope of a given claim from what it would otherwise be using the open-ended linking verb.

[0013] Details associated with the embodiments described above and others are presented below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The following drawings illustrate by way of example and not limitation. For the sake of brevity and clarity, every feature of a given structure is not always labeled in every figure in which that structure appears. Identical reference numbers do not necessarily indicate an identical structure. Rather, the same reference number may be used to indicate a similar feature or a feature with similar functionality, as may non-identical reference numbers.

[0015] **FIG. 1** depicts a side view of one embodiment of the present wound dressings having one of the present wound inserts and coupled to a wound site and to a wound treatment apparatus.

[0016] **FIG. 2A** depicts an enlarged side view of the wound insert of **FIG. 1**.

[0017] **FIGS. 2B** and **2C** depict photographs showing experimental comparisons of fluid interaction of hydrophilic wound inserts relative to that of a prior hydrophobic wound insert.

[0018] **FIG. 3** depicts a schematic block diagram of one embodiment of a wound treatment apparatus that can comprise and/or be coupled to and/or be used with the present wound dressings and/or wound inserts.

[0019] **FIG. 4** depicts a perspective view of one of the present check-valve assemblies.

[0020] **FIG. 5** depicts a cross-sectional side view of the check-valve assembly of **FIG. 4**.

[0021] **FIG. 6** depicts a cross-sectional side view of the check-valve assembly of **FIG. 4**.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0022] The term "coupled" is defined as connected, although not necessarily directly, and not necessarily mechanically; two items that are "coupled" may be integral with each other. The terms "a" and "an" are defined as one or more unless this disclosure explicitly requires otherwise. The terms "substantially," "approximately," and "about" are defined as largely but not necessarily wholly what is specified, as understood by a person of ordinary skill in the art.

[0023] The terms "comprise" (and any form of comprise, such as "comprises" and "comprising"), "have" (and any form of have, such as "has" and "having"), "include" (and any form of include, such as "includes" and "including") and "contain" (and any form of contain, such as "contains" and "containing") are open-ended linking verbs. As a result, a method that "comprises," "has," "includes" or "contains" one or more steps possesses those one or more steps, but is not limited to possessing only those one or more steps. Likewise, a wound dressing that "comprises," "has," "includes" or "contains" one or more elements possesses those one or more elements, but is not limited to possessing only those elements. For example, in a wound dressing that comprises a wound insert and a drape, the wound dressing includes the specified elements but is not limited to having only those elements. For example, such a wound dressing could also include a connection pad.

[0024] Further, a device or structure that is configured in a certain way is configured in at least that way, but it can also be configured in other ways than those specifically described.

[0025] Referring now to the drawings, and more particularly to **FIG. 1**, shown therein is an embodiment of one of the present wound treatment system **10**. In the embodiment shown, apparatus **10** comprises a wound-treatment apparatus **14**, and a wound dressing **18** coupled to apparatus **14** by a conduit **22**. As shown, dressing **18** is configured to be coupled to (and is shown coupled to) a wound **26** of a patient **30**. More particularly, in the embodiment shown, dressing **18** comprises a wound insert **34** and a drape **38**. As shown, wound insert **34** is configured to be positioned (and is shown positioned) on wound **26** (e.g., on or adjacent to wound surface **42**), and/or drape **38** is configured to be coupled to (and is shown coupled to) skin **46** of the patient adjacent to wound **26** such that drape **38** covers wound insert **34** and wound **26**, and forms a space **50** between drape **38** and wound **26** (e.g., wound surface **42**).

[0026] Apparatus **14** can comprise, for example, a vacuum source configured to be actuatable (and/or actuated) to apply negative pressure (e.g., via conduit **22**) to wound dressing **18**, a fluid source configured to be actuatable (and/or actuated) to deliver (e.g., via conduit **22**) a fluid (e.g., an installation fluid such as a medicinal fluid, antibacterial fluid, irrigation fluid, and or the like) to wound dressing **18**. System **10** can be implemented and/or actuated and/or coupled to patient **30** in any of various configurations and/or methods similar to those described in the prior art. For example, various wound therapy systems and components are commercially available through and/or from KCI USA, Inc. of San Antonio, Texas, U.S.A.

[0027] Conduit 22 can comprise a single lumen conduit (e.g., switched between a vacuum source and/or a fluid source and apparatus 14), or can comprise multiple single-lumen conduits or a multi-lumen conduit such that, for example, fluid can be delivered and/or negative pressure can be applied to wound dressing 18 individually and/or simultaneously.

5 Additionally, conduit 22 can comprise, for example, a first lumen for the application of negative pressure and/or fluid delivery, and at least one additional lumen for coupling to pressure sensor(s) to sense pressure (absolute pressure) or negative pressure (relative to atmospheric pressure) between drape 38 and surface 42. In some embodiments, conduit 22 can comprise multiple lumens (e.g., as in a single conduit with a central lumen for application
10 of negative pressure and/or fluid delivery, and one or more peripheral lumens disposed adjacent or around the central lumen such that the peripheral lumens can be coupled to a pressure sensor to sense a pressure or negative pressure between drape 38 and surface 42 (e.g. in space 50). The lumens may be arranged with a central lumen and other lumens disposed radially around the central lumen, or in other suitable arrangements. The lumens may also be
15 provided in separate conduits. In the embodiment shown, system 10 further comprises a wound dressing connection pad 54 configured to be coupled (and is shown coupled) to conduit 22. One example of a suitable connection pad 54 is the "V.A.C. T.R.A.C.® Pad," commercially available from KCI. One example of a suitable drape 38 includes the "V.A.C.® Drape" commercially available from KCI. Another example of a connection pad 54 is
20 disclosed in U.S. Pat. App. No. 11/702,822, published as Pub. No. US 2007/0219512 A1.

[0028] One example of a suitable drape 38 includes the "V.A.C.® Drape" commercially available from KCI USA, Inc. (and its affiliates) of San Antonio, Texas, U.S.A.

[0029] Referring now to FIG. 2A, a side view of wound insert 34 is shown. Wound insert 34 has an upper side 100, a lower side 104, lateral sides 108, 112, and interior volume
25 116. Although only one side is shown of wound insert 34, it will be understood by those of ordinary skill in the art that wound insert 34 includes a three-dimensional rectangular volume having a depth extending perpendicular to the side shown. In other embodiments, wound insert 34 can have any suitable shape, such as, for example, a round cylindrical shape, a fanciful shape, or may be trimmed to fit an irregular shape of a wound (e.g., 26 and/or wound
30 surface 42).

[0030] The present embodiments of wound insert 34 comprise a foam (e.g., an open-celled foam, which may also be reticulated) that is configured to exhibit hydrophilic properties. In contrast to hydrophobic foams traditionally used with NPWT systems and methods, the hydrophilic properties of wound insert 34 provide improved movement of fluid

(e.g., liquids such as instillation fluids, body fluids, exudate, and the like) through the wound insert, such that fluid is encouraged to travel through wound insert **34** rather than around the wound insert **34** or adjacent to the interface between drape **38** and skin **46**.

[0031] With traditional hydrophobic wound inserts, fluid typically travels in a path such that the fluid minimizes contact with the foam, and such that fluid is repelled from the foam and may generate pressure between the foam and interface between drape **38** and skin **46**. As such, hydrophobic wound inserts may force drape **38** away from skin **46** about the perimeter of wound **26**. More particularly, with traditional hydrophobic wound inserts, very little of the fluid is retained or transferred through the foam itself. Because fluid may be forced outward from the hydrophobic wound insert, the fluid can generate a positive pressure (in excess of atmospheric pressure) at the interface between the drape and skin adjacent to the wound. This can lead to a ballooning effect which can stress the interface between the drape and the adjacent skin, and can lead to failure of the adhesive generally used to couple the drape to the skin. The ballooning effect can be particularly problematic if negative pressure is applied cyclically (e.g., on and off) and if fluids are introduced into the wound (e.g., instillation therapy).

[0032] However, with the present hydrophilic wound inserts **34**, fluid can travel through or in at least a portion of wound insert **34** (e.g., evenly dispersed throughout wound insert **34**), thus decreasing the positive pressure within the space **50** and at the interface between drape **38** and skin **46**. As such, with the present hydrophilic wound inserts **34**, fluid typically will not reach the interface between drape **38** and skin **46** as quickly, such that the integrity of adhesive or the like coupling drape **38** to skin **46** is maintained longer and permits more durable adhesion between drape **38** and skin **46**. In this way, wound dressings **18** comprising drape **38** and wound insert **34** are typically more durable and/or less prone to failure.

[0033] As illustrated in **FIG. 1**, embodiments of the present wound dressings **18** comprise a wound insert **34** configured to be positioned on a wound **26** (e.g., wound surface **42**) of a patient (e.g., **30**), the wound insert comprising a foam (e.g., an open-celled foam, which may also be reticulated) configured to exhibit hydrophilic properties; and a drape **38** configured to be coupled to skin **46** of the patient adjacent the wound such that drape **38** covers wound insert **34** and wound **26** and forms a space **50** between the drape and the wound. Wound insert **34** can comprise any suitable material and/or combination of materials that permit wound insert **34** to exhibit hydrophilic properties. For example, in some embodiments, wound insert **34** comprises an open-celled hydrophobic foam that is coated with a hydrophilic

coating (e.g., a coating configured to cause the hydrophobic foam to exhibit hydrophilic properties). In some embodiments, the hydrophilic coating comprises polyvinyl alcohol (PVOH), plasticizer (e.g., triethyl citrate, or the like), hydrophilic polyurethane, gelatin, hyaluronic acid, heparin, and/or any other suitable coating configured to cause the coated hydrophobic foam to exhibit hydrophilic properties.

[0034] Embodiments of the present methods of forming wound insert **34** comprise: applying a hydrophilic coating to an open-celled (which may also be reticulated) hydrophobic foam, where the coating is configured to cause the foam to exhibit hydrophilic properties. In some embodiments, the hydrophilic coating comprises polyvinyl alcohol (PVOH), plasticizer (e.g., triethyl citrate, or the like), hydrophilic polyurethane, gelatin, hyaluronic acid, heparin, and/or any other suitable coating configured to cause the coated hydrophobic foam to exhibit hydrophilic properties. In such embodiments, the coating can comprise a fluid coating, such as those that may be applied to a foam in a liquid state and dried, cross-linked, and/or otherwise cured to coat the foam (e.g., such that the coating is stable on the foam even in the presence of a fluid or liquid).

[0035] Referring now to **FIGS. 2B** and **2C**, embodiments of the present wound inserts **34a** and **34b** are shown adjacent to a prior hydrophobic wound insert **36**. In **FIG. 2B**, wound inserts **34a**, **34b**, and **36** are shown with a lower end disposed in a fluid. Wound insert **34a** comprises a hydrophobic foam coated with a hydrophilic coating. Wound insert **34b** comprises a hydrophilic foam. In **FIG. 2C**, wound inserts **34a**, **34b**, and **36** are shown removed from the fluid such that the dispersion of fluid in each of the wound inserts can be seen relative to one another. As shown, hydrophilic foam wound inserts **34a** and **34b** permit fluid to traverse upward and disperse throughout wound inserts **34a** and **34b**. In contrast, hydrophobic wound insert **36** expands and substantially repels the fluid from traversing, entering, or otherwise becoming dispersed throughout wound insert **36**. In this way, wound insert **36** effectively forces fluid to the edges of wound insert **36** such that if wound insert **36** is used in a wound dressing **18**, the fluid that is repelled from wound insert **36** can exert an outward force on the interface between drape **38** and skin **46**, and/or can infiltrate the adhesive between drape **38** and skin **46**, as described above. In contrast, and as illustrated in **FIGS. 2B** and **2C**, hydrophilic foam wound inserts **34a** and **34b** permit fluid to traverse wound inserts **34a** and **34b** to substantially prevent and/or reduce outward forces on drape **38** (e.g., caused by positive pressure between drape **38** and wound **30**), and/or fluid infiltration of adhesive between drape **38** and skin **46**.

[0036] Embodiments of the present wound treatment methods may be better understood with reference to **FIG. 3**. **FIG. 3** depicts the schematic block diagram of one embodiment of system **10**. In the embodiment shown, wound dressing **18** is coupled to apparatus **14**, and apparatus **14** comprises a vacuum source **200** (e.g., a vacuum pump and/or the like) coupled to a canister **204** (e.g., configured to receive exudate and or the like from wound dressing **18**) by way of a conduit **208**. In the embodiment shown, apparatus **14** further comprises: a pressure sensor **212** having a first pressure transducer **216** coupled to conduit **208** by way of conduit **220** and/or tee-fitting **224**, and a second pressure transducer **228** coupled to canister **204** and/or wound dressing **18** by way of conduit **232**. Pressure sensor **212** is configured to sense the negative pressure in wound dressing **18** and/or any of the various conduits coupled to wound dressing **18**, pressure sensor **212**, and/or vacuum source **200**.

[0037] In the embodiment shown, apparatus **14** further comprises a pressure release valve **236** coupled to conduit **232**. Further, in the embodiment shown, canister **204** and vacuum source **200** are coupled to wound dressing **18** by way of a conduit **238**, a check-valve assembly **240** (which may also be referred to as a one-way valve assembly **240**), and a conduit **242**. More particularly, conduit **238** couples canister **204** to check-valve assembly **240**, and conduit **242** couples check-valve assembly **240** to wound dressing **18**. In the embodiment shown, canister **204** comprises a filter **244** at or near an outlet of canister **204** to prevent liquid or solid particles from entering conduit **208**. Filter **244** can comprise, for example, a bacterial filter that is hydrophobic and/or lipophilic such that aqueous and/or oily liquids will bead on the surface of the filter. Apparatus **14** can be configured such that during operation of vacuum source **200** will provide sufficient airflow through a filter **244** that the pressure drop across filter **244** is not substantial (e.g., such that the pressure drop will not substantially interfere with the application of negative pressure to wound dressing **18** from vacuum source **200**).

[0038] In various embodiments, such as the one shown in **FIG. 3**, apparatus **14** can be configured such that as soon as liquid in the canister reaches a level where filter **244** is occluded, a much-increased negative (or subatmospheric) pressure occurs in conduit **208** and is sensed by transducer **216**. Transducer **216** can be connected to circuitry that interprets such a pressure change as a filled canister and signals this by means of a message on an LCD and/or buzzer that canister **204** requires emptying and/or replacement, and/or that automatically shuts off or disables vacuum source **200**.

