



(51) International Patent Classification:

A61F 5/453 (2006.01) A61F 5/44 (2006.01)
A61F 5/455 (2006.01)

(21) International Application Number:

PCT/US2021/026607

(22) International Filing Date:

09 April 2021 (09.04.2021)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/008,112 10 April 2020 (10.04.2020) US

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(54) Title: FLUID COLLECTION ASSEMBLIES INCLUDING ONE OR MORE LEAK PREVENTION FEATURES

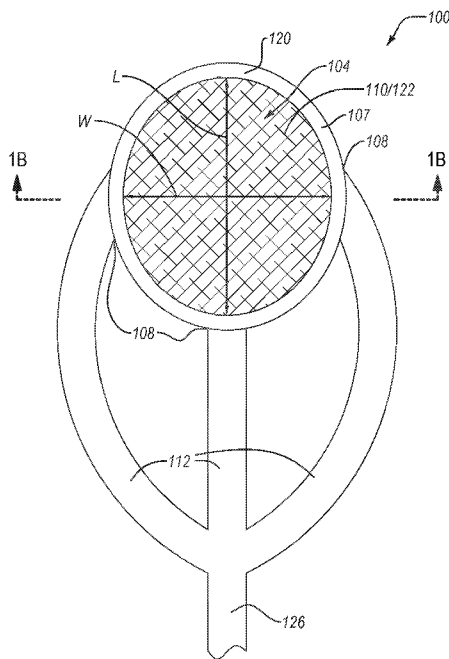


FIG. 1A

(57) Abstract: An example fluid collection assembly (100, 200, 300, 400, 500a, 500b, 600, 700, 800, 900, 1000) includes a fluid impermeable barrier (102, 202, 302, 402, 502a, 502b, 602, 702, 802, 902) defining at least one opening (104, 204, 304, 504a, 504b, 604, 704, 904), a chamber (106, 206, 306, 406, 506a, 506b, 606, 706, 906) in fluid communication with the at least one opening (104, 204, 304, 504a, 504b, 604, 704, 904), and at least one fluid outlet (108, 208, 308, 908). The fluid collection assembly (100, 200, 300, 400, 500a, 500b, 600, 700, 800, 900, 1000) also includes at least one porous material (110, 210, 310, 410, 510a, 510b, 610, 710, 810, 910) (e.g., at least one wicking material) disposed in the chamber (106, 206, 306, 406, 506a, 506b, 606, 706, 906). The fluid collection assembly (100, 200, 300, 400, 500a, 500b, 600, 700, 800, 900, 1000) also includes at least one conduit (112, 212, 312, 412, 612, 712, 912) attached to the fluid outlet (108, 208, 308, 908). Further, the fluid collection assembly (100, 200, 300, 400, 500a, 500b, 600, 700, 800, 900, 1000) includes one or more leak prevention features.



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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, 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))

FLUID COLLECTION ASSEMBLIES INCLUDING ONE OR MORE LEAK PREVENTION FEATURES

BACKGROUND

5 [0001] A person or animal may have limited or impaired mobility such that typical urination processes are challenging or impossible. For example, a person may experience or have a disability that impairs mobility. A person may have restricted travel conditions such as those experienced by pilots, drivers, and workers in hazardous areas. Additionally, sometimes bodily fluids collection is needed for monitoring purposes or
10 clinical testing.

[0002] Urinary catheters, such as a Foley catheter, can be used to address some of these circumstances, such as incontinence. Unfortunately, urinary catheters can be uncomfortable, painful, and can lead to complications, such as infections. Additionally, bed pans, which are receptacles used for the toileting of bedridden patients are sometimes
15 used. However, bedpans can be prone to discomfort, spills, and other hygiene issues.

SUMMARY

[0003] In an embodiment, a fluid collection assembly is disclosed. The fluid collection assembly includes a fluid impermeable barrier defining, at least one opening, a chamber in fluid communication with the at least one opening, and at least one fluid
20 outlet. The fluid collection assembly also includes at least one porous material disposed in the chamber. Further, the fluid collection assembly includes at least one conduit attached to the at least one fluid outlet. The fluid collection assembly additionally includes one or more leak prevention features configured to at least inhibit bodily fluids leaking from the chamber

25 [0004] Features from any of the disclosed embodiments may be used in combination with one another, without limitation. In addition, other features and advantages of the present disclosure will become apparent to those of ordinary skill in the art through consideration of the following detailed description and the accompanying drawings.

[0005] The drawings illustrate several embodiments of the present disclosure,
30 wherein identical reference numerals refer to identical or similar elements or features in different views or embodiments shown in the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] The drawings illustrate several embodiments of the present disclosure,
35 wherein identical reference numerals refer to identical or similar elements or features in different views or embodiments shown in the drawings.

- [0007] FIG. 1A is a top plan view of a fluid collection assembly that includes one or more leak prevention features, according to an embodiment.
- [0008] FIG. 1B is a cross-sectional view of the fluid collection assembly taken along line 1B-1B shown in FIG. 1A, according to an embodiment.
- 5 [0009] FIG. 2A is a top plan view of a fluid collection assembly, according to an embodiment.
- [0010] FIG. 2B is a cross-sectional view of the fluid impermeable barrier taken along line 2B-2B, according to an embodiment.
- [0011] FIGS. 3A and 3B are isometric and cross-sectional views of a fluid collection
10 assembly, respectively, according to an embodiment.
- [0012] FIG. 3C is an isometric view of the conduit illustrating how the at least one conduit inlet may facilitate removing bodily fluids from the chamber when the individual using the fluid collection assembly is in a position other than lying down, according to an embodiment.
- 15 [0013] FIG. 3D is an isometric view of a conduit that may be used in any of the fluid collection assemblies disclosed herein, according to an embodiment.
- [0014] FIG. 3E is an isometric view of a conduit that may be used in any of the fluid collection assemblies disclosed herein, according to an embodiment.
- [0015] FIG. 3F is an isometric view of a plurality of conduits that may be used in any
20 of the fluid collection assemblies disclosed herein, according to an embodiment.
- [0016] FIG. 3G is an isometric view of a system that includes the first, second, and third conduits and a suction control apparatus, according to an embodiment.
- [0017] FIG. 4 is cross-sectional view of a fluid collection assembly that includes a fluid reservoir extending along the conduit, according to an embodiment.
- 25 [0018] FIG. 5A is a schematic cross-sectional view of a leak prevention layer, according to an embodiment.
- [0019] FIG. 5B is a schematic partial cross-sectional view of a portion of a fluid collection assembly that includes at least one leak prevention layer, according to an embodiment.
- 30 [0020] FIG. 5C is a schematic partial cross-sectional view of a portion of a fluid collection assembly that includes at least one leak prevention layer, according to an embodiment.
- [0021] FIG. 6 is a schematic partial cross-sectional view of a portion of the fluid collection assembly, according to an embodiment.

[0022] FIG. 7 is a schematic cross-sectional view of a fluid collection assembly that is configured to conform to the vulva and the region about the vulva, according to an embodiment.

[0023] FIG. 8 is a bottom plan view of a fluid collection assembly that is configured to conform to the vulva and the region about the vulva, according to an embodiment.

[0024] FIG. 9A is an isometric view of a fluid collection assembly according to an embodiment.

[0025] FIG. 9B is a cross-sectional view of the fluid collection assembly of FIG. 9A taken along the plane B-B of FIG. 9A, according to an embodiment.

[0026] FIG. 10 is a block diagram of a system for fluid collection, according to an embodiment.

DETAILED DESCRIPTION

[0027] Embodiments are directed to bodily fluids collection assemblies that include one or more leak prevention features along with systems including and methods of using such bodily fluids collection assemblies. An example fluid collection assembly includes a fluid impermeable barrier defining at least one opening, a chamber in fluid communication with the at least one opening, and at least one fluid outlet. The fluid collection assembly also includes at least one porous material (*e.g.*, at least one wicking material) disposed in the chamber. The fluid collection assembly also includes at least one conduit attached to the fluid outlet. During operation, the fluid collection assembly may receive bodily fluids (*e.g.*, urine) from an individual (*e.g.*, human) through the opening and into the chamber. The porous material may receive at least some of the bodily fluids that enter the chamber. A suction applied from the conduit to the chamber may direct the bodily fluids in chamber towards the conduit. The conduit may then remove the bodily fluids from the chamber.

[0028] The fluid collection assembly includes one or more leak prevention features. The leak prevention features decrease the likelihood that the fluid collection assembly leaks compared to a substantially similar fluid collection assembly that does not include the leak prevention features. For example, the bodily fluids may leak from the fluid collection assembly when the bodily fluids flow out of the chamber through the opening or the bodily fluids fail to enter the chamber. The leaked bodily fluids may cause the individual embarrassment and an create unsanitary environment. The bodily fluids may leak from the fluid collection assembly for a variety of reasons, examples of which include movement of the individual, oversaturation of the porous material, and/or the

opening of the fluid collection assembly becoming spaced from the individual. The leak prevention features of the fluid collection assembly are configured to minimize or prevent at least some of the reasons that cause the fluid collection assembly to leak.

[0029] FIG. 1A is a top plan view of a fluid collection assembly 100 that includes one or more leak prevention features, according to an embodiment. FIG. 1B is a cross-sectional view of the fluid collection assembly 100 taken along line 1B-1B shown in FIG. 1A, according to an embodiment. The fluid collection assembly 100 includes a fluid impermeable barrier 102. The fluid impermeable barrier 102 defines at least one opening 104 configured to receive bodily fluids from an individual. The fluid impermeable barrier 102 also defines a chamber 106 that is in fluid communication with the opening 104 and at least one fluid outlet 108. The fluid collection assembly 100 also include at least one porous material 110 disposed in the chamber 106 and at least one conduit 112 attached to the fluid outlet 108. The fluid collection assembly 100 also include one or more leak prevention features.

[0030] In an embodiment, the leak prevention features of the fluid collection assembly 100 includes forming the fluid collection assembly 100 to exhibit a generally non-cylindrical shape. For example, some conventional fluid collection assemblies exhibit a generally cylindrical shape (*e.g.*, bent generally cylindrical shape). Generally, the conventional fluid collection assemblies exhibiting the generally cylindrical shape rely on the thighs of the individual contacting the sides of the conventional fluid collection assembly to maintain the conventional fluid collection assembly against the vulva. However, the thighs of thinner individuals may be unable to contact the sides of the conventional fluid collection assembly and/or separating the legs of the individual (*e.g.*, for comfort or movement) may cause the thighs to cease contacting the sides of the conventional fluid collection assembly. When the thighs of the individual do not contact the sides of the conventional fluid collection assembly, at least a portion of the conventional fluid collection assembly may move away from the individual thereby creating a passageway through which bodily fluids may flow without entering the chamber of the conventional fluid collection assembly. As such, in the illustrated embodiment, the fluid collection assembly 100 exhibits a generally disk-like shape. The generally disk-like shape of the fluid collection assembly 100 has the technical effect of allowing the fluid collection assembly 100 to contact the thighs of the individual even when the individual is thin or is separating the thighs thereof.

[0031] The generally disk-like shape of the fluid collection assembly 100 allows the fluid collection assembly 100 to be relatively flat. In particular, the generally disk-like shape of the fluid collection assembly 100 allows the opening 104 and the portion of the porous material 110 adjacent to the opening 104 to be generally flat. The generally flat shape of the fluid collection assembly 100 allows the fluid collection assembly 100 to exhibit a relatively small thickness relative to conventional fluid collection assemblies. The thickness of the fluid collection assembly 100 is measured from an outer surface 120 of a portion of the fluid impermeable barrier 102 defining the opening 104 to an opposing portion of the outer surface 120 of the fluid impermeable barrier 102 in a direction that is perpendicular to a width W and length L of the opening 104. For example, the fluid collection assembly 100 may exhibit a thickness that is about 10 mm or less, about 7.5 mm or less, about 5 mm or less, or in ranges of about 2.5 mm to about 7.5 mm or about 5 mm to about 10 mm. Such thickness may make using the fluid collection assembly 100 more comfortable than conventional fluid collection assemblies which, for example, may exhibit a thickness greater than about 2 cm. It is noted that, in some embodiments, the fluid collection assembly 100 may exhibit a thickness that is greater than about 1 cm, such as at least about 2 cm or at least about 3 cm. The relatively flat shape of the fluid collection assembly 100 may also have the technical effect of allowing the fluid collection assembly 100 to collect bodily fluids from orifices other than a urethral opening, such as from a wound or sacral drainage. It is noted that other non-cylindrically shaped fluid collection assemblies disclosed herein other than the generally disk-like shaped fluid collection assembly 100 (*e.g.*, the fluid collection assembly 200 of **FIGS. 2A-2B**) may also exhibit the relatively flat shape and the relatively small thickness.

[0032] The generally disk-like shape of the fluid collection assembly 100 allows the opening 104 to exhibit a larger width W than conventional fluid collection assemblies. For example, conventional fluid collection assemblies may exhibit an opening exhibiting a length (*e.g.*, maximum dimension of the opening) that is significantly greater than a width (*e.g.*, a dimension of the opening that is measured perpendicular to the length) of the opening, such as the length of the opening being more than 2.5 times greater than the width. However, the generally disk-like shape of the fluid collection assembly 100 allows the opening 104 to exhibit a width W that is 50% (*i.e.*, half of) to 100% (*i.e.*, equal to) the length L. For example, the width W may be about 50% to about 70%, about 60% to about 80%, about 70% to about 90%, or about 80% to about 100% of the length L. The increased width W of the opening 104 relative to the length L may

allow the fluid collection assembly 100 to receive more bodily fluid (*i.e.*, prevent leaks) that flow in a direction that is generally parallel (*e.g.*, $\pm 30^\circ$) to the width W compared to conventional fluid collection assemblies while receiving the same or substantially the same amount of bodily fluids that flow in a direction that is generally parallel to the length L.

5 The increased width W of the opening 104 relative to the length L may also allow the fluid collection assembly 100 to accommodate larger displacements (*e.g.*, caused by the individual moving) in a direction that is generally parallel to the width W without leaking than conventional fluid collection assemblies while being able to accommodate the same or substantially same displacements in a direction that is generally parallel to the length

10 L. In other words, the larger width W of the opening 104 relative to the length L of the opening 104 is another leak prevention feature of the fluid collection assembly 100.

[0033] In an embodiment, the generally flat shape of the fluid collection assembly 100 and/or the relatively large width W of the opening 104 relative to the length L of the opening 104 allows the fluid collection assembly 100 to be secured to the individual by

15 merely resting the fluid collection assembly 100 on the individual (*e.g.*, resting the fluid collection assembly 100 adjacent to the urethral opening). In an embodiment, the generally flat shape of the fluid collection assembly 100 and/or the relatively large width W of the opening 104 relative to the length L of the opening 104 allows the fluid collection assembly 100 to be secured to the individual using an adhesive, straps, or

20 underwear (*e.g.*, the underwear includes a pocket that receives the fluid collection assembly 100 and/or the underwear is configured to press the fluid collection assembly 100 against the urethral opening).

[0034] As will be discussed in more detail below, the fluid collection assembly 100 may exhibit a shape that is not a generally disk-like shape. For example, the fluid

25 collection assembly 100 may exhibit a generally semi-cylindrical shape (**FIGS. 2A** and **2B**), a generally flat elongated shape, a generally cylindrical shape (**FIG. 3A**), or any other suitable shape.

[0035] Referring to **FIG. 1B**, in an embodiment, the one or more leak prevention features includes occupying substantially all of the chamber 106 with the porous material

30 110. For example, some fluid collection assemblies (*e.g.*, the fluid collection assemblies 300, 400, 600, and 700 of **FIGS. 3B, 4, 6** and **7**) include substantially unoccupied fluid reservoir in which bodily fluids may pool before the bodily fluids are removed from the chamber. During normal operation, gravity, the suction force, and fluid dynamics (capillary action and wicking) pulls the bodily fluids from the opening towards these fluid

reservoirs. However, movement of the individual using these fluid collection assemblies may cause the bodily fluids pooled in the fluid reservoirs to shift (*e.g.*, splash) into the porous materials in sufficient quantities that gravity, the suction force, and fluid dynamics cannot prevent at least some of the bodily fluids from exiting the chamber through the opening. However, referring back to the fluid collection assembly 100, substantially occupying all of the chamber 106 with the porous material 110 prevents the bodily fluids from pooling in a single location. Instead, the bodily fluids are distributed through the chamber 106. As such, no single location in the chamber 106 may include a sufficient quantity of bodily fluids that, when the individual using the fluid collection assembly 100 moves, gravity, the suction force, and fluid dynamics does not pull the bodily fluids towards at least one inlet 114 of the conduit 112. In other words, substantially occupying the chamber 106 with the porous material 110 may decrease the likelihood that the fluid collection assembly 100 leaks fluids when the individual moves. Further, substantially occupying the chamber 106 allows the conduit 112 to remove the bodily fluids regardless of the quantity of bodily fluids that are present in the chamber 106, unlike the fluid reservoirs that must receive a certain quantity of bodily fluids before the conduit 112 may remove the bodily fluids. As such, the fluid reservoirs may cause a delay between receiving the bodily fluids and removing the bodily fluids which may increase the likelihood of leaks while substantially occupying all of the chamber 106 with the porous material 110 prevents such leaks.

[0036] In an embodiment, the one or more leak prevention features includes at least one additional porous material 116 at least partially occupying an interior of the conduit 112. As used herein, the additional porous material 116 may be integrally formed with at least a portion of the porous material 110 that is disposed in the chamber 106 (*e.g.*, the additional porous material 116 and at least a portion of the porous material 110 exhibit single piece construction) or the additional porous material 116 may be distinct from the porous material 110. When the conduit 112 is not at least partially occupied with the additional porous material 116, the conduit 112 may require a suction force to remove bodily fluids from the chamber 106. In some embodiments, the suction force applied to the conduit 112 is not continuous since the constant air flow may dry the skin and/or the suction force may cause hickeys. As such, the suction force may not be applied to the conduit 112 when discharge of the bodily fluids (*e.g.*, urination) is not expected. However, unexpected bodily fluid discharge may saturate the porous material 110 and cause the fluid collection assembly 100 to leak when a suction force is not applied to the

conduit 112 without the additional porous material 116. However, when the conduit 112 is at least partially occupied by the additional porous material 116, the additional porous material 116 may pull the bodily fluids into the conduit 112 via capillary action, absorption, and/or wicking even when a suction force is not applied to the conduit 112. Even though the additional porous material 116 may be unable to pull the fluid completely through the conduit 112 or may pull the bodily fluids through the conduit 112 more slowly than the suction force, the additional porous material 116 may increase the quantity of bodily fluids that the fluid collection assembly 100 may receive before the porous material 110 saturates and the fluid collection assembly 100 leaks.

10 **[0037]** The additional porous material 116 extends inwardly from the inlet 114 of the conduit 112. The additional porous material 116 is positioned in the conduit 112 to contact the porous material 110 or such that any gap between the porous material 110 and the additional porous material 116 is sufficiently small that only a small quantity of bodily fluids is necessary to bridge the gap. In an embodiment, the additional porous material 116 may extend through an entirety of the conduit 112 which allows the additional porous material 116 to pull the bodily fluids a far distance into the conduit 112, such as through an entirety of the conduit 112. In an embodiment, the additional porous material 116 only extends inwardly from the inlet 114 for a distance that is less than a length of the conduit 112. Only extending the additional porous material 116 through a portion of the conduit 112 may improve fluid flow in the conduit 112. For example, the additional porous material 116 may slightly obstruct fluid flow in the portions of the conduit 112.

25 **[0038]** In an embodiment, the one or more leak prevention features includes a plurality of fluid outlets 108 and at least one conduit 112 extending from each of the fluid outlets 108. For example, the conduit 112 preferentially removes bodily fluids that are closer to the inlet 114. The plurality of fluid outlets 108 and the conduit 112 attached to each of the fluid outlets 108 allows a larger volume of the bodily fluids that are present in the chamber 106 to be preferentially removed from the chamber 106. In other words, the plurality of fluid outlets 108 and the conduit 112 decrease the amount of bodily fluids that remain in the chamber 106 thereby decreasing the likelihood that the fluid collection assembly 100 leaks. Further, the plurality of conduits 112 better distribute any pressure that is applied from the fluid collection assembly 100 to the individual thereby decreasing the likelihood that the fluid collection assembly 100 causes pressure ulcers. The conduits

112 may also be flat tubes which may make the conduits 112 more comfortable against the skin.

[0039] As previously discussed, the fluid impermeable barrier 102 at least partially defines an opening 104 and a chamber 106 (*e.g.*, interior region). For example, at least one inner surface 118 of the fluid impermeable barrier 102 at least partially defines the chamber 106 within the fluid collection assembly 100. The fluid impermeable barrier 102 temporarily stores the bodily fluids in the chamber 106. The fluid impermeable barrier 102 may be formed of any suitable fluid impermeable material(s), such as a fluid impermeable polymer (*e.g.*, silicone, polypropylene, polyethylene, polyethylene terephthalate, a polycarbonate, etc.), a metal film, natural rubber, another suitable material, or combinations thereof. As such, the fluid impermeable barrier 102 substantially prevents the bodily fluids from passing through the fluid impermeable barrier 102. In an example, the fluid impermeable barrier 102 may be air permeable and fluid impermeable. In such an example, the fluid impermeable barrier 102 may be formed of a hydrophobic material that defines a plurality of pores. At least one or more portions of at least an outer surface 120 of the fluid impermeable barrier 102 may be formed from a soft and/or smooth material, thereby reducing chaffing. During use, the outer surface 120 of the fluid impermeable barrier 102 may contact the wearer. The fluid impermeable barrier 102 may be sized and shaped to fit in the gluteal cleft between the legs of a female user.

[0040] The opening 104 provides an ingress route for bodily fluids to enter the chamber 106. The opening 104 may be defined by the fluid impermeable barrier 102 such as by an inner edge of the fluid impermeable barrier 102. For example, the opening 104 is formed in and extends through the fluid impermeable barrier 102, from the outer surface 120 to the inner surface 118, thereby enabling the bodily fluids to enter the chamber 106 from outside of the fluid collection assembly 100. In an embodiment, the opening 104 may be an elongated hole (the length L is more than 50% greater than the width W, as shown in **FIG. 3A**) in the fluid impermeable barrier 102. For example, the opening 104 may be defined as a cut-out in the fluid impermeable barrier 102. The opening 104 may be located and shaped to be positioned adjacent to a female urethral opening.

[0041] The fluid collection assembly 100 may be positioned proximate to the female urethral opening and urine may enter the chamber 106 of the fluid collection assembly 100 via the opening 104. The fluid collection assembly 100 is configured to receive the

bodily fluids into the chamber 106 via the opening 104. When in use, the opening 104 may extend from a first location above the urethral opening (*e.g.*, at or near the top of the urethral opening or the pubic hair) to a second location below the urethral opening (*e.g.*, at or near the anus or the vaginal opening).

5 [0042] In some examples, as previously discussed, the fluid impermeable barrier 102 may define an fluid outlet 108 sized to receive the conduit 112. The at least one conduit 112 may be disposed in the chamber 106 or otherwise in fluid communication with the chamber 106 via the fluid outlet 108. The fluid outlet 108 may be sized and shaped to form an at least substantially fluid tight seal against the conduit 112 or the at least one
10 tube thereby substantially preventing the bodily fluids from escaping the chamber 106.

[0043] The fluid impermeable barrier 102 may include markings thereon, such as one or more markings to aid a user in aligning the fluid collection assembly 100 on the wearer. For example, a line on the fluid impermeable barrier 102 (*e.g.*, opposite the opening 104) may allow a healthcare professional to align the opening 104 over the
15 urethral opening of the individual wearing the fluid collection assembly 100. In examples, the markings may include one or more of alignment guide or an orientation indicator, such as a stripe or hashes. Such markings may be positioned to align the fluid collection assembly 100 to one or more anatomical features such as a pubic bone, etc.

[0044] As previously discussed, the fluid collection assembly 100 includes porous material 110 disposed in the chamber 106. The porous material 110 may cover at least a
20 portion (*e.g.*, all) of the opening 104. The porous material 110 is exposed to the environment outside of the chamber 106 through the opening 104. The permeable properties referred to herein may be wicking, capillary action, absorption, diffusion, or other similar properties or processes, and are referred to herein as “permeable” and/or
25 “porous.” The porous material 110 may also wick the bodily fluids generally towards an interior of the chamber 106, as discussed in more detail below. The porous material 110 may include one or more of a fluid permeable membrane 122 or a fluid permeable support 124.

[0045] In an embodiment, at least a portion of the porous material 110 may be a
30 wicking material configured to wick any of the bodily fluids away from the opening 104, thereby preventing bodily fluids from escaping the chamber 106. The wicking material may not include absorption of the bodily fluids into the wicking material. Put another way, substantially no absorption of the bodily fluids into the wicking material may take place after the wicking material is exposed to the bodily fluids. While no absorption is

desired, the term “substantially no absorption” may allow for nominal amounts of absorption of the bodily fluids into the wicking material (*e.g.*, absorbency), such as less than about 30 wt% of the dry weight of the wicking material, less than 20 wt%, less than 10 wt%, less than about 7 wt%, less than about 5 wt%, less than about 3 wt%, less than about 2 wt%, less than about 1 wt%, or less than about 0.5 wt% of the dry weight of the wicking material. In an embodiment, at least a portion of the porous material 100 may include an absorbent or adsorbent material.

[0046] The fluid collection assembly 100 may include the fluid permeable membrane 122 disposed in the chamber 106. The fluid permeable membrane 122 may cover at least a portion (*e.g.*, all) of the opening 104. The fluid permeable membrane 122 may be composed to pull/push the bodily fluids away from the opening 104, thereby preventing the bodily fluids from escaping the chamber 106.

[0047] The fluid permeable membrane 122 may include any material that may be permeable to the bodily fluids. For example, the fluid permeable membrane 122 may include fabric, such as a gauze (*e.g.*, a silk, linen, or cotton gauze), another soft fabric, or another smooth fabric. Forming the fluid permeable membrane 122 from gauze, soft fabric, and/or smooth fabric may reduce chaffing caused by the fluid collection assembly 100.

[0048] The fluid collection assembly 100 may include the fluid permeable support 124 disposed in the chamber 106. The fluid permeable support 124 is configured to support the fluid permeable membrane 122 since the fluid permeable membrane 122 may be formed from a relatively foldable, flimsy, or otherwise easily deformable material. For example, the fluid permeable support 124 may be positioned such that the fluid permeable membrane 122 is disposed between the fluid permeable support 124 and the fluid impermeable barrier 102. As such, the fluid permeable support 124 may support and maintain the position of the fluid permeable membrane 122. The fluid permeable support 124 may include any material that may be permeable to the bodily fluids, such as any of the fluid permeable membrane materials disclosed herein above. For example, the fluid permeable membrane material(s) may be utilized in a more dense or rigid form than in the fluid permeable membrane 122 when used as the fluid permeable support 124. The fluid permeable support 124 may be formed from any fluid permeable material that is less deformable than the fluid permeable membrane 122. For example, the fluid permeable support 124 may include a porous polymer (*e.g.*, nylon, polyester, polyurethane, polyethylene, polypropylene, etc.) structure (*e.g.*, spun fibers, such as spun nylon fibers)

or an open cell foam. In some examples, the fluid permeable support 124 may be formed from a natural material, such as cotton, wool, silk, or combinations thereof. In such examples, the material may have a coating to prevent or limit absorption of the bodily fluids into the material, such as a water repellent coating. In some examples, the fluid permeable support 124 may be formed from fabric, felt, gauze, or combinations thereof. In some examples, the fluid permeable membrane 122 may be optional. For example, the porous material 110 may include only the fluid permeable support 124. In some examples, the fluid permeable support 124 may be optionally omitted from the fluid collection assembly 100. For example, the porous material 110 may only include the fluid permeable membrane 122.

[0049] In an embodiment, the fluid permeable membrane 122 and the fluid permeable support 124 are wicking materials. In such an embodiment, the fluid permeable support 124 may have a greater ability to wick the bodily fluids than the fluid permeable membrane 122, such as to move the bodily fluids inwardly from the outer surface 120 of the fluid collection assembly 100. In some examples, the wicking ability of the fluid permeable support 124 and the fluid permeable membrane 122 may be substantially the same.

[0050] As previously discussed, the fluid permeable membrane 122 and the fluid permeable support 124 may at least substantially completely fill the portions of the chamber 106 that are not occupied by the conduit 112. In an example, not shown, the fluid permeable membrane 122 and the fluid permeable support 124 may not substantially completely fill the portions of the chamber 106 that are not occupied by the conduit 112. In such an example, the fluid collection assembly 100 includes a fluid reservoir (*e.g.*, fluid reservoir 336 illustrated in **FIG. 3B**) disposed in the chamber 106.

[0051] The fluid reservoir is a substantially unoccupied portion of the chamber 106. The fluid reservoir may be defined between the fluid impermeable barrier 102 and one or both of the fluid permeable membrane 122 and fluid permeable support 124. The bodily fluids that are in the chamber 106 may flow through the fluid permeable membrane 122 and/or fluid permeable support 124 to the fluid reservoir. The fluid reservoir may retain of the bodily fluids therein. The bodily fluids that are in the chamber 106 may flow through the fluid permeable membrane 122 and/or fluid permeable support 124 and, optionally, to the fluid reservoir. The fluid impermeable barrier 102 may retain the bodily fluids in the fluid reservoir. The fluid reservoir may be located in a portion of the chamber 106 that is designed to be located in a gravimetrically low point of the fluid

collection assembly when the device is worn. In some examples (not shown), the fluid collection assembly 100 may include multiple fluid reservoirs, such as fluid reservoirs that are located adjacent to each of the fluid outlets 108.

[0052] In an embodiment, not shown, the conduit 112 may be at least partially disposed in the chamber 106. The conduit 112 may be used to remove fluid from the chamber 106. The conduit 112 (*e.g.*, a tube) includes the inlet 114 and an outlet (not shown) positioned downstream from the inlet 114. The outlet may be operably coupled to a suction source, such as a vacuum pump for withdrawing the bodily fluids from the chamber through the conduit 112. The conduit 112 fluidly couples the chamber 106 with the fluid storage container (not shown) or the vacuum source (not shown).

[0053] The conduit 112 may include a flexible material such as plastic tubing (*e.g.*, medical tubing). Such plastic tubing may include a thermoplastic elastomer, polyvinyl chloride, ethylene vinyl acetate, polytetrafluoroethylene, etc., tubing. In some examples, the conduit 112 may include silicon or latex. In some examples, the conduit 112 may include one or more portions that are resilient, such as to by having one or more of a diameter or wall thickness that allows the conduit to be flexible. In an embodiment, the conduit 112 may include a plurality of conduits 112 extending from each of the fluid outlet 108. In such an embodiment, each of the conduits 112 may be connected to a common conduit 126 that is connected to the vacuum source or each of the conduits 112 may be connected to the same vacuum source or different vacuum sources.

[0054] In an example, the conduit 112 is configured to be at least insertable into the chamber 106. In such an example, the conduit 112 may include one or more markers (not shown) on an exterior thereof that are located to facilitate insertion of the conduit 112 into the chamber 106. For example, the conduit 112 may include one or more markings thereon that are configured to prevent over or under insertion of the conduit 112, such as when the conduit 112 defines an inlet 114 that is configured to be disposed in or adjacent to the reservoir. In another example, the conduit 112 may include one or more markings thereon that are configured to facilitate correct rotation of the conduit 112 relative to the chamber 106. The one or more markings may include a line, a dot, a sticker, or any other suitable marking.

[0055] As described in more detail below, the conduit 112 is configured to be coupled to, and at least partially extend between, one or more of the fluid storage container (Fluid storage container 1090 of **FIG. 10**) and the vacuum source (vacuum source 1092 of **FIG. 10**). In an example, the conduit 112 is configured to be directly connected to the vacuum

source (not shown). In such an example, the conduit 112 may extend from the fluid impermeable barrier 102 by at least one foot, at least two feet, at least three feet, or at least six feet. In another example, the conduit 112 is configured to be indirectly connected to at least one of the fluid storage container (not shown) and the vacuum source (not shown). In some examples, the conduit 112 is secured to a wearer's skin with a catheter securement device, such as a STATLOCK® catheter securement device available from C. R. Bard, Inc., including but not limited to those disclosed in U.S. Patent Nos. 6,117,163; 6,123,398; and 8,211,063, the disclosures of which are all incorporated herein by reference in their entirety.

10 [0056] The inlet 114 and the outlet of the conduit 112 are configured to fluidly couple (*e.g.*, directly or indirectly) the vacuum source (not shown) to the chamber 106 (*e.g.*, the reservoir). As the vacuum source (**FIG. 10**) applies a vacuum/suction in the conduit 112, the bodily fluids in the chamber 106 may be drawn into the inlet 114 and out of the fluid collection assembly 100 via the conduit 112. In some examples, the conduit 112 may be
15 frosted or opaque (*e.g.*, black) to obscure visibility of the bodily fluids therein.

[0057] **FIG. 2A** is a top plan view of a fluid collection assembly 200, according to an embodiment. Except as otherwise disclosed herein, the fluid collection assembly 200 is the same or substantially similar to any of the fluid collection assemblies disclosed herein. For example, the fluid collection assembly 200 includes a fluid impermeable barrier 202
20 defining an opening 204, a chamber 206, and at least one fluid outlet 208. The fluid collection assembly 200 also includes at least one porous material 210 disposed in the chamber 206 and a conduit 212 attached to the fluid outlet 208.

[0058] The fluid collection assembly 200 exhibits a generally elongated shape. The elongated shape of the fluid collection assembly 200 may allow the fluid collection
25 assembly 200 to exhibit a size and shape that fits in the gluteal cleft between the legs of an individual, especially a non-thin individual. The elongated shape of the fluid collection assembly 200 allows the opening 204 to exhibit an elongated shape wherein a length L of the opening 204 is greater (*e.g.*, at least about 1.5 times greater, at least about 2 times greater, or at least 3 times greater) than the width W of the opening 204. The
30 opening 204 may have an elongated shape because the space between the legs of a female is relatively small when the legs of the female are closed, thereby only permitting the flow of the bodily fluids along a path that corresponds to the elongated shape of the opening 204 (*e.g.*, longitudinally extending opening). The opening 204 in the fluid impermeable barrier 202 may exhibit a length that is measured along the longitudinal axis

of the fluid collection assembly 200 that may be at least about 10% of the length of the fluid collection assembly 200, such as about 25% to about 50%, about 40% to about 60%, about 50% to about 75%, about 65% to about 85%, or about 75% to about 95% of the length of the fluid collection assembly 200.

5 [0059] The leak prevention feature of the fluid impermeable barrier 202 may include the cross-sectional shape of the fluid impermeable barrier 202. FIG. 2B is a cross-sectional view of the fluid impermeable barrier 202 taken along line 2B-2B, according to an embodiment. As shown in FIG. 2B, the fluid impermeable barrier 202 may exhibit a concavely curved cross-sectional shape, such as a generally semi-circular (*e.g.*, generally
10 half circular) cross-sectional shape or other generally elliptical cross-sectional shape. In an embodiment, the concavely curved cross-sectional shape of the fluid impermeable barrier 202 inhibits leaks because the curved outermost surface 228 of the porous material 210 (*e.g.*, the surface of the porous material 210 extending across the opening 204) is able to press against the labia folds of the vulva and may even cause the outermost surface 228
15 to extend between labia folds. Pressing the outermost surface 228 against the labia folds may cause the fluid collection assembly 200 to receive bodily fluids that would otherwise flow between the labia folds.

[0060] In an embodiment, the concavely curved cross-sectional shape of the fluid impermeable barrier 202 allows the conduit 212 to be positioned adjacent to a back
20 surface 218 of the fluid impermeable barrier 202. Since the conduit 212 is positioned adjacent to the back surface 218, any air flow caused by a suction force applied to the conduit 212 is concentrated between the inlet of the conduit 212 and the opening 204. This concentration of the air flow may increase the amount of bodily fluids that are sucked into the conduit 212 and are removed from the chamber 206. Meanwhile, a
25 substantially similar fluid collection assembly that includes a conduit spaced from the back surface may cause some of the air to flow between the conduit and the back surface of the fluid impermeable barrier thereby decreasing the amount of air flow between the opening and the conduit and the amount of bodily fluids received by the conduit.

[0061] The porous material 210 of the fluid impermeable barrier 202 includes a fluid
30 permeable membrane 222 and a fluid permeable support 224. In an embodiment, the porous material 210 may include at least one absorbent layer 230 positioned between the fluid permeable membrane 222 and the fluid impermeable support 224. The absorbent layer 230 may be a leak prevention feature of the fluid impermeable barrier 202. For example, the fluid permeable membrane 222 may be a wicking material. Disposing the

absorbent layer 230 downstream from the fluid permeable membrane 222 may help pull bodily fluids through the fluid permeable membrane 222. As such the absorbent layer 230 may increase the flow rate of bodily fluids through the fluid permeable membrane 222 and through the chamber 206 as a whole thereby decreasing leaking caused by oversaturation of the porous material 210. The absorbent layer 230 may include any suitable absorbent material, such as, super absorbent polymers, absorbent materials used in diapers, absorbent materials used in astronaut underwear, sponge-like material, one or more hydrophilic materials, etc.

[0062] It is noted that the fluid collection assembly 200 may exhibit shapes other than the concavely curved cross-sectional shape illustrated in **FIG. 2B**. In an example, the fluid collection assembly 200 may exhibit an elongated shape exhibiting a generally rectangular cross-sectional shape (*e.g.*, a generally square cross-sectional shape or a generally rectangular cross-sectional shape with one or more curved surfaces) that exhibits some of the benefits of the fluid collection assembly 100 illustrated in **FIGS. 1A** and **1B**. In an example, the fluid collection assembly 200 may exhibit a generally cylindrical shape.

[0063] **FIGS. 3A** and **3B** are isometric and cross-sectional views of a fluid collection assembly 300, according to an embodiment. Except as otherwise disclosed herein, the fluid collection assembly 300 may be the same or substantially to any of the fluid collection assemblies disclosed herein. For example, the fluid collection assembly 300 may include a fluid impermeable barrier 302 defining an opening 304, a chamber 306, and a fluid outlet 308. The fluid impermeable barrier 300 also includes at least one porous material 310 disposed in the chamber 306 and at least one conduit 312 secured to the fluid outlet 308.

[0064] The fluid collection assembly 300 exhibits a generally cylindrical shape. The elongated shape of the fluid collection assembly 300 may allow the fluid collection assembly 300 to exhibit a size and shape that fits in the gluteal cleft between the legs of an individual, especially a non-thin individual. The elongated shape of the fluid collection assembly 300 allows the opening 304 to exhibit an elongated shape wherein a length of the opening 304 is significantly greater than the width of the opening 304. The opening 304 may have an elongated shape because the space between the legs of a female is relatively small when the legs of the female are closed, thereby only permitting the flow of the bodily fluids along a path that corresponds to the elongated shape of the opening 304 (*e.g.*, longitudinally extending opening). Further, the curved outermost

surface of the fluid collection assembly 300, and more particularly the curved outermost surface 328 of the porous material 310, will press against the labia folders.

[0065] Referring to **FIG. 3B**, the fluid collection assembly 300 includes a first end 332 and a second end 334 spaced from the first end 332. The first end 332 may define a substantially unoccupied fluid reservoir 336. The second end 334 may define the fluid outlet 308. The conduit 312 may include an outlet portion 338 disposed in the fluid outlet 308. For example, the outlet portion 338 may secure the conduit 312 to the fluid outlet 308 via press fitting, an adhesive, ultrasonic welding, or any other suitable attachment technique. The conduit 312 may extend longitudinally from the fluid outlet 308, behind at least partially of the porous material 310 (*e.g.*, through a central region of the porous material 310), to the fluid reservoir 336. For example, the conduit 312 may include an open terminal end 340 that is positioned adjacent to or within the fluid reservoir 336. The open terminal end 340 is configured to remove bodily fluids that are present in the fluid reservoir 336, for example, when a suction force is applied to the conduit 312.

[0066] The open terminal end 340 of the conduit 312 may substantially only remove bodily fluids when the bodily fluids are present in the fluid reservoir 336 in sufficient quantity that the bodily fluids contact the open terminal end 340. As such, solely relying on the open terminal end 340 to remove bodily fluids may delay removal of the bodily fluids from the chamber 306 since the bodily fluids must first flow into the fluid reservoir 336 in sufficient quantity to be removed and at least some of the bodily fluids may not be removed from the chamber 306 when the quantity of bodily fluids in the fluid reservoir 336 are insufficient to contact the open terminal end 340, both of which may increase the likelihood that the fluid collection assembly 300 leaks. As such, the one or more leak prevention features of the fluid collection assembly 300 may include at least one conduit inlet 342 formed in the conduit 312 (*e.g.*, the conduit 312 includes a plurality of inlets, namely the open terminal end 340 and the at least one conduit inlet 342). The conduit inlet 342 includes an inlet formed in the conduit 312 between the outlet portion 338 and the open terminal end 340 that is in fluid communication with an interior 362 (*e.g.*, passageway) of the conduit 312. As used herein, the conduit inlet 342 refer to inlets formed in the conduit 312 that are distinct from the open terminal end 340. The conduit inlet 342 allows the conduit 312 to remove bodily fluids from the chamber 306 that are spaced from the fluid reservoir 336 in addition to the bodily fluids that are present in the fluid reservoir 336. In an embodiment, not shown, the open terminal end 340 of the

conduit 312 may be omitted and the conduit 312 may only include one or more conduit inlets 342.

[0067] In an embodiment, the conduit inlet 342 may include a one-way valve (not shown). The one-way valve may be configured to allow the bodily fluids to flow from an exterior (*e.g.*, the chamber 306) of the conduit 312 into an interior 362 of the conduit 312 and restrict the flow of the bodily fluids from the interior 362 to the exterior of the conduit 312. The one-way valve may prevent bodily fluids that are received upstream from one of the conduit inlet 342 from exiting the conduit 312. Allowing the bodily fluids to exit the conduit 312 at a location downstream from where the bodily fluids were received may increase the likelihood that the fluid collection assembly 300 leaks. The one-way valve may include any suitable one-way valve. In an example, the one-way valve is a flap formed in the interior 362 of the conduit 312. The flap may be configured to open when the flow of the bodily fluids is from the exterior to the interior 362 of the conduit 312 and close when the flow of the bodily fluids is from the interior 362 to the exterior of the conduit 312. In an example, the one-way valve includes a ball valve that substantially only permits the bodily fluids to flow from the exterior to the interior 362 of the conduit 312.

[0068] The conduit inlets 342 may also allow the fluid collection assembly 300 to be used when the individual using the fluid collection assembly 300 is in different positions. For example, when the individual is lying down, the fluid reservoir 336 is the gravimetrically lowest point of the chamber 306. As such, gravity pulls the bodily fluids towards the fluid reservoir 336 in addition to the permeability of the porous material 310 and the suction force. However, switching the position of the individual from the lying position to another position (*e.g.*, sitting or standing position) may change the gravimetrically low point of the chamber 306. **FIG. 3C** is an isometric view of the conduit 312 illustrating how the at least one conduit inlet 342 may facilitate removing bodily fluids from the chamber 306 when the individual using the fluid collection assembly 300 is in a position other than lying down, according to an embodiment. For example, the conduit 312 may include one or more of the open terminal end 340 that is configured to receive bodily fluids when the individual is lying down, at least one first conduit inlet 343 that is configured to receive bodily fluids when the individual is sitting down, at least one second conduit inlet 344 that is configured to receive bodily fluids when the individual is standing up, and at least one third conduit inlet 345 that is configured to receive bodily fluids when the individual is leaning forward. In such an

example, the conduit 312 may exhibit a length measured from the open terminal end 340 to the outlet portion 338 (cross-hatched for illustrative purposes). The first conduit inlet 343 may be spaced from the open terminal end 340 by about 20% to about 40% (e.g., about 20% to about 30%, about 25% to about 35%, about 30% to about 40%, or about 5 33%) of the length of the conduit 312 which may position the first conduit inlet 343 at or near the gravimetrically lowest point of the chamber 306 when the individual is sitting. The second conduit inlet 344 may be spaced from the open terminal end 340 by about 40% to about 60% (e.g., about 40% to about 50%, about 45% to about 55%, about 50% to about 60%, or about 50%) of the length of the conduit 312 which may position the second 10 conduit inlet 344 at or near the gravimetrically lowest point of the chamber 306 when the individual is standing. The third conduit inlet 345 may be spaced from the open terminal end 340 by about 60% to about 99% (e.g., about 60% to about 80%, about 70% to about 90%, about 80% to about 99%) of the length of the conduit 312 which may position the third conduit inlet 345 at or near the gravimetrically lowest point of the chamber 306 15 when the individual is leaning forward. It is noted that the distance of the first, second, and third conduit inlets 343, 344, 345 may vary depending on the size and placement of the fluid collection assembly 300 but the values provided above are accurate for most embodiments where the fluid collection assembly 300 exhibits an elongated shape.

[0069] In an embodiment, the conduit 312 may include valve (not shown) that closes 20 at least one of the inlets of the conduit 312 (e.g., the open terminal end 340 or one of the conduit inlets 342) when the inlet is not at or near the gravimetrically low point of the chamber 306. The valve may close the inlet when the inlet is not at or near the gravimetrically low point of the chamber 306 since the inlet is more likely to pull air into the conduit 312 when the inlet is not at or near the gravimetrically low point of the 25 chamber 306 and decreases the overall efficiency of the conduit 312. In an example, the valve may include a ball valve that is configured to close an inlet of the conduit 312 when the inlet is not at or near the gravimetrically low point of the chamber 306 and open the inlet of the conduit 312 when the inlet is at or near the gravimetrically low point of the chamber 306. For instance, a ball of the ball valve may press against the inlet of the 30 conduit 312 when the inlet is not at or near the gravimetrically low point of the chamber 306 and the ball of move into a recess thereby opening the inlet when the inlet is at or near the gravimetrically low point of the chamber 306.

[0070] FIG. 3D is an isometric view of a conduit 312a that may be used in any of the fluid collection assemblies disclosed herein, according to an embodiment. Except as

otherwise disclosed herein, the conduit 312a may be the same or substantially similar to any of the conduits disclosed herein. For example, the conduit 312a includes an open terminal end 340a and at least one conduit inlet 342a. Generally, the open terminal end 340a removes more bodily fluids from a chamber (*e.g.*, chamber 306 of **FIG. 3A**) than the conduit inlets 342a and the conduit inlets 342a closer to the open terminal end 340a remove more bodily fluids from the chamber than other conduit inlets 342a. Further, the inlets of the conduit 312a (*e.g.*, the open terminal end 340a and the conduit inlets 342a) will remove air from the chamber preferentially over bodily fluids. In other words, if any of the inlets of the conduit 312a are exposed to air instead of bodily fluids, the conduit 312a will remove significantly less bodily fluids than if each of the inlets were exposed to the bodily fluids. As such, the inlets of the conduit 312a may be configured to exhibit different sizes (*e.g.*, diameter) depending on the likelihood that the inlets will remove bodily fluids or air at any given time. For example, the open terminal end 340a may exhibit the largest opening (*e.g.*, largest diameter) of the conduit 312a since the open terminal end 340a is most likely to remove the most bodily at any given time. The conduit inlets 342a may also exhibit different sizes, wherein the size (*e.g.*, diameter) of the conduit inlets 342a progressively get smaller with increased distance from the open terminal end 340a since the conduit inlets 342a are less likely to remove bodily fluids with increased distance from the open terminal end 340a. The various sizes of the openings of the conduit 312a are leak prevention features since they decrease the amount of air pulled into the conduit 312a thereby increasing the amount of bodily fluids that are pulled into the conduit 312a and decreasing the likelihood of leaks.

[0071] The conduit inlets illustrated in **FIGS. 3C** and **3D** exhibit a generally circular shape. However, the conduit inlets may exhibit any suitable shape. For example, **FIG. 3E** is an isometric view of a conduit 312b that may be used in any of the fluid collection assemblies disclosed herein, according to an embodiment. Except as otherwise disclosed herein, the conduit 312b may be the same or substantially similar to any of the conduits disclosed herein. For example, the conduit 312b may include an open terminal end 340b and at least one conduit inlet 342b. The conduit inlet 342b, in the illustrated embodiment, exhibits a slot-like shape instead of the generally circular shapes illustrated in **FIGS. 3C** and **3D**. The slot-like shape of the conduit inlet 342b may increase the volume of bodily fluids that are preferentially pulled into the conduit inlet 342b. The slot-like shape of the conduit inlet 342b may also increase the flexibility of the conduit 312b thereby allowing the fluid collection assembly that includes the conduit 312b to more easily conform to the

shape the individual. In other words, the slot-like shape of the conduit inlets 342b are leak prevention features since it may improve the amount of bodily fluids that are pulled into the conduit 312b and may allow the fluid collection assembly to better conform to the shape of the individual, both of which may decrease the likelihood that the fluid collection assembly leaks.

[0072] FIG. 3F is an isometric view of a plurality of conduits that may be used in any of the fluid collection assemblies disclosed herein (*e.g.*, the fluid collection assembly may include the plurality of conduits instead of a single conduits), according to an embodiment. The plurality of conduits are illustrated and discussed as having a first conduit 312c, a second conduit 312d, and a third conduit 312e. However, this is for illustrative purposes only and it is understood that the plurality of conduits may include two conduits or four or more conduits and that the same principles disclosed herein are applicable regardless of the number of conduits. Except as otherwise disclosed herein, each of the first, second, and third conduits 312c, 312d, 312e may be the same or substantially similar to any of the conduits disclosed herein. For example, each of the first, second, and third conduits 312c, 312d, 312e may include a first, second, and third outlet portion 338c, 338d, 338e (cross-hatched for illustrative purposes) and a first, second, and third open terminal end 340c, 340d, 340e, respectively. At least one of the first, second, or third conduits 312c, 312d, 312e may also include at least one conduit inlet (not shown).

[0073] The first conduit 312c exhibits a first length measured from the first outlet portion 338c to the first open terminal end 340c. The second conduit 312d exhibits a second length measured from the second outlet portion 338d to the second open terminal end 340d. The third conduit 312e exhibits a third length measured from the third outlet portion 338e to the third open terminal end 340e. In an embodiment, as illustrated, the first distance is greater than the second distance and the second distance is greater than the third distance. The different distances of the first, second, and third conduits 312c, 312d, 312e causes the first, second, and third open terminal ends 340c, 340d, 340e to be positioned in different locations of a chamber. Similar to the different locations of the inlets of the conduits discussed in FIGS. 3B-3E, the different locations of the first, second, and third opening terminal ends 340c, 340d, 340e are leak prevention features since it allows bodily fluids to be removed from a variety of different locations in the chamber. In an embodiment, at least one of the first, second, or third distances are the same which allows the a greater volume of bodily fluids to be removed from a single

location of the chamber (*e.g.*, a fluid reservoir). In an embodiment, the first open terminal end 340c is larger than the second open terminal end 340d and the second open terminal end 340d is larger than the third open terminal end 340e. In such an embodiment, the first, second, and third conduits 312c, 312d, 312e may operate similar to the conduit 312b illustrated in **FIG. 3D**.

[0074] In an embodiment, the first, second, and third conduits 312c, 312d, 312e may intersect and form a common conduit or intersect at the fluid storage container. In such an embodiment, a suction force applied to one of the first, second, and third conduits 312c, 312d, 312e is also applied to the other ones of the first, second, and third conduits 312c, 312d, 312e. As such, each of the first, second, and third conduits 312c, 312d, 312e may include any of the valves discussed so that the first, second, and third conduits 312c, 312d, 312e to pull the bodily fluids therein and minimize the amount of air pulled therein. In an embodiment, the first, second, and third conduits 312c, 312d, 312e may each be connected to separate vacuum sources thereby eliminating the need for valves. However, many locations (*e.g.*, hospitals) may not include multiple vacuum sources and/or the multiple vacuum sources may increase the cost of using a fluid collection assembly that includes the first, second, and third conduits 312c, 312d, 312e.

[0075] In an embodiment, the first, second, and third conduits 312c, 312d, 312e may be connected to a suction control apparatus that controls the amount of suction that is applied to each of the first, second, and third conduits 312c, 312d, 312e. **FIG. 3G** is an isometric view of a system 346 that includes the first, second, and third conduits 312c, 312d, 312e and a suction control apparatus 348, according to an embodiment. The first, second, and third conduits 312c, 312d, 312e are connected to the suction control apparatus 348 and the suction control apparatus 348 is configured to control how much suction is applied to each of the first, second, and third conduits 312c, 312d, 312e. For example, the suction control apparatus 348 may include one or more sensors that detect whether the first, second, and/or third conduits 312c, 312d, 312e are removing bodily fluids or air. The sensors may include one or more moisture sensors configured to detect the presence of the bodily fluids in the conduit 312, one or more optical sensors configured to detect the presence of the bodily fluids in an at least partially transparent conduit 312, one or more acoustic sensors configured to detect the sound of bodily fluids through the conduit 312, one or more oxygen sensors configured to detect the presence of oxygen (*e.g.*, air) in the conduit 312, or any other suitable sensor. The suction control apparatus 348 may include control circuitry that, responsive to what is sensed by the

sensors, may decrease the suction force applied to which ever ones of the first, second, and/or third conduits 312c, 312d, 312e are removing air while maintaining and/or increasing the suction force applied to whichever ones of the first, second, and/or third conduits 312c, 312d, 312e are pulling bodily fluids. The suction control apparatus 348
5 may be a leak prevention features since the suction control apparatus 348 may cause more bodily fluids to be removed from the chamber than if the system 346 did not include the suction control apparatus 348.

[0076] As previously discussed, the conduits discussed with regards to **FIGS. 3A-3F** are configured to collect bodily fluids from a variety of locations in the chamber.
10 However, the ability of the conduits to remove the bodily fluids are partially obstructed and slowed by the porous material. For example, as previously discussed, the porous material may obstruct flow of the bodily fluids more than unoccupied space. As such, a leak prevention feature that may be used in any of the fluid collection assemblies disclosed herein includes a substantially unoccupied fluid reservoir extending along the
15 conduit to improve fluid flow to the different locations along the conduit. For example, **FIG. 4** is a cross-sectional view of a fluid collection assembly 400 that includes a fluid reservoir 436 extending along the conduit 412, according to an embodiment. Except as otherwise disclosed herein, the fluid collection assembly 400 is the same or substantially similar to any of the fluid collection assemblies disclosed herein. For example, the fluid
20 collection assembly 400 is illustrated as being substantially similar to the fluid collection assembly 200 and, as such, includes a fluid impermeable barrier 402 defining a chamber 406, at least partially porous material 410 disclosed in the chamber 406, and at least one conduit 412. However, it is noted that the principles discussed herein are also applicable to the other fluid collection assemblies disclosed herein.

[0077] The fluid collection assembly 400 includes at least one fluid reservoir 436 that is substantially unoccupied. As previously discussed, the fluid reservoir 436 extends at least partially along the length of the conduit 412. The fluid reservoir 436 may be a leak prevention feature since the fluid reservoir 436 may facilitate quick removal of any bodily fluids that are present in the chamber 406. For example, the conduit 412 may define a
30 plurality of inlets 414 longitudinally spaced from each other, which allows the conduit 412 to remove bodily fluids from a plurality of different locations in the chamber 406. At least one of the plurality of inlets 414 of the conduit 412 may be adjacent to the fluid reservoir 436. The fluid reservoir 436 may allow the bodily fluids to quickly and easily flow to the plurality of inlets 414. For instance, the fluid reservoir 436 may allow the

bodily fluids to accumulate adjacent to at least one of the inlets 414 when the individual is in a sitting position. The fluid reservoir 436 may then allow the bodily fluids to quickly and easily flow to another one(s) of the inlets 414 when the individual moves, such as moves from the sitting position to a standing position. Thus, the fluid reservoir 436
5 allows for the quick removal of bodily fluids from the chamber 406, even when the individual moves.

[0078] In the illustrated embodiment, the fluid reservoir 436 is defined by and positioned between the fluid impermeable barrier 402 and the conduit 412. For example, the fluid impermeable barrier 402 may include a bulge 450 extending outwardly from the
10 rest of the fluid impermeable barrier 402. The bulge 450 may partially define the fluid reservoir 436. In an embodiment, the fluid reservoir 436 is defined between at least the porous material 410 and the conduit 412, between at least the fluid impermeable barrier 402 and the porous material 410, or within the porous material 410.

[0079] In an embodiment, the one or more leak prevention features of any of the fluid
15 collection assemblies disclosed herein may include a leak prevention layer that forms a portion of the porous material. The leak prevention layer is configured to encourage flow of the bodily fluids therein in a first direction and discourage flow of the bodily fluids therein in a second direction that is opposite the first direction thereby inhibiting the bodily fluids from leaking from the chamber. **FIG. 5A** is a schematic cross-sectional
20 view of a leak prevention layer 552, according to an embodiment. The leak prevention layer 552 includes a plurality of sheets 554. For example, the leak prevention layer 552 may include at least one first sheet 554a and at least one second sheet 554b positioned downstream from the first sheet 554a. As used with regards to **FIGS. 5A-5C**, downstream is the direction that the leak prevention layer 552 encourages the bodily
25 fluids to flow. The downstream direction extends from the first sheet 554a towards the second sheet 554b and, during operation, generally extends from the urethral opening of the individual towards the chamber. The leak prevention layer 552 may also include one or more additional sheets positioned downstream from the second sheet 554b, such as the at least one third sheet 554c illustrated in **FIG. 5A**.

[0080] Each of the sheets 554 define a plurality of void spaces 556 extending
30 therethrough. The void spaces 556 may include apertures (as shown), a plurality of interconnected pores, etc. The plurality of void spaces 556 are configured to control the flow rate of the bodily fluids flowing therethrough. Generally, the void spaces 556 are configured such that the flow rate of the bodily fluids increases the further downstream

the bodily fluids flow (*e.g.*, with further distance from the first sheet 554a and/or the urethral opening) which encourages the bodily fluids to flow in the downstream direction. The void spaces 556 also discourage the bodily fluids flowing in an upstream direction (*e.g.*, a direction opposite the downstream direction) since the flow rate of the bodily fluids flowing in an upstream direction generally decreases. For example, referring to **FIG. 5A**, the leak prevention layer 552 inhibits leaks because any bodily fluids that are present in the second sheet 554b are more likely to flow to and through the third sheet 554c than the first sheet 554a (ignoring suction forces, wicking and capillary actions, and gravity). In such an example, any bodily fluids that are present in the second sheet 554b are more likely to flow to and through the third sheet 554c than the first sheet 554a since more of the bodily fluids may flow through the third sheet 554c during a given time period than the first sheet 554a.

[0081] In an embodiment, the rate at which the bodily fluids flow through each of the sheets 554 may depend on the collective cross-sectional area of the void spaces 556 (*e.g.*, the sum of the cross-sectional area of each of the void spaces 556 along a selected plane). Generally, increasing the collective cross-sectional area of the void spaces 556 increases the flow rate of the bodily fluids and decreasing the collective cross-sectional area of the void spaces 556 decreases the flow rate of the bodily fluids. As such, the collective cross-sectional area of the void spaces 556 generally increases in the downstream direction.

[0082] In an embodiment, the collective cross-sectional area of the void spaces 556 depends on the number density of void spaces 556 that are formed in each of the sheets 554 in a selected area. In such an embodiment, the number density of void spaces 556 formed in each sheet 554 generally increases in the downstream direction. For example, as illustrated, the first sheet 554a may exhibit a first number density of the void spaces 556, the second sheet 554b may exhibit a second number density of void spaces 556 that is greater than the first number density, and the third sheet 554c may exhibit a third number density of void spaces 556 that is greater than the second number density.

[0083] In an embodiment, the collective cross-sectional area of the void spaces 556 depends on the average cross-sectional area of each of the void spaces 556 that are formed in each of the sheets 554 in a selected area. In such an embodiment, the average cross-sectional area of each of the void spaces 556 formed in each sheet 554 generally increases in the downstream direction. For example, as illustrated, each of the void spaces 556 of the first sheet 554a may exhibit a first average cross-sectional area, each of the void spaces 556 of the second sheet 554b may exhibit a second average cross-

sectional area that is greater than the first average cross-sectional area, and each of the void spaces 556 of the third sheet 554c may exhibit a third average cross-sectional area that is greater than the second average cross-sectional area.

[0084] In an embodiment, each of the sheets 554 are not attached to each other or only selected portions of the sheets 554 are attached to each other. In such an embodiment, passageways 558 are allowed to form between adjacent sheets 554. For example, as illustrated, the void spaces 556 of adjacent sheets 554 may not align with each other. Without the passageways 558, the bodily fluid may be unable to flow through void spaces 556 that are not aligned with each other, especially if the sheets 554 are formed from a fluid impermeable material or a material exhibiting limited fluid permeability. Thus, without the passageways 558, the leak prevention layer 552 may be unable to encourage the bodily fluids to flow in the downstream direction.

[0085] In an embodiment, the leak prevention layer 552 may be formed from wicking materials (*e.g.*, at least one hydrophobic material). In an embodiment, the leak prevention layer 552 may be formed from any of the same materials as the fluid permeable membranes or the fluid permeable supports disclosed herein. In an embodiment, the leak prevention layer 552 may be formed from non-wicking material, such as at least one non-polyester polymer, at least one hydrophilic material, or any other absorbent or adsorbent material.

[0086] **FIG. 5B** is a schematic partial cross-sectional view of a portion of a fluid collection assembly 500a that includes at least one leak prevention layer 552a, according to an embodiment. Except as otherwise disclosed herein, the fluid collection assembly 500a is the same or substantially similar to any of the fluid collection assemblies disclosed herein. For example, the fluid collection assembly 500a may include a fluid impermeable barrier 502a defining an opening 504a and a chamber 506a. The fluid collection assembly 500a may also include at least one porous material 510a.

[0087] The porous material 510a includes the leak prevention layer 552a and at least one additional layer 560a. The additional layer 560a may include, for example, a fluid permeable membrane, a fluid permeable support, or an absorption layer. The leak prevention layer 552a extends at least partially across the opening 504a. As such, the leak prevention layer 552a may contact or otherwise be positioned proximate to the urethral opening of the individual during operation. The additional layer 560a may be positioned downstream from the leak prevention layer 552a and support the leak prevention layer 552a.

[0088] FIG. 5C is a schematic partial cross-sectional view of a portion of a fluid collection assembly 500b that includes at least one leak prevention layer 552b, according to an embodiment. Except as otherwise disclosed herein, the fluid collection assembly 500b is the same or substantially similar to any of the fluid collection assemblies disclosed herein. For example, the fluid collection assembly 500b may include a fluid impermeable barrier 502b defining an opening 504b and a chamber 506b. The fluid collection assembly 500b may also include at least one porous material 510b.

[0089] The porous material 510b includes the leak prevention layer 552b, a fluid permeable membrane 522, and at least one additional layer 560b. The additional layer 560b may include, for example, a fluid permeable support, or an absorption layer. The fluid permeable membrane 522 may be selected to be softer or otherwise more comfortable when contacting the vulva of an individual than the leak prevention layer 552b. As such, the fluid permeable membrane 522 extends at least partially across the opening 504b thereby preventing the leak prevention layer 552b from contacting the vulva. Instead, the fluid permeable membrane 522 may contact or otherwise be positioned proximate to the a urethral opening of the individual during operation. The leak prevention layer 552 may be positioned between the fluid permeable membrane 522 and the additional layer 560b thereby allowing the additional layer 560b to be positioned downstream from and support the leak prevention layer 552b.

[0090] FIG. 6 is a schematic partial cross-sectional view of a portion of the fluid collection assembly 600, according to an embodiment. Except as otherwise disclosed herein, the fluid collection assembly 600 is the same or substantially similar to any of the fluid collection assemblies disclosed herein. For example, the fluid collection assembly 600 may include a fluid impermeable barrier 602 defining an opening 604 and a chamber 606. The fluid collection assembly 600 further includes a porous material 610 and a conduit 612 disposed in the chamber 606.

[0091] The fluid collection assembly 600 also includes a fluid reservoir 636 that is substantially unoccupied. The conduit 612 includes at least one inlet 614 (e.g., open terminal end or conduit inlet) that is adjacent to or positioned in the fluid reservoir 636. The conduit 612 may not extend all the way into the fluid reservoir 636 to prevent the fluid impermeable barrier 602 from being suctioned to and completely obstructing the inlet 614. Generally, the conduit 612 is only able to remove bodily fluids that accumulate in the fluid reservoir 636 once the bodily fluids contact or are adjacent to the inlet 614, otherwise the inlet 614 merely pull air into the conduit 612. In other words, the conduit

612 may only remove bodily fluids from the fluid reservoir 636 when a certain quantity of bodily fluids are present in the fluid reservoir 636. As such, there may be a delay from when the bodily fluids enter the fluid reservoir 636 and when the conduit 612 begins to remove the bodily fluids from the fluid reservoir 636. Further, bodily fluids may remain in the fluid reservoir 636 long after the individual discharges the bodily fluids. The delay in removing the bodily fluids and leaving some bodily fluids in the fluid reservoir 636 may increase the likelihood that the fluid collection assembly 600 leaks.

[0092] The fluid collection assembly 600 may include a leak prevention feature that is configured to minimize any delay in removing the bodily fluids and minimize the amount of bodily fluids that remain the fluid reservoir 636. The leak prevention feature may include an additional porous material 616 that is partially disposed in at least a portion of an interior 662 of conduit 612. The additional porous material 616 also extends from the inlet 614 into the fluid reservoir 636, such as from the inlet 614 to the fluid impermeable barrier 602. During operation, the bodily fluids that enter the fluid reservoir 636 contact the additional porous material 616 before the bodily fluids contact or are adjacent to the inlet 614 of the conduit 612. The additional porous material 616 pulls the bodily fluids into the interior 662 of the conduit 612 via wicking, capillary action, or absorption. The conduit 612 may remove the bodily fluids that are pulled into the interior 662 of the conduit 612. Thus, the additional porous material 616 may decrease the delay between the bodily fluids entering the fluid reservoir and removing the bodily fluids from the fluid reservoir 636. Further, the additional porous material 616 may continue to pull the bodily fluids from the fluid reservoir 636 even when the individual ceases to discharge bodily fluids into the chamber 606. For example, the additional porous material 616 may remove the bodily fluids from the fluid reservoir 636 until all or substantially all of the bodily fluids are removed from the fluid reservoir 636. Thus, the additional porous material 616 decreases the likelihood that the fluid collection assembly 600 leaks the bodily fluids.

[0093] In an embodiment, the one or more leak prevention features of any of the fluid collection assemblies disclosed herein include one or more features that are configured to allow the fluid collection assemblies to conform to a shape of a vulva and a region about the vulva. For example, the shape, size, and topography of the vulva and the region about the vulva may vary. These variations may cause gaps to form between the fluid collection assembly and the vulva and the region about the vulva and bodily fluids may leak through these gaps. As such, the leak prevention features may be configured to

cause the fluid collection assembly to better conform to the shape, size, and topography of the vulva and the region about the vulva to eliminate or at least minimize any gaps between the fluid collection assembly and the vulva and the region about the vulva. For example, **FIG. 7** is a schematic cross-sectional view of a fluid collection assembly 700 that is configured to conform to the vulva and the region about the vulva, according to an embodiment. Except as otherwise disclosed herein, the fluid collection assembly 700 may be the same or substantially similar to any of the fluid collection assemblies disclosed herein. For example, the fluid collection assembly 700 may include a fluid impermeable barrier 702 defining an opening 704 and a chamber 706. The fluid collection assembly 700 may also include at least one porous material 710 and at least one conduit 712 disposed in the chamber 706.

[0094] The conduit 712 exhibits a “crinkle” structure. For example, the conduit 712 may include one or more peaks 764 (*e.g.*, a plurality of circumferentially extending peaks 764 or single helically extending peak 764). The conduit 712 may also include one or more valleys 766 (*e.g.*, a plurality of circumferentially extending valleys 766 or a single helically extending valley 766) disposed between portions of the peaks 764 spaced apart along a longitudinal direction of the conduit 712. The conduit 712 may be configured to be bent. The peaks 764 and valleys 766 may allow the conduit 712 to more freely bend when an external force is applied thereto and to maintain the bent shape after the external force is removed. The bent shape of the conduit 712 also causes the rest of the fluid collