



(51) International Patent Classification:

A61M 1/00 (2006.01) A61L 15/60 (2006.01)
A61F 13/00 (2006.01)

(21) International Application Number:

PCT/IB2020/059722

(22) International Filing Date:

15 October 2020 (15.10.2020)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/923,996 21 October 2019 (21.10.2019) US

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(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, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN,
KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO,
NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW,
SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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, RW, SD, SL, ST, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, 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,

(54) Title: DRESSING INTERFACE CONFIGURED TO PROVIDE NEGATIVE-PRESSURE TREATMENT WITHIN FLOW-
ABLE MANIFOLD

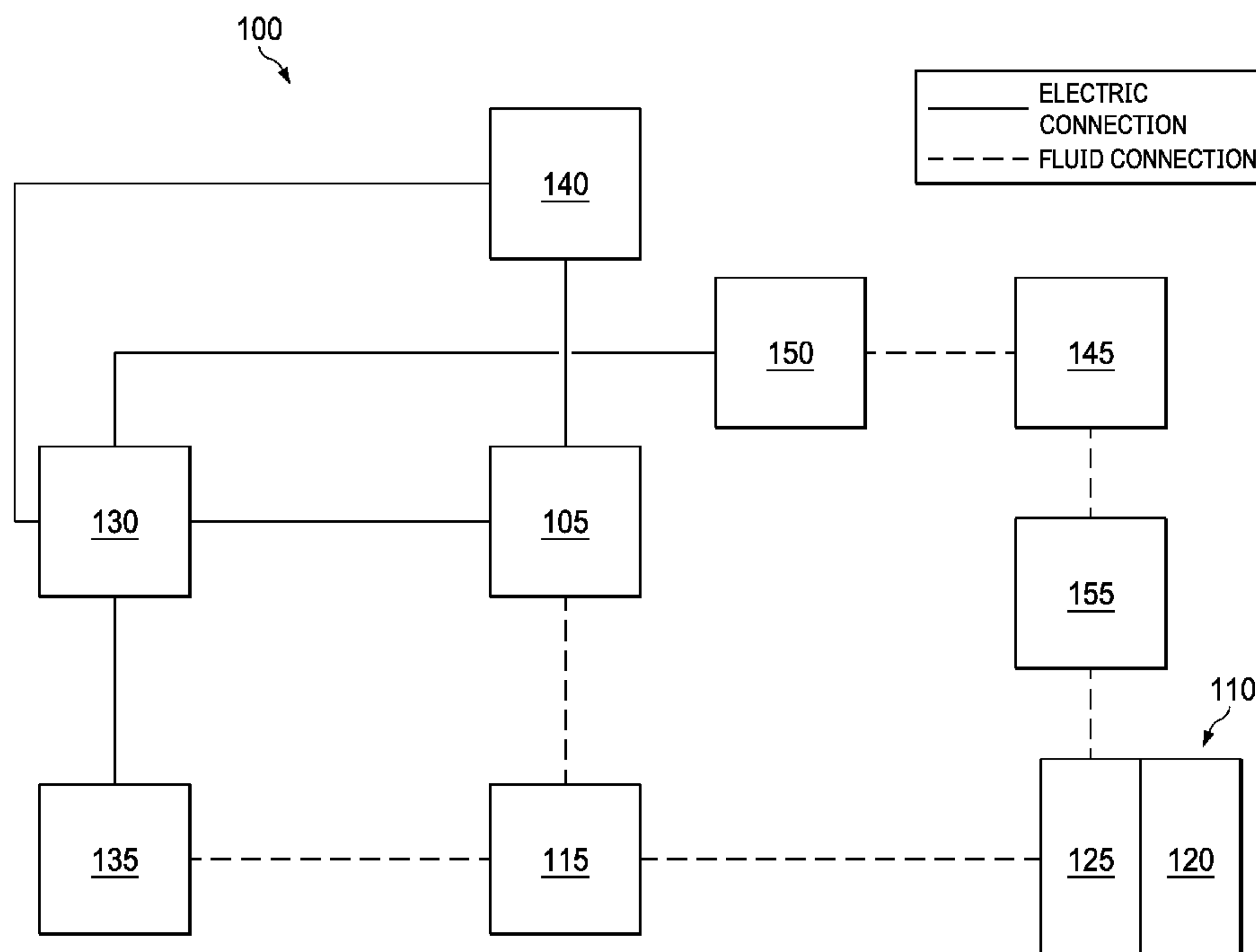


FIG. 1

(57) Abstract: In administering negative-pressure therapy to a tissue site, a dressing typically may be applied to the tissue site. In some embodiments, at least the manifold portion of the dressing may be formed using flowable materials. Such alternative methods of applying a manifold may be better utilized with a dressing interface that is specifically configured for use with flowable manifold materials. For example, the dressing interface may have a distal end configured for use within the flowable manifold and/or may be configured to simultaneously provide negative pressure in more than one direction and/or at more than one level.

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,
KM, ML, MR, NE, SN, TD, TG).

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*
- *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

DRESSING INTERFACE CONFIGURED TO PROVIDE NEGATIVE-PRESSURE TREATMENT WITHIN FLOWABLE MANIFOLD

5 CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Provisional Application No. 62/923,996, filed on October 21, 2019, which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

10 [0002] The invention set forth in the appended claims relates generally to tissue treatment systems and more particularly, but without limitation, to methods and systems for administering negative-pressure therapy to a tissue site.

BACKGROUND

15 [0003] Clinical studies and practice have shown that reducing pressure in proximity to a tissue site can augment and accelerate growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but it has proven particularly advantageous for treating wounds. Regardless of the etiology of a wound, whether trauma, surgery, or another cause, proper care of the wound is important to the outcome. Treatment of wounds or other tissue with reduced pressure may be commonly
20 referred to as "negative-pressure therapy," but is also known by other names, including "negative-pressure wound therapy," "reduced-pressure therapy," "vacuum therapy," "vacuum-assisted closure," and "topical negative-pressure," for example. Negative-pressure therapy may provide a number of benefits, including migration of epithelial and subcutaneous tissues, improved blood flow, and micro-deformation of tissue at a wound site. Together, these benefits can increase development of granulation
25 tissue and reduce healing times.

[0004] There is also widespread acceptance that cleansing a tissue site can be highly beneficial for new tissue growth. For example, a wound or a cavity can be washed out with a liquid solution for therapeutic purposes. These practices are commonly referred to as "irrigation" and "lavage" respectively. "Instillation" is another practice that generally refers to a process of slowly introducing
30 fluid to a tissue site and leaving the fluid for a prescribed period of time before removing the fluid. For example, instillation of topical treatment solutions over a wound bed can be combined with negative-pressure therapy to further promote wound healing by loosening soluble contaminants in a wound bed and removing infectious material. As a result, soluble bacterial burden can be decreased, contaminants removed, and the wound cleansed.

[0005] While the clinical benefits of negative-pressure therapy and/or instillation therapy are widely known, improvements to therapy systems, components, and processes may benefit healthcare providers and patients.

BRIEF SUMMARY

[0006] New and useful systems, apparatuses, and methods for treating a tissue site in a negative-pressure therapy environment are set forth in the appended claims. Illustrative embodiments are also provided to enable a person skilled in the art to make and use the claimed subject matter.

[0007] For example, in some embodiments, a manifold may be applied to a wound or tissue site in a flowable state. In some embodiments, the outer surface of the manifold may form a skin (e.g. when solidified) that may act as a seal or cover over the tissue site. In some embodiments, it may be preferable to use a dressing interface configured for use with such flowable manifold materials, in order to better supply negative pressure to the tissue dressing. For example, the dressing interface may be configured to be placed into the manifold material during or immediately after delivery has occurred, such that at least a portion of the dressing interface may be encased, entrapped, anchored, or otherwise retained within the manifold material. In some embodiments, the dressing interface may be configured to provide negative pressure to the manifold in more than one direction. For example, the dressing interface may be configured to deliver negative pressure above and below the dressing interface. Some embodiments of the dressing interface may be configured to deliver negative pressure within the solidified manifold in such a way as to provide omni-directional manifolding. For example, fluid may be drawn from substantially all portions of the manifold by the dressing interface located within the manifold. Some embodiments may have a flared end. In some embodiments, the dressing interface may be configured to prevent fouling and/or blocking of negative pressure delivery through the dressing interface, for example preventing formation of a skin on the flowable manifold in proximity to the dressing interface as it cures. Some embodiments of the dressing interface may not need separate attachment or adhesive systems to allow connection to the manifold.

[0008] More generally, an apparatus for coupling a flowable manifold to a negative-pressure source may comprise: a housing or conduit with a fluid pathway; at least one aperture in a distal end of the housing, conduit, or fluid pathway configured to provide fluid interaction between the fluid pathway and the tissue site; and a port in a proximal end of the housing, conduit, or fluid pathway configured for application of negative pressure into the fluid pathway. In some embodiments, the distal end may be configured for use within the flowable tissue dressing. In some embodiments, the distal end of the housing or conduit may comprise an applicator (e.g. serving as the negative pressure application site for the dressing interface), which may be fluidly coupled at the distal end of the fluid pathway and may comprise the at least one aperture. In some embodiments, the dressing interface may consist essentially of the applicator.

[0009] By way of example, some embodiments may comprise: a conduit or housing comprising a proximal end, a distal end, and a fluid pathway therethrough (e.g. between and fluid coupling the proximal end to the distal end); at least one aperture in the distal end configured to provide fluid interaction between the fluid pathway and the manifold and/or tissue site; and a port in the proximal end configured for application of negative pressure into the fluid pathway. In some embodiments, the at least one aperture may be configured to direct negative pressure within the fluid pathway outward (e.g. into the manifold) in more than one direction. In some embodiments, the at least one aperture may be configured to direct negative pressure within the fluid pathway to more than one level within the manifold. Some embodiments may be configured to be positioned at different levels within the manifold. In some embodiments, the at least one aperture may comprise two or more apertures oriented to direct negative pressure in different directions. In some embodiments, the at least one aperture may comprise two or more apertures, with at least a first aperture in a first surface and a second aperture in a second surface. In some embodiments, the first surface may be opposite the second surface, so that the first aperture and the second aperture may open in opposite directions. In some embodiments, the first aperture and the second aperture may be aligned. Some embodiments may further comprise a through-opening that extends from the first surface to the second surface. In some embodiments, the through-opening may comprise the first aperture and the second aperture (e.g. along with a recessed space between the first aperture and the second aperture, in some embodiments). In some embodiments, the at least one aperture may be configured to direct negative pressure out of the fluid pathway and into the manifold in more than one direction and/or at more than one level. In some embodiments, the at least one aperture may be configured to direct negative pressure into the manifold so as to provide omni-directional manifolding, for example with the configuration allowing fluid to be drawn into the at least one aperture from substantially all portions of the manifold.

[0010] In some embodiments, the apparatus may further comprise: a support layer; and an envelope comprising the first surface and the second surface and encompassing the support layer, wherein the support layer supports the envelope to define the enclosed fluid pathway within the envelope. The support layer of some embodiments may be configured within the envelope to maintain the fluid pathway in an open configuration when under compression. In some embodiments, the apparatus may be low-profile. In some embodiments, the support layer may comprise a thermoformed support structure. The support layer of some embodiments may comprise a plurality of supports configured to support the envelope. The plurality of supports may be substantially co-extensive with the fluid pathway in some embodiments. Each of the plurality of supports, in some embodiments, may comprise a hollow standoff, which is sealed to maintain an internal pressure. In some embodiments, the envelope may further comprise a first layer and a second layer; the first layer and the second layer may be coupled to form the envelope with enclosed fluid pathway between the first layer and the second layer; and the plurality of supports may be located between the first layer and the second layer. In some

embodiments, the support layer may further comprise a spacer layer, and the plurality of supports may extend from an inner surface of the spacer layer.

[0011] In some embodiments, the plurality of supports may comprise a first plurality of supports and a second plurality of supports; and the first plurality of supports may be in stacked relationship with the second plurality of supports. In some embodiments, the support layer may further comprise a first spacer layer and a second spacer layer; and the plurality of supports may comprise a first plurality of supports extending inward from the first spacer layer and a second plurality of supports extending inward from the second spacer layer. The first plurality of supports of the first spacer layer may be aligned with and in stacked relationship with the second plurality of supports of the second spacer layer in some embodiments. In some embodiments, the first spacer layer and the second spacer layer may each comprise an opening; the opening in the first spacer layer may be aligned with the opening in the second spacer layer; the first aperture and the second aperture may be aligned; and the openings in the first spacer layer and the second spacer layer may be aligned with the first aperture and the second aperture (e.g. jointly forming the through-opening). In some embodiments, the plurality of supports may be arranged in rows that extend longitudinally. Typically, the support layer may not comprise any foam.

[0012] In some embodiments, the apparatus may further comprise one or more pressure-sensing pathways extending substantially parallel to the fluid pathway. The one or more pressure-sensing pathways may be pneumatically isolated from the fluid pathway between the proximal end and distal end, in some embodiments. For example, the one or more pressure-sensing pathways may each comprise an open distal end in fluid communication with the at least one aperture in the distal end, and the one or more pressure-sensing pathways may only be in fluid communication with the fluid pathway at the distal end. In some embodiments, the distal end may be configured to prevent blockage of the fluid pathway by the flowable manifold material. For example, the distal end may comprise an anti-fouling surface treatment and/or the distal end may comprise a protective cap. In some embodiments, the apparatus may be configured to be self-securing within the flowable manifold material. For example, the distal end may be configured to be self-securing within the flowable manifold material as the flowable manifold material solidifies around the distal end.

[0013] Alternatively, other example embodiments may comprise: a housing or conduit with a fluid pathway therethrough; at least one aperture in a distal end of the housing or conduit (e.g. in an applicator) configured to provide fluid interaction between the fluid pathway and the tissue site, wherein the distal end is configured for use within the manifold and comprises an anti-fouling surface treatment; and a port in a proximal end configured for application of negative pressure into the fluid pathway. In some embodiments, the anti-fouling surface treatment may comprise a coating configured to prevent formation of a skin when the flowable manifold solidifies (e.g. cures). For example, the coating may comprise one or more hydrogels. In some embodiments, the anti-fouling surface treatment may

comprise a coating configured to create pores in the flowable manifold upon contact with the flowable manifold. In some embodiments, the anti-fouling surface treatment may comprise a coating having at least one part of a 2-part blowing agent system, while other embodiments of the anti-fouling surface treatment may comprise both parts of the 2-part blowing agent system. In some embodiments, both parts of the 2-part blowing agent system may be powder mixes in a water-sensitive polymer configured to be activated by moisture in the flowable manifold. For example, the water-sensitive polymer may comprise at least one of PVP and PEO. In some embodiments, the anti-fouling surface treatment may comprise citric acid and/or sodium bicarbonate. In some embodiments, the anti-fouling surface treatment may comprise poly methylhydrosiloxane and/or poly dimethylsiloxane.

[0014] Still other embodiments may comprise: a housing or conduit with a fluid pathway therethrough; at least one aperture in a distal end of the housing or conduit (e.g. in an applicator) configured to provide fluid interaction between the fluid pathway and the tissue site, wherein the distal end is configured for use within the flowable manifold and comprises a protective cap spanning the fluid pathway; and a port in a proximal end of the housing or conduit configured for application of negative pressure into the fluid pathway. In some embodiments, the protective cap may comprise a plug temporarily sealing the at least one aperture to substantially block fluid interaction between the fluid pathway and the flowable manifold; and the plug may be configured to dissolve upon contact with the flowable manifold material (e.g. water soluble). For example, the plug may comprise cellulose. In some embodiments, the protective cap may comprise a soluble membrane spanning the at least one aperture and retaining a high pH solution that disrupts formation of a skin as the flowable manifold solidifies. The soluble membrane may dissolve upon contact with the manifold material (e.g. water soluble). In some embodiments, the soluble membrane may retain the high pH solution by comprising the high pH solution (e.g. in the membrane); in other embodiments, the high pH solution may be separate from the soluble membrane, may be held in place within the housing by the soluble membrane, and may be released out of the at least one aperture when the soluble membrane dissolves. In some embodiments, the high pH solution may comprise sodium carbonate.

[0015] Yet other embodiments may comprise: a housing or conduit with a fluid pathway therethrough; at least one aperture in a distal end of the housing (e.g. in an applicator) configured to provide fluid interaction between the fluid pathway and the tissue site, wherein the housing or conduit (e.g. the distal end of the housing or conduit) is configured to be self-securing within the flowable manifold material (e.g. upon solidification of the flowable manifold material at the tissue site); and a port in a proximal end of the housing or conduit configured for application of negative pressure into the fluid pathway. In some embodiments, the dressing interface may be configured to be self-securing within the flowable manifold material. In some embodiments, the housing (e.g. applicator) may comprise an external surface finish configured to retain the housing (e.g. the distal end) within the (solidified) flowable manifold. For example, the external surface finish may comprise StandexTM surface finish. In some embodiments, the external surface finish may comprise a dry adhesive coating

that bonds to the flowable manifold material. For example, the dry adhesive may comprise a cold seal adhesive. In some embodiments, the external surface finish may comprise a coating of material homologous to the flowable manifold. In some embodiments, the housing (e.g. the distal end or applicator) may comprise material homologous to the flowable manifold. The distal end (e.g. applicator) may be flared in some embodiments. For example, the distal end may comprise a width or diameter that is larger than the width or diameter of the proximal end. The flared distal end may anchor the dressing interface within the solid state of the manifold material (e.g. after the flowable manifold material has solidified). In some embodiments, the aperture may comprise a diameter larger than that of the port.

[0016] In some embodiments, a conduit for fluidly coupling a negative-pressure source to a manifold having a delivery state (e.g. which may be flowable) and a treatment state (e.g. which may be solidified) may comprise a first end configured to be fluidly coupled to the negative-pressure source; a second end configured to be disposed within the manifold in the delivery state and retained in the manifold in the treatment state; and a fluid pathway between the first end and the second end. In some embodiments, the second end may comprise one or more apertures configured to direct negative pressure outward from the fluid pathway in more than one direction. In more particular examples, the second end may comprise at least one through-hole (e.g. which may comprise two apertures), which may be fluidly coupled to the fluid pathway. The through-hole may also be configured to receive a portion of the manifold in the delivery state, and can anchor the conduit to the manifold in the treatment state. Additionally, or alternatively, the second end may be flared in some examples. The first end may have a first width, the second end may have a second width, and the second width may be greater than the first width. In some embodiments, the conduit may comprise one or more of the following: an anti-fouling surface treatment; a protective cap spanning the fluid pathway; and a self-securing configuration for use with flowable manifold material.

[0017] Systems for providing negative-pressure therapy to a tissue site are also described herein. For example, system embodiments may comprise: a manifold having a delivery state (e.g. which may be flowable) and a treatment state (e.g. which may be solidified); and a dressing interface configured for use within the manifold. The dressing interface of the system embodiments may comprise any of the dressing interfaces described herein. For example, the dressing interface may comprise a distal end (e.g. an applicator) configured for use within the manifold. In some embodiments, the dressing interface may comprise a coating having a first part of a 2-part blowing agent system, and the manifold may comprise a second part of the 2-part blowing agent system. For example, the first part may comprise poly methylhydrosiloxane, and the second part may comprise poly dimethylsiloxane. In some embodiments, the dressing interface may comprise a soluble membrane configured to retain a high pH solution, and the flowable manifold may comprise a pH sensitive group. For example, the high pH solution may comprise sodium carbonate, and the pH sensitive group may comprise carboxylic.

[0018] In some embodiments, the manifold may comprise two reactants separated until application of or preparation for application of the manifold on the tissue site (e.g. the flowable manifold reactants may be mixed in proximity to the tissue site). In some embodiments, the flowable manifold may comprise a reacted polymer in a carrier. For example, the reacted polymer may be hydrophilic. In some embodiments, the flowable manifold may be contained within one or more delivery devices before application to the tissue site. In some embodiments, the flowable manifold may be configured to simultaneously form a tissue interface and a cover upon solidification. For example, the flowable manifold may be configured to form a skin upon solidification (e.g. curing) that acts as the cover. Other embodiments may further comprise a cover. For example, the cover may comprise a drape, or the cover may comprise a flowable material that solidifies to form a gas-impermeable seal over the tissue site for negative-pressure therapy (e.g. in a separate delivery device).

[0019] Methods of providing negative-pressure therapy to a tissue site are also described herein. For example, method embodiments may comprise the steps of: delivering a manifold in a flowable state to the tissue site; placing a dressing interface within the flowable manifold; and solidifying the manifold. Some embodiments may further comprise the step of fluidly coupling a negative-pressure source to the dressing interface. Negative pressure may be applied to the tissue site through the dressing interface and the manifold. In some embodiments, delivering a flowable manifold may comprise delivering a first portion of the manifold in a flowable state to the tissue site before placing the dressing interface, and delivering a second portion of the manifold in a flowable state to the tissue site after placing the dressing interface, for example with the second portion of the manifold covering the dressing interface. In some embodiments, the step of placing the dressing interface may comprise inserting a distal end of the dressing interface into the flowable manifold prior to solidification (e.g. curing) of the flowable manifold. In some embodiments, placing the dressing interface may comprise placing the distal end (e.g. applicator) of the dressing interface within the flowable manifold.

[0020] Some method embodiments may further comprise applying a cover over the tissue site. In some embodiments, applying the cover may occur before delivering the flowable manifold, while in other embodiments applying the cover may occur after delivering the flowable manifold. In some embodiments, applying the cover may comprise delivering a flowable cover material atop the flowable manifold. For example, the step of delivering the flowable cover material may occur after solidification of the flowable manifold. Some embodiments may further comprise selecting an appropriate amount and/or type of flowable manifold for the tissue site. In some embodiments, after placement within the flowable manifold, the distal end of the dressing interface may be oriented substantially parallel to the tissue site and/or exterior surface of the flowable manifold. In some embodiments, the distal end may comprise at least two apertures, and the at least two apertures may be located at different levels and/or may direct negative pressure in different directions within the flowable manifold. In some embodiments, negative pressure may be applied in more than one direction within the solidified

flowable manifold. For example, negative pressure may be applied beneath an external surface of the manifold, may be applied through the distal end of the dressing interface at more than one level and/or in more than one direction within the manifold, and/or may be applied above and below the distal end of the dressing interface.

5 **[0021]** In some embodiments, the method may further comprise preventing formation of a skin in proximity to the dressing interface (e.g. where the flowable manifold contacts the distal end of the dressing interface). For example, responsive to the dressing interface contacting the flowable dressing material, the method may further comprise dissolving a soluble plug, forming pores in a skin of the flowable manifold, and/or dissolving a soluble membrane to release a high pH solution. Some method
10 embodiments may further comprise automatically securing the dressing interface within the manifold during solidification. In some embodiments, the method may further comprise orienting a flared distal end so that its aperture is approximately perpendicular to the tissue site surface, so that the aperture is approximately perpendicular to the external surface of the manifold, and/or so that the aperture spans more than one level within the manifold. Typically, the step of placing the dressing interface may not
15 require any cutting of the manifold.

[0022] Methods of manufacturing a dressing interface are also described herein. For example, method embodiments may comprise the steps of: forming a housing or conduit for a dressing interface (e.g. with the housing or conduit comprising a fluid pathway between its proximal end and its distal end); and applying a coating to the dressing interface and/or applying a soluble plug or membrane to an
20 aperture in the dressing interface. For example, the coating may comprise one or more of the following: an anti-fouling coating, a pore-forming coating, and/or a self-securing coating. In some embodiments, the step of forming the dressing interface may comprise forming a flared distal end of the housing or conduit. In some embodiments, the flared distal end may comprise a flared aperture, for example with a diameter greater than that of the proximal end of the fluid pathway. In some embodiments, the step
25 of forming the dressing interface may comprise forming a plurality of apertures oriented for multi-directional negative-pressure delivery.

[0023] Objectives, advantages, and a preferred mode of making and using the claimed subject matter may be understood best by reference to the accompanying drawings in conjunction with the following detailed description of illustrative embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Figure 1 is a simplified functional block diagram of an example embodiment of a therapy system that can provide negative-pressure treatment and instillation treatment in accordance with this specification;

35 **[0025]** Figure 2 is a graph illustrating additional details of example pressure control modes that may be associated with some embodiments of the therapy system of Figure 1;

[0026] Figure 3 is a graph illustrating additional details that may be associated with another example pressure control mode in some embodiments of the therapy system of Figure 1;

[0027] Figure 4 is a chart illustrating details that may be associated with an example method of operating the therapy system of Figure 1;

5 [0028] Figure 5A is a schematic view of an exemplary method for forming a dressing at a tissue site using flowable materials;

[0029] Figure 5B is another schematic view showing the tissue site from Figure 5A after the manifold material has solidified and is ready for application of negative-pressure therapy;

10 [0030] Figure 6 is yet another schematic view, illustrating exemplary details that may be associated with some embodiments of a therapy system/method in relation to Figure 5A that can provide negative-pressure treatment;

[0031] Figure 7A is a schematic cross-sectional view, illustrating details that may be associated with some embodiments of a delivery device having a first zone and a second zone;

15 [0032] Figure 7B is a schematic cross-sectional view, illustrating details that may be associated with some alternative embodiments of a delivery device having a first zone, a second zone, and a third zone;

[0033] Figure 7C is a schematic cross-sectional view, illustrating details that may be associated with some alternative embodiments of a delivery device having a first zone, a second zone, and a third zone;

20 [0034] Figure 7D is a schematic cross-sectional view, illustrating details that may be associated with some alternative embodiments of a delivery device having a first zone, a second zone, and a canister;

25 [0035] Figure 7E is a schematic cross-sectional view, illustrating details that may be associated with some alternative embodiments of a delivery device having a first zone, a second zone, and a ultraviolet light source;

[0036] Figure 8 is a schematic cross-sectional view, illustrating details that may be associated with some alternative embodiments of a delivery device having a first zone, a second zone, and a third zone in separate containers;

30 [0037] Figure 9 is a schematic cross-sectional view, illustrating details that may be associated with some alternative embodiments of a delivery device having a single container;

[0038] Figure 10 is a top isometric view of an exemplary embodiment of a dressing interface;

[0039] Figure 11 is a schematic longitudinal cross-sectional view of the dressing interface of Figure 10;

35 [0040] Figure 12 is a schematic lateral cross-sectional view of the dressing interface of Figure 10;

[0041] Figure 13 is an exploded view of the dressing interface of Figure 10;

[0042] Figure 14 is an isometric view of another example embodiment of a dressing interface, shown with a slight bend to illustrate the distal aperture and the proximal port;

[0043] Figure 15 is a schematic view of a kit containing an exemplary flowable manifold delivery device and an exemplary dressing interface;

5 [0044] Figure 16 is a schematic view of an exemplary negative-pressure therapy system illustrating the solidified manifold in place on a tissue site with a dressing interface distal end therein;

[0045] Figure 17 is a schematic plan view of the negative-pressure therapy system shown in Figure 16; and

10 [0046] Figure 18 is a schematic view of an exemplary negative-pressure therapy system illustrating the solidified manifold in place on a tissue site with a flared dressing interface distal end therein.

DESCRIPTION OF EXAMPLE EMBODIMENTS

15 [0047] The following description of example embodiments provides information that enables a person skilled in the art to make and use the subject matter set forth in the appended claims, but it may omit certain details already well known in the art. The following detailed description is, therefore, to be taken as illustrative and not limiting.

20 [0048] The example embodiments may also be described herein with reference to spatial relationships between various elements or to the spatial orientation of various elements depicted in the attached drawings. In general, such relationships or orientation assume a frame of reference consistent with or relative to a patient in a position to receive treatment. However, as should be recognized by those skilled in the art, this frame of reference is merely a descriptive expedient rather than a strict prescription.

25 [0049] Figure 1 is a simplified functional block diagram of an example embodiment of a therapy system 100 that can provide negative-pressure therapy with instillation of topical treatment solutions to a tissue site in accordance with this specification.

30 [0050] The term “tissue site” in this context broadly refers to a wound, defect, or other treatment target located on or within tissue, including, but not limited to, bone tissue, adipose tissue, muscle tissue, neural tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, or ligaments. A wound may include chronic, acute, traumatic, subacute, and dehiscent wounds, partial-thickness burns, ulcers (such as diabetic, pressure, or venous insufficiency ulcers), flaps, and grafts, for example. The term “tissue site” may also refer to areas of any tissue that are not necessarily wounded or defective, but are instead areas in which it may be desirable to add or promote the growth of additional tissue. For example, negative pressure may be applied to a tissue site to grow additional tissue that may
35 be harvested and transplanted.

[0051] The therapy system 100 may include a source or supply of negative pressure, such as a negative-pressure source 105, and one or more distribution components. A distribution component is preferably detachable and may be disposable, reusable, or recyclable. A dressing, such as a dressing 110, and a fluid container, such as a container 115, are examples of distribution components that may be associated with some examples of the therapy system 100. As illustrated in the example of Figure 1, the dressing 110 may comprise or consist essentially of a tissue interface 120, a cover 125, or both in some embodiments.

[0052] A fluid conductor is another illustrative example of a distribution component. A “fluid conductor,” in this context, broadly includes a tube, pipe, hose, conduit, or other structure with one or more lumina or open pathways adapted to convey a fluid between two ends. Typically, a tube is an elongated, cylindrical structure with some flexibility, but the geometry and rigidity may vary. Moreover, some fluid conductors may be molded into or otherwise integrally combined with other components. Distribution components may also include or comprise interfaces or fluid ports to facilitate coupling and de-coupling other components. In some embodiments, for example, a dressing interface may facilitate coupling a fluid conductor to the dressing 110. For example, such a dressing interface may be a SENSAT.R.A.C.[™] Pad available from Kinetic Concepts, Inc. of San Antonio, Texas.

[0053] The therapy system 100 may also include a regulator or controller, such as a controller 130. Additionally, the therapy system 100 may include sensors to measure operating parameters and provide feedback signals to the controller 130 indicative of the operating parameters. As illustrated in Figure 1, for example, the therapy system 100 may include a first sensor 135 and a second sensor 140 coupled to the controller 130.

[0054] The therapy system 100 may also include a source of instillation solution. For example, a solution source 145 may be fluidly coupled to the dressing 110, as illustrated in the example embodiment of Figure 1. The solution source 145 may be fluidly coupled to a positive-pressure source, such as a positive-pressure source 150, a negative-pressure source, such as the negative-pressure source 105, or both in some embodiments. A regulator, such as an instillation regulator 155, may also be fluidly coupled to the solution source 145 and the dressing 110 to ensure proper dosage of instillation solution (e.g. saline) to a tissue site. For example, the instillation regulator 155 may comprise a piston that can be pneumatically actuated by the negative-pressure source 105 to draw instillation solution from the solution source during a negative-pressure interval and to instill the solution to a dressing during a venting interval. Additionally or alternatively, the controller 130 may be coupled to the negative-pressure source 105, the positive-pressure source 150, or both, to control dosage of instillation solution to a tissue site. In some embodiments, the instillation regulator 155 may also be fluidly coupled to the negative-pressure source 105 through the dressing 110, as illustrated in the example of Figure 1.

[0055] Some components of the therapy system 100 may be housed within or used in conjunction with other components, such as sensors, processing units, alarm indicators, memory, databases, software, display devices, or user interfaces that further facilitate therapy. For example, in some embodiments, the negative-pressure source 105 may be combined with the controller 130, the solution source 145, and other components into a therapy unit.

[0056] In general, components of the therapy system 100 may be coupled directly or indirectly. For example, the negative-pressure source 105 may be directly coupled to the container 115 and may be indirectly coupled to the dressing 110 through the container 115. Coupling may include fluid, mechanical, thermal, electrical, or chemical coupling (such as a chemical bond), or some combination of coupling in some contexts. For example, the negative-pressure source 105 may be electrically coupled to the controller 130 and may be fluidly coupled to one or more distribution components to provide a fluid path to a tissue site. In some embodiments, components may also be coupled by virtue of physical proximity, being integral to a single structure, or being formed from the same piece of material.

[0057] A negative-pressure supply, such as the negative-pressure source 105, may be a reservoir of air at a negative pressure or may be a manual or electrically-powered device, such as a vacuum pump, a suction pump, a wall suction port available at many healthcare facilities, or a micro-pump, for example. "Negative pressure" generally refers to a pressure less than a local ambient pressure, such as the ambient pressure in a local environment external to a sealed therapeutic environment. In many cases, the local ambient pressure may also be the atmospheric pressure at which a tissue site is located. Alternatively, the pressure may be less than a hydrostatic pressure associated with tissue at the tissue site. Unless otherwise indicated, values of pressure stated herein are gauge pressures. References to increases in negative pressure typically refer to a decrease in absolute pressure, while decreases in negative pressure typically refer to an increase in absolute pressure. While the amount and nature of negative pressure provided by the negative-pressure source 105 may vary according to therapeutic requirements, the pressure is generally a low vacuum, also commonly referred to as a rough vacuum, between -5 mm Hg (-667 Pa) and -500 mm Hg (-66.7 kPa). Common therapeutic ranges are between -50 mm Hg (-6.7 kPa) and -300 mm Hg (-39.9 kPa).

[0058] The container 115 is representative of a container, canister, pouch, or other storage component, which can be used to manage exudates and other fluids withdrawn from a tissue site. In many environments, a rigid container may be preferred or required for collecting, storing, and disposing of fluids. In other environments, fluids may be properly disposed of without rigid container storage, and a re-usable container could reduce waste and costs associated with negative-pressure therapy.

[0059] A controller, such as the controller 130, may be a microprocessor or computer programmed to operate one or more components of the therapy system 100, such as the negative-pressure source 105. In some embodiments, for example, the controller 130 may be a microcontroller,

which generally comprises an integrated circuit containing a processor core and a memory programmed to directly or indirectly control one or more operating parameters of the therapy system 100. Operating parameters may include the power applied to the negative-pressure source 105, the pressure generated by the negative-pressure source 105, or the pressure distributed to the tissue interface 120, for example.

5 The controller 130 is also preferably configured to receive one or more input signals, such as a feedback signal, and programmed to modify one or more operating parameters based on the input signals.

[0060] Sensors, such as the first sensor 135 and the second sensor 140, are generally known in the art as any apparatus operable to detect or measure a physical phenomenon or property, and generally provide a signal indicative of the phenomenon or property that is detected or measured. For example, 10 the first sensor 135 and the second sensor 140 may be configured to measure one or more operating parameters of the therapy system 100. In some embodiments, the first sensor 135 may be a transducer configured to measure pressure in a pneumatic pathway and convert the measurement to a signal indicative of the pressure measured. In some embodiments, for example, the first sensor 135 may be a piezo-resistive strain gauge. The second sensor 140 may optionally measure operating parameters of 15 the negative-pressure source 105, such as a voltage or current, in some embodiments. Preferably, the signals from the first sensor 135 and the second sensor 140 are suitable as an input signal to the controller 130, but some signal conditioning may be appropriate in some embodiments. For example, the signal may need to be filtered or amplified before it can be processed by the controller 130. Typically, the signal is an electrical signal, but may be represented in other forms, such as an optical 20 signal.

[0061] The tissue interface 120 can be generally adapted to partially or fully contact a tissue site. The tissue interface 120 may take many forms, and may have many sizes, shapes, or thicknesses, depending on a variety of factors, such as the type of treatment being implemented or the nature and size of a tissue site. For example, the size and shape of the tissue interface 120 may be adapted to the 25 contours of deep and irregular shaped tissue sites. Any or all of the surfaces of the tissue interface 120 may have an uneven, coarse, or jagged profile.

[0062] In some embodiments, the tissue interface 120 may comprise or consist essentially of a manifold. A manifold in this context may comprise or consist essentially of a means for collecting or distributing fluid across the tissue interface 120 under pressure. For example, a manifold may be 30 adapted to receive negative pressure from a source and distribute negative pressure through multiple apertures across the tissue interface 120, which may have the effect of collecting fluid from across a tissue site and drawing the fluid toward the source. In some embodiments, the fluid path may be reversed or a secondary fluid path may be provided to facilitate delivering fluid, such as fluid from a source of instillation solution, across a tissue site.

35 [0063] In some illustrative embodiments, a manifold may comprise a plurality of pathways, which can be interconnected to improve distribution or collection of fluids. In some illustrative

embodiments, a manifold may comprise or consist essentially of a porous material having interconnected fluid pathways. Examples of suitable porous material that can be adapted to form interconnected fluid pathways (e.g., channels) may include cellular foam, including open-cell foam, such as reticulated foam; porous tissue collections; and other porous material, such as gauze or felted mat, that generally include pores, edges, and/or walls. Liquids, gels, and other foams may also include or be cured to include apertures and fluid pathways. In some embodiments, a manifold may additionally or alternatively comprise projections that form interconnected fluid pathways. For example, a manifold may be molded to provide surface projections that define interconnected fluid pathways.

[0064] In some embodiments, the tissue interface 120 may comprise or consist essentially of reticulated foam having pore sizes and free volume that may vary according to needs of a prescribed therapy. For example, reticulated foam having a free volume of at least 90% may be suitable for many therapy applications, and foam having an average pore size in a range of 400-600 microns (40-50 pores per inch) may be particularly suitable for some types of therapy. The tensile strength of the tissue interface 120 may also vary according to needs of a prescribed therapy. For example, the tensile strength of foam may be increased for instillation of topical treatment solutions. The 25% compression load deflection of the tissue interface 120 may be at least 0.35 pounds per square inch, and the 65% compression load deflection may be at least 0.43 pounds per square inch. In some embodiments, the tensile strength of the tissue interface 120 may be at least 10 pounds per square inch. The tissue interface 120 may have a tear strength of at least 2.5 pounds per inch. In some embodiments, the tissue interface 120 may be foam comprised of polyols, such as polyester or polyether; isocyanate, such as toluene diisocyanate; and polymerization modifiers, such as amines and tin compounds. In some examples, the tissue interface 120 may be reticulated polyurethane foam, such as found in GRANUFOAM™ dressing or V.A.C. VERAFLOR™ dressing, both available from Kinetic Concepts, Inc. of San Antonio, Texas.

[0065] The thickness of the tissue interface 120 may also vary according to needs of a prescribed therapy. For example, the thickness of the tissue interface 120 may be decreased to reduce tension on peripheral tissue. The thickness of the tissue interface 120 can also affect the conformability of the tissue interface 120. In some embodiments, a thickness in a range of about 5 millimeters to 10 millimeters may be suitable.

[0066] The tissue interface 120 may be either hydrophobic or hydrophilic. In an example in which the tissue interface 120 may be hydrophilic, the tissue interface 120 may also wick fluid away from a tissue site, while continuing to distribute negative pressure to the tissue site. The wicking properties of the tissue interface 120 may draw fluid away from a tissue site by capillary flow or other wicking mechanisms. An example of a hydrophilic material that may be suitable is a polyvinyl alcohol, open-cell foam, such as V.A.C. WHITEFOAM™ dressing available from Kinetic Concepts, Inc. of San Antonio, Texas. Other hydrophilic foams may include those made from polyether. Other foams that

may exhibit hydrophilic characteristics include hydrophobic foams that have been treated or coated to provide hydrophilicity.

[0067] In some embodiments, the tissue interface 120 may be constructed from bioresorbable materials. Suitable bioresorbable materials may include, without limitation, a polymeric blend of polylactic acid (PLA) and polyglycolic acid (PGA). The polymeric blend may also include, without limitation, polycarbonates, polyfumarates, and caprolactones. The tissue interface 120 may further serve as a scaffold for new cell-growth, or a scaffold material may be used in conjunction with the tissue interface 120 to promote cell-growth. A scaffold is generally a substance or structure used to enhance or promote the growth of cells or formation of tissue, such as a three-dimensional porous structure that provides a template for cell growth. Illustrative examples of scaffold materials include calcium phosphate, collagen, PLA/PGA, coral hydroxy apatites, carbonates, or processed allograft materials.

[0068] In some embodiments, the cover 125 may provide a bacterial barrier and protection from physical trauma. The cover 125 may also be constructed from a material that can reduce evaporative losses and provide a fluid seal between two components or two environments, such as between a therapeutic environment and a local external environment. The cover 125 may comprise or consist of, for example, an elastomeric film or membrane that can provide a seal adequate to maintain a negative pressure at a tissue site for a given negative-pressure source. The cover 125 may have a high moisture-vapor transmission rate (MVTR) in some applications. For example, the MVTR may be at least 250 grams per square meter per twenty-four hours in some embodiments, measured using an upright cup technique according to ASTM E96/E96M Upright Cup Method at 38°C and 10% relative humidity (RH). In some embodiments, an MVTR up to 5,000 grams per square meter per twenty-four hours may provide effective breathability and mechanical properties.

[0069] In some example embodiments, the cover 125 may be a polymer drape, such as a polyurethane film, that is permeable to water vapor but impermeable to liquid. Such drapes typically have a thickness in the range of 25-50 microns. For permeable materials, the permeability generally should be low enough that a desired negative pressure may be maintained. The cover 125 may comprise, for example, one or more of the following materials: polyurethane (PU), such as hydrophilic polyurethane; celluloses; hydrophilic polyamides; polyvinyl alcohol; polyvinyl pyrrolidone; hydrophilic acrylics; silicones, such as hydrophilic silicone elastomers; natural rubbers; polyisoprene; styrene butadiene rubber; chloroprene rubber; polybutadiene; nitrile rubber; butyl rubber; ethylene propylene rubber; ethylene propylene diene monomer; chlorosulfonated polyethylene; polysulfide rubber; ethylene vinyl acetate (EVA); co-polyester; and polyether block polyamide copolymers. Such materials are commercially available as, for example, Tegaderm® drape, commercially available from 3M Company, Minneapolis Minnesota; polyurethane (PU) drape, commercially available from Avery Dennison Corporation, Pasadena, California; polyether block polyamide copolymer (PEBAX), from Arkema S.A., Colombes, France; and Inspire 2301 and Inspire 2327 polyurethane films, commercially

available from Transcontinental Advanced Coating, Wrexham, United Kingdom. In some embodiments, the cover 125 may comprise INSPIRE 2301 having an MVTR (upright cup technique) of $2600 \text{ g/m}^2/24 \text{ hours}$ and a thickness of about 30 microns.

[0070] An attachment device may be used to attach the cover 125 to an attachment surface, such as undamaged epidermis, a gasket, or another cover. The attachment device may take many forms. For example, an attachment device may be a medically-acceptable, pressure-sensitive adhesive configured to bond the cover 125 to epidermis around a tissue site. In some embodiments, for example, some or all of the cover 125 may be coated with an adhesive, such as an acrylic adhesive, which may have a coating weight of about 25-65 grams per square meter (g.s.m.). Thicker adhesives, or combinations of adhesives, may be applied in some embodiments to improve the seal and reduce leaks. Other example embodiments of an attachment device may include a double-sided tape, paste, hydrocolloid, hydrogel, silicone gel, or organogel.

[0071] The solution source 145 may also be representative of a container, canister, pouch, bag, or other storage component, which can provide a solution for instillation therapy. Compositions of solutions may vary according to a prescribed therapy, but examples of solutions that may be suitable for some prescriptions include hypochlorite-based solutions, silver nitrate (0.5%), sulfur-based solutions, biguanides, cationic solutions, and isotonic solutions.

[0072] In operation, the tissue interface 120 may be placed within, over, on, or otherwise proximate to a tissue site. If the tissue site is a wound, for example, the tissue interface 120 may partially or completely fill the wound, or it may be placed over the wound. The cover 125 may be placed over the tissue interface 120 and sealed to an attachment surface near a tissue site. For example, the cover 125 may be sealed to undamaged epidermis peripheral to a tissue site. Thus, the dressing 110 can provide a sealed therapeutic environment proximate to a tissue site, substantially isolated from the external environment, and the negative-pressure source 105 can reduce pressure in the sealed therapeutic environment.

[0073] The fluid mechanics of using a negative-pressure source to reduce pressure in another component or location, such as within a sealed therapeutic environment, can be mathematically complex. However, the basic principles of fluid mechanics applicable to negative-pressure therapy and instillation are generally well-known to those skilled in the art, and the process of reducing pressure may be described illustratively herein as “delivering,” “distributing,” or “generating” negative pressure, for example.

[0074] In general, exudate and other fluid flow toward lower pressure along a fluid path. Thus, the term “downstream” typically implies something in a fluid path relatively closer to a source of negative pressure or further away from a source of positive pressure. Conversely, the term “upstream” implies something relatively further away from a source of negative pressure or closer to a source of positive pressure. Similarly, it may be convenient to describe certain features in terms of fluid “inlet”

or “outlet” in such a frame of reference. This orientation is generally presumed for purposes of describing various features and components herein. However, the fluid path may also be reversed in some applications, such as by substituting a positive-pressure source for a negative-pressure source, and this descriptive convention should not be construed as a limiting convention.

5 **[0075]** Negative pressure applied across the tissue site through the tissue interface 120 in the sealed therapeutic environment can induce macro-strain and micro-strain in the tissue site. Negative pressure can also remove exudate and other fluid from a tissue site, which can be collected in container 115.

10 **[0076]** In some embodiments, the controller 130 may receive and process data from one or more sensors, such as the first sensor 135. The controller 130 may also control the operation of one or more components of the therapy system 100 to manage the pressure delivered to the tissue interface 120. In some embodiments, controller 130 may include an input for receiving a desired target pressure and may be programmed for processing data relating to the setting and inputting of the target pressure to be applied to the tissue interface 120. In some example embodiments, the target pressure may be a
15 fixed pressure value set by an operator as the target negative pressure desired for therapy at a tissue site and then provided as input to the controller 130. The target pressure may vary from tissue site to tissue site based on the type of tissue forming a tissue site, the type of injury or wound (if any), the medical condition of the patient, and the preference of the attending physician. After selecting a desired target pressure, the controller 130 can operate the negative-pressure source 105 in one or more control modes
20 based on the target pressure and may receive feedback from one or more sensors to maintain the target pressure at the tissue interface 120.

[0077] Figure 2 is a graph illustrating additional details of an example control mode that may be associated with some embodiments of the controller 130. In some embodiments, the controller 130 may have a continuous pressure mode, in which the negative-pressure source 105 is operated to provide
25 a constant target negative pressure, as indicated by line 205 and line 208, for the duration of treatment or until manually deactivated. Additionally or alternatively, the controller 130 may have an intermittent pressure mode, as illustrated in the example of Figure 2. In Figure 2, the x-axis represents time and the y-axis represents negative pressure generated by the negative-pressure source 105 over time. In the example of Figure 2, the controller 130 can operate the negative-pressure source 105 to cycle between
30 a target pressure and atmospheric pressure. For example, the target pressure may be set at a value of 135 mmHg, as indicated by line 205, for a specified period of time (e.g., 5 min), followed by a specified period of time (e.g., 2 min) of deactivation, as indicated by the gap between the solid lines 215 and 218. The cycle can be repeated by activating the negative-pressure source 105, as indicated by line 218, which can form a square wave pattern between the target pressure and atmospheric pressure.

35 **[0078]** In some example embodiments, the increase in negative pressure from ambient pressure to the target pressure may not be instantaneous. For example, the negative-pressure source 105 and the

dressing 110 may have an initial rise time, as indicated by the dashed line 225. The initial rise time may vary depending on the type of dressing and therapy equipment being used. For example, the initial rise time for one therapy system may be in a range of about 20-30 mmHg/second and in a range of about 5-10 mmHg/second for another therapy system. If the therapy system 100 is operating in an intermittent mode, the repeating rise time, as indicated by the solid line 218, may be a value substantially equal to the initial rise time as indicated by the dashed line 225.

[0079] Figure 3 is a graph illustrating additional details that may be associated with another example pressure control mode in some embodiments of the therapy system 100. In Figure 3, the x-axis represents time and the y-axis represents negative pressure generated by the negative-pressure source 105. The target pressure in the example of Figure 3 can vary with time in a dynamic pressure mode. For example, the target pressure may vary in the form of a triangular waveform, varying between a negative pressure of 50 and 135 mmHg with a rise time 308 set at a rate of +25 mmHg/min. and a descent time 310 set at -25 mmHg/min. In other embodiments of the therapy system 100, the triangular waveform may vary between negative pressure of 25 and 135 mmHg with a rise time 308 set at a rate of +30 mmHg/min and a descent time 310 set at -30 mmHg/min.

[0080] In some embodiments, the controller 130 may control or determine a variable target pressure in a dynamic pressure mode, and the variable target pressure may vary between a maximum and minimum pressure value that may be set as an input prescribed by an operator as the range of desired negative pressure. The variable target pressure may also be processed and controlled by the controller 130, which can vary the target pressure according to a predetermined waveform, such as a triangular waveform, a sine waveform, or a saw-tooth waveform. In some embodiments, the waveform may be set by an operator as the predetermined or time-varying negative pressure desired for therapy.

[0081] Figure 4 is a chart illustrating details that may be associated with an example method 400 of operating the therapy system 100 to provide negative-pressure treatment and instillation treatment to the tissue interface 120. In some embodiments, the controller 130 may receive and process data, such as data related to instillation solution provided to the tissue interface 120. Such data may include the type of instillation solution prescribed by a clinician, the volume of fluid or solution to be instilled to a tissue site ("fill volume"), and the amount of time prescribed for leaving solution at a tissue site ("dwell time") before applying a negative pressure to the tissue site. The fill volume may be, for example, between 10 and 500 mL, and the dwell time may be between one second to 30 minutes. The controller 130 may also control the operation of one or more components of the therapy system 100 to instill solution, as indicated at 405. For example, the controller 130 may manage fluid distributed from the solution source 145 to the tissue interface 120. In some embodiments, fluid may be instilled to a tissue site by applying a negative pressure from the negative-pressure source 105 to reduce the pressure at the tissue site, drawing solution into the tissue interface 120, as indicated at 410. In some embodiments, solution may be instilled to a tissue site by applying a positive pressure from the positive-

pressure source 150 to move solution from the solution source 145 to the tissue interface 120, as indicated at 415. Additionally or alternatively, the solution source 145 may be elevated to a height sufficient to allow gravity to move solution into the tissue interface 120, as indicated at 420.

[0082] The controller 130 may also control the fluid dynamics of instillation at 425 by providing a continuous flow of solution at 430 or an intermittent flow of solution at 435. Negative pressure may be applied to provide either continuous flow or intermittent flow of solution at 440. The application of negative pressure may be implemented to provide a continuous pressure mode of operation at 445 to achieve a continuous flow rate of instillation solution through the tissue interface 120, or it may be implemented to provide a dynamic pressure mode of operation at 450 to vary the flow rate of instillation solution through the tissue interface 120. Alternatively, the application of negative pressure may be implemented to provide an intermittent mode of operation at 455 to allow instillation solution to dwell at the tissue interface 120. In an intermittent mode, a specific fill volume and dwell time may be provided depending, for example, on the type of tissue site being treated and the type of dressing being utilized. After or during instillation of solution, negative-pressure treatment may be applied at 460. The controller 130 may be utilized to select a mode of operation and the duration of the negative pressure treatment before commencing another instillation cycle at 465 by instilling more solution at 405.

[0083] In some embodiments, the dressing 110 may be formed at least in part using flowable materials. For example, one or more delivery devices may deliver a flowable manifold material, which can readily conform to the size and shape of the tissue site to form at least a portion of the tissue interface 120 of the dressing 110. As used herein, the term “flowable” refers to an ability of a substance to be transported by gravity or under pressure from a storage vessel to a tissue site. Examples of a “flowable” substance may include, but are not limited to, a liquid, a gel, a slurry, a suspension, an aerosol, and any combination thereof. As used herein, the term “flowable material,” can refer to a flowable hydrophilic material, a flowable hydrophobic material, or both. The methods and devices described herein can form dressings in various configurations. In some embodiments, only the tissue interface 120 (e.g. the manifold) may be formed using flowable materials, for example with the flowable materials solidified under the cover 125 or the cover 125 may be applied after the material is solidified. In other embodiments, the flowable materials may simultaneously form the tissue interface 120 and the cover 125 for the tissue site. For example, the outer surface of the tissue interface 120 formed of flowable materials may form a skin that acts as an integral cover in some embodiments. In other embodiments, a first flowable material may be applied to the tissue site to form the tissue interface 120, and then a second flowable material may be applied atop the first flowable material to form the cover 125. Typically, the flowable manifold materials may be non-toxic and/or may form (e.g. react and/or solidify) at a temperature which will not damage the tissue site (or cause significant distress to the patient).

[0084] Figure 5A is a schematic view of an exemplary method of forming a dressing for a tissue site using flowable materials, illustrating additional details that may be associated with some embodiments. In some embodiments, the method of Figure 5A may include positioning a cover 125 adjacent to a tissue site 510. A distal end 515 of a tissue dressing material delivery tube 520 can be positioned beneath the cover 125 and adjacent to the tissue site 510. A flowable manifold material from a delivery device 525 can be delivered, for example, through the tissue dressing material delivery tube 520 to the tissue site 510. For example, the flowable manifold material may be delivered into a cavity or void space 530, such as a wound space. In some embodiments, the flowable manifold material may be poured, injected, or sprayed onto or into a tissue site, for example, with or without use of the tissue dressing material delivery tube 520. Alternatively, a flowable manifold material may be delivered through the tissue dressing material delivery tube 520 to the tissue site 510, and then a cover 125 may be positioned over the flowable manifold material and tissue site 510. In some embodiments, the tissue site 510 can include an internal site (e.g., void space 530), and the flowable manifold material may be delivered percutaneously.

[0085] In some embodiments, the method may include solidifying the flowable manifold material to form a foam, for example, an open cell foam or a closed cell foam adjacent to the tissue site 510. In some embodiments, an open cell foam manifold can be formed having a plurality of flow channels in fluid communication with the tissue site 510. Solidifying the flowable manifold material can be achieved by any known means in the art, for example, via cooling, reacting, heating, curing, cross-linking, exposure to ultraviolet light, and combinations thereof. In some embodiments, the foam may have a higher molecular weight (M_n), for example, greater than or equal to about 100,000, greater than or equal to about 500,000 or about 1,000,000; or from about 100,000 to about 1,000,000, about 250,000 to about 1,000,000 or about 500,000 to about 1,000,000. Additionally or alternatively, the foam may have a moisture vapor transmission rate MVTR of about 250 g/m²/24 hours to about 1500 g/m²/24 hours, or about 500 g/m²/24 hours to about 1500 g/m²/24 hours, or about 1000 g/m²/24 hours to about 1500 g/m²/24 hours.

[0086] In some embodiments, the flowable manifold material may be allowed to react completely, e.g., foaming has stopped and/or the majority of heat is released, before applying the flowable manifold material to a tissue site. In other embodiments, the flowable manifold material may be applied to a tissue site while still reacting, e.g., foaming. In such instances, a cooler temperature of the tissue site can slow and/or stop the foaming.

[0087] Figure 5B is another schematic view of the method shown in Figure 5A, illustrating additional details that may be associated with some embodiments. For example, Figure 5B may illustrate the exemplary tissue site 510 after the flowable manifold material has solidified and is ready for application of negative-pressure therapy. In Figure 5B, the method may include applying a negative pressure to the tissue site 510 through the plurality of flow channels of the open cell foam 535, for

example, via a manifold delivery tube 540 or the tissue dressing material delivery tube 520 (not shown in Figure 5B). In some embodiments, the manifold delivery tube 540 may be integral with a dressing interface (e.g. connector pad 545). A negative-pressure source 105 for applying the negative pressure can be in fluid communication with the tissue dressing material delivery tube 520, the manifold delivery tube 540, or both, for example via a fluid conductor. As illustrated in Figure 5B, the delivery device (of Figure 5A) may not be in fluid communication with the negative-pressure source 105, i.e., the delivery device is physically separate from the negative-pressure source 105.

[0088] Figure 6 is yet another schematic view of the method shown in Figure 5A, illustrating additional details that may be associated with some embodiments. For example, Figure 6 may illustrate another configuration after the flowable manifold material has solidified and is ready for application of negative-pressure therapy. In the embodiment of Figure 6, the delivery device 525 can be in fluid communication with the negative-pressure source 105, for example, via a fluid conductor 605 and a fluid conductor 610. The flowable manifold material may be delivered to tissue site 510 via fluid conductor 605 and fluid conductor 610; for example, the delivery device 525 may be in fluid communication with the therapy system 100 and delivery of the flowable manifold material may be automatic.

[0089] In some embodiments, the flowable manifold material can be formed in the delivery device 525 by mixing a first reactant with a second reactant to form the flowable manifold material. A device for delivering a flowable manifold material may include a first zone comprising a first reactant and a second zone comprising a second reactant. The first zone may be physically separate from the second zone.

[0090] Figure 7A is a schematic cross-section view of an exemplary delivery device 525 for the flowable manifold materials, illustrating additional details that may be associated with some embodiments. In some embodiments, the delivery device 525 may be a single container 705 including a first zone 710 and a second zone 715 therein. The delivery device 525 can further include a wall 720 defined therein, which separates the first zone 710 and the second zone 715. The wall 720 can be at least partially removable to allow for mixing between the first reactant and the second reactant to form a flowable manifold material upon removal of at least a portion of the wall 720. For example, the wall 720 may be formed of a material and/or configured so that it can be pierced, punctured, or removed by a user (e.g. these and other means may be used to at least partially remove the wall). In some embodiments, the wall 720 may comprise one or more material that does not substantially chemically react to the separated components of the flowable manifold (e.g. the first reactant and/or the second reactant). Exemplary materials that the wall 720 may comprise include, but are not limited to, a metal (e.g., aluminum, steel, and stainless steel), optionally coated with a polymeric coating (e.g., polyurethanes, epoxies, thermosets, such as phenol formaldehyde, urea formaldehyde, melamine formaldehyde, or polyolefins, blends and copolymers thereof), and a polymeric material (e.g.,

polyamides, acetals, polyesters, and other engineering polymers, such as aramids and aromatic polyesters). Mixing can be achieved by a user, for example, by partially removing a wall as described herein, e.g., wall 720, to allow the first reactant and the second reactant to mix with one another, and/or by agitating the device. Additionally or alternatively, an optional mixer 725 for mixing the first reactant with the second reactant may be included in the device, for example, as illustrated in Figure 7A in device 525. Examples of a suitable mixer 725 may include, but are not limited to, a ball (e.g., metal, glass, or plastic ball), a mechanical reciprocating plunger, and a magnetically coupled impeller or beads, for example, where an external magnetic source rotates the impeller or agitates the beads. Although not shown, the mixer 725 can be present in any of the delivery device embodiments described herein.

[0091] The first reactant and the second reactant may be any suitable multipart polymer reaction system, which, when mixed together and/or reacted, form a flowable manifold material, such as a polymer foam, for example, a polyurethane foam. Examples of a suitable first reactant may include, but are not limited to, a polyol, a polyaldehyde, a polyamine, and combinations thereof. Examples of a suitable second reactant may include, but are not limited to, a multi-isocyanate (e.g., diisocyanate, triisocyanate), a multi-isocyanate prepolymer, a polycarbamate, a polycarboxylic acid, an anhydride, and combinations thereof. As used herein, the term “multi-isocyanate prepolymer” refers to a multi-isocyanate, such as a diisocyanate, having at least a portion of the active isocyanate groups already reacted, leaving fewer isocyanate groups to react with a polyol. For example, the first reactant may be a polyol and the second reactant may be a multi-isocyanate (e.g., diisocyanate). Once the polyol and the multi-isocyanate are mixed together in the presence of water, for example, either present in the device and/or present as ambient water, they can react to form a polyurethane foam, which can be delivered to a tissue site as a flowable manifold material. Similarly, a polyaldehyde (i.e., first reactant) and a polycarbamate (i.e., second reactant) when mixed together can react to form a polyurethane foam.

[0092] Figure 7B is a schematic cross-section view of another exemplary delivery device 525 for flowable manifold material, illustrating additional details that may be associated with some embodiments. The delivery device 525 of Figure 7B may be similar to that of Figure 7A, and may have an additional zone therein in some embodiments. Optionally, as illustrated in Figure 7B, a third zone 730 may be included in some embodiments of the delivery device 525 for mixing the first reactant from the first zone 710 with the second reactant from the second zone 715 to form a flowable manifold material and/or for delivering the flowable manifold material. In the example in Figure 7B, partially-removable walls 720 may be defined therein, which physically separate the first zone 710 and the second zone 715 from the third zone 730. For example, the third zone 730 may be located between the first zone 710 and the second zone 715, with one at least partially-removable wall 720 separating the first zone 710 from the third zone 730, and another at least partially-removable wall 720 separating the second zone 715 from the third zone 730. Upon removal of at least a portion of the at least partially-removable walls 720, the first reactant and the second reactant may enter the third zone 730 and be admixed to form a flowable manifold material.

[0093] Figure 7C is a schematic cross-section view of another exemplary delivery device for flowable manifold materials, illustrating additional details that may be associated with some embodiments. The delivery device 525 of Figure 7C may be similar to that of Figure 7B, with reconfiguration of the zones. For example, Figure 7C illustrates an example configuration of the delivery device 525 having the first zone 710, the second zone 715, the third zone 730, and the wall 720 defined therein, which is at least partially removable. Delivery device 525 of Figure 7C may further include an irremovable wall 735 defined therein, which physically separates the first zone 710 and the second zone 715. In Figure 7C, the first zone 710 and the second zone 715 may be located below the third zone 730 (for example, with the first zone 710 and the second zone 715 side-by-side), and the at least partially-removable wall 720 may separate the first zone 710 and the second zone 715 from the third zone 730. Upon removal of at least a portion of the wall 720, the first reactant and the second reactant may enter the third zone 730 and be admixed to form the flowable manifold material.

[0094] Figure 7D is a schematic cross-section view of another exemplary delivery device for flowable manifold materials, illustrating additional details that may be associated with some embodiments. The delivery device 525 of Figure 7D may be similar to that of Figure 7A, while optionally further including a propellant. As illustrated for example in Figure 7D, a canister 740 may be in fluid communication with the single container 705 of a delivery device 525 in some embodiments. The canister 740 can contain a propellant, as further described below, for further enabling delivery of a flowable manifold material from the delivery device 525. For example, the propellant may expand to force the flowable manifold material out of the delivery device 525, for example, through holes in a spray nozzle as an aerosol. Although not shown, it is contemplated herein that canister 740 can be present in any of the delivery device embodiments described herein. Additionally, the canister 740 may be removable or irremovable.

[0095] Figure 7E is a schematic cross-section view of another exemplary delivery device for flowable manifold materials, illustrating additional details that may be associated with some embodiments. The delivery device 525 of Figure 7E may be similar to that of Figure 7A, while additionally including an ultraviolet (UV) light source which may aid solidification of the flowable manifold material. As illustrated in Figure 7E, an optional UV light source 745 may be included with the delivery device 525, for example, for further solidifying a flowable manifold material at a tissue site. While Figure 7E illustrates a UV light source 745 as integral to the single container 705, it is contemplated herein that the UV light source 745 may be removable from the single container 705 and/or may be separate from the single container 705. Although not shown, it is contemplated herein that UV light source 745 can be present in any of the device embodiments described herein.

[0096] Figure 8 is a schematic cross-section view of another exemplary delivery device 525 for flowable manifold materials, illustrating additional details that may be associated with some embodiments. While conceptually Figure 8 may be similar to Figure 7B, in Figure 8, each zone may

be located in a separate container. In the embodiment illustrated in Figure 8, the delivery device 525 may include the first zone 710 comprising the first reactant in a first container 805 and the second zone 715 comprising the second reactant in a second container 810. In some embodiments, the delivery device 525 may further include the third zone 730 in a third container 815 for combining and/or mixing the first reactant with the second reactant to form a flowable manifold material. For example, the first container 805, the second container 810, and the third container 815 may each include a removable cap 820, so that the first reactant and the second reactant can be removed from the first container 805 and the second container 810 and added to the third container 815. The first reactant and the second reactant may be mixed in any of the first container 805, the second container 810, and the third container 815. It is contemplated herein, if the first reactant and the second reactant are mixed in the first container 805 or the second container 810, the third container 815 may be absent. Some embodiments may only comprise two containers, for example the first container 805 and the second container 810.

[0097] Figure 9 is a schematic cross-section view of another exemplary delivery device 525 for flowable manifold materials, illustrating additional details that may be associated with some embodiments. The delivery device 525 of Figure 9 may be similar to that of Figure 7A, but may only have a single zone (e.g. with no dividing wall). In Figure 9, the delivery device 525 for delivering a flowable manifold material may include the flowable manifold material comprising a reacted polymer present in a carrier. In some embodiments, the delivery device 525 may contain the flowable manifold material in a single container 705. Examples of a suitable reacted polymer include, but are not limited to, a polyurethane, a polyester, a polyamide, an acrylic polymer, an acrylate polymer, a polyvinyl acetate, a polysiloxane, and combinations and copolymers thereof.

[0098] Alternatively, the flowable manifold material present in single container 705 may be a flowable hydrophilic manifold material including a reacted polymer (i.e., a hydrophilic reacted polymer) present in a carrier. Examples of a suitable hydrophilic reacted polymer may include, but are not limited to, polyvinylpyrrolidone (PVP), a polyvinyl alcohol, polyethylene oxide (PEO), hydrophilically-modified polyurethane, and combinations and copolymers thereof. The hydrophilically-modified polyurethane can include any suitable hydrophilic moieties, such as, but not limited to, a hydroxyl moiety, a carboxyl moiety, an ester moiety, a quaternary ammonium ion moiety, a metal ion moiety (e.g., sodium ion, potassium ion, sodium salt, and potassium salt), a nitrogen-containing moiety (e.g., an amine, an amide, and an imine), and combinations thereof. In some embodiments, peroxide and/or hydrogen peroxide may be included with the reacted polymer in the carrier. Additionally or alternatively, the hydrophilic reacted polymer may include polymer segments with a low glass transition temperature, for example, less than or equal to about 25°C.

[0099] In some embodiments, the reacted polymer (including the hydrophilic reacted polymer) may be dissolved or dispersed in a suitable carrier, such as, but not limited to, a low-boiling-point liquid, water, a compressed gas, and combinations thereof. The reacted polymer (including the hydrophilic

reacted polymer) and carrier may be in the form of a dispersion, solution, or emulsion. Examples of a low-boiling-point liquid may include, but are not limited to, a fluorocarbon, a chlorofluorocarbon, a hydrofluorocarbon (e.g., tetrafluoropropene, Solkane®) a hydrochlorofluorocarbon, and combinations thereof. Examples of a compressed gas may include, but are not limited to, compressed carbon dioxide, compressed nitrogen, a compressed alkane (e.g., methane, ethane, propane, and the like), and combinations thereof.

[00100] As illustrated in Figures 7A–7E and 9, a delivery tube 520 may optionally be present for delivering a flowable manifold material from the delivery device 525. Although not shown in Figure 8, a delivery tube 520 may be present in one or more of the first container 805, the second container 810, and/or the third container 815. In some embodiments, a delivery means 905 may be in fluid communication with the delivery tube 520 for delivering the flowable manifold material to a tissue site. Examples of suitable delivery means 905 may include, but are not limited to, a nozzle, such as a spray nozzle, or a manifold delivery tube. In some embodiments, the flowable dressing material may be transferred and/or mixed in a separate vessel (e.g., measuring cup) from which it can be poured onto a tissue site. It is also contemplated herein that a delivery tube 520 may be absent, and/or any of the devices described herein may include a removable cap, so that a flowable manifold material can be poured from the devices onto a tissue site.

[00101] In some embodiments, the delivery device 525 embodiments described herein may be made of any suitable material, such as, but not limited to, metal, plastic, or a combination thereof. Suitable metals include, but are not limited to, aluminum and coated steels. Suitable plastics may include, but are not limited to, polycarbonates, polyesters, and polyolefins. In any embodiment, an interior of the devices described herein may be sterile and the contents of the device may be sterile. Sterilization can be achieved by any known methods in the art, for example, via gamma sterilization or electron beam (e-beam) sterilization. In the case of e-beam sterilization, the delivery devices described herein may include a window, for example, a plastic window, to permit transmission of the e-beam.

[00102] Some delivery device embodiments can include one or more additional agents for incorporation into a flowable manifold material and/or for use in the formation of a flowable manifold material. Each additional agent may be present in the first zone 710, the second zone 715, the third zone 730, or a combination thereof. In some embodiments, a cell opener can be included in the devices described herein to promote opening or rupturing of cell walls and to enhance an open cell structure as the polymer foam is produced. Examples of a suitable cell opener may include, but are not limited to, a silicone, a polyether siloxane, a mineral (e.g., clays, silicas, calcium carbonate, and the like), and combinations thereof.

[00103] Additionally or alternatively, some delivery device embodiments can further include a foaming agent, a propellant, or a combination thereof to assist with foam formation and delivery. As used herein, a foaming agent includes any suitable surfactants and blowing agents as known in the art

for producing a flowable manifold material, e.g., a polymer foam. Examples of suitable foaming agents may include, but are not limited to, a low-boiling-point liquid, water, a compressed gas, hydrocarbons (e.g. pentane, isopentane, cyclopentane), liquid carbon dioxide, and combinations thereof. Examples of a low-boiling-point liquid may include, but are not limited to, a fluorocarbon, a chlorofluorocarbon, a hydrofluorocarbon (e.g., tetrafluoropropene, Solkane®) a hydrochlorofluorocarbon, and combinations thereof. Examples of a compressed gas may include, but are not limited to, compressed carbon dioxide, compressed nitrogen, a compressed alkane (e.g., methane, ethane, propane, and the like), and combinations thereof. Examples of a suitable propellant may include, but are not limited to, low-boiling-point liquids as described herein. The propellant may be present within the delivery devices described herein, for example, in the first zone 710, in the second zone 715, in the third zone 730, or a combination thereof, or in the single container 705. Alternatively, with reference to Figure 7D, the propellant may be present in a separate canister 740 in fluid communication with the devices described herein. In addition to aiding in delivery of a flowable manifold material, the propellant may also aid in mixing of the first reactant with the second reactant or mixing the reacted polymer.

[00104] Additionally or alternatively, some delivery device embodiments can further include a catalyst, for example, when the first reactant and the second reactant are present, to assist in formation of a flowable manifold material, e.g., a polymer foam. Any suitable catalysts known in the art for producing polymer foams can be used. For example, suitable gelling catalysts and/or blowing catalysts may be used for forming a polyurethane foam. Examples of catalysts may include, but are not limited to, tertiary amine catalysts (e.g., 1,4-diazabicyclo[2.2.2]octane), metal complex catalysts, such as metal carboxylates (e.g., tin carboxylates, bismuth carboxylates, zinc carboxylates, zirconium carboxylates, nickel carboxylates), dibutyltin dilaurate, bismuth octanoate, and platinum catalysts.

[00105] Additionally or alternatively, some delivery device embodiments and/or the flowable manifold material can further include a softener, such as water-soluble particles, to encourage a certain degree of porosity at the tissue site interface, which upon contact with water present in the wound can soften and/or dissolve to leave pores or fissures in foam. Examples of suitable water-soluble particles may include, but are not limited to, a salt, a water-soluble polymer, and combinations thereof. Examples of a salt may include, but are not limited to, sodium chloride, magnesium chloride, calcium chloride, sodium carbonate, potassium carbonate, and combinations thereof. Examples of water-soluble polymers may include, but are not limited to, PVP, a polyvinyl alcohol, PEO, carboxy modified polyurethane, hydroxy modified polyurethane, and combinations thereof.

[00106] Additionally or alternatively, some delivery device embodiments and/or the flowable manifold material can further include an antimicrobial agent. Examples of suitable antimicrobial agents may include, but are not limited to, organic acids, such as carboxylic acids, silver, gold, zinc, copper, polyhexamethylene biguanide (PHMB), iodine, and combinations thereof. Exemplary carboxylic acids may include, but are not limited to, ascorbic acid (e.g., (R)-3,4-dihydroxy-5-((S)- 1,2-

dihydroxyethyl)furan-2(5H)-one or Vitamin C), formic acid, gluconic acid, lactic acid, oxalic acid, tartaric acid, peroxy-pyruvic acid, and combinations thereof. Examples of carboxylic acids may include, but are not limited to, citric acid and acetic acid (i.e., ethanoic acid). The metal (e.g., silver) may be present in metallic form, in ionic form (e.g., a silver salt), or both.

5 **[00107]** Additionally or alternatively, some delivery device embodiments and/or the flowable manifold material can further include a polysaccharide, such as chitosan and/or an anionic polysaccharide. The anionic polysaccharide may be substantially insoluble in water at pH 7. Additionally or alternatively, the anionic polysaccharide may have a molecular weight greater than about 20,000, more preferably greater than about 50,000. The anionic polysaccharide may be in the
10 form of a film, or fibers having a length greater than 1 mm. Suitable anionic polysaccharides may include, but are not limited to, polycarboxylates, alginates, hyaluronates, pectins, carrageenans, xanthan gums, sulfated dextrans, cellulose derivatives, such as carboxymethyl celluloses, and oxidized celluloses. The term “oxidized cellulose” refers to any material produced by the oxidation of cellulose, for example with dinitrogen tetroxide. Such oxidation converts primary alcohol groups on the
15 saccharide residues to carboxylic acid groups, forming uronic acid residues within the cellulose chain. The oxidation generally does not proceed with complete selectivity, and as a result, hydroxyl groups on carbons 2 and 3 are occasionally converted to the keto form. These keto units introduce an alkali-labile link, which at pH 7 or higher initiates the decomposition of the polymer via formation of a lactone and sugar ring cleavage. In some embodiments, oxidized cellulose may be oxidized regenerated cellulose
20 (ORC), which may be prepared by oxidation of a regenerated cellulose, such as rayon. It has been known that ORC has haemostatic properties. ORC has been available as a haemostatic fabric called SURGICEL® (Johnson & Johnson Medical, Inc.) since 1950. This product may be produced by the oxidation of a knitted rayon material.

[00108] Additionally or alternatively, some delivery device embodiments and/or the flowable
25 manifold material can further include one or more super absorbent polymers, for example in particle form. Examples of suitable super absorbent polymers may include, but are not limited to polyacrylic acid, a salt of polyacrylic acid (e.g. sodium polyacrylate (Luquasorb® 1160, Luquasorb® 1161; BASF)), polyacrylamide, cellulosic polymer, 2-acrylamido-2-methylpropanesulfonic acid (AMPS), polyethylene oxide (PEO), and a combination thereof.

30 **[00109]** Additionally or alternatively, some delivery device embodiments and/or the flowable manifold material can further include an alcohol, a colorant (e.g., a pigment, a dye), a release agent (e.g., wax, fluorocarbon), and a combination thereof. For example, an alcohol can be included as a further solvent and/or suspending agent along with the reacted polymer. Examples of a suitable alcohol may include, but are not limited to ethanol, isopropyl alcohol, and a combination thereof.

35 **[00110]** Additionally or alternatively, some delivery device embodiments and/or the flowable manifold material can further include a photoinitiator that is capable of undergoing photopolymerization

or radiation curing, i.e., producing a free radical when exposed to radiation, e.g., UV light, which can react, for example, with the first reactant and/or the second reactant, to initiate polymer chain growth. Examples of a suitable photoinitiator may include, but are not limited to, 2,2-dimethoxy-1,2-diphenylethan-1-one, 1-hydroxy-cyclohexyl-phenyl-ketone (IRGACURE® 184); 1-[4-(2-hydroxyethoxy)-phenyl]-2-hydroxy-2-methyl-1-propane-1-one (IRGACURE® 2959); and 2-benzyl-2-(dimethylamino)-1-[4-(4-morpholinyl) phenyl]-1-butanone (IRGACURE® 369).

[00111] When a manifold is formed using flowable materials (e.g. to form the manifold in-situ in proximity to the tissue site, for example as discussed above), the dressing interface may be configured for operation with the flowable manifold. For example, the distal end of the dressing interface may be configured for use within the manifold (e.g. not simply on the external surface of the tissue dressing). In some embodiments, the dressing interface may be configured to provide negative pressure in more than one direction within the flowable manifold and/or at more than one level within the flowable manifold. For example, the distal end may comprise at least one aperture configured to direct negative pressure outward into the flowable manifold in more than one direction and/or at more than one level. In some embodiments, the distal end of the dressing interface may be configured to allow manifolding both above the distal end (e.g. towards the external surface of the manifold) and below the distal end (e.g. towards the tissue site surface). In some embodiments, the distal end of the dressing interface may be configured to draw fluid omni-directionally from throughout the manifold. In some embodiments, the distal end may be configured to resist fouling or clogging caused by solidification of the flowable manifold (e.g. when the dressing interface is inserted into or covered with flowable manifold material before solidification of the manifold). For example, the distal end of the dressing interface may be configured to prevent formation of skin in proximity to the distal end (e.g. where the flowable manifold contacts the distal end of the dressing interface). Some embodiments may be configured so that the distal end is self-securing. For example, the distal end may be configured to interact with the solidified flowable manifold to resist removal of the distal end from the solidified manifold. Some self-securing embodiments may allow the dressing interface to be used effectively with the flowable manifold without the need for any separate adhesive or other attachment mechanism to hold the dressing interface in place with respect to the tissue site and/or the manifold.

[00112] Figure 10 is a top isometric view of an exemplary dressing interface 1005, illustrating additional details that may be associated with some embodiments. The embodiment of Figure 10 may comprise a low-profile conduit or housing 1010 that may be associated with some example embodiments of the therapy system 100. The dressing interface 1005 may comprise the housing 1010 with a distal end 1015 and a proximal end 1020. The distal end 1015 may be configured to interact with the flowable manifold at the tissue site (e.g. by being anchored within the flowable manifold once it has solidified and/or by fluidly communicating with the manifold), while the proximal end 1020 may be configured to extend out of the flowable manifold for connection to the negative-pressure source. The distal end 1015 may comprise one or more apertures configured to deliver negative pressure to the

tissue site, while the proximal end 1020 may comprise a port 1025 for introduction of negative pressure (e.g. via fluid communication with a negative-pressure source). In some embodiments, the one or more apertures may form a through-opening 1030 in the distal end 1015. The port 1025 may be configured to fluidly couple to the negative-pressure source. In some embodiments, the distal end 1015 of the dressing interface 1005 may comprise or consist essentially of an applicator, which for example may comprise the through-opening 1030. The applicator may be configured to be positioned in fluid communication with the tissue interface of the dressing (e.g. within the flowable manifold). In some embodiments, the applicator may be bulbous or any shape suitable for facilitating a connection with the dressing. For example, the applicator (or the distal end 1015) may have a width W1 greater than the width W2 at the proximal end 1020 of the dressing interface 1005. In some embodiments, the housing 1010 may be substantially flexible. In some embodiments, the dressing interface may consist essentially of the applicator. For example, the dressing interface may not be elongate, and the conduit connecting the dressing interface to the negative-pressure source may be configured to partially enter the flowable manifold to fluidly communicate with the applicator.

[00113] Figure 11 is a schematic longitudinal cross-sectional view of the exemplary dressing interface 1005 of Figure 10, illustrating additional details that may be associated with some embodiments. In some embodiments, the housing 1010 may comprise an internal fluid pathway 1105 extending from the port 1025 to the one or more aperture. In Figure 11, the housing 1010 may comprise two apertures, which may be aligned to form the through-opening 1030 which passes entirely through the thickness of the distal end 1015. For example, the through-opening 1030 may comprise a first aperture 1110 on a first surface 1115 of the housing 1010 and a second aperture 1120 on a second surface 1125 of the housing 1010, with a recessed space 1130 therebetween (such that the first aperture 1110 and the second aperture 1120 may be in fluid communication with each other). In Figure 11, the recessed space 1130 may extend inward between the first surface 1115 and the second surface 1125. In some embodiments, the recessed space 1130 may comprise an open portion of the fluid pathway 1105 within the housing 1010 without supports, for example between the first aperture 1110 and the second aperture 1120. In some embodiments, the first aperture 1110 and the second aperture 1120 may be aligned, and the recessed space 1130 may also be aligned with the apertures in the distal end 1015 (e.g. with a common central axis). In some embodiments, the fluid pathway 1105 may be configured to fluidly communicate with the ambient environment (e.g. the flowable manifold) through the recessed space 1130 and/or the one or more apertures in the distal end 1015. In some embodiments, the port 1025 may be located on the first surface 1115 of the proximal end 1020 of the housing 1010. In some embodiments, the through-opening 1030 may be perpendicular to the fluid pathway 1105 (e.g. with the central axis of the through-opening 1030 being substantially perpendicular to the longitudinal axis of the fluid pathway 1105).

[00114] In some embodiments, the fluid pathway 1105 may be configured to be pneumatically isolated from the ambient environment (e.g. the manifold) except through the recessed space 1130

and/or the one or more apertures in the distal end 1015 of the dressing interface 1005. In some embodiments, the one or more apertures (e.g. the first aperture 1110 and the second aperture 1120) may be configured to allow fluid communication between the recessed space 1130 (e.g. an open portion of the fluid pathway 1105) and the ambient environment. In some embodiments, the fluid pathway 1105 may be configured to be in fluid communication with the ambient environment (e.g. the manifold and/or tissue site) through the one or more apertures. In some embodiments, the one or more apertures (e.g. the first aperture 1110 and the second aperture 1120) may be configured and/or oriented to open in different directions (e.g. to deliver or direct negative pressure outward to the manifold in two or more different directions simultaneously) and/or to allow for negative pressure delivery simultaneously at more than one level within the manifold (e.g. above and below, or on both sides of, the dressing interface).

[00115] In some embodiments, the port 1025 and the one or more apertures (e.g. the first aperture 1110 and the second aperture 1120) may be in fluid communication through the fluid pathway 1105. In some embodiments, the fluid pathway 1105 may be configured so that fluid may flow from the one or more apertures in the distal end 1015 towards the port 1025 (e.g. when negative pressure is applied to the port). In some embodiments, the fluid pathway 1105 may be configured so that negative pressure applied to the port 1025 may be transmitted through the fluid pathway 1105 to the one or more apertures and/or the recessed space 1130. In some embodiments, the fluid pathway 1105 may extend longitudinally from the distal end 1015 to the proximal end 1020 (e.g. between the one or more aperture and the port).

[00116] As shown in Figure 11, the fluid pathway 1105 may be supported to maintain an open pathway configuration by a plurality of supports 1135 within the housing 1010. In some embodiments, the plurality of supports 1135 may be configured to support the fluid pathway 1105 substantially along its entire length and/or width. For example, the supports 1135 may be co-extensive with the fluid pathway 1105. In some embodiments, the plurality of supports 1135 may be arranged in rows, and the rows may be aligned and may extend longitudinally (see for example, Figure 10). For example, the rows may extend the length of the dressing interface 1005, with longitudinally extending spaces of the fluid pathway 1105 separating the rows. The row configuration of supports 1135 may allow fluid (and/or negative-pressure) flow longitudinally from one end of the fluid pathway 1105 to the other, for example even when the dressing interface 1005 is under compression. For example, in the row configuration of supports 1135, the longitudinally extending spaces may provide unobstructed flow channels of the fluid pathway 1105 between the rows of supports 1135.

[00117] In some embodiments, each of the supports 1135 may comprise a hollow standoff 1140, which may be sealed to maintain internal pressure within the plurality of hollow standoffs 1140. In some embodiments, each of the plurality of supports 1135 may comprise the standoff 1140 and a base, with the standoff 1140 having a closed surface extending away from the base. The supports 1135

may comprise a variety of shapes, for example substantially circular, hexagonal, oval, triangular, and/or square (e.g. in lateral cross-section). In some embodiments, the standoffs 1140 may each comprise a blister, a bubble, or a cell. In some embodiments, all of the standoffs 1140 may be similarly sized and/or shaped. In some embodiments, the supports 1135 may each comprise a diameter from approximately two to four millimeters and/or a height from approximately two to five millimeters.

[00118] Figure 12 is a schematic lateral cross-section view of the exemplary dressing interface 1005 of Figure 10, illustrating additional details that may be associated with some embodiments. As shown in Figure 12, the housing 1010 of the dressing interface 1005 may comprise an envelope 1205 encompassing a support layer, such as the plurality of supports 1135. The support layer may be configured to support the fluid pathway 1105 within the envelope 1205, to maintain an open configuration (e.g. allowing fluid flow and/or negative pressure distribution through the fluid pathway 1105 even when the dressing interface 1005 experiences external compression, such as a patient lying atop the dressing interface 1005, and/or draw-down by internal negative pressure). In some embodiments, the support layer may comprise the plurality of supports 1135 configured to support the envelope 1205 to define the fluid pathway 1105 within the envelope 1205.

[00119] In some embodiments, the plurality of supports 1135 may comprise a first plurality of supports 1210 and a second plurality of supports 1215. In some embodiments, the first plurality of support 1210 may be opposingly aligned with the second plurality of supports 1215, for example stacked to jointly support the fluid pathway 1105. In some embodiments, the first plurality of supports 1210 and the second plurality of supports 1215 may jointly support the fluid pathway 1105 to maintain an open pathway with a height substantially equal to the height of one of the first plurality of supports 1210 and one of the second plurality of supports 1215 taken together (e.g. stacked to provide a cumulative height). The first plurality of supports 1210 and the second plurality of supports 1215 may each be aligned into longitudinally extending rows. For example, the first plurality of supports 1210 may be aligned into rows that match the rows of the second plurality of supports 1215, so that the first plurality of supports 1210 may be opposingly aligned and stacked with the second plurality of supports 1215.

[00120] In some embodiments, the plurality of supports 1135 (e.g. the first plurality of supports 1210 and the second plurality of supports 1215 in Figure 12) may be located within the envelope 1205. The envelope 1205 may encompass the plurality of supports 1135 to define the internal fluid pathway 1105 between the distal end and the proximal end (e.g. defining an enclosed conduit pneumatically isolated from the ambient external environment except through the one or more apertures in the distal end). The envelope 1205 may be made of a material that is impermeable to liquid and/or is substantially air-tight (e.g. allowing a vacuum to be drawn through the envelope 1205). In some embodiments, the envelope 1205 may comprise at least one vapor-transfer surface that is permeable to vapor. In some embodiments, the supports 1135 may structurally support the envelope 1205 to define

the internal fluid pathway 1105. The fluid pathway 1105 may fluidly couple the distal end to the proximal end. For example, the fluid pathway 1105 may fluidly couple the one or more apertures in the distal end to the port in the proximal end. The envelope 1205 may comprise the first surface 1115 (e.g. outward-facing when the dressing interface is in place on a tissue site) and the second surface 1125 (e.g. patient-facing). In some embodiments, the envelope 1205 may comprise a first layer 1210 and a second layer 1225, which may be coupled together (e.g. welded) about a perimeter to form the envelope 1205 with an enclosed conduit or space of the fluid pathway 1105. For example, the first layer 1220 may form the first surface 1115 of the envelope 1205, while the second layer 1225 may form the second surface 1125 of the envelope 1205.

[00121] In some embodiments, the fluid pathway 1105 may be configured to maintain an open pathway despite application of internal negative pressure and/or external compression loading. In some embodiments, the plurality of supports 1135 are configured to maintain the fluid pathway 1105 as an open pathway, for example allowing negative pressure to be applied to a tissue site through the fluid pathway 1105 even when the fluid pathway experiences compressive loads. For example, the fluid pathway 1105 may be maintained in an open position or configuration, without collapsing in a way that may close off the fluid pathway 1105, even if the patient is lying atop the dressing interface 1005. In some embodiments, the plurality of supports 1135 may be configured to support the fluid pathway 1105 substantially along its entire length and/or width. For example, the supports 1135 may be co-extensive with the fluid pathway 1105. In some embodiments, the supports 1135 may be sealed to maintain an internal pressure. For example, the supports 1135 may be maintained at a pressure at or above atmospheric pressure, which may aid in resisting compression or collapse.

[00122] In some embodiments, the dressing interface 1005 may be configured with a low profile. For example, the dressing interface 1005 may have a height (H) of approximately 5 millimeters. Some embodiments may have a height of less than approximately 5 millimeters, less than 6 millimeters, less than 7 millimeters or from about 5-7 millimeters.

[00123] Some embodiments of the dressing interface 1005 may optionally have one or more pressure-sensing pathways 1230 that each extends from one or more of the apertures (e.g. from the recessed space) to the port. In some embodiments, the one or more pressure-sensing pathways 1230 may extend approximately parallel to the fluid pathway 1105. The one or more pressure-sensing pathways 1230 may each be pneumatically isolated from the fluid pathway 1105 and/or the external environment, except at the distal ends. For example, the one or more pressure-sensing pathways 1230 may be pneumatically isolated between the proximal end and distal end. For example, a barrier 1235 (such as a weld) may extend between the inner surface of the first layer 1220 and the inner surface of the second layer 1225 to form each pressure sensing pathway 1230 within the enclosed space of the envelope 1205. The barrier 1235 may pneumatically isolate the pressure-sensing pathway 1230 from the fluid pathway 1105 except through the recessed space in the distal end. In some embodiments, the

one or more pressure-sensing pathways 1230 may each comprise an open distal end in fluid communication with the at least one aperture and/or recessed space in the distal end of the housing. In some embodiments, the one or more pressure-sensing pathways 1230 may only be in fluid communication with the fluid pathway at the distal end. In some embodiments, the port may further be configured to fluidly couple the pressure-sensing pathway 1230 to a pressure sensor. For example, the port may comprise multiple lumens, allowing the single port to simultaneously fluidly couple the fluid pathway 1105 to the negative-pressure source, while also coupling the one or more pressure-sensing pathway 1230 to the pressure sensor. In some embodiments, the pressure-sensing pathway 1230 may comprise a plurality of pressure supports 1240, which may be similar to the plurality of supports 1135 but configured to support the pressure-sensing pathway 1230.

[00124] Figure 13 is an exploded or assembly view of the exemplary dressing interface 1005 of Figure 10, illustrating additional details that may be associated with some embodiments. In Figure 13, exemplary layers forming the dressing interface 1005 are illustrated. The dressing interface 1005 in Figure 13 may comprise the first layer 1220, a first spacer layer 1305, a second spacer layer 1310, and the second layer 1225. For example, the first spacer layer 1305 and the second spacer layer 1310 may jointly form the support layer in Figure 13. In some embodiments, the first spacer layer 1305 and the second spacer layer 1310 may be adjacent and in stacked relationship with each other. The first layer 1220 may be adjacent to and in stacked relationship with the first spacer layer 1305, opposite the second spacer layer 1310. The second layer 1225 may be adjacent to and in stacked relationship with the second spacer layer 1310, opposite the first spacer layer 1305. The first layer 1220 and the second layer 1225 may be sealed together about the perimeter, forming the envelope defining the enclosed fluid pathway supported by the first spacer layer 1305 and the second spacer layer 1310. In some embodiments, the first spacer layer 1305 may comprise the first plurality of supports, and the second spacer layer 1310 may comprise the second plurality of supports. For example, the first plurality of supports may extend inward from an inner surface of the first spacer layer 1305, and the second plurality of supports may extend inward from an inner surface of the second spacer layer 1310. Thus, in Figure 13, the supports of the first spacer layer 1305 and the supports of the second spacer layer 1310 may extend inward towards each other. For example, the first plurality of supports of the first spacer layer 1305 may be stacked with the second plurality of supports of the second spacer layer 1310, with supporting faces substantially parallel and/or contacting. In the embodiment of Figure 13, there is no foam within the envelope. For example, the support layer may not comprise foam in some embodiments, but may rather comprise the plurality of thermoformed supports.

[00125] In some embodiments, each of the first plurality of supports of the first spacer layer 1305 may comprise a hollow standoff, and the first layer 1220 may be sealed to the first spacer layer 1305 to maintain internal pressure within the plurality of hollow standoffs. Similarly, each of the second plurality of supports of the second spacer layer 1310 may comprise a hollow standoff, and the second layer 1225 may be sealed to the second spacer layer 1310 to maintain internal pressure within the

standoffs of the second plurality of supports. In some embodiments, the first layer 1220 and/or the second layer 1225 may comprise a polyurethane film from approximately 80 to 120 micron in thickness. In some embodiments, the first spacer layer 1305 and/or the second spacer layer 1310 may be thermoformed structures with integral open pathway features, such as supports 1135. In some
 5 embodiments, the thermoformed structures may comprise thermoplastic polyurethane, for example thermoplastic polyurethane film from approximately 200 to 500 microns in thickness.

[00126] In Figure 13, the distal end 1015 of both the first layer 1220 and the second layer 1225 may each comprise one of the apertures. For example, the distal end 1015 of the first layer 1220 may comprise the first aperture 1110, and the distal end 1015 of the second layer 1225 may comprise the
 10 second aperture 1120. Each of the apertures may be configured to allow fluid communication between the fluid pathway and the ambient environment (e.g. the flowable manifold). In some embodiments, the first layer 1220 may comprise the port 1025, for example in the proximal end 1020. In some embodiments, the first spacer layer 1305 may comprise a port opening 1315 in its proximal end 1020, which may be aligned (e.g. concentric) with the port 1025 in the first layer 1220. Together, the port
 15 1025 and the port opening 1315 may allow negative pressure from the negative-pressure source to enter the fluid pathway (e.g. between the first spacer layer 1305 and the second spacer layer 1310). The spacer layers may also comprise openings located in the distal end 1015 in some embodiments, which may be concentric (e.g. aligned) with the apertures. For example, the first spacer layer 1305 may comprise a first opening 1320 in its distal end 1015, which typically may be aligned (e.g. concentric)
 20 with the first aperture 1110 in the first layer 1220. The second spacer layer 1310 may comprise a second opening 1325 in its distal end 1015, which typically may be aligned (e.g. concentric) with the second aperture 1120 of the second layer 1225. In Figure 13, the first opening 1320 may be aligned with the second opening 1325, and the first aperture 1110, the first opening 1320, the second opening 1325, and the second aperture 1120 together may jointly form the through-opening in the distal end 1015. The
 25 openings in the spacer layers (e.g. the first opening 1320 and the second opening 1325) may allow fluid flow through the first spacer layer 1305 and/or the second spacer 1310 layer respectively. Each of the openings do not comprise any supports in those open portions of their respective spacer layer, and may create the recessed space within the fluid pathway. The aligned openings and/or apertures may have a common central axis.

[00127] In some embodiments, the first layer 1220 and the second layer 1225 may each be formed of a film. Other embodiments may form the fluid pathway as an open pathway using only a single spacer layer. Other embodiments may form the fluid pathway by sealing the first spacer layer to the second spacer layer about the perimeter, for example without the need for any exterior film layers (e.g. with the envelope formed by sealing the spacer layers together about their perimeter, without the
 35 need for any additional outer layers). Other embodiments may form the fluid pathway within the envelope with only a single spacer layer located therein to define the fluid pathway. Other embodiments may form the fluid pathway between the first layer and the second layer, while having the plurality of

supports located therebetween without any spacer layer. For example, longitudinal tubular supports might be located between the first layer and the second layer in some alternate embodiments. During negative-pressure therapy, fluid may be removed through the longitudinally extending rows between the plurality of supports. This may be true whether or not external compression is applied to the dressing interface. During negative-pressure therapy in some embodiments, the first plurality of supports may be drawn towards the second plurality of supports, so that the supporting faces substantially contact (e.g. preventing closure of the fluid pathway due to draw-down under negative internal pressure). For example, some supporting faces of the supports may directly contact opposing support faces.

[00128] In some embodiments, the dressing interface housing may be configured to be flexible, for example with the dressing interface being sufficiently flexible to allow bending (e.g. for positioning of the distal end within the flowable manifold in the tissue site) or even folding. In some embodiments, the dressing interface may be configured so that the distal end is capable of being positioned at different levels within the foam. In some embodiments, the dressing interface may also be configured so that, when bent or folded, the fluid pathway remains open for negative-pressure therapy. For example, bending or folding the dressing interface may not substantially restrict fluid flow therethrough. In some embodiments, the plurality of supports may maintain sufficiently open fluid pathway to allow effective negative-pressure therapy.

[00129] Figure 14 is an isometric view of another exemplary dressing interface 1005, illustrating additional details that may be associated with some embodiments. In some embodiments, the conduit or housing 1010 of Figure 14 may comprise a hollow tubular body. In Figure 14, the dressing interface 1005 may comprise a flared distal end (e.g. wedge-shaped). For example, the housing 1010 of Figure 14 may be substantially tubular, with the fluid pathway 1105 extending longitudinally from the proximal end 1020 to the distal end 1015. In some embodiments, the fluid pathway 1105 may extend along the central axis of the housing of the dressing interface 1005. In some embodiments, the distal end 1015 of the fluid pathway 1105 may form the aperture 1405, while the proximal end 1020 of the fluid pathway 1105 may form the port 1410. In proximity to the distal end 1015, the tubular housing may flare outward to have a larger diameter (e.g. larger than the proximal end). In some embodiments, the distal end 1015 may flare out to a diameter D1 at least twice the diameter D2 of the proximal end 1020. For example, the diameter D2 of the proximal end 1020 (and typically the majority of the length of the dressing interface) may be approximately 9 mm, while the diameter D1 of the distal end 1015 may be approximately 18 mm. In some embodiments, the aperture 1405 at the distal end 1015 (e.g. the distal end of the fluid pathway 1105) may also be larger than the port 1410 at the proximal end 1020 (e.g. the proximal end of the fluid pathway 1105). Typically, the distal end 1015 of the aperture 1405 may be larger than the fluid pathway 1105 along the majority of the dressing interface 1005. For example, the diameter of the fluid pathway 1105 may enlarge (e.g. flare outward) at the distal end 1015 to form the aperture 1405 with diameter D3, which is larger than the diameter D4 of the port 1410 of the proximal end 1020 of the fluid pathway. In some embodiments, the aperture 1405 may flare out in

proportion to the amount that the distal end 1015 as a whole flares out. For example, the aperture 1405 may have a diameter D3 twice as large as the diameter D4 of the port 1410. Some embodiments of the dressing interface 1005 may also comprise one or more pressure-sensing pathways 1230. For example, the one or more pressure-sensing pathways 1230 may extend longitudinally from the distal end 1015 to the proximal end 1020. In some embodiments, the one or more pressure-sensing pathways 1230 may run substantially parallel to the fluid pathway 1105. In Figure 14, four pressure-sensing pathways 1230 are shown, for example spaced approximately equally around the fluid pathway 1105 (e.g. with distal openings spaced approximately equally about the aperture 1405 in the distal end 1015, and proximal openings spaced approximately equally about the port 1410 in the proximal end 1020).

[00130] In some embodiments, the flared distal end 1015 itself may provide for a mechanical securement within the flowable manifold upon solidification, by providing larger surface area and interference fit to aid in retention within the solidified flowable manifold (e.g. anchoring the distal end within the solidified manifold). The flared distal end 1015 may also have a flared aperture 1405 that is sufficiently wide to span more than one level within the flowable manifold when oriented substantially perpendicularly to the tissue site surface and/or the external surface of the manifold. For example, the flared aperture 1405 may be sufficiently wide to provide negative pressure in close proximity to the tissue site surface and also at a level above the tissue site surface, facilitating delivery of negative pressure at more than one level within the manifold and/or in more than one direction. For example, the flared aperture 1405 may facilitate delivery of negative pressure to and/or drawing fluid from substantially throughout the entire manifold. In some embodiments, the housing 1010 for the dressing interface 1005 may be sufficiently flexible to allow positioning of the distal end 1015 in such a perpendicular orientation. In some embodiments, the dressing interface 1005 may be configured to allow the distal end 1015 to be positioned at different positions or levels within the flowable manifold.

[00131] In some embodiments, the distal end 1015 of the dressing interface 1005 may be configured to prevent or reduce blockage of the fluid pathway 1105 (e.g. at the distal end 1015 and/or one or more apertures) by the flowable manifold material. In some embodiments, the dressing interface 1005 may initially comprise a protective cap. The protective cap may protect the one or more apertures from clogging when flowable manifold material is introduced. For example, the protective cap may span the one or more apertures, pressure-sensing pathway openings, and/or distal end 1015 of the dressing interface 1005. In some embodiments, the protective cap may prevent the flowable manifold material from entering the fluid pathway 1105 and/or one or more apertures prior to its solidification (e.g. seal the one or more apertures), and may be configured to automatically dissipate (e.g. dissolve) to open the aperture once the flowable manifold has solidified. In some embodiments, the protective cap may comprise a plug 1412 temporarily sealing the at least one aperture to substantially block fluid interaction between the fluid pathway 1105 and the flowable manifold. In some embodiments, the plug 1412 may cover the one or more aperture and the one or more pressure-sensing pathways openings 1230. In other embodiments, one or more separate pressure plugs may seal the one or more pressure-

sensing pathways at the distal end. The plug 1412 may be configured to dissolve upon contact with the flowable manifold material, in some embodiments. For example, the plug 1412 may comprise cellulose, which may break down and dissolve upon contact with the flowable manifold in order to open the one or more apertures (e.g. release the seal).

5 **[00132]** In other embodiments, the protective cap may comprise a soluble membrane spanning the at least one aperture and retaining a high pH solution that disrupts formation of a skin when the flowable manifold solidifies (e.g. cures). In some embodiments, the soluble membrane itself may comprise the high pH solution (e.g. with the high pH solution retained within the soluble membrane itself). When the soluble membrane contacts the flowable manifold material, the soluble membrane
10 may dissolve to release the high pH solution into contact with the flowable manifold and/or to open the one or more apertures. In other embodiments, the high pH solution may be separate from the soluble membrane. Rather, the high pH solution may be held in place within the housing (e.g. one or more aperture) by the soluble membrane, and may be released out of the at least one aperture when the soluble membrane dissolves (e.g. due to contact with the flowable manifold). In some embodiments, the high
15 pH solution may comprise sodium carbonate.

[00133] Some embodiments may comprise an anti-fouling surface treatment 1415. For example, in Figure 14, the distal end 1015 of the housing 1010 may comprise the anti-fouling surface treatment 1415. In some embodiments, the anti-fouling surface treatment 1415 may be located on the exterior surface of the housing 1010 of the dressing interface 1005. Typically, the anti-fouling surface
20 treatment 1415 may be configured to help prevent clogging of the fluid pathway 1105, for example when the distal end 1015 of the dressing interface 1005 is located within the flowable manifold as it solidifies. For example, the anti-fouling surface treatment 1415 may comprise a coating configured to prevent formation of a skin in proximity to the distal end 1015 and/or one or more aperture when the flowable manifold solidifies (e.g. cures).

25 **[00134]** In some embodiments, the anti-fouling surface treatment 1415 may comprise a coating comprising one or more hydrogels. In some embodiments, the anti-fouling surface treatment 1415 may comprise a coating configured to create pores in the flowable manifold upon contact with the flowable manifold. For example, a chemical reaction may occur as the coating contacts the flowable manifold, and that chemical reaction may create pores in the flowable manifold in proximity to the point
30 of contact as it solidifies. The pores may eliminate the clogging effect of any skin that would typically form at the point of contact between the flowable manifold and the dressing interface, for example by allowing fluid flow therethrough. In some embodiments, the anti-fouling surface treatment may comprise a coating having at least one part of a 2-part blowing agent system. In some embodiments, the anti-fouling surface treatment 1415 may comprise both parts of the 2-part blowing agent system.
35 For example, both parts of the 2-part blowing agent system may be powder mixes in a water-sensitive polymer configured to be activated by moisture in the flowable manifold (e.g. when the flowable

manifold contacts the coating). In such an example, the anti-fouling surface treatment may comprise at least one of citric acid and sodium bicarbonate. In some embodiments, the water sensitive polymer may comprise at least one of PVP (e.g. Polyvinylpyrrolidone) and PEO (e.g. poly(ethylene oxide)). In some embodiments, the anti-fouling surface treatment may comprise at least one of poly methylhydrosiloxane and poly dimethylsiloxane. While some example coatings may comprise both parts of the 2-part blowing agent system, in other embodiments the coating may only comprise one part of the 2-part blowing agent system. When the coating only contains a first part of the 2-part blowing agent system, the second part of the 2-part blowing agent system may be located within the flowable manifold. So typically, contacting the coating on the dressing interface with the flowable manifold may activate the anti-fouling surface treatment, for example initiating a chemical reaction that generates pores in the flowable manifold in proximity to the aperture and/or distal end.

[00135] In some embodiments, the dressing interface 1005 may be configured with a distal end 1015 that is self-securing within the flowable manifold (e.g. configured to help retain itself within the flowable manifold once the flowable manifold solidifies). In some embodiments, the housing may comprise an external surface finish 1420 configured to retain the distal end 1015 of the housing within the flowable manifold. In an example, the external surface 1420 finish may comprise StandexTM surface finish or some other textured surface finish that improves grip and/or increase friction resistance to removal. In another example, the external surface finish 1420 may comprise a dry adhesive coating that bonds to the flowable manifold material. The dry adhesive may comprise a cold seal adhesive, in some embodiments, for example as provided by Bostik and Dow. In some embodiments, the external surface finish may comprise a coating of material homologous to the flowable manifold, such that the flowable manifold material may bond to the exterior surface of the housing of the dressing interface 1005.

[00136] In some embodiments, the distal end may be configured to be self-securing in ways other than or in addition to an external surface finish. In some embodiments, the distal end of the housing may comprise material homologous to the flowable manifold. In some embodiments, the housing itself may be made up of materials configured to chemically bond to the flowable manifold, at least at the distal end. In some embodiments, the distal end of the dressing interface may be flared. The larger distal end may serve as a mechanical, interference-type restriction on removal of the distal end from the flowable manifold (e.g. upon solidification). For example, the distal end may comprise a width or diameter at least twice that of the proximal end. In some embodiments, the distal end may comprise a through-opening, and introduction of flowable manifold material through the through-opening may mechanically anchor the dressing interface to the solidified manifold.

[00137] Figure 15 is a schematic view of an exemplary kit or system 1505 with an exemplary delivery device 525 of flowable manifold and exemplary dressing interface 1005 configured for use with the flowable manifold, illustrating additional details that may be associated with some

embodiments. Typically, the dressing interface 1005 may be selected for effective interaction with the specific flowable dressing material, for example with its distal end 1015 configured for use within the flowable manifold. In some embodiments, the dressing interface 1005 may comprise a coating having a first part of a 2-part blowing agent system, and the flowable manifold may comprise a second part of the 2-part blowing agent system. For example, the first part may comprise poly methylhydrosiloxane, and the second part may comprise poly dimethylsiloxane. In some embodiments, the dressing interface may comprise a soluble membrane configured to retain a high pH solution, and the flowable manifold may comprise a pH sensitive group. For example, the high pH solution may comprise sodium carbonate, and the pH sensitive group may comprise carboxylic.

[00138] In some embodiments, the flowable manifold may comprise two reactants separated until application of the flowable manifold on the tissue site. For example, the reactants may form an open-cell foam manifold upon mixing, which may solidify into a foam manifold within the cavity of the tissue site. Alternatively, some embodiments of the flowable manifold may comprise a reacted polymer in a carrier. The reacted polymer may foam and solidify (e.g. cure) after application to the tissue site to form a solid open-cell foam manifold. In some embodiments, the reacted polymer may be hydrophilic. In some embodiments, the flowable manifold may be contained within one or more delivery devices before application to the tissue site, as discussed above for example with respect to Figures 5A-9. In some embodiments, the flowable manifold may be configured to simultaneously form a tissue interface and a cover upon solidifying (e.g. curing). For example, the flowable manifold may be configured to form a skin (e.g. at its external surface) upon solidifying that acts as the cover. In some embodiments, the kit may further comprise a separate cover (not shown here). For example, the cover may be a drape (which may be cut to size and shape for a particular tissue site and/or adhered over the tissue site), or may be a separate flowable material configured to solidify into an effective cover material, which may be provided in a separate delivery device. Typically, for embodiments without a separate cover, the flowable manifold may be selected so that it forms an integral skin to act as the cover.

[00139] Figure 16 is a schematic view of an exemplary negative-pressure therapy system in place on a tissue site 1605, illustrating additional details that may be associated with some embodiments. The system may comprise a flowable manifold 1610 and a dressing interface 1005 configured for use with the distal end 1015 located within the flowable manifold 1610. Some embodiments may also comprise a negative-pressure source 105, which may be in fluid communication with the proximal end 1020 of the dressing interface 1005. In some embodiments, the flowable manifold material 1610 may be configured to form a skin 1620 on its external surface (e.g. upon solidifying), as shown in Figure 16, capable of serving as a cover for the dressing. For example, the skin 1620 may effectively seal the tissue site 1605 to allow for negative-pressure therapy (e.g. in a cavity). In practice, the flowable manifold 1610 may be placed within (e.g. in a cavity) and/or atop the tissue site 1605, and the distal end 1015 of the dressing interface 1005 may be located within the flowable manifold 1610 (e.g. at a

location beneath the exterior surface of the flowable manifold). In some embodiments, the distal end 1015 of the dressing interface 1005 may be located in close proximity to the tissue site surface. In Figure 16, the distal end 1015 of the dressing interface 1005 may be configured to simultaneously deliver and/or direct negative pressure outward into the manifold 1610 in more than one direction and/or at more than one level. For example, the dressing interface 1005 may comprise two apertures in the distal end 1015, oriented to direct negative-pressure from within the dressing interface 1005 out to the manifold 1610 in more than one direction and/or at more than one level. In some embodiments, the distal end 1015 of the dressing interface 1005 may be oriented to be approximately parallel to the tissue site surface 1615 and/or the external surface (e.g. skin 1620) of the flowable manifold 1610. The distal end 1015 may allow distribution of negative pressure both above and below the distal end 1015 (e.g. simultaneously).

[00140] In some embodiments, the different levels for negative pressure delivery within the manifold may be various depths within a wound cavity at the tissue site, for example with each level spaced vertically apart from another level by approximately 1mm, 2mm, 3mm, 4mm, 5mm, 6mm, 7mm, 5-7mm, less than 7 mm, or less than 6 mm. In some embodiments, the various levels may be approximately parallel to the tissue site surface and/or external surface of the manifold in the cavity. In some embodiments, delivering negative pressure at two or more levels within the manifold may facilitate negative pressure delivery throughout the manifold (e.g. drawing fluid from substantially all portions of the manifold). In Figure 16, the first aperture 1110 and the second aperture 1120 (e.g. of the through-opening 1030) open and/or direct negative pressure outward in opposite directions and/or may allow negative-pressure manifolding both above and below the distal end 1015 of the dressing interface 1005 (e.g. on both sides of the dressing interface) simultaneously. For example, the first aperture 1110 and the second aperture 1120 may direct negative pressure from the fluid pathway to two levels within the manifold (e.g. a first level above the distal end 1015 and a second level below the distal end 1015, separated by the height of the distal end 1015). In some embodiments, the one or more apertures may be configured to allow delivery of negative pressure to the flowable manifold 1610 in more than one direction and/or at more than one level. In some embodiments, the one or more apertures may be configured to direct negative pressure into the flowable manifold 1610 omni-directionally. For example, the configuration of the one or more apertures may provide negative pressure substantially throughout the flowable manifold 1610 while the distal end 1015 is located within the flowable manifold 1610, which may effectively draw fluid from all parts of the flowable manifold 1610.

[00141] Figure 17 is a schematic plan view of the exemplary negative-pressure therapy system of Figure 16, illustrating additional details that may be associated with some embodiments. As shown in Figure 17, the distal end 1015 of the dressing interface 1005 may be located within the flowable manifold 1610 in a cavity of the tissue site 1605. The through-opening 1030 may be located within the flowable manifold 1610, for introduction of negative pressure into the flowable manifold 1610. In some embodiments, the through-opening 1030 may be located to provide negative pressure within the

flowable manifold 1610 in more than one direction, at more than one level, and/or omni-directionally, for example drawing fluid from both above and below the distal end 1015 and/or drawing fluid from substantially the entirety of the flowable manifold 1610. In some embodiments, the distal end 1015 may be oriented approximately parallel to the tissue site surface and/or the external surface of the flowable manifold 1610. In some embodiments, the through-opening 1030 may be oriented with its centerline approximately perpendicular to the tissue site surface and/or the external surface of the flowable manifold 1610. In some embodiments, the manifold material may fill the through-opening 1030 (e.g. in addition to surrounding the distal end 1015), which may further anchor the dressing interface (e.g. distal end) within the manifold. For example, the solidified manifold material extending through the through-opening 1030 may mechanically anchor the dressing interface within the manifold.

[00142] Figure 18 is a schematic view of another exemplary negative-pressure therapy system in place on a tissue site 1605, illustrating additional details that may be associated with some embodiments. The system may comprise a flowable manifold 1610 and a dressing interface 1005. In Figure 18, the dressing interface 1005 may comprise a flared distal end 1015. In some embodiments, the flared distal end 1015 may be located within the flowable manifold 1610 (e.g. below the surface) and/or may be oriented so that that flared aperture 1405 spans more than one level within the flowable manifold 1610. For example, the flared distal end 1015 (e.g. flared aperture 1405) may be oriented substantially perpendicular to the tissue site surface and/or the external surface of the flowable manifold 1610, and may be sized so that the flared aperture 1405 spans several levels of the flowable manifold 1610 applied to the tissue site 1605. Such an orientation, when used with a flared distal end and/or flared aperture 1405, may allow the dressing interface 1005 to direct negative pressure in more than one direction and/or at more than one level within the manifold 1610. In some embodiments, the distal end 1015 may be located in close proximity to the tissue site surface. In Figure 18, a separate cover 125 may span the opening (e.g. cavity) of the tissue site 1605, for example sealing the tissue site 1605 to allow effective application of negative-pressure therapy at the tissue site 1605. In some embodiments, the cover 125 may be applied to the tissue site 1605 first, and the flowable manifold 1610 may be applied to the tissue site 1605 under the cover 125. In some embodiments, the flowable manifold 1610 may be applied to the tissue site 1605 first, and then the cover 125 may be applied atop the flowable manifold 1610 (for example, after it has solidified). While the cover 125 may be a pre-formed drape, in some embodiments a flowable (e.g. spray-on) cover material may be applied atop the flowable manifold material. In other embodiments, the flowable manifold 1610 may form a skin on the exterior surface (e.g. when it solidifies), and that skin may serve as an effective cover. Once the dressing interface 1005 is in place with its distal end 1015 located within the solidified flowable manifold material 1610, negative-pressure may be applied through the dressing interface 1005 to the manifold 1610 (and thereby to the tissue site 1605). For example, the negative-pressure source 105 may be fluidly coupled to the proximal end 1020 of the dressing interface 1005.

[00143] Also described herein are method embodiments for providing negative-pressure therapy to a tissue site. For example, method embodiments may comprise: delivering a flowable manifold (e.g. in a flowable delivery state) to the tissue site; placing a distal end of a dressing interface within the flowable manifold; and solidifying (e.g. curing) the flowable manifold (e.g. into a solidified treatment state of the manifold). Some method embodiments may further comprise attaching a negative-pressure source to a port in the dressing interface and applying negative pressure to the tissue site. In some embodiments, the step of delivering a flowable manifold may comprise delivering a first portion of the manifold to the tissue site before placing the distal end of the dressing interface, and delivering a second portion of the flowable manifold to the tissue site after placing the distal end of the dressing interface. For example, the second portion of the flowable manifold may cover the distal end of the dressing interface. In some embodiments, the step of placing the distal end of the dressing interface may comprise inserting the distal end of the dressing interface into the flowable manifold prior to solidification (e.g. curing) of the flowable manifold.

[00144] Some embodiments may further comprise the step of applying a cover over the tissue site. In some embodiments, the step of applying the cover may occur before delivering the flowable manifold, while in other embodiments applying the cover may occur after delivering the flowable manifold. In some embodiments, the step of applying the cover may comprise delivering a flowable cover material atop the flowable manifold. Delivering the flowable cover material, in some embodiments, may occur after solidification (e.g. curing) of the flowable manifold. In some embodiments, the method may further comprise selecting an appropriate amount and/or type of flowable manifold for the tissue site and/or an appropriate cover.

[00145] In some embodiments, after placement within the flowable manifold, the distal end of the dressing interface may be oriented substantially parallel to the tissue site and/or external surface. The distal end may comprise at least two apertures in some embodiments, and the at least two apertures may be located at different levels and/or be oriented to direct negative pressure outward in different directions within the manifold. In some embodiments, the negative pressure may be applied to produce omni-directional manifolding within the solidified (e.g. cured) manifold. In some embodiments, the negative pressure may be applied beneath an external surface of the solidified (e.g. cured) manifold. In some embodiments, the negative pressure may be applied through the distal end of the dressing interface at more than one level and/or in more than one direction within the manifold. For example, negative pressure may be applied above and below the distal end of the dressing interface, for example simultaneously. In some embodiments, the step of placing the distal end may locate the distal end in close proximity to a tissue site surface. The distal end may be flared and may comprise an aperture in some embodiments, and method embodiments may further comprise the step of orienting the flared distal end so that its aperture is approximately perpendicular to the tissue site surface and/or the external

surface of the manifold. For example, the flared distal end may be oriented so that the aperture spans more than one level within the manifold.

[00146] Some method embodiments may further comprise the step of preventing formation of a skin where the flowable manifold contacts the distal end of the dressing interface (e.g. in proximity to the distal end). For example, responsive to the distal end contacting the flowable dressing material, the method may further comprise dissolving a soluble plug, forming pores in a skin of the flowable manifold (e.g. by chemical reaction occurring when the flowable manifold material contacts a coating on the distal end), and/or dissolving a soluble membrane to release a high pH solution. In some embodiments, the method may further comprise automatically securing the distal end within the flowable manifold during solidification of the flowable manifold. In some embodiments, the step of placing the distal end may not require any cutting (for example, cutting of a cover). Method embodiments may use one or more of the flowable manifold embodiments and/or the dressing interface embodiments described above.

[00147] Also described herein are method embodiments for forming or manufacturing a dressing interface for a negative-pressure therapy system in conjunction with a flowable manifold. For example, method embodiments may comprise: forming a housing for the dressing interface (e.g. with the housing comprising a fluid pathway between a port in its proximal end and at least one aperture in its distal end); and applying a coating (e.g. anti-fouling, pore-forming, and/or self-securing) to the housing and/or applying a soluble plug or membrane to the aperture in the distal end of the housing. For example, the coating may comprise one or more of the following: an anti-fouling coating, a pore-forming coating, and/or a self-securing coating. In some embodiments, the step of forming the housing may comprise forming a flared distal end. In some embodiments, the flared distal end may comprise a flared aperture, for example with a diameter greater than that of the port.

[00148] In some embodiments, the step of forming the housing may comprise the step of forming a plurality of apertures in the distal end oriented and/or configured to deliver and/or direct negative pressure outward in more than one direction and/or at more than one level. In some embodiments, the step of forming the housing may comprise: providing a support layer; encasing the support layer within an envelope, wherein the support layer supports the envelope to form an enclosed fluid pathway having a distal end in fluid communication with a proximal end; forming a port in the proximal end of the envelope; and forming one or more aperture in the distal end of the envelope. In some embodiments, the step of providing the support layer may comprise providing one or more spacer layer and/or a plurality of supports. For example, the step of providing the support layer may comprise providing a first spacer layer with a first plurality of supports and a second spacer layer with a second plurality of supports; and stacking the first spacer layer and the second spacer layer (e.g. with the first plurality of supports facing, aligned with, and/or stacked with the second plurality of supports). In some embodiments, the step of providing a first spacer layer and a second spacer layer may comprise

thermoforming the first spacer layer and the second spacer layer. Some embodiments may also comprise the step of forming one or more pressure-sensing pathways, parallel to and/or fluidly isolated from the fluid pathway except at the distal end. In some embodiments, forming the pressure-sensing pathway may comprise forming a weld between the first surface of the envelope and the second surface of the envelope. In some embodiments, forming the port may comprise forming a port configured to allow separate interaction between the fluid pathway and the negative-pressure source and the pressure-sensing pathway and the pressure sensor. Method embodiments may relate to one or more of the dressing interface embodiments described above, and may incorporate features thereof.

[00149] The systems, apparatuses, and methods described herein may provide significant advantages. For example, the delivery devices described herein can provide a flowable manifold material that can be readily applied to wounds of varying sizes without needing timely customization. Advantageously, when delivering flowable hydrophilic manifold material, the hydrophilic nature of the manifold material can allow for enhanced breathability, absorbency and/or wicking of the manifold material applied to the tissue site. The nature of the flowable manifold material can also allow for better adhesion between the manifold material and skin of a tissue site. Additionally, the devices for delivery of a flowable manifold material can eliminate the need for additional dressing material components, such as support and release layers. Furthermore, the delivery devices are portable and can be used in many environments and settings to produce manifolds in various configurations. Some embodiments of the flowable manifold may simultaneously form a sealing skin, which may eliminate the need for a separate cover.

[00150] Additionally, dressing interface embodiments specifically configured for use with such flowable manifold materials may provide further benefits. For example, the distal end of the dressing interface may be located within the manifold, away from the external surface. This may simplify the application process, for example eliminating the need for cutting and/or customization of the cover, separate attachment/securement steps, and/or even placement of a separate cover. With the distal end located within the manifold, the dressing interface may be better secured to the tissue site and/or any potential damage to the tissue site from the dressing interface may be minimized. For example, attachment of the dressing interface directly within the manifold may allow the foam of the manifold to operate as strain relief and/or may protect the patient's skin from directly contacting the dressing interface. This approach may also provide better manifolding, for example by allowing the distal end to be placed in close communication with the tissue site. Multi-directional negative pressure delivery may also be possible, also providing improved manifolding. Embodiments may also be configured to help reduce the risk of clogging, which may be particularly important when the dressing interface is used within a flowable manifold.

[00151] While shown in a few illustrative embodiments, a person having ordinary skill in the art will recognize that the systems, apparatuses, and methods described herein are susceptible to various

changes and modifications that fall within the scope of the appended claims. Moreover, descriptions of various alternatives using terms such as “or” do not require mutual exclusivity unless clearly required by the context, and the indefinite articles "a" or "an" do not limit the subject to a single instance unless clearly required by the context. Components may be also be combined, eliminated, or separated in various configurations for purposes of sale, manufacture, assembly, or use. For example, in some configurations the dressing 110, the container 115, or both may be separated from other components for manufacture or sale. In other example configurations, the controller 130 may also be manufactured, configured, assembled, or sold independently of other components.

[00152] The appended claims set forth novel and inventive aspects of the subject matter described above, but the claims may also encompass additional subject matter not specifically recited in detail. For example, certain features, elements, or aspects may be omitted from the claims if not necessary to distinguish the novel and inventive features from what is already known to a person having ordinary skill in the art. Features, elements, and aspects described in the context of some embodiments may also be omitted, combined, or replaced by alternative features serving the same, equivalent, or similar purpose without departing from the scope of the invention defined by the appended claims.

CLAIMS

What is claimed is:

1. A conduit for use with a flowable manifold to provide negative-pressure therapy to a tissue site, comprising:

a fluid pathway having a proximal end and a distal end;
at least one aperture in the distal end configured to provide fluid interaction between the fluid pathway and the flowable manifold, wherein the at least one aperture is configured to direct negative pressure within the fluid pathway outward in more than one direction; and

a port in the proximal end configured for application of negative pressure into the fluid pathway.

2. The dressing interface of claim 1, wherein the at least one aperture is configured to direct negative pressure within the fluid pathway to more than one level within the flowable manifold.

3. The dressing interface of any of claims 1-2, wherein the at least one aperture is configured to direct negative pressure outward from the fluid pathway into the flowable manifold so as to provide omni-directional manifolding within the flowable manifold.

4. The dressing interface of any of claims 1-3, wherein the distal end is configured to be positionable at different levels within the foam.

5. The dressing interface of any of claims 1-4, wherein the at least one aperture comprises two or more apertures oriented to direct negative pressure in different directions.

6. The dressing interface of any of claims 1-4, wherein the at least one aperture comprises two or more apertures, with at least a first aperture in a first surface of the conduit and a second aperture in a second surface of the conduit.

7. The dressing interface of claim 6, wherein the first surface is opposite the second surface, so that the first aperture and the second aperture direct negative pressure in opposite directions.

8. The dressing interface of claim 7, wherein the first aperture and the second aperture are aligned.

9. The dressing interface of any of claims 1-4, further comprising a through-opening that extends from a first surface of the conduit to a second surface of the conduit.
- 5 10. The dressing interface of claim 9, wherein the at least one aperture comprises a first aperture in the first surface of the conduit and a second aperture in the second surface of the conduit, and the through-hole comprises the first aperture and the second aperture.
- 10 11. The dressing interface of any of claims 6-10, wherein the conduit further comprises:
a support layer; and
an envelope comprising the first surface and the second surface and encompassing the support layer, wherein the support layer supports the envelope to define the enclosed fluid pathway within the envelope.
- 15 12. The dressing interface of claim 11, wherein the support layer is configured within the envelope to maintain the fluid pathway in an open configuration when under compression.
13. The dressing interface of any of claims 11-12, wherein the conduit is low-profile.
- 20 14. The dressing interface of any of claims 11-13, wherein the support layer comprises a thermoformed support structure.
15. The dressing interface of any of claims 11-14, wherein the support layer comprises a plurality of supports configured to support the envelope.
- 25 16. The dressing interface of claim 15, wherein the plurality of supports are substantially co-extensive with the fluid pathway.
17. The dressing interface of any of claims 15-16, wherein each of the plurality of supports comprises a hollow standoff which is sealed to maintain an internal pressure.
- 30 18. The dressing interface of any of claims 15-17, wherein:
the envelope further comprises a first layer and a second layer;
the first layer forms the first surface, and the second layer forms the second surface;
the first layer and the second layer are coupled to form the envelope with enclosed
35 fluid pathway between the first layer and the second layer; and
the plurality of supports are located between the first layer and the second layer.

19. The dressing interface of any of claims 15-18, wherein the support layer further comprises a spacer layer, and the plurality of supports extend from an inner surface of the spacer layer.

20. The dressing interface of any of claims 15-19, wherein:

5 the plurality of supports comprises a first plurality of supports and a second plurality of supports; and

 the first plurality of supports are in stacked relationship with the second plurality of supports.

10 21. The dressing interface of any of claims 15-18, wherein:

 the support layer further comprises a first spacer layer and a second spacer layer; and

 the plurality of supports comprises a first plurality of supports extending inward from the first spacer layer and a second plurality of supports extending inward from the second spacer layer.

15

22. The dressing interface of claim 21, wherein the first plurality of supports are aligned with and in stacked relationship with the second plurality of supports.

23. The dressing interface of any of claims 21-22, wherein:

20 the first spacer layer and the second spacer layer each comprise an opening;

 the opening in the first spacer layer is aligned with the opening in the second spacer layer;

 the first aperture and the second aperture are aligned; and

25 the opening in the first spacer layer and the opening in the second spacer layer are aligned with the first aperture and the second aperture.

24. The dressing interface of any of claims 15-23, wherein the plurality of supports are arranged in rows that extend longitudinally.

30 25. The dressing interface of any of claims 11-24, wherein the support layer does not comprise any foam.

26. The dressing interface of any of claims 1-25, wherein the conduit further comprises one or more pressure-sensing pathways extending substantially between the port and the at least one aperture.

35

27. The dressing interface of claim 26, wherein the one or more pressure sensing pathways are pneumatically isolated from the fluid pathway between the proximal end and distal end.
28. The dressing interface of claim 27, wherein the one or more pressure sensing pathways each
5 comprise an open distal end in fluid communication with the at least one aperture in the distal end of the conduit, and the one or more pressure sensing pathways are only in fluid communication with the fluid pathway at the distal end.
29. The dressing interface of any of claims 1-28, wherein the distal end is configured to prevent
10 blockage of the fluid pathway by the flowable manifold material.
30. The dressing interface of any of claims 1-29, wherein the distal end comprises an anti-fouling surface treatment.
31. The dressing interface of any of claims 1-30, wherein the distal end comprises a protective
15 cap spanning the fluid pathway.
32. The dressing interface of any of claims 1-31, wherein the conduit is configured to be self-securing within the flowable manifold material.
20
33. The dressing interface of claim 32, wherein the distal end of the conduit is configured to be self-securing within the flowable manifold material.
34. A dressing interface for use with a flowable manifold to provide negative-pressure therapy to
25 a tissue site, comprising:
a housing with a fluid pathway therethrough;
at least one aperture in a distal end of the housing configured to provide fluid interaction between the fluid pathway and the tissue site, wherein the distal end is configured for use within the flowable manifold and comprises an anti-fouling surface treatment; and
30 a port in a proximal end of the housing configured for application of negative pressure into the fluid pathway.
35. The dressing interface of any of claims 30-34, wherein the anti-fouling surface treatment
35 comprises a coating configured to prevent formation of a skin when the flowable manifold solidifies.

36. The dressing interface of any of claims 30-35, wherein the anti-fouling surface treatment comprises a coating comprising one or more hydrogels.
37. The dressing interface of any of claims 30-34, wherein the anti-fouling surface treatment comprises a coating configured to create pores in the flowable manifold upon contact with the flowable manifold.
38. The dressing interface of any of claims 30-34 and 37, wherein the anti-fouling surface treatment comprises a coating having at least one part of a 2-part blowing agent system.
39. The dressing interface of claim 38, wherein the anti-fouling surface treatment comprises both parts of the 2-part blowing agent system.
40. The dressing interface of claim 39, wherein both parts of the 2-part blowing system are powder mixes in a water sensitive polymer configured to be activated by moisture in the flowable manifold.
41. The dressing interface of any of claims 38-40, wherein the anti-fouling surface treatment comprises at least one of citric acid and sodium bicarbonate.
42. The dressing interface of any of claims 40-41, wherein the water sensitive polymer comprises at least one of PVP and PEO.
43. The dressing interface of any of claims 38-40, wherein the anti-fouling surface treatment comprises at least one of poly methylhydrosiloxane and poly dimethylsiloxane.
44. A dressing interface for use with a flowable manifold to provide negative-pressure therapy to a tissue site, comprising:
a housing with a fluid pathway therethrough;
at least one aperture in a distal end of the housing configured to provide fluid interaction between the fluid pathway and the tissue site, wherein the distal end is configured for use within the flowable manifold and comprises a protective cap spanning the fluid pathway; and
a port in a proximal end of the housing configured for application of negative pressure into the fluid pathway.
45. The dressing interface of any of claims 31-33 and 44, wherein:

the protective cap comprises a plug temporarily sealing the at least one aperture to substantially block fluid interaction between the fluid pathway and the flowable manifold; and

the plug is configured to dissolve upon contact with the flowable manifold material.

5

46. The dressing interface of claim 45, wherein the plug comprises cellulose.

10

47. The dressing interface of any of claims 31-33 and 44, wherein the protective cap comprises a soluble membrane spanning the at least one aperture and retaining a high pH solution that disrupts formation of a skin as the flowable manifold solidifies.

48. The dressing interface of claim 47, wherein the soluble membrane comprises the high pH solution.

15

49. The dressing interface of claim 47, wherein the high pH solution is separate from the soluble membrane, is held in place within the housing by the soluble membrane, and is released out of the at least one aperture when the soluble membrane dissolves.

20

50. The dressing interface of any of claims 47-49, wherein the high pH solution comprises sodium carbonate.

25

51. A dressing interface for use with a flowable manifold to provide negative-pressure therapy to a tissue site, comprising:

a housing with a fluid pathway therethrough;

at least one aperture in a distal end of the housing configured to provide fluid interaction between the fluid pathway and the tissue site, wherein the housing is configured to be self-securing within the flowable manifold material; and

a port in a proximal end of the housing configured for application of negative pressure into the fluid pathway.

30

52. The dressing interface of any of claims 32 and 51, wherein the distal end of the housing is configured to be self-securing within the flowable manifold material.

35

53. The dressing interface of any of claims 32-33 and 51-52, wherein the housing comprises an external surface finish configured to retain the distal end of the housing within the flowable manifold.

54. The dressing interface of claim 53, wherein the external surface finish comprises a dry adhesive coating that bonds to the flowable manifold material.

55. The dressing interface of claim 54, wherein the dry adhesive comprises a cold seal adhesive.

56. The dressing interface of claim 53, wherein the external surface finish comprises a coating of material homologous to the flowable manifold.

57. The dressing interface of any of claims 32-33 and 51-52, wherein the distal end of the housing comprises material homologous to the flowable manifold.

58. The dressing interface of any of claims 32-33 and 51-57, wherein the distal end is flared.

59. The dressing of claim 58, wherein the distal end comprises a width or diameter larger than that of the proximal end.

60. The dressing interface of claim 59, wherein the distal end comprises a width or diameter at least twice that of the proximal end.

61. The dressing interface of any of claims 32-33 and 51-57 wherein:
the housing comprises a hollow tubular body;
the distal end flares out to a diameter at least twice that of the proximal end; and
the aperture comprises a diameter larger than that of the port.

62. A system for providing negative-pressure therapy to a tissue site, comprising:
a flowable manifold; and
a dressing interface with a distal end configured for use within the flowable manifold.

63. The system of claim 62, wherein the dressing interface comprises the dressing interface any of claims 1-61.

64. The system of claim 63, wherein the dressing interface comprises a coating having a first part of a 2-part blowing agent system, and the flowable manifold comprises a second part of the 2-part blowing agent system.

65. The system of claim 64, wherein the first part comprises poly methylhydrosiloxane, and the second part comprises poly dimethylsiloxane.

66. The system of any of claims 63-65, wherein the dressing interface comprises a soluble membrane configured to retain a high pH solution, and the flowable manifold comprises a pH sensitive group.

67. The system of claim 66, wherein the high pH solution comprises sodium carbonate, and the pH sensitive group comprises carboxylic.

68. The system of any of claims 62-67, wherein the flowable manifold comprises two reactants separated until application of the flowable manifold on the tissue site.

69. The system of any of claims 62-67, wherein the flowable manifold comprises a reacted polymer in a carrier.

70. The system of claim 69, wherein the reacted polymer is hydrophilic.

71. The system of any of claims 62-70, wherein the flowable manifold is configured to simultaneously form a tissue interface and a cover upon solidification.

72. The system of claim 71, wherein the flowable manifold is configured to form a skin upon solidification that acts as the cover.

73. The system of any of claims 62-70, further comprising a cover.

74. The system of claim 73, wherein the cover comprises a drape.

75. The system of claim 73, wherein the cover comprises a flowable material that solidifies to form a seal over the tissue site for negative-pressure therapy.

76. A method of providing negative-pressure therapy to a tissue site, comprising:

delivering a manifold to the tissue site in a flowable state;

placing a distal end of a dressing interface within the flowable state of the

manifold; and

solidifying the manifold.

77. The method of claim 76, further comprising attaching a negative-pressure source to a port in the dressing interface and applying negative pressure to the tissue site.

78. The method of any of claims 76-77, wherein delivering a manifold comprises delivering a first portion of the manifold to the tissue site in a flowable state before placing the distal end of the dressing interface, and delivering a second portion of the manifold in a flowable state to the tissue site after placing the distal end of the dressing interface.

79. The method of claim 78, wherein the second portion covers the distal end of the dressing interface.

80. The method of any of claims 76-77, wherein placing the distal end of the dressing interface comprises inserting the distal end of the dressing interface into the manifold prior to solidification of the manifold.

81. The method of any of claims 76-80, further comprising applying a cover over the tissue site.

82. The method of claim 81, wherein applying the cover occurs before delivering the manifold.

83. The method of claim 81, wherein applying the cover occurs after delivering the manifold.

84. The method of claim 83, wherein applying the cover comprises delivering a cover material in a flowable state atop the manifold.

85. The method of claim 84, wherein delivering the cover material occurs after solidification of the manifold.

86. The method of any of claims 76-85, further comprising selecting an appropriate amount and/or type of manifold for the tissue site.

87. The method of any of claims 76-86, wherein after placement within the manifold in a flowable state, the distal end of the dressing interface is oriented substantially parallel to the tissue site.

88. The method of any of claims 76-87, wherein the distal end comprises at least two apertures, and wherein the at least two apertures are located at different levels and/or direct negative pressure outward in different directions within the manifold.

89. The method of any of claims 77-88, wherein negative pressure is simultaneously applied in more than one direction within the manifold.

5 90. The method of any of claims 77-89, wherein negative pressure is applied beneath an external surface of the manifold.

10 91. The method of claim 90, wherein negative pressure is applied through the distal end of the dressing interface at more than one level and/or in more than one direction within the manifold.

92. The method of any of claims 90-91, wherein negative pressure is applied above and below the distal end of the dressing interface.

15 93. The method of any of claims 76-92, wherein placing the distal end locates the distal end in close proximity to a tissue site surface.

94. The method of any of claims 76-93, further comprising preventing formation of a skin where the manifold contacts the distal end of the dressing interface.

20 95. The method of any of claims 76-94, wherein responsive to the distal end contacting the manifold, the method further comprises dissolving a soluble plug, forming pores in a skin of the manifold, and/or dissolving a soluble membrane to release a high pH solution.

25 96. The method of any of claims 76-95, further comprising automatically securing the distal end within the manifold during solidification.

30 97. The method of any of claims 89-91 and 93-96, wherein the distal end is flared and comprises an aperture, the method further comprising orienting the flared distal end so that the aperture is approximately perpendicular to the tissue site surface.

35 98. The method of any of claims 76-96, wherein the distal end is flared and comprises an aperture, the method further comprising orienting the flared distal end so that the aperture spans more than one level within the manifold.

99. The method of any of claims 76-98, wherein placing the distal end does not require any cutting.

100. A conduit for fluidly coupling a negative-pressure source to a manifold having a delivery state and a treatment state, the conduit comprising:

5 a first end configured to be fluidly coupled to the negative-pressure source;
a second end configured to be disposed within the manifold in the delivery state and retained in the manifold in the treatment state; and
a fluid pathway between the first end and the second end.

10 101. The conduit of claim 100, wherein the second end comprises at least one through-opening.

102. The conduit of claim 101, wherein the through-opening is fluidly coupled to the fluid pathway.

15 103. The conduit of claim 101 wherein the through-opening is configured to receive a portion of the dressing in the delivery state.

104. The conduit of claim 101, wherein the second end is flared.

20 105. The conduit of claim 101, wherein the second end has a textured finish.

106. The conduit of claim 101, wherein:

25 the first end has a first width;
the second end has a second width; and
the second width is greater than the first width.

107. The conduit of claim 100, wherein the second end is flared.

30 108. The conduit of claim 107, wherein the second end has a textured finish.

35 109. The conduit of claim 100, wherein:

the first end has a first width;
the second end has a second width; and
the second width is greater than the first width.

40 110. The conduit of claim 109, wherein the second end comprises a textured finish.

111. The conduit of any of claims 100-110, wherein the second end comprises a hydrogel coating.

5

112. The conduit of any of claims 100-110, wherein the second end comprises a dry adhesive coating.

10

113. The conduit of any of claims 100-112, further comprising a soluble plug configured to separate the fluid pathway from the manifold in the delivery state.

15

114. The conduit of any of claims 100-113, wherein the delivery state is a flowable state and the treatment state is a solid state.

115. The systems, apparatuses, and methods substantially as described.

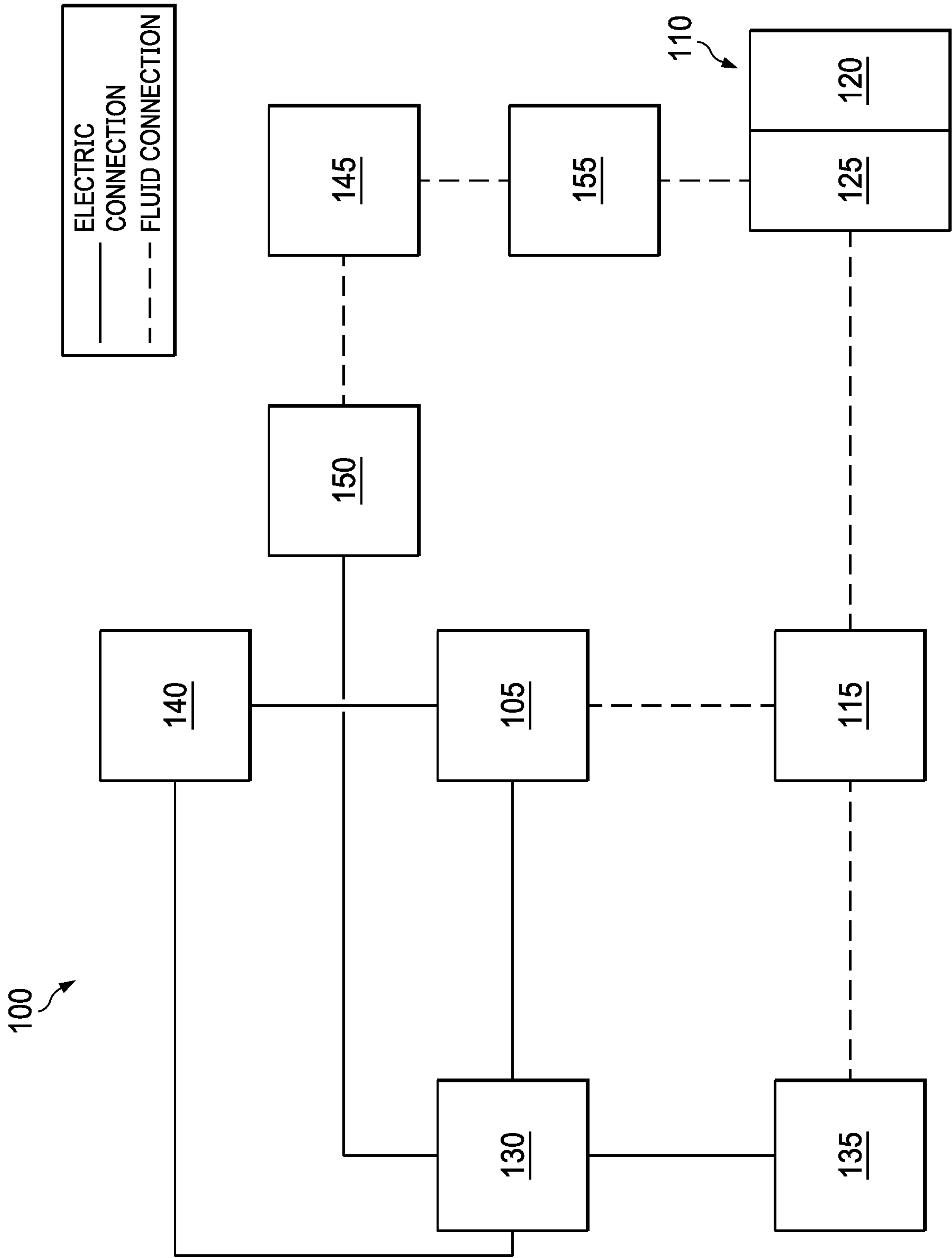


FIG. 1

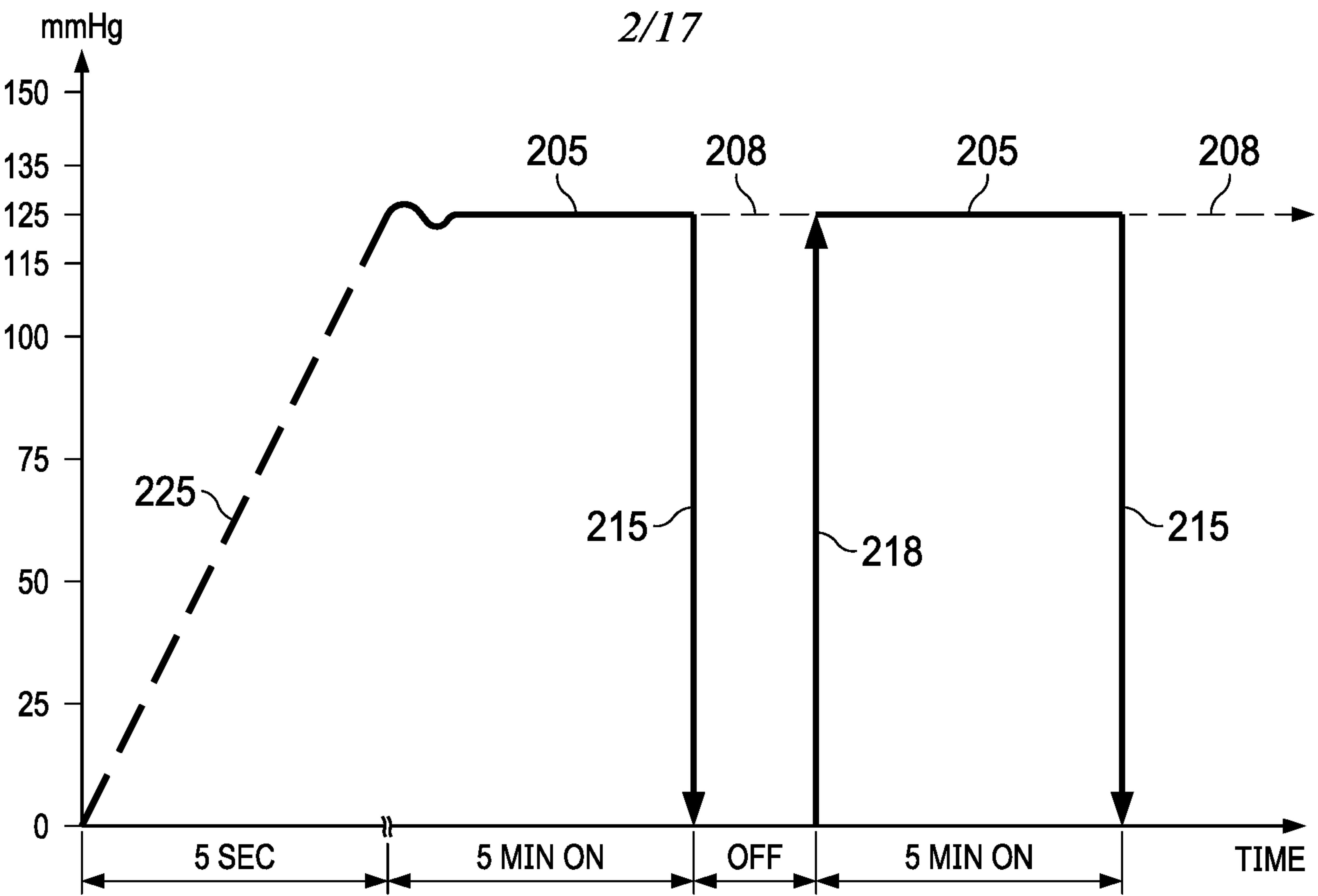


FIG. 2

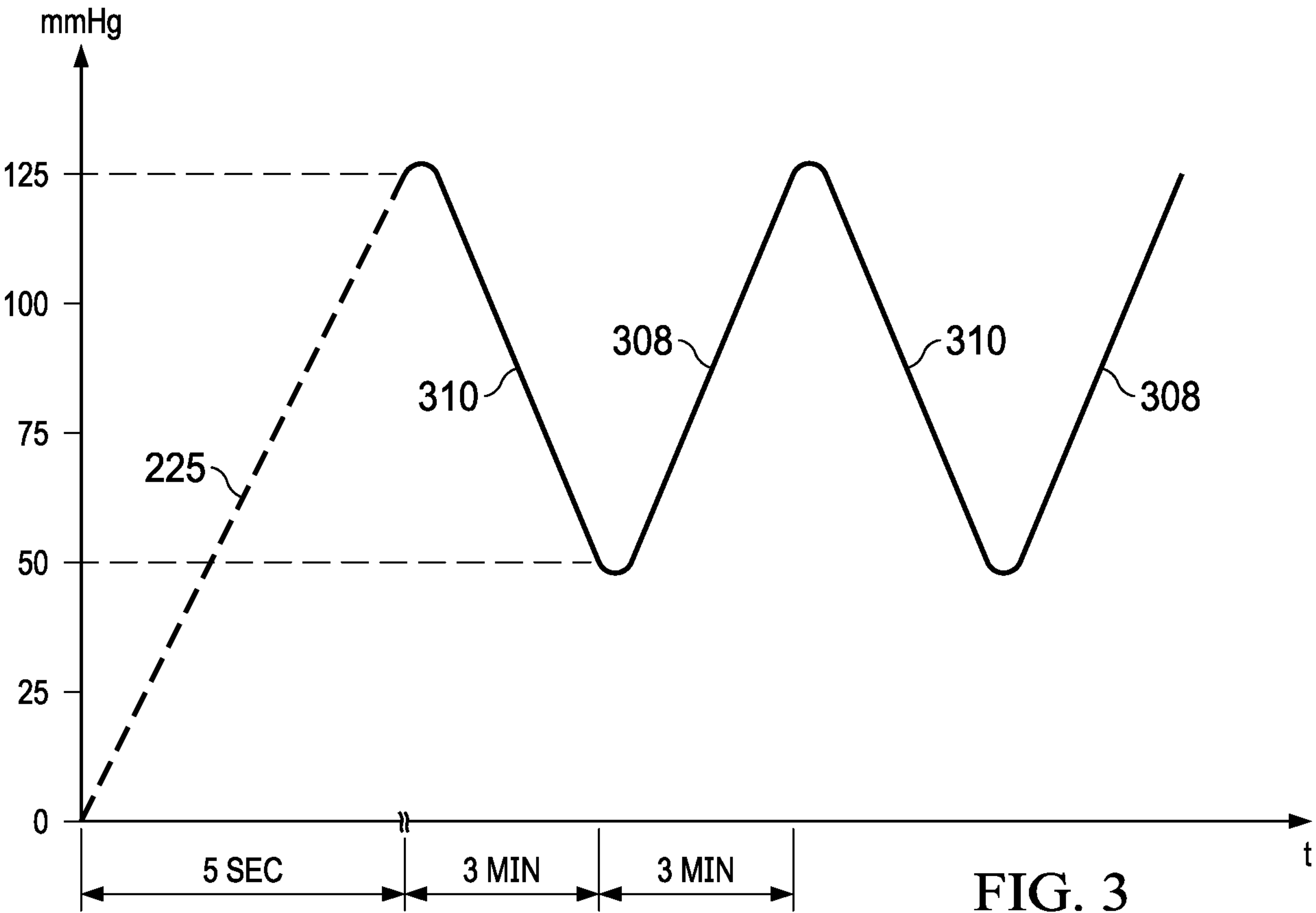


FIG. 3

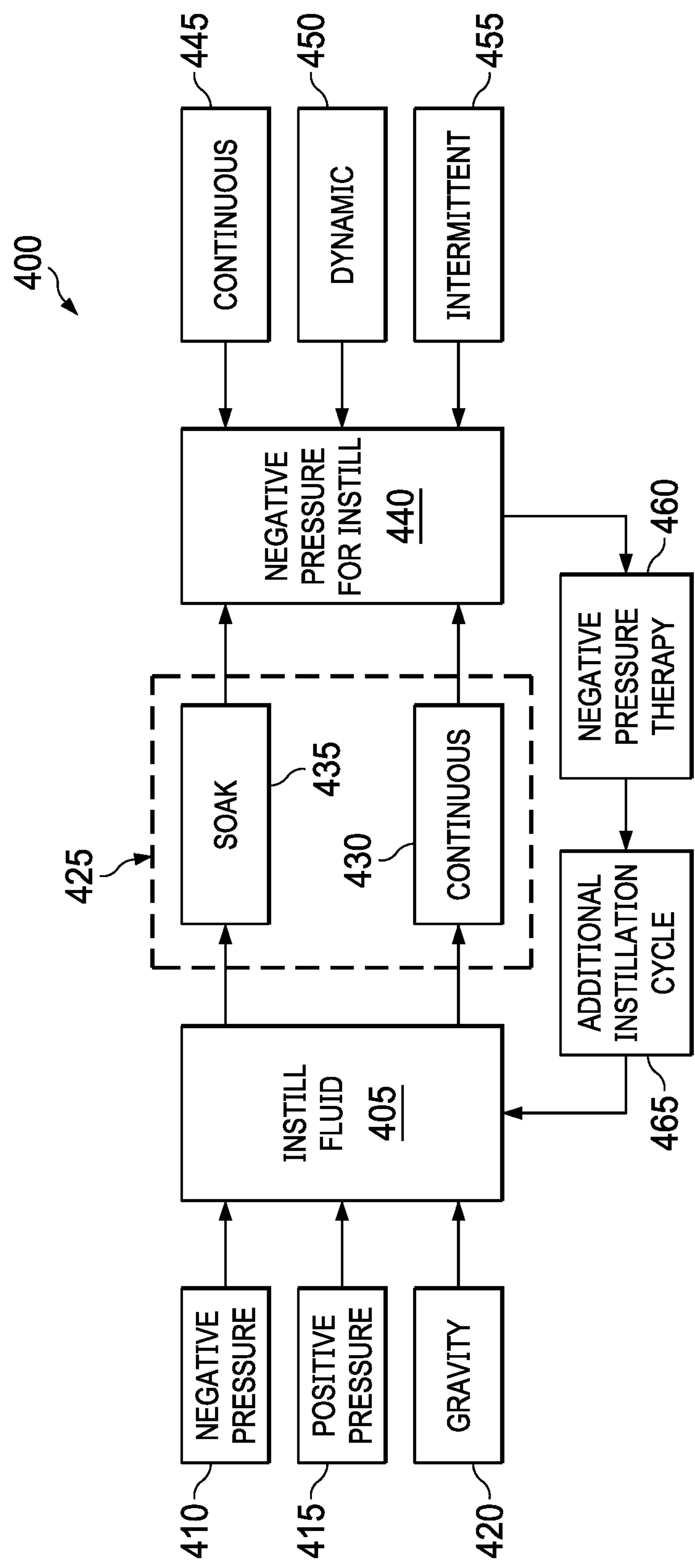


FIG. 4

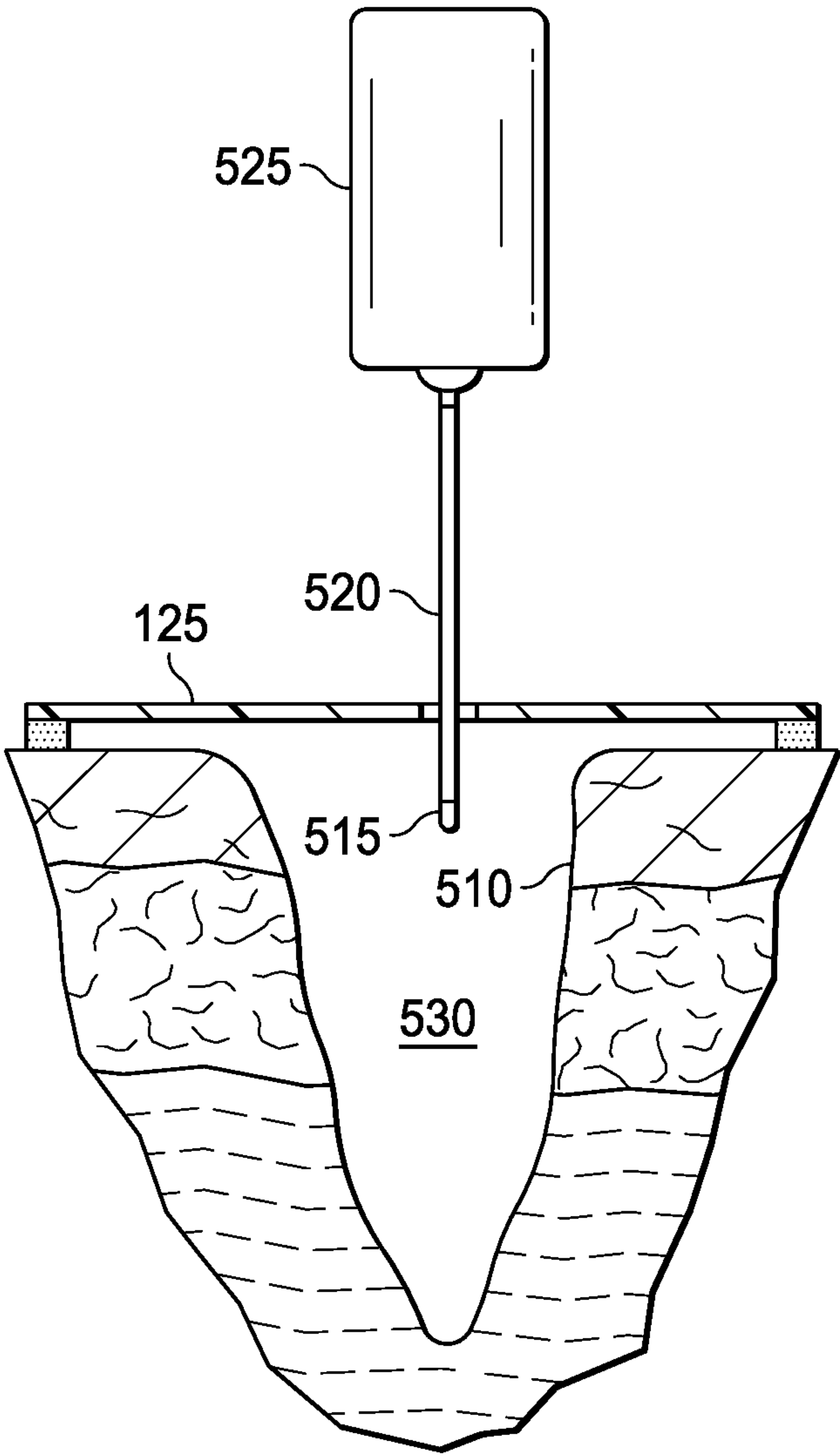
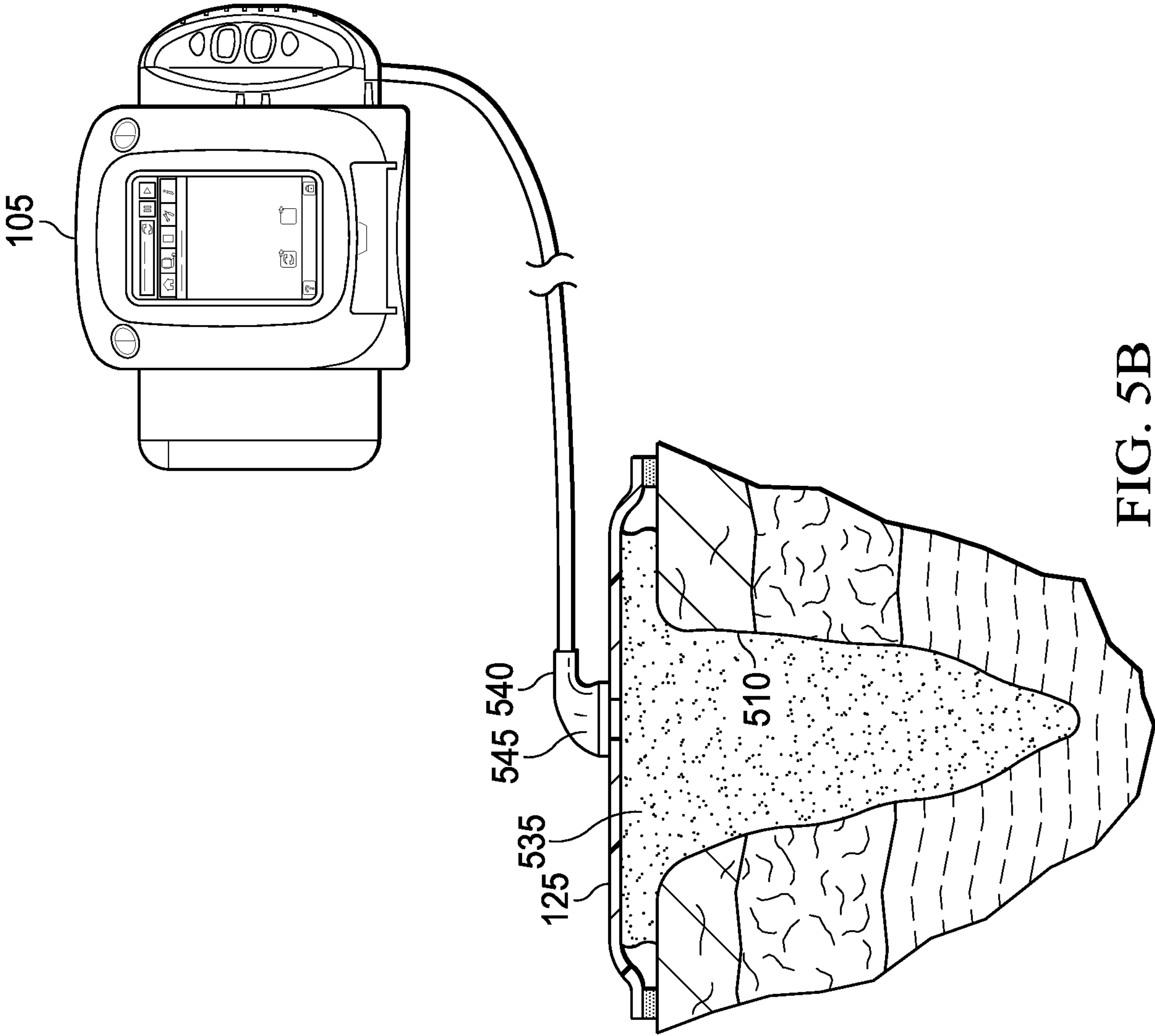


FIG. 5A



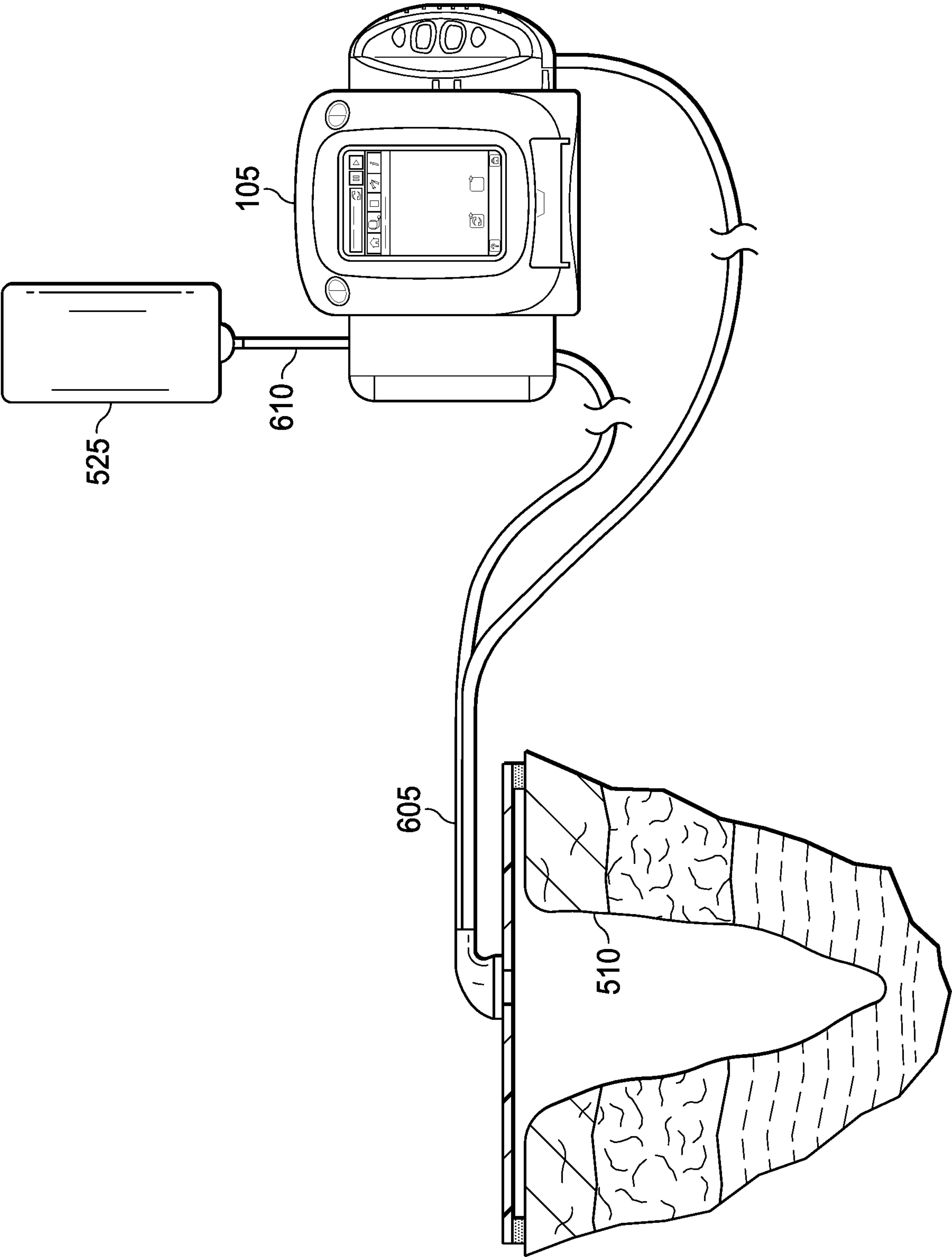


FIG. 6

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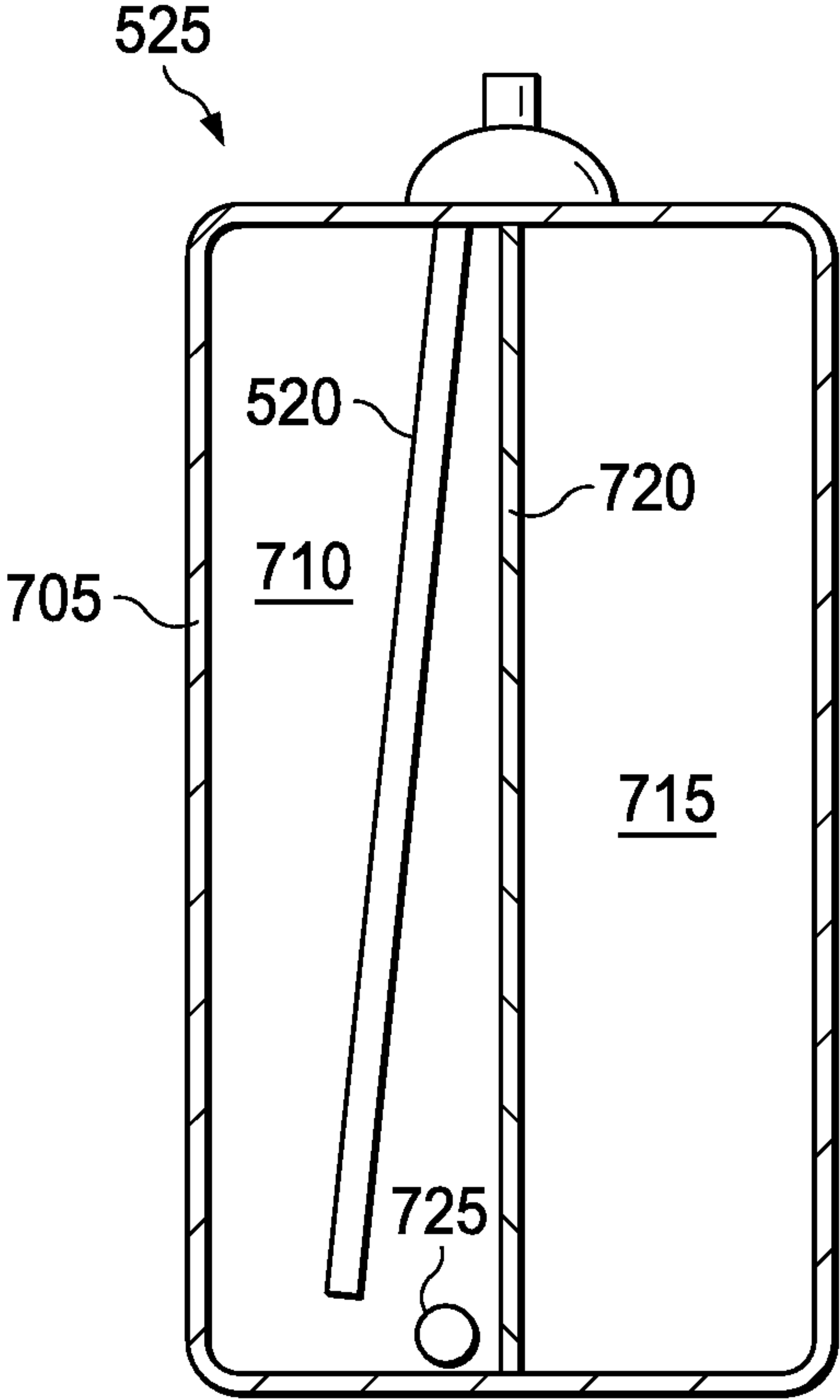


FIG. 7A

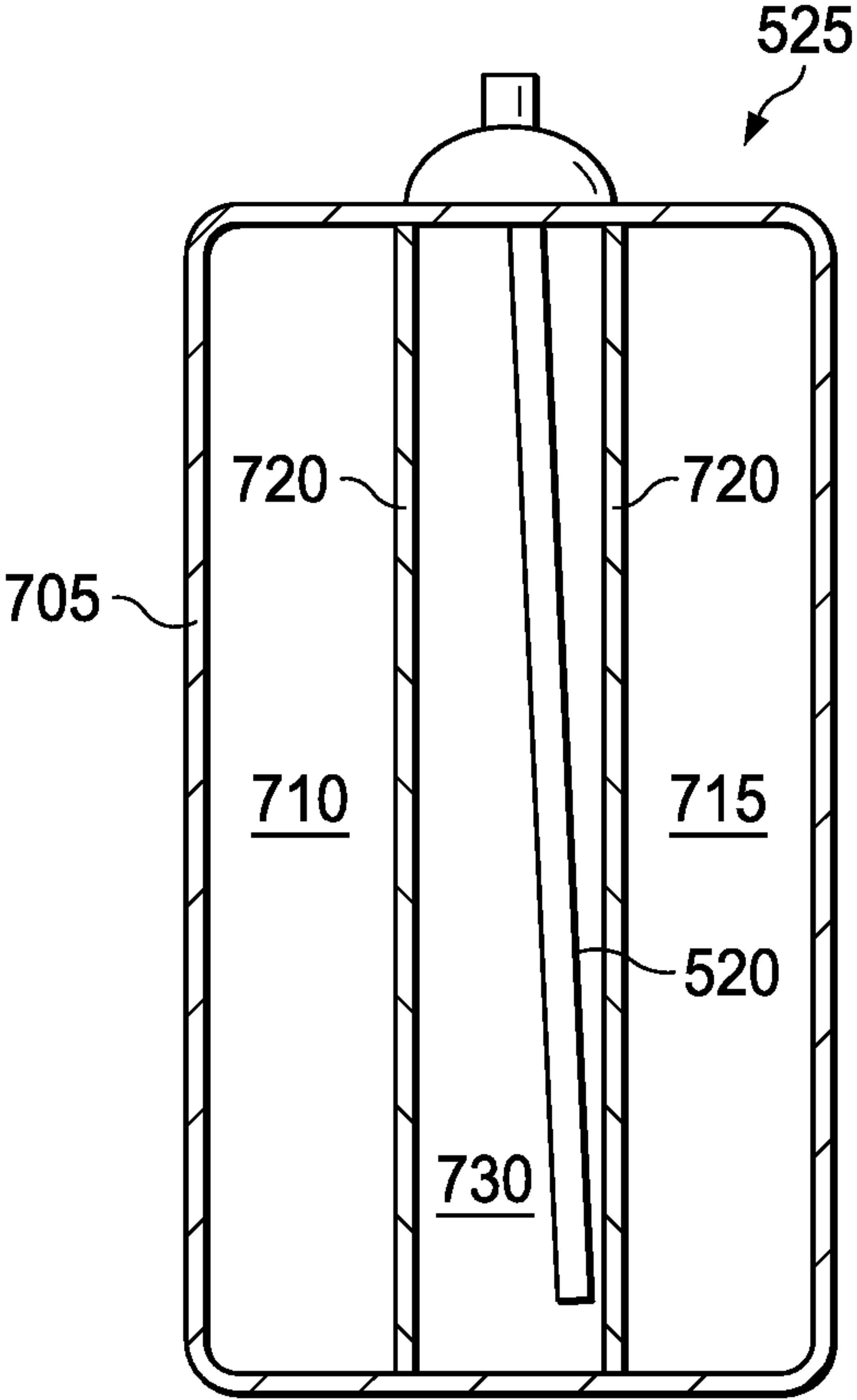


FIG. 7B

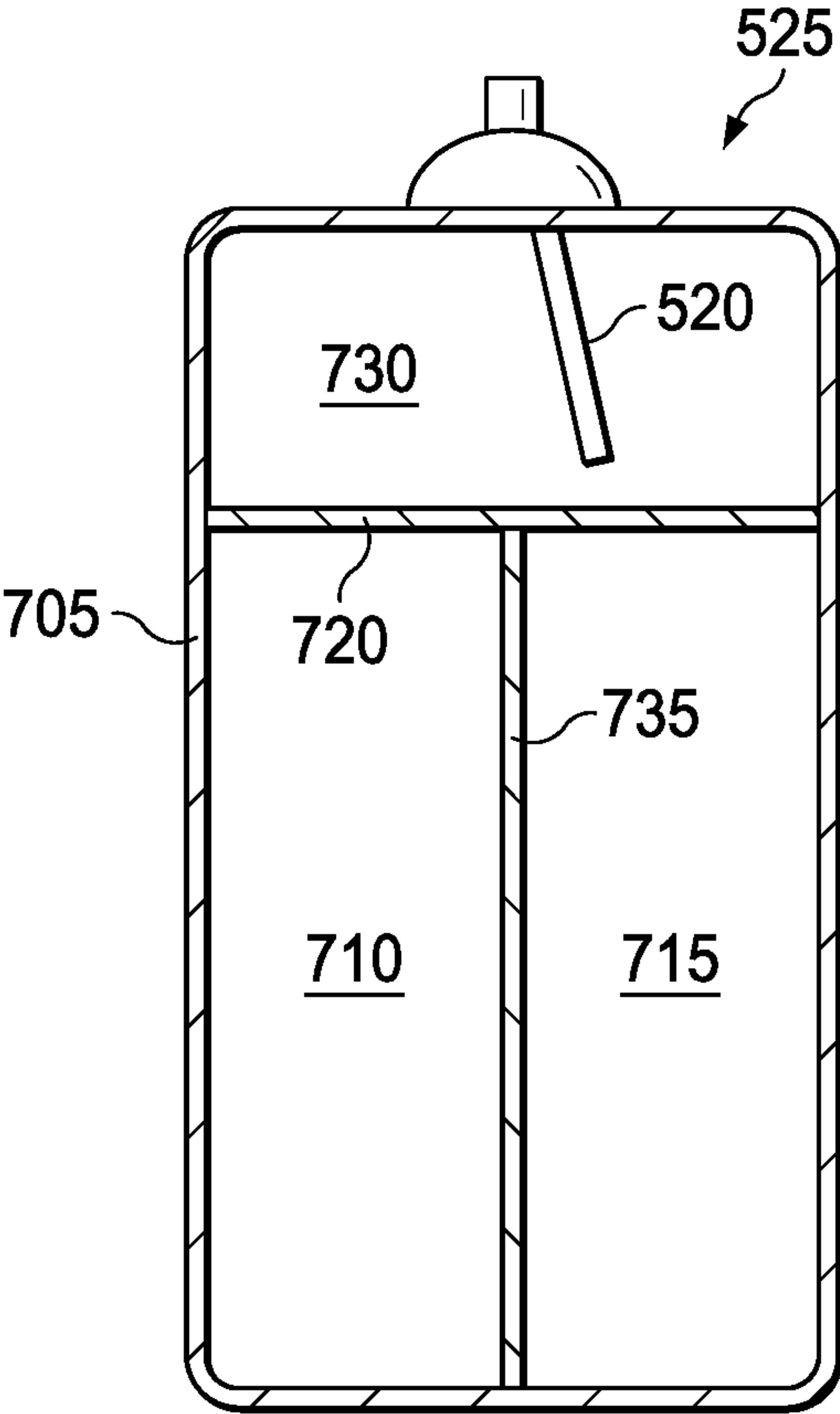


FIG. 7C

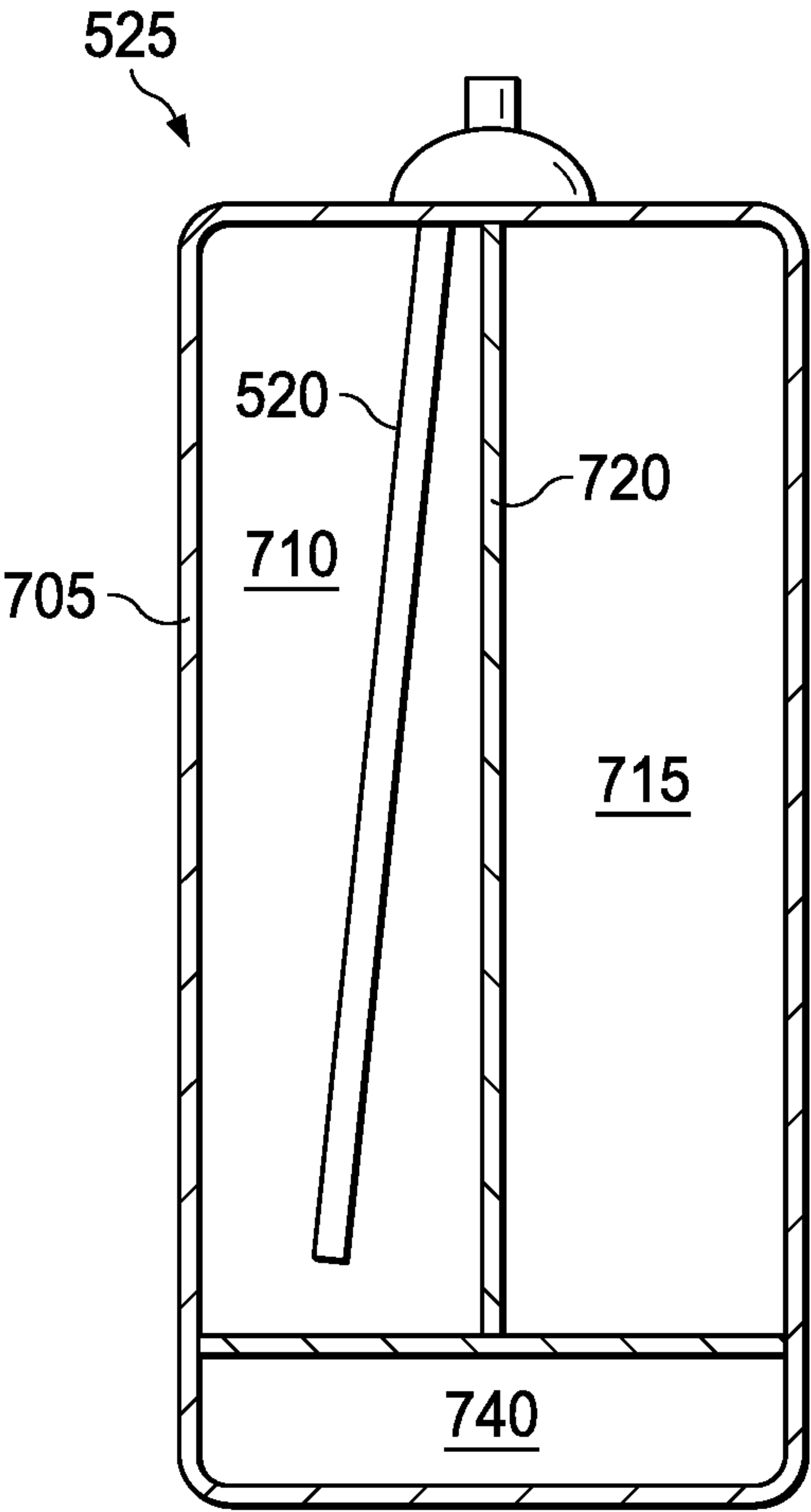


FIG. 7D

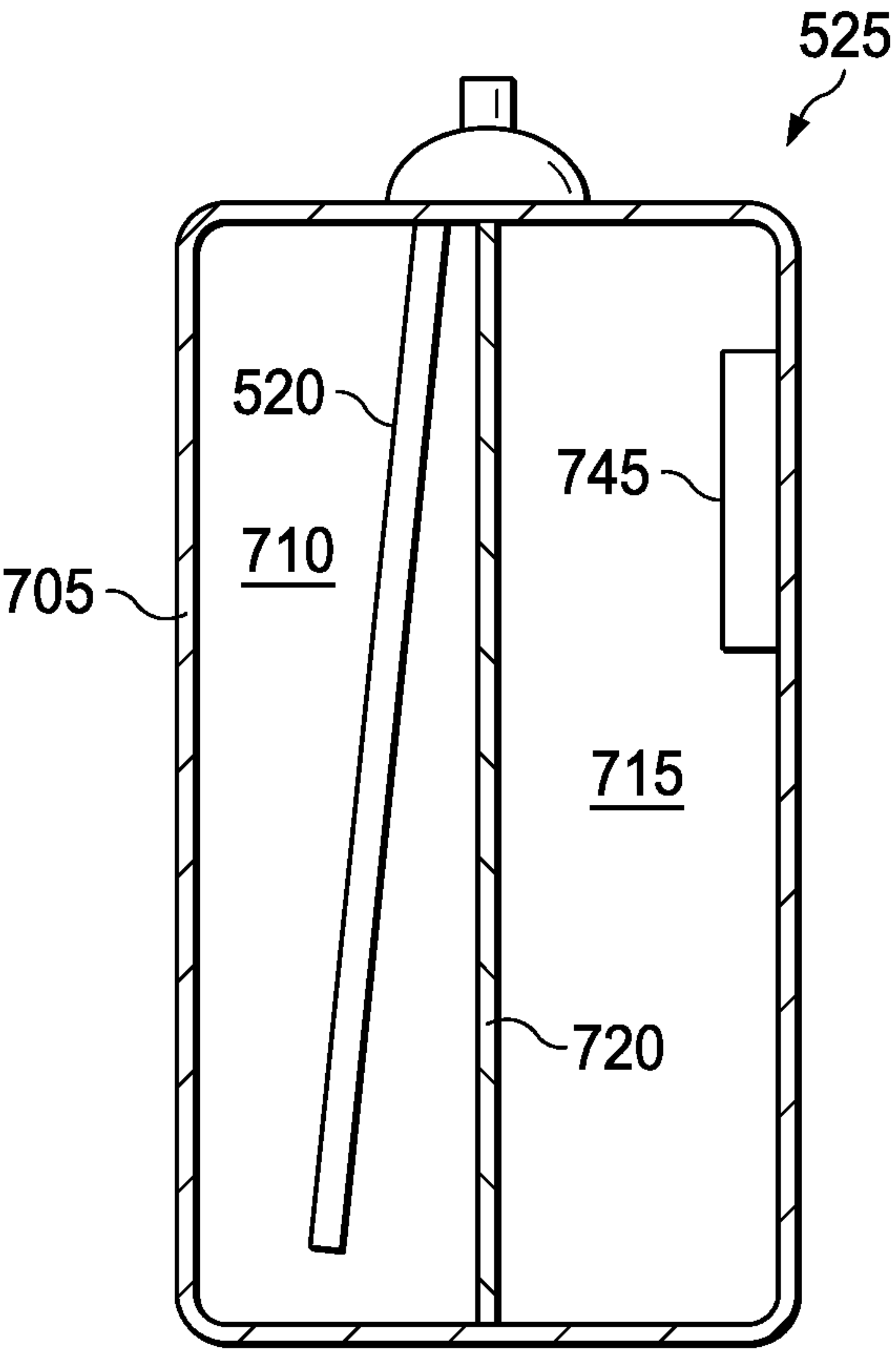


FIG. 7E

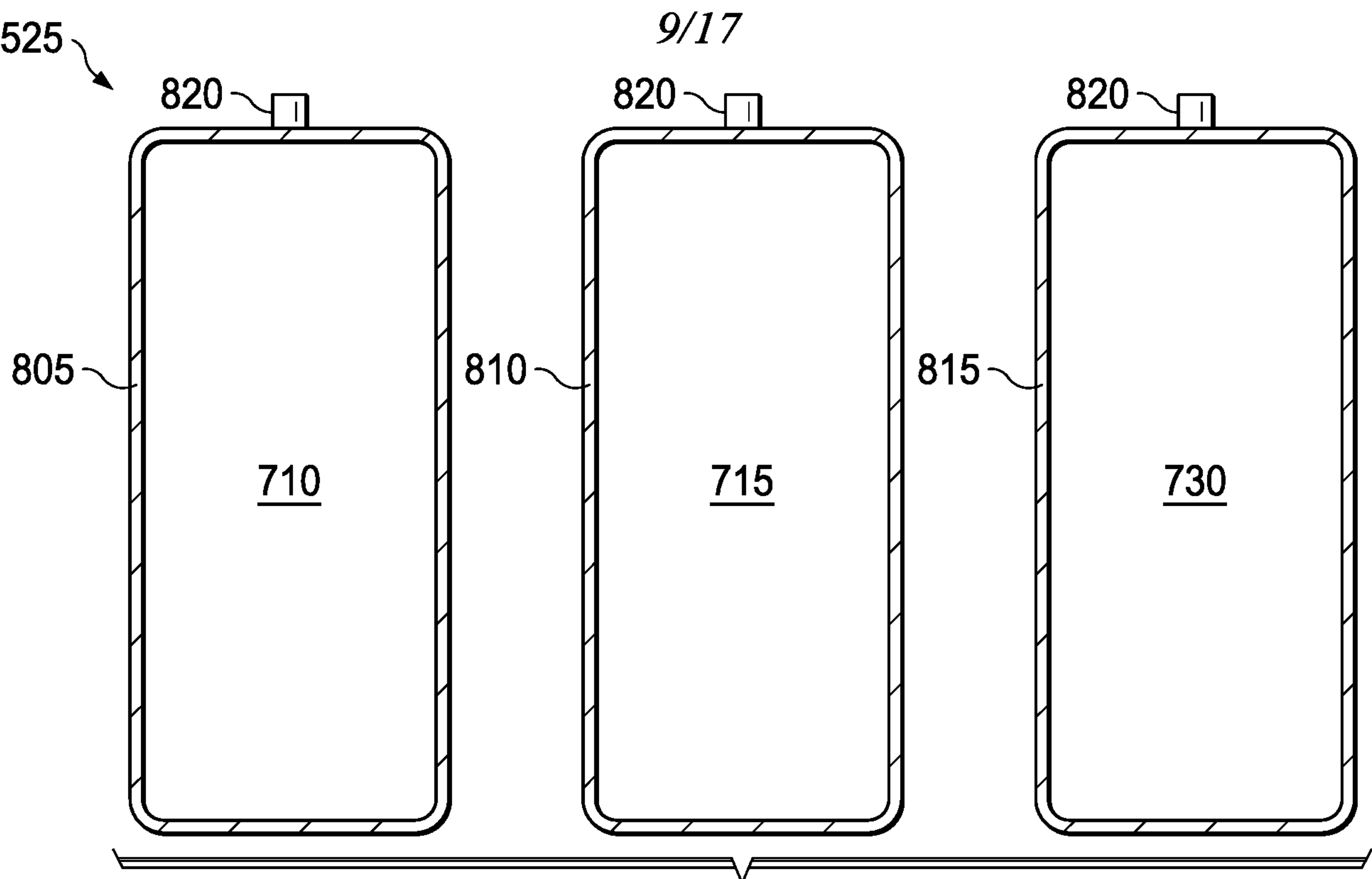


FIG. 8

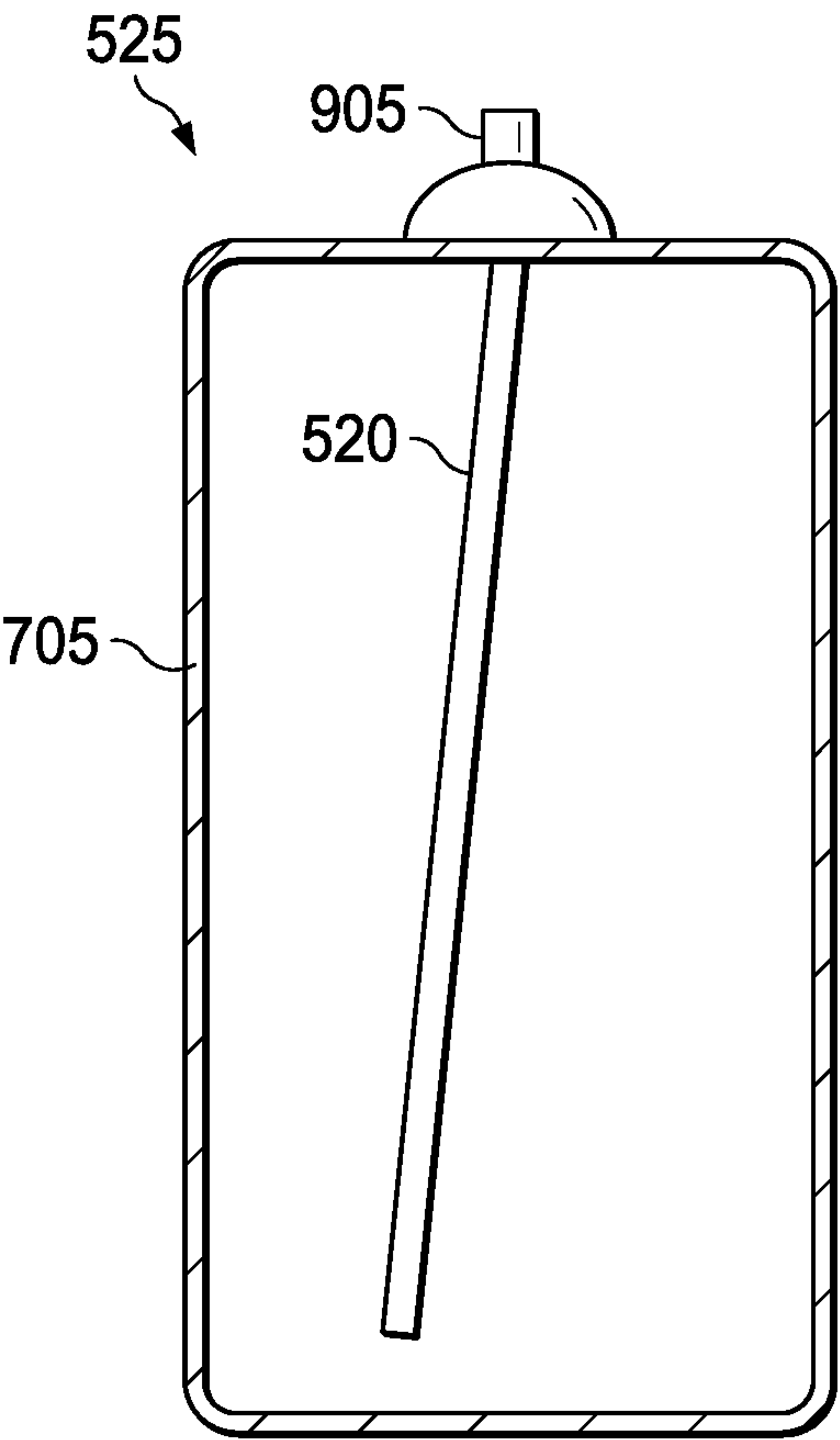
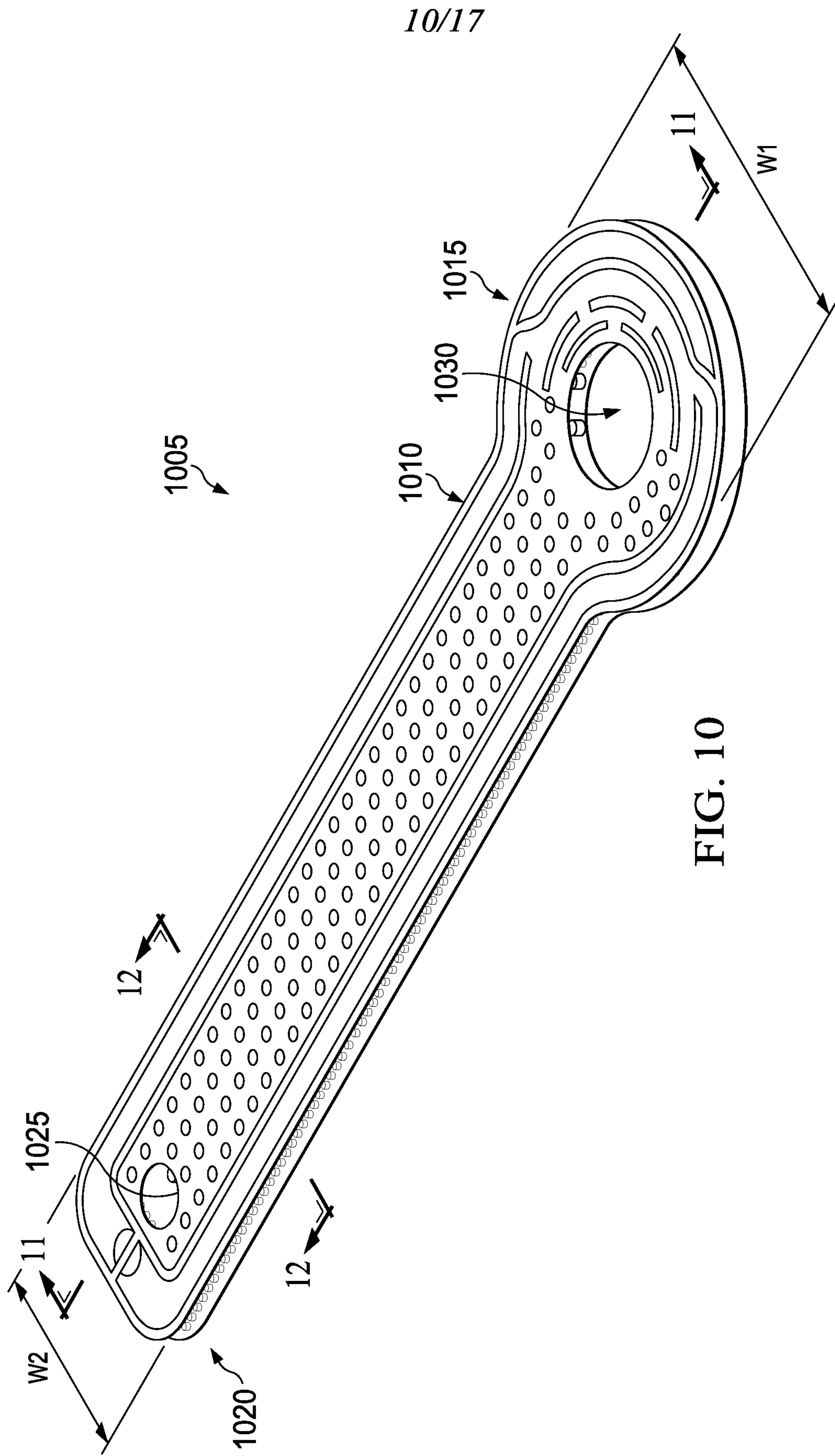


FIG. 9



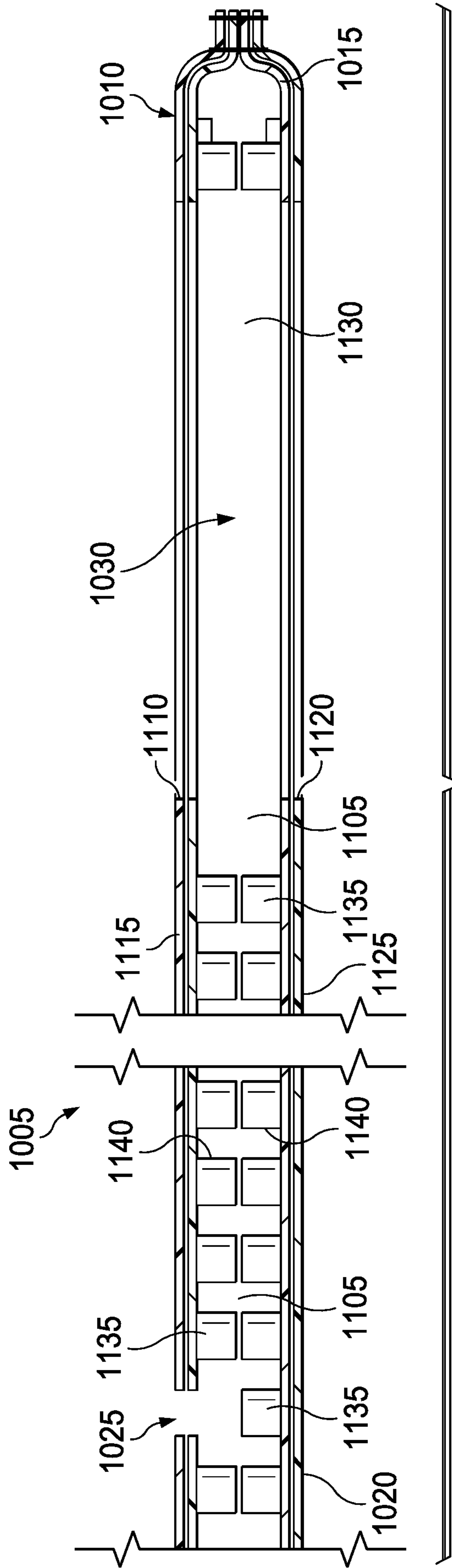


FIG. 11

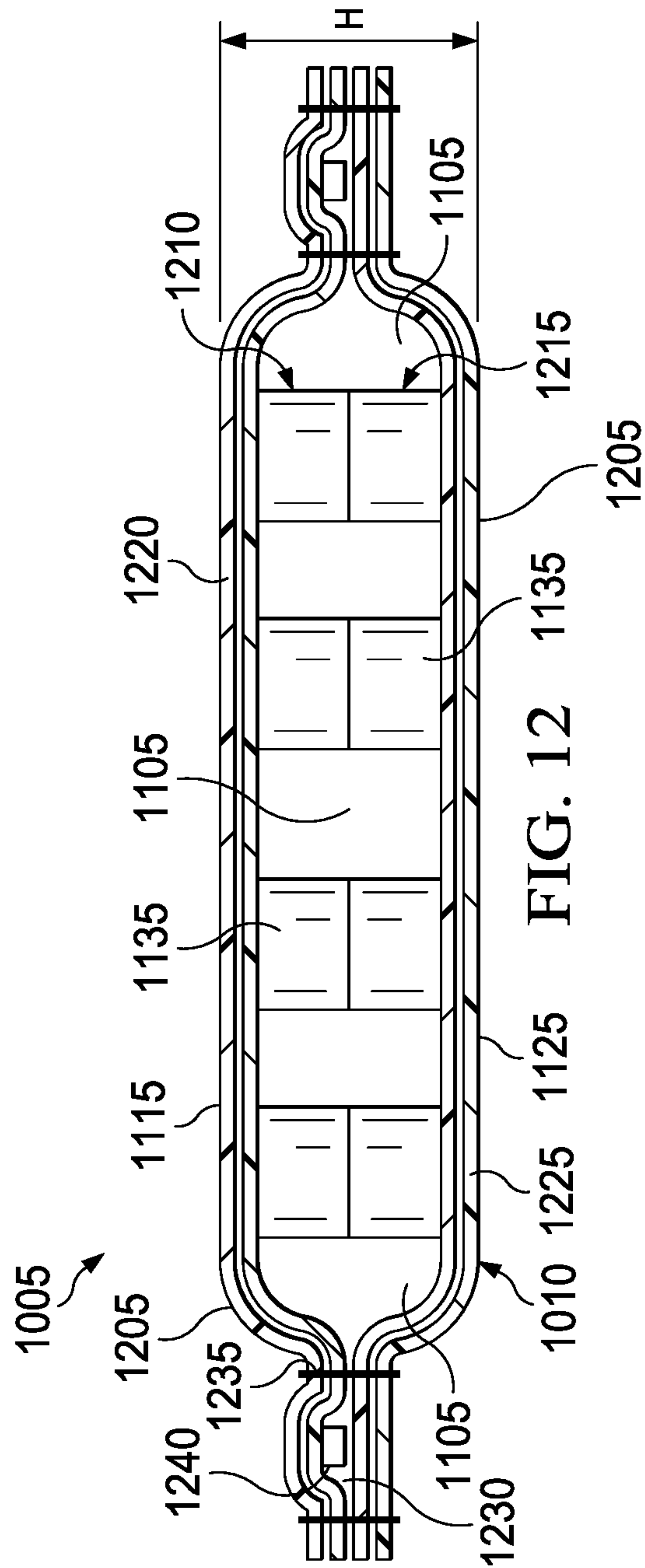


FIG. 12

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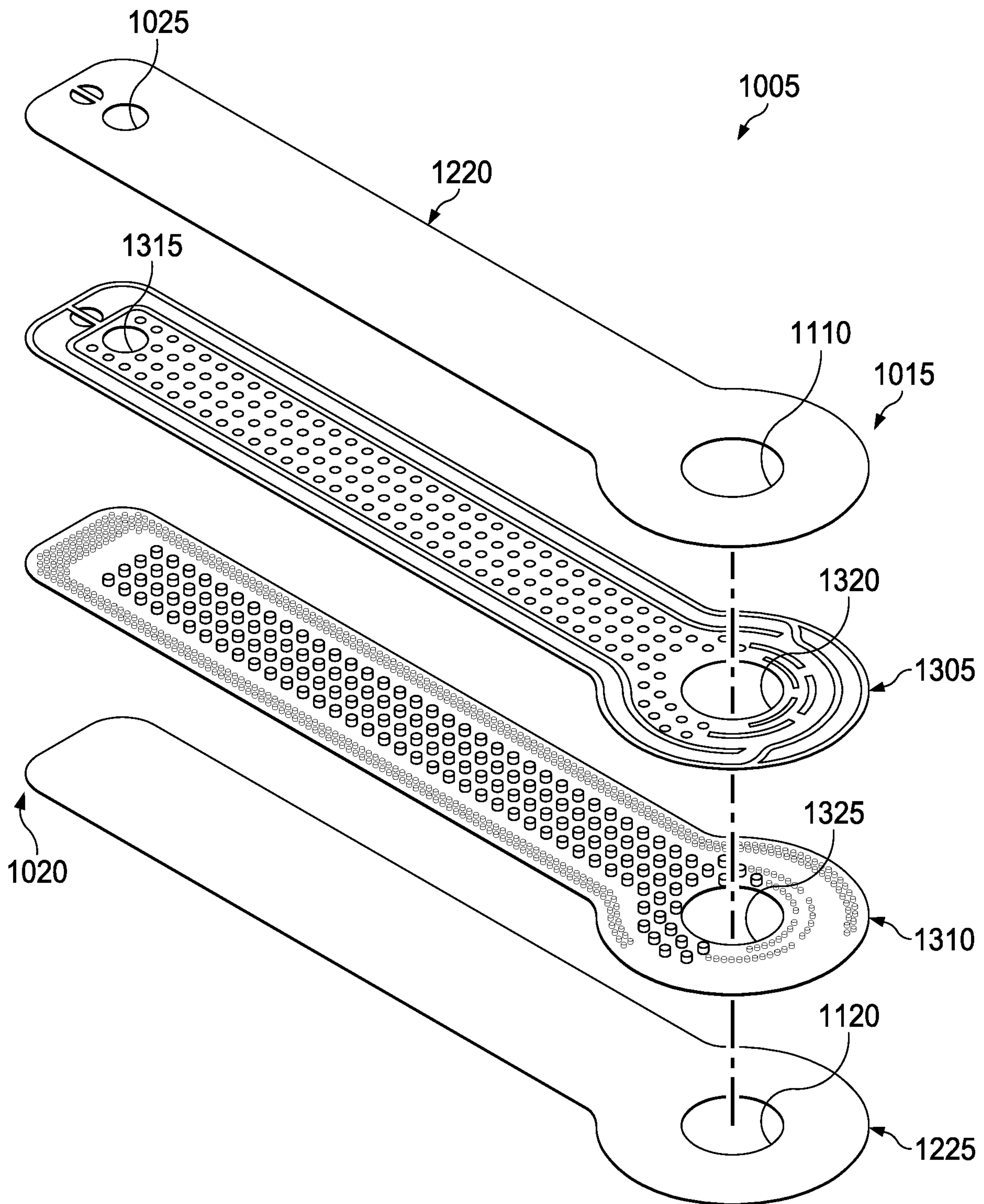


FIG. 13

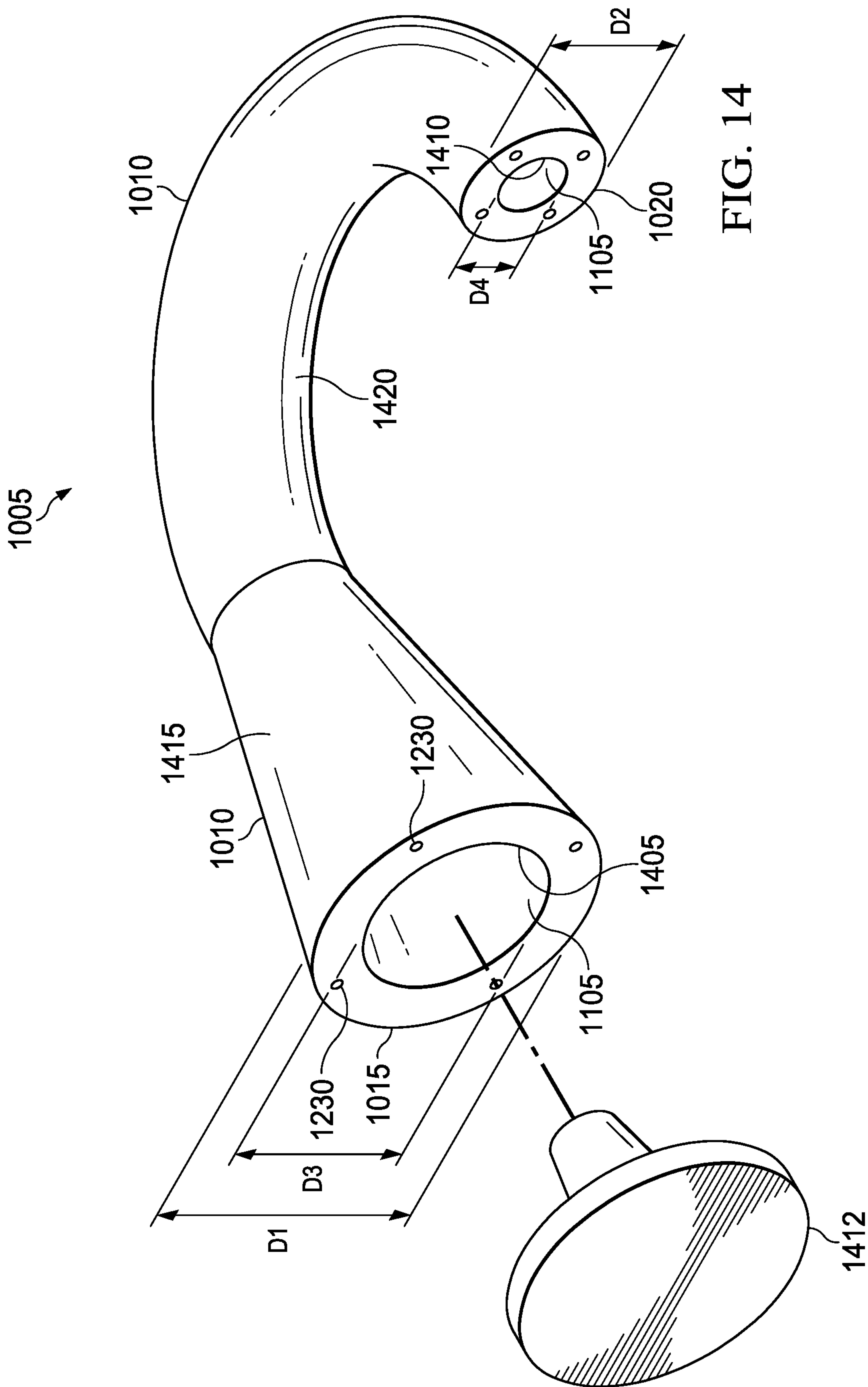


FIG. 14

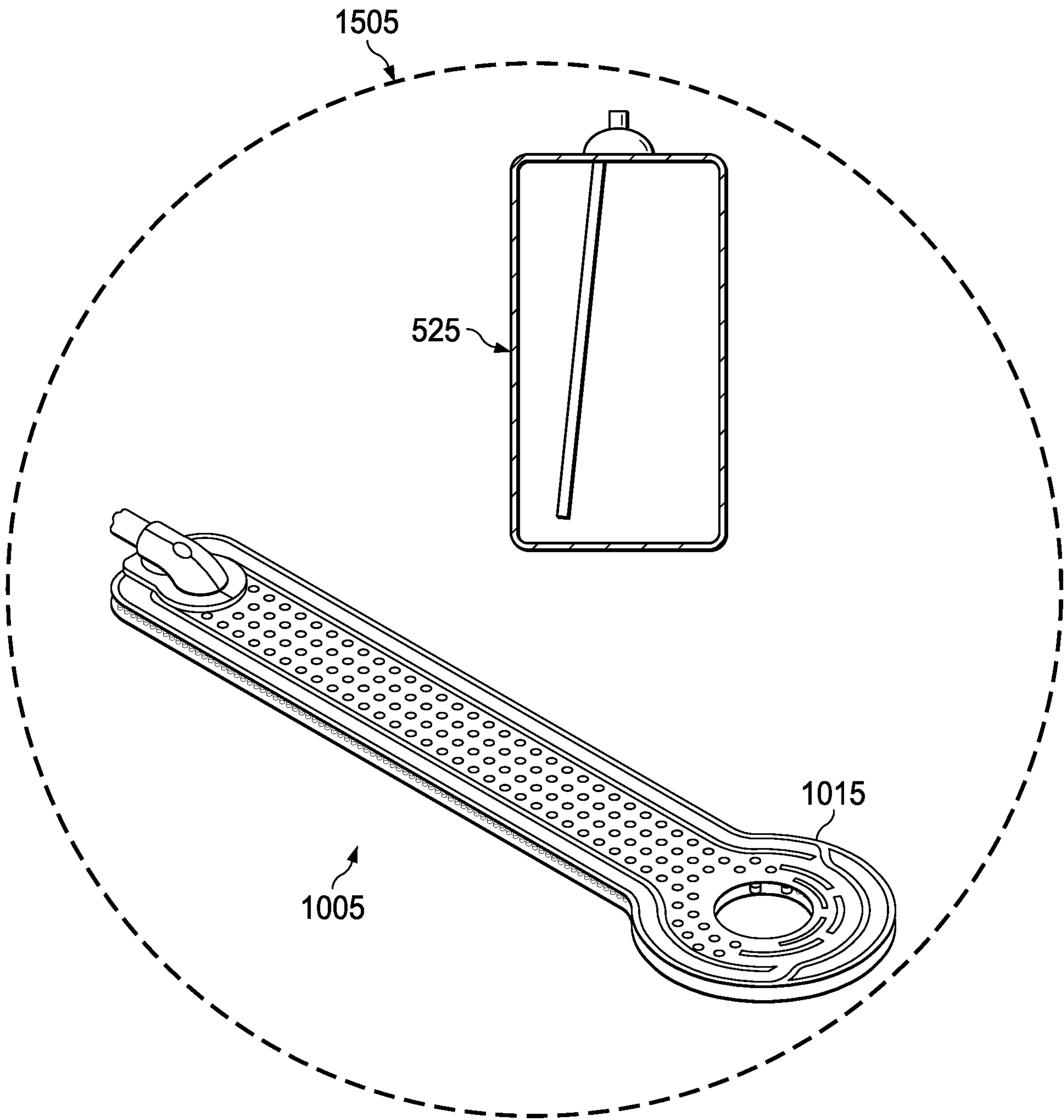


FIG. 15

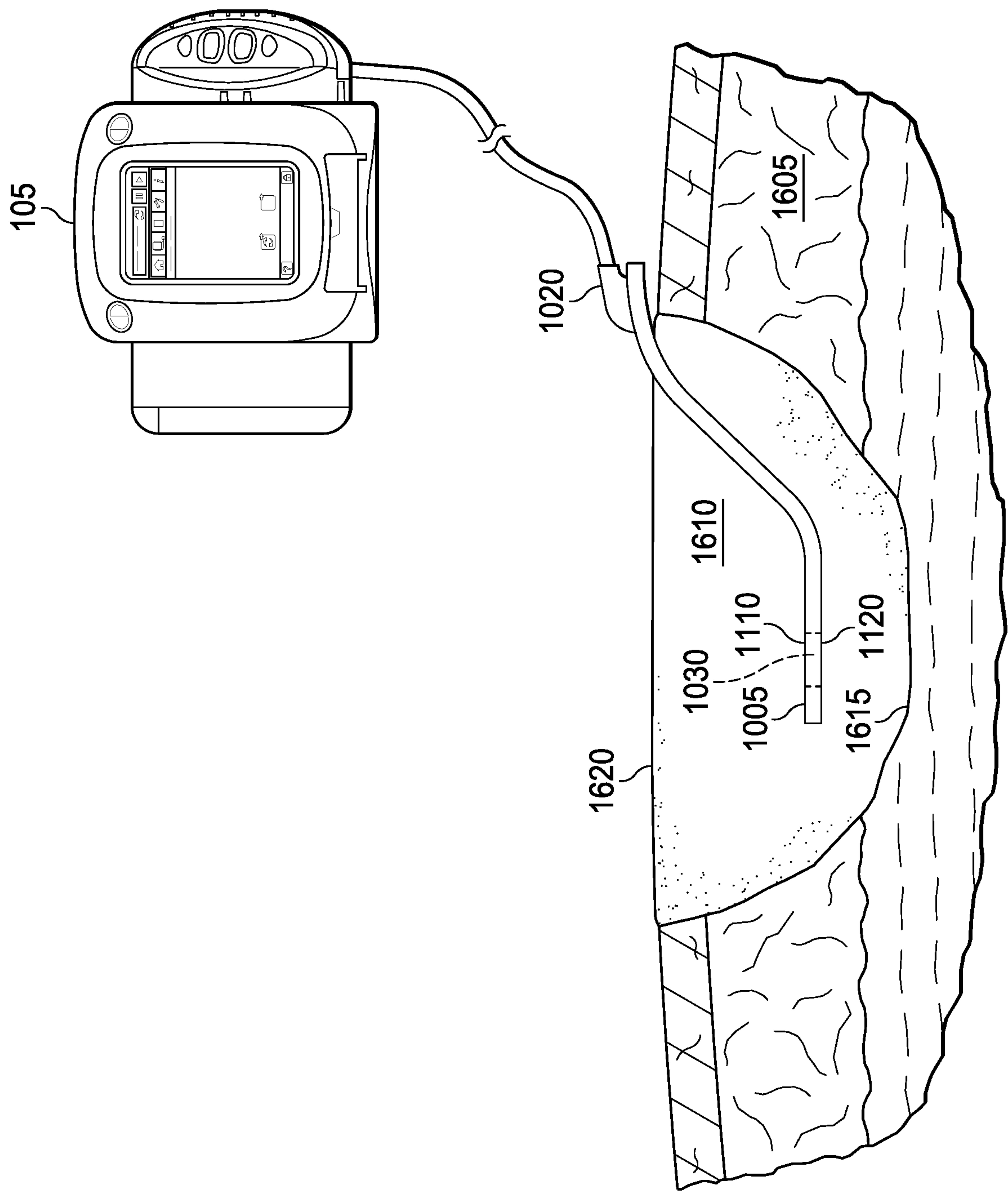


FIG. 16

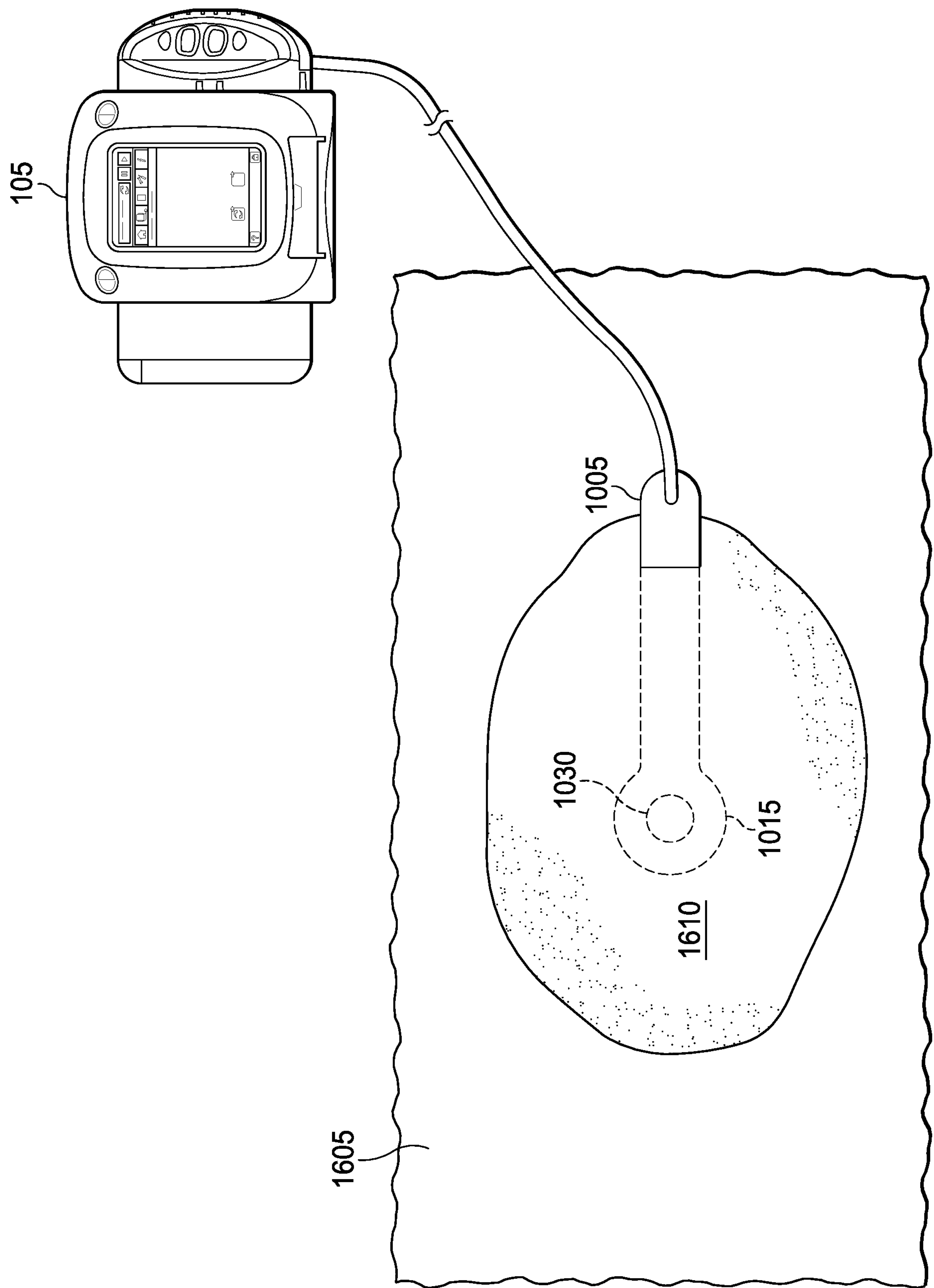


FIG. 17

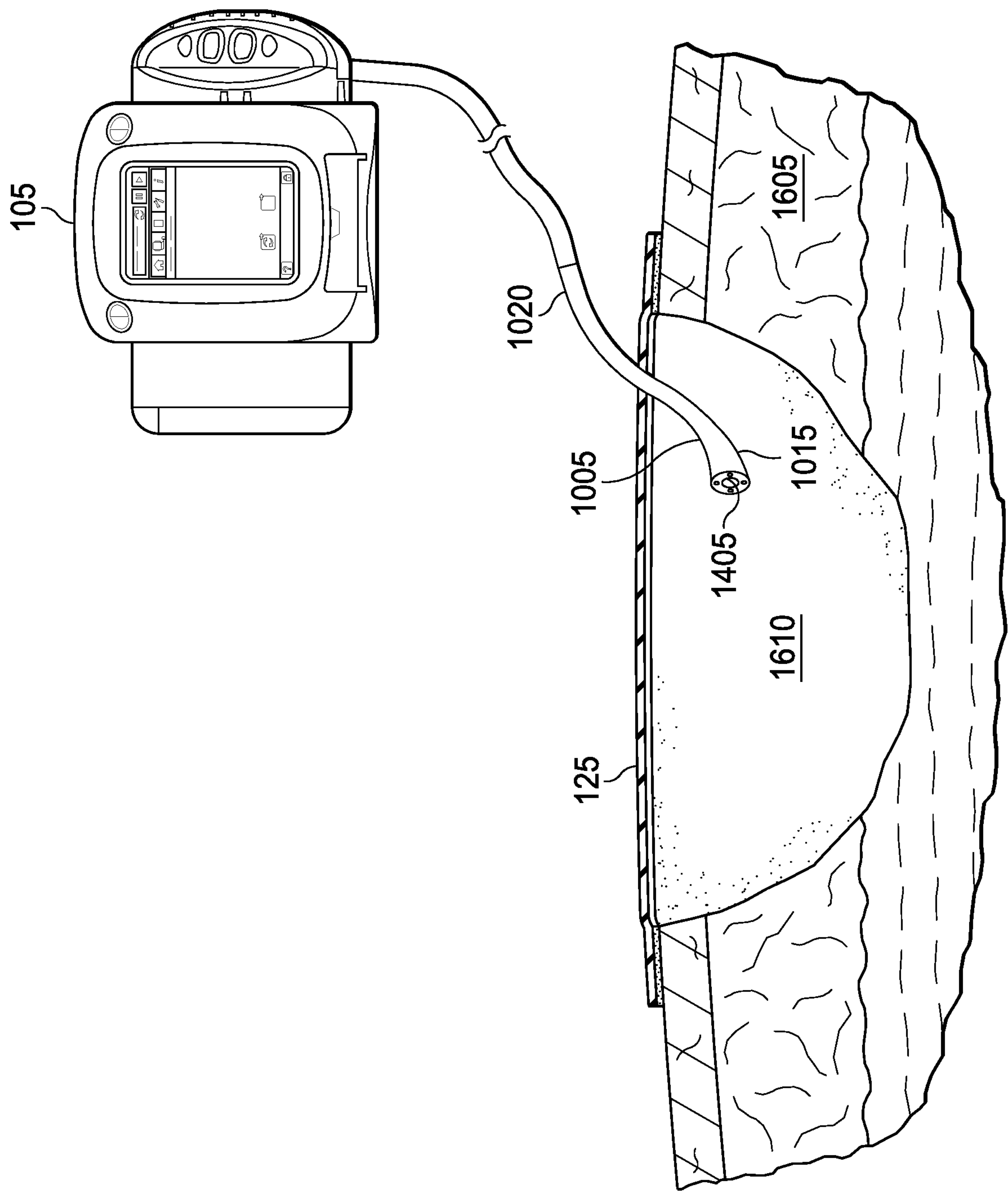


FIG. 18

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2020/059722

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M1/00 A61F13/00 A61L15/60
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M A61L A61F

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/219471 A1 (JOHNSON ROYCE W [US] ET AL) 20 September 2007 (2007-09-20) paragraphs 0127, 0128, 0138; figures 27, 27A	1
X	----- WO 2013/019438 A1 (KCI LICENSING INC [US]; ROBINSON TIMOTHY MARK [GB] ET AL.) 7 February 2013 (2013-02-07) paragraphs 0075-0078; figures 1, 9; claim 6 -----	1



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

18 December 2020

Date of mailing of the international search report

10/03/2021

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Martin Amezaga, J

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2020/059722

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

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

1. ☒ Claims Nos.: 76-99
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☒ Claims Nos.: 2-33, 115
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

see additional sheet

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

1

Remark on Protest

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claim: 1

A conduit for use with a flowable manifold to provide negative-pressure therapy to a tissue site, comprising: a fluid pathway having a proximal end and a distal end; at least one aperture in the distal end configured to provide fluid interaction between the fluid pathway and the flowable manifold, wherein the at least one aperture is configured to direct negative pressure within the fluid pathway outward in more than one direction; and a port in the proximal end configured for application of negative pressure into the fluid pathway.

2. claims: 34-75, 100-114

An apparatus for use with a flowable manifold to provide negative-pressure, the apparatus comprising a fluid pathway having a proximal and a distal end, the distal end configured to provide fluid interaction between the fluid pathway and the flowable manifold, wherein the distal end is configured for use within the flowable manifold.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 76-99

Claims 76-99 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) PCT. The method disclosed therein is explicitly worded as "A method of providing negative-pressure therapy to a tissue site", hence it is considered a method for treatment of the human or animal body by therapy/surgery.

Continuation of Box II.2

Claims Nos.: 2-33, 115

Claims 2-33 refer back to the dressing interface of claim 1, whereas claim 1 does not recite any dressing interface. According to e.g. paragraph 00112 of the description, the dressing interface and the conduit are different entities, wherein the dressing interface comprises the conduit, therefore the claims above refer back to an entity which is more general than the conduit recited in claim 1. Given that there are three different independent claims directed to a dressing interface (claims 34, 44, 51), it is neither entirely clear which of these different dressing interfaces the dependent claims above refer to. Therefore, a meaningful search of Claims 2-33 could not be carried out. Claim 115 contains references to the description. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2020/059722

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