[0039] Apparatus **14** can also be configured to apply intermittent negative (or subatmospheric) pressure to the wound site, and/or such that pressure relief valve **236** enables

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

[0040] In the embodiment shown, apparatus 14 further comprises a fluid source 248 coupled to wound dressing 18 by way of a conduit 252 such that fluid source 248 is actuatable to deliver a fluid to wound dressing 18 (e.g., to the wound through the wound dressing). Fluid source 248 can be any suitable mechanism capable of delivering fluid, such as, for example, a syringe, a fluid pump, and/or the like. Typically, in systems such as apparatus 14 that do not have a check-valve assembly, before fluid is delivered to the wound dressing, the wound dressing (e.g., the space in the wound dressing) is returned to atmospheric pressure, and the conduit (e.g., conduit 238) between the wound dressing and the canister is clamped to prevent backflow of fluids of fluids through the check-valve assembly. This can lead to leakage and/or rupture of the adhesive boundary between the wound dressing 18 and the skin of the patient, because as fluid is delivered to the sealed (or substantially sealed) environment within the wound dressing, it can pressurize the wound dressing and/or force fluids to the boundary of the wound dressing.

[0041] However, in the embodiment shown, check-valve assembly 240 is configured to substantially prevent (prevent up to all, but may be subject to some leakage, such as during transition between open and closed configurations, as described in this disclosure) backflow (flow back towards wound dressing 18) of fluids through check-valve assembly 240 (e.g., from conduit 238 to conduit 242) and/or into wound dressing 18; and to substantially prevent pressure in the space adjacent the wound (e.g., within wound dressing 18) from exceeding atmospheric pressure, such as when pressure release valve 236 is opened to prevent canister 204 from exceeding atmospheric pressure (or if canister 204 is otherwise vented to prevent conduit 238 from exceeding atmospheric pressure). It should be appreciated that some backflow may occur from conduit 242 into wound dressing, but will be substantially prevented upstream of check-valve assembly 240 (e.g., from conduit 238). In some

embodiments, backflow from conduit **242** is minimized by placing or disposing check-valve assembly **240** adjacent to wound dressing **18** (e.g., within 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20 cm of wound dressing **18**) and/or making check-valve assembly **240** a part of wound dressing **18** (e.g., such that check valve assembly **240** is disposable with wound dressing **18**). For example, in some embodiments, check-valve assembly **240** is disposed within 5 cm or less of wound dressing **18** such that the volume is minimized within conduit **242** between check-valve assembly **240** and wound dressing **18**.

[0042] In the embodiment shown, negative pressure (a pressure below atmospheric pressure) in the wound dressing **18** can be maintained (e.g., the wound dressing **18** need not be returned to atmospheric pressure) prior to delivering fluid to the wound dressing, such that backflow is substantially prevented through the check-valve assembly **240** into wound dressing **18**, and such that as pressure in wound-dressing **18** increases to the pressure in conduit **238**, check-valve assembly will permit the flow of fluids (and the release of pressure) from one side of the check-valve assembly to the other (e.g., from wound dressing **18** and conduit **242**, through check-valve assembly **240**, to conduit **238**). In this way, check-valve assembly **240** is configured to maintain negative pressure at wound dressing **18** prior to instillation therapy (delivery of fluid to the wound dressing), thereby minimizing liquid leaks caused from ballooning and/or failure of the drape adhesive, and to minimize the amount of fluid that is wasted. For example, during normal operation, negative pressure can be maintained for a period of time at the wound dressing, and atmospheric pressure can be introduced at the canister (e.g., by venting canister **204** to atmosphere to cause the pressure in canister **204** to increase to atmospheric pressure (with the corresponding decrease in "negative pressure")). As fluid is metered into the wound dressing, the pressure at the wound site will increase until it reaches atmospheric pressure. Once the pressure in wound dressing **18** (and conduit **242**) reaches or exceeds the pressure in conduit **238** (and canister **204**), check-valve assembly **240** will permit flow across the check-valve assembly from conduit **242** to conduit **238**, and thereby prevent the wound dressing from overfilling.

[0043] Referring now to **FIGS. 4-6**, an embodiment **240a** is shown of the present check-valve assemblies. More particularly, **FIG. 4** depicts a perspective view of check-valve assembly **240a**; **FIG. 5** depicts a cross-sectional side view of check-valve assembly **240a**; and **FIG. 6** depicts a cross-sectional side view of check-valve assembly **240a**. In the embodiment shown, check-valve assembly **240a** comprises: a housing **300** defining a first connection **304**, and a second connection **308**. Housing **300** further defines a first passageway **312** between first and second connections **304** and **308**, and a second passageway **316** between first and

second connections **304** and **308**. As shown, second passageway **316** is distinct from (e.g., separate from and not in fluid communication with) first passageway **312**. In the embodiment shown, check-valve assembly **240a** further comprises a check valve **320** disposed in first passageway **312**, and configured to: permit fluid to pass through check valve **320** (e.g.,
5 through first passageway **312**) from first connection **304** to second connection **308** if the pressure at second connection **308** is less than the pressure at first connection **304**. In the embodiment shown, check valve **320** is further configured to substantially prevent (prevent up to all, but may be subject to some leakage, such as during transition between open and closed configurations, as described in this disclosure) fluid from passing through check valve **320**
10 from first connection **304** to second connection **308** if the pressure at second connection **308** is greater than the pressure at first connection **304**. For example, in the apparatus of **FIG. 3**, first connection **304** of check-valve assembly **240a** would be coupled to conduit **242**, and second connection **308** would be coupled to conduit **238**.

[0044] In the embodiment shown, housing **300** comprises a first member **324** and a
15 second member **328** configured to be coupled to one another by any suitable structure or method, such as, for example, with interlocking tabs, adhesive, screws, rivets, ultrasonic welding, thermal welding, or the like. In the embodiment shown, second member **328** has a coupling end **332** (e.g., opposing second connection **308**) having a groove **336** (e.g., a peripheral groove, as shown), and first member **324** has a coupling end **340** (e.g., opposing
20 first connection **304**) having a ridge **344** (e.g., a peripheral ridge, as shown) configured to extend into groove **336** when the first and second members **324** and **328** are coupled to one another, as shown in **FIGS. 5** and **6**, such that ridge **344** and groove **336** cooperate to improve the connection (e.g., the strength and/or integrity of the connection) between first and second members **324** and **328**. In the embodiment shown, first and second members **324** and **328** are
25 configured to be coupled to one another with adhesive and/or by ultrasonic welding. As shown, first and second members **324** and **328** cooperate to define first and second passageways **312** and **316**, and/or check valve **320** cooperates with first and second members **324** and **328** to seal between first and second housings **324** and **328** such that first passageway **312** is distinct from second passageway **316** (e.g., fluid communication is substantially
30 prevented between first and second passageways **312** and **316**).

[0045] In the embodiment shown, first connection **304** comprises a multi-lumen connection having a first lumen **348** in communication with first passageway **312**, and a second lumen **352** in communication with second passageway **316**. Additionally, in the embodiment shown, second connection **308** comprises a multi-lumen connection having a

first lumen **356** in communication with first passageway **312**, and a second lumen **360** in communication with second passageway **316**. More particularly, in the embodiment shown, second lumen **352** of first connection **304** is an annular lumen disposed around first lumen **348** of first connection **304**; and second lumen **360** of second connection **308** is an annular lumen disposed around first lumen **356** of second connection **308**.

[0046] In the embodiment shown, check valve **320** is a duckbill valve. In the embodiment shown, valve **320** comprises an enlarged base portion **364** configured to fit around the perimeter of first passageway **312** in housing **300**. Additionally, first and second members **324** and **328** (and/or enlarged base portion **364**) are configured such that when valve **320** is disposed in first passageway **312**, and first and second members **324** and **328** are coupled to one another, as shown in **FIGS. 5** and **6**, the first and second members compress at least a portion of enlarged base portion **364** to provide a seal between first and second members **324** and **328** and to substantially prevent fluid communication between first and second passageways **312** and **316** within housing **300**. More particularly, in the embodiment shown, first member **324** comprises a circular protrusion **368** having an angled or chamfered outer edge; and second member **328** comprises an angled ledge **372**. Protrusion **368** and ledge **372** are configured such that when valve **320** is disposed in first passageway **312**, and first and second members **324** and **328** are coupled to one another: protrusion **368** extends into the middle of and presses against an inner surface of enlarged base portion **364**, and ledge **372** presses against an outer surface of enlarged base portion **364**, such that protrusion **368** and ledge **372** cooperate to compress enlarged base portion **364** around the perimeter of first passageway **312**, as shown in **FIGS. 5** and **6**.

[0047] In the embodiment shown, the multi-lumen configuration of first and second connections permits check-valve assembly **240a** to be coupled to a multi-lumen conduit (e.g., a multi-lumen PVC tubing) between a wound dressing (e.g., **18**) and an apparatus comprising a vacuum source (e.g., **200**) and a pressure sensor (e.g., pressure transducer **212**). For example, some commercially available NPWT apparatuses are configured to combine the vacuum or negative pressure conduit (e.g., **240**, **242**) and the pressure-sensor conduit (e.g., **232**) into a single multi-lumen conduit (not shown), such that the pressure-sensor conduit comprises a plurality of peripheral lumens disposed around a central vacuum or negative pressure lumen in the multi-lumen conduit. To ensure communication between peripheral pressure-sensor lumens, first member **324** includes a shelf **376** in annular lumen **352**, and second member **328** includes a shelf **380** in annular lumen **360**, to prevent the peripheral pressure lumens in a multi-lumen tube from being blocked by first member **324**, such that

communication is permitted between the peripheral pressure-sensor lumens and the second passageway **316**.

[0048] In the embodiment shown, second member **328** comprises indents **384** (two indents **384** on opposite sides of first passageway **312**), and check valve **320** comprises protrusions **388** (two protrusions **388** on opposite sides of valve **320**) that correspond to indents **384**, such that indents **384** and protrusions **388** cooperate to orient valve **320** in body **300** and/or to prevent rotation of valve **320** in body **300**. Although valve **320** is shown as a duckbill valve, in other embodiments check valve **320** can comprise a ball valve or an umbrella valve.

[0049] Some embodiments of the present wound-treatment methods comprise: applying negative pressure through a check-valve assembly (e.g., **240**, **240a**) and wound dressing (e.g., **18**) to a wound (e.g., **26**) of a patient (e.g., **30**), the wound dressing coupled to skin (e.g., **46**) adjacent the wound such that the wound dressing covers the wound to form a substantially enclosed space (e.g., **50**) adjacent the wound. Some embodiments comprise delivering a fluid to the wound dressing (e.g., from a fluid source **248**). In some embodiments, the check-valve assembly is configured to: substantially prevent backflow of fluids through the check-valve assembly, and substantially prevent pressure in the space between the drape and the wound from exceeding atmospheric pressure. In some embodiments, delivering a fluid comprises activating a fluid source (e.g., **248**) that is coupled to the wound dressing. In some embodiments, applying negative pressure comprises activating a vacuum source (e.g., **200**) that is coupled to the wound dressing.

[0050] Some embodiments of the present wound-treatment methods comprise: coupling a wound dressing (e.g., **18**) to skin (e.g., **46**) adjacent a wound (e.g., **26**) of a patient (e.g., **30**) such that the wound dressing covers the wound to form a substantially enclosed space (e.g., **50**) adjacent the wound. Some embodiments comprise: coupling the wound dressing to a fluid source (e.g., **248**) such that the fluid source is actuatable to deliver fluid to the wound dressing. Some embodiments comprise: coupling the wound dressing to a check-valve assembly (e.g., **240**, **240a**) and a vacuum source (e.g., **200**) such that the check-valve assembly: substantially prevents backflow of fluids through the check-valve assembly. In some embodiments, the system can be configured such that the check-valve assembly substantially prevents pressure in the space adjacent the wound from exceeding atmospheric pressure, such as when pressure release valve **236** is opened to prevent canister **204** from exceeding atmospheric pressure (or if canister **204** is otherwise vented to prevent conduit **238** from exceeding atmospheric pressure). In some embodiments, the wound dressing comprises

a wound insert (e.g., 34) and a drape (e.g., 38), and coupling the wound dressing comprises: positioning the wound insert on the wound; and coupling the drape to skin adjacent the wound such that the drape covers the wound insert and the wound, and forms a space between the drape and the wound. Some embodiments comprise: applying a negative pressure to the wound through the check-valve assembly and the wound dressing; and delivering a fluid to the wound through the wound dressing.

[0051] Embodiments of any of the present methods can utilize, include the use of, and/or otherwise comprise any of the apparatuses, wound dressings, wound inserts, and/or check-valve assemblies described in this disclosure. In any of the present wound-treatment methods, fluid can be delivered to the wound dressing 18 prior to applying negative pressure to wound dressing 18, negative pressure can be applied to wound dressing 18 prior to fluid being delivered to wound dressing 18, and/or fluid can be delivered wound dressing 18 simultaneously with negative pressure being applied to wound dressing 18.

[0052] In some embodiments of the present wound-treatment methods, a skin preparation can be used in combination with the present wound dressings 18 to improve the adhesion and durability of the interface between drape 38 and skin 46, such as, for example, to mitigate and/or reduce leaks. For example, skin 46 adjacent wound 26 can be cleaned and coated with a coating that is impervious and/or insoluble in water. In this way, adhesion between drape 28 and coated skin 46 can be improved and/or can be made more durable by reducing its susceptibility to infiltration from water-based installation fluids that may be delivered to wound dressing 18 and/or to space 50. By way of another example, a coating can be applied to the skin (e.g., in a manner similar to certain adhesives) that dries or sets into a layer on top of the skin that is durable enough to reduce and/or prevent maceration of the skin to reduce trauma to the underlying skin upon removal of the drape from the skin.

[0053] The present embodiments of the systems, methods, and when dressings reduce the risks associated with fluid instillation by delaying and/or minimizing fluid contact and/or infiltration of the interface between drape 38 and skin 46 that could degrade adhesive that is often used to couple drape 38 to skin 46 when wound dressing 18 is coupled to a patient 30. Additionally, improved fluid management can decrease the positive pressure that might otherwise be generated at the interface between drape 38 and skin 46 so as to reduce mechanical strains that would otherwise act to pull drape 38.

[0054] The various illustrative embodiments of devices, systems, and methods described herein are not intended to be limited to the particular forms disclosed. Rather, they include all modifications and alternatives falling within the scope of the claims.

[0055] The claims are not intended to include, and should not be interpreted to include, means-plus- or step-plus-function limitations, unless such a limitation is explicitly recited in a given claim using the phrase(s) "means for" or "step for," respectively.

[0056] It will be understood that the benefits and advantages described above may relate to one embodiment or may relate to several embodiments. It will further be understood that reference to 'an' item refers to one or more of those items, unless otherwise specified.

[0057] The steps of the methods described herein may be carried out in any suitable order, or simultaneously where appropriate.

[0058] 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.

[0059] It will be understood that the above description of preferred embodiments is given by way of example only and that various modifications may be made by those skilled in the art. The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments. Although various embodiments have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of this invention.

CLAIMS

1. A check-valve assembly comprising:
a housing defining a first connection, a second connection, a first passageway between
5 the first and second connections, and a second passageway between the first
and second connections that is distinct from the first passageway;
a check valve disposed in the first passageway and configured to:
permit fluid to pass through the check valve assembly from the first connection
to the second connection if the pressure at the second connection is less
10 than the pressure at the first connection; and
substantially prevent fluid from passing through the check valve from the
second connection to the first connection if the pressure at the second
connection is greater than the pressure at the first connection.
- 15 2. The check-valve assembly of claim 1, where the check valve comprises a duckbill
valve.
3. The check-valve assembly of claim 1, where the check valve comprises a ball valve.
- 20 4. The check-valve assembly of any of claims 1-3, where the first connection comprises a
multi-lumen connection having a first lumen in communication with the first passageway, and
a second lumen in communication with the second passageway, and where the second
connection comprises a multi-lumen connection having a first lumen in communication with
the first passageway, and a second lumen in communication with the second passageway.
- 25 5. The check-valve assembly of claim 4, where the second lumen of the first connection
is an annular lumen disposed around the first lumen of the first connection, and where the
second lumen of the second connection is an annular lumen disposed around the first lumen of
the second connection.
- 30 6. A wound-treatment system comprising:
a fluid source configured to be coupled to a wound dressing such that the fluid source
is actuatable to deliver a fluid to the wound dressing;
a check-valve assembly configured to be coupled to the wound dressing;

a vacuum source configured to be coupled to the check-valve assembly such that the vacuum source is actuatable to apply negative pressure to the wound dressing through the check-valve assembly;

where the system is configured such that the check-valve assembly:

5 prevents fluid flow through the check-valve assembly towards the wound dressing.

7. The system of claim 6, where the system can be configured such that the check-valve assembly also substantially prevents pressure in the space adjacent the wound from exceeding
10 atmospheric pressure.

8. The system of claim 6, wherein the wound dressing comprises:
a wound insert; and
a drape configured to be coupled to skin adjacent a wound of a patient such that the
15 drape covers the wound insert and the wound to form a space between the drape and the wound;

9. The system of claim 8, where the wound insert comprises an open-celled hydrophilic foam.
20

10. The system of claim 8, where the wound insert comprises a hydrophobic foam coated with a hydrophilic coating.

11. The system of any of claims 6-10, where the check-valve assembly comprises a check
25 valve assembly of any of claims 1-5.

12. A wound-treatment system of any of claims 6-11 for the treatment of wounds using negative pressure wound therapy.

30 13. A wound-treatment method comprising:
applying negative pressure through a check-valve assembly and wound dressing to a wound of a patient, the wound dressing coupled to skin adjacent the wound such that the wound dressing covers the wound to form a substantially enclosed space adjacent the wound; and

delivering a fluid to the wound dressing;

where the check-valve assembly is configured to:

substantially prevent backflow of fluids through the check-valve assembly, and

substantially prevent pressure in the space between the drape and the wound

from exceeding atmospheric pressure.

14. The method of claim 13, where the wound dressing comprises:

a wound insert; and

a drape coupled to skin adjacent the wound such that the drape covers the

wound insert and the wound to form the substantially enclosed space

between the drape and the wound.

15. The method of any of claims 13-14, where delivering a fluid comprises activating a fluid source that is coupled to the wound dressing.

16. The method of any of claims 13-15, where applying negative pressure comprises activating a vacuum source that is coupled to the wound dressing.

17. The method of any of claims 13-16, where the wound insert comprises hydrophilic foam.

18. The method of any of claims 13-16, where the wound insert comprises a hydrophobic foam coated with a hydrophilic coating.

19. The method of any of claims 13-14, where the check-valve assembly comprises:

a housing defining a first connection configured to be coupled to the wound dressing, a

second connection configured to be coupled to the vacuum source, a first

passageway between the first and second connections, and a second

passageway between the first and second connections;

a check valve disposed in the first passageway and configured to:

permit fluid to pass through the check valve from the first connection to the

second connection when the pressure at the second connection is less

than the pressure at the first connection; and

substantially prevent fluid from passing through the check valve from the first connection to the second connection when the pressure at the second connection is greater than the pressure at the first connection.

- 5 20. A wound-treatment method comprising:
coupling a wound dressing to skin adjacent a wound of a patient such that the wound
dressing covers the wound to form a substantially enclosed space adjacent the
wound;
coupling the wound dressing to a fluid source such that the fluid source is actuatable to
10 deliver fluid to the wound dressing;
coupling the wound dressing to a check-valve assembly and a vacuum source such that
the check-valve assembly:
substantially prevents backflow of fluids through the check-valve assembly.
- 15 21. The method of claim 20, further comprising:
 configuring the system such that the check-valve assembly also substantially
 prevents pressure in the space adjacent the wound from exceeding
 atmospheric pressure.
- 20 22. The method of claim 20, where the wound dressing comprises:
 a wound insert comprising an open-celled foam configured to exhibit
 hydrophilic properties; and
 a drape; and
where coupling the wound dressing comprises:
25 positioning the wound insert on the wound; and
 coupling the drape to skin adjacent the wound such that the drape covers the
 wound insert and the wound, and forms a space between the drape and
 the wound.
- 30 23. The method of claim 20, further comprising:
 applying a negative pressure to the wound through the check-valve assembly and the
 wound dressing; and
 delivering a fluid to the wound through the wound dressing.

24. The method of any of claims 20-23, where the wound insert comprises hydrophilic foam.

25. The method of any of claims 20-23, where the wound insert comprises a hydrophobic
5 foam coated with a hydrophilic coating.

1/6

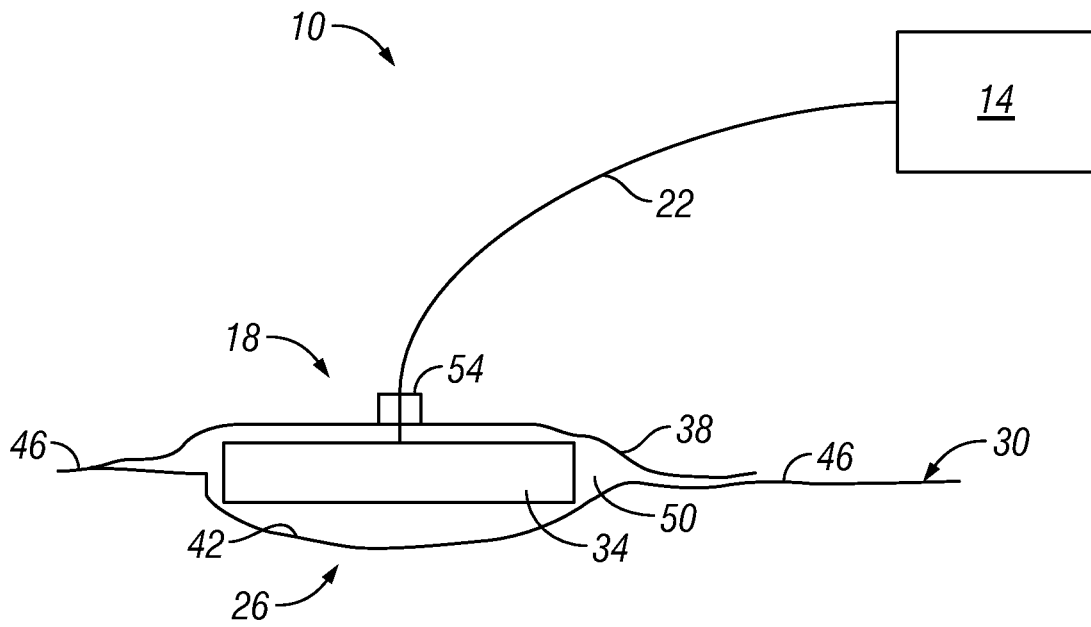


FIG. 1

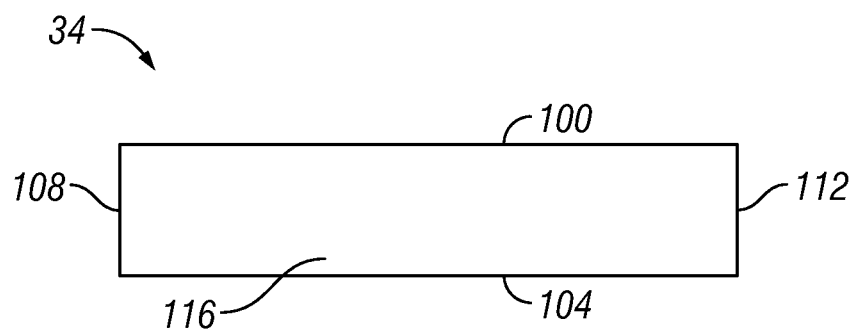


FIG. 2A

2/6

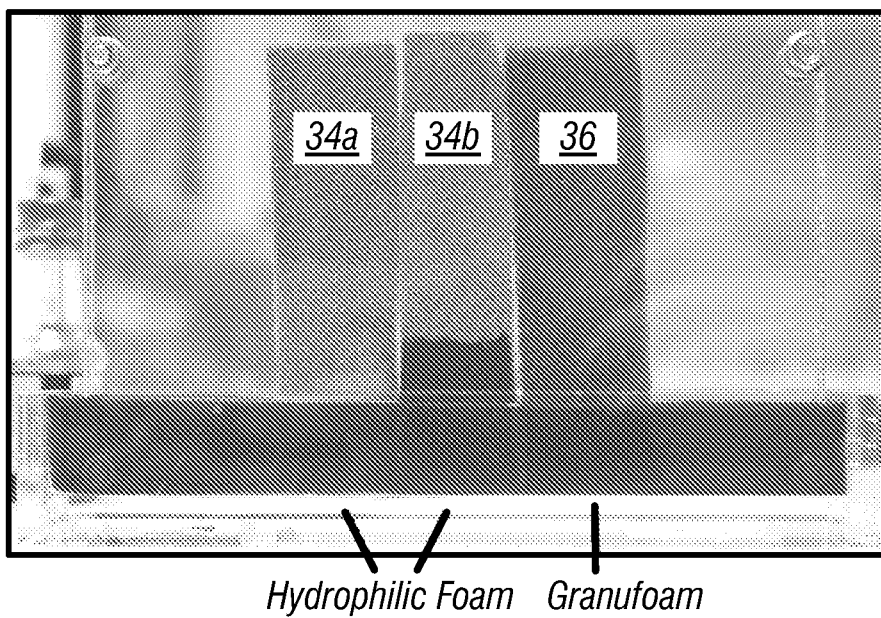


FIG. 2B

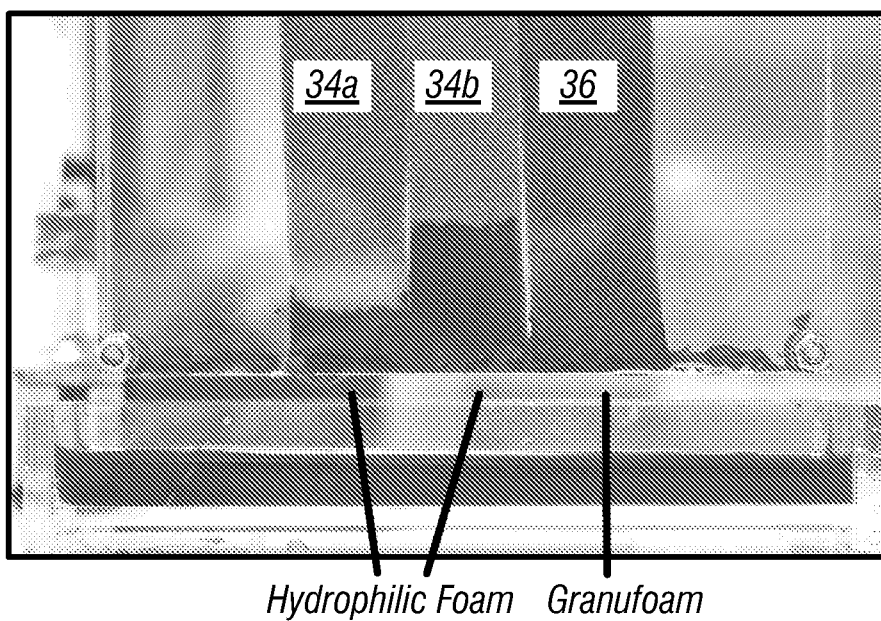
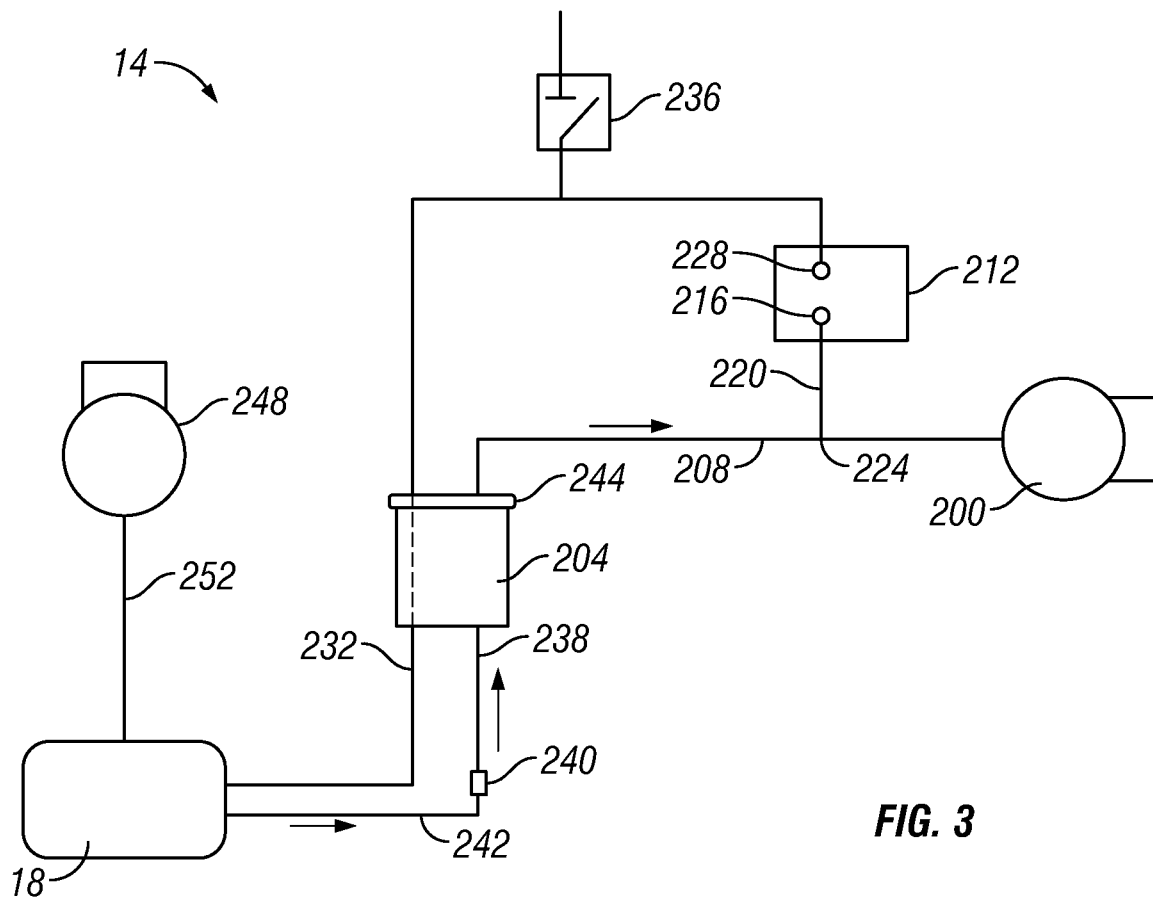
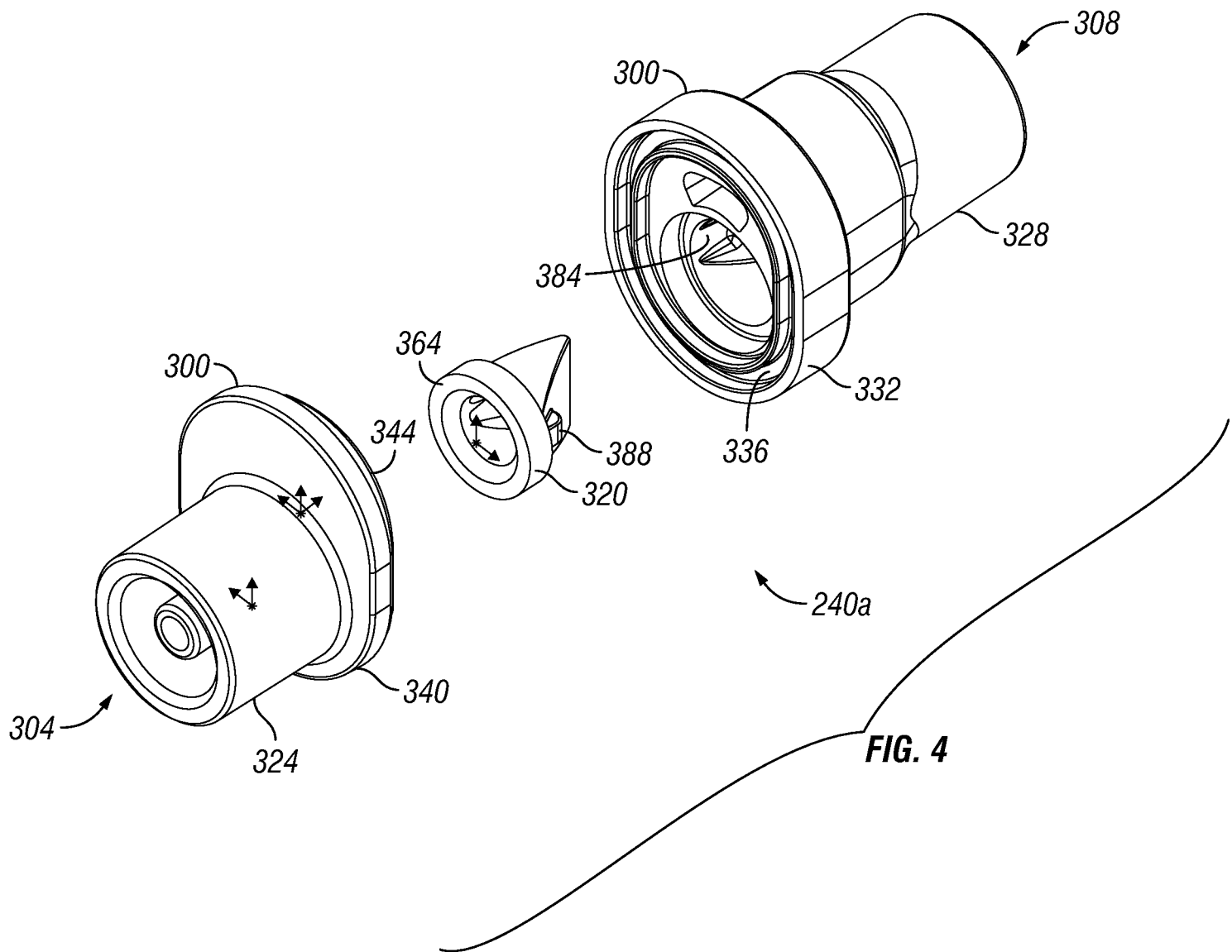


FIG. 2C

3/6

**FIG. 3**

4/6



5/6

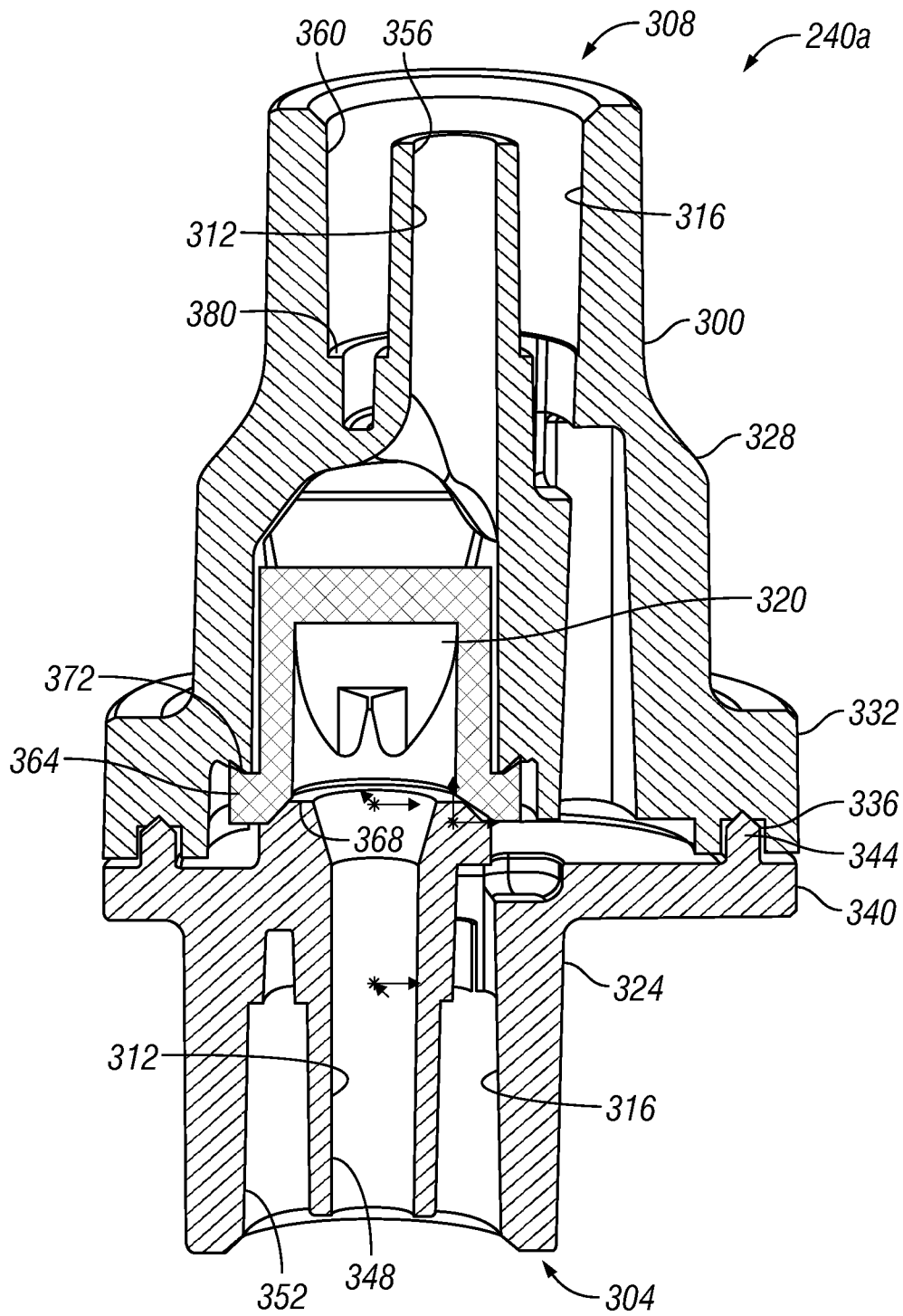


FIG. 5

6/6

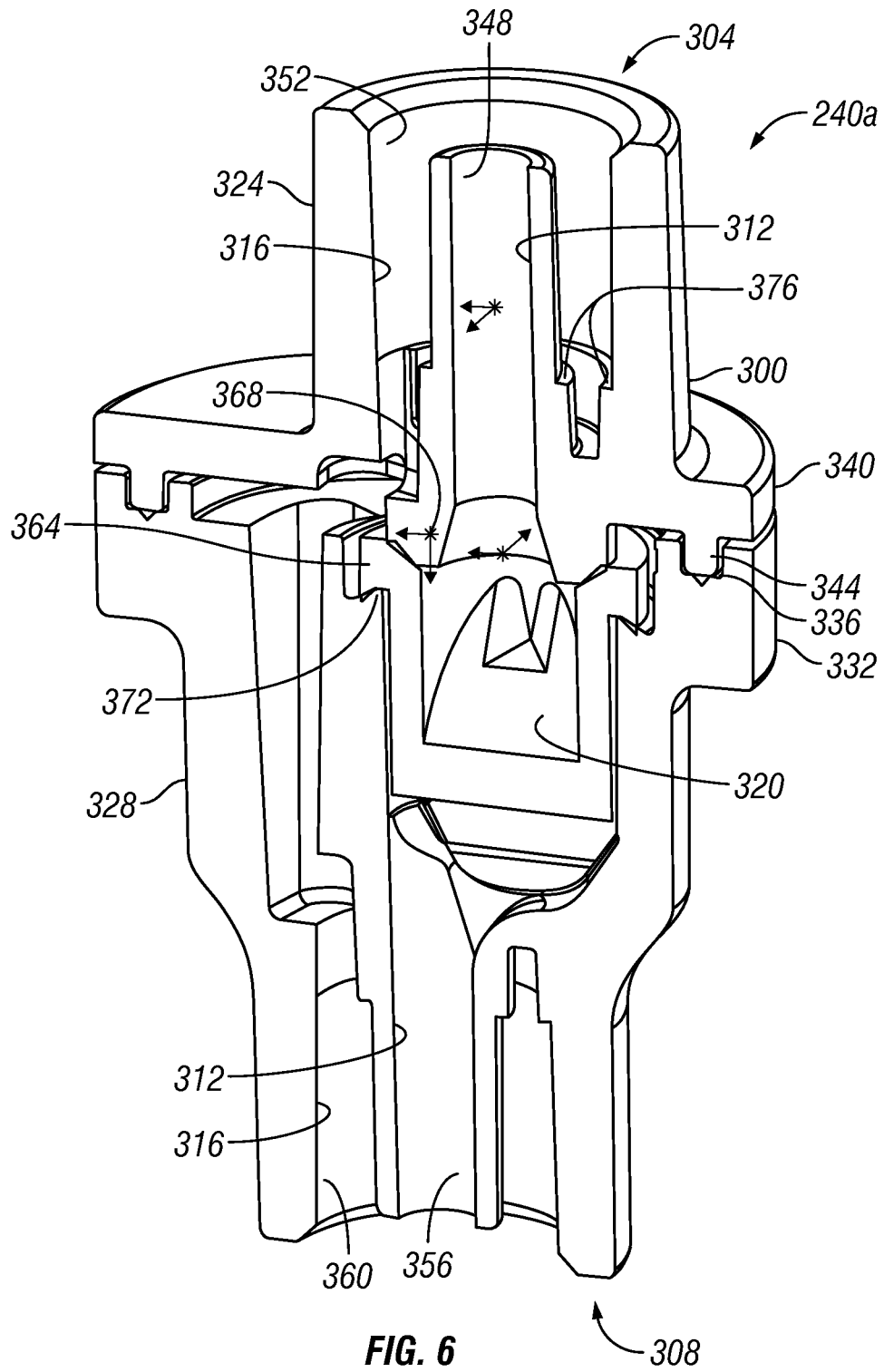


FIG. 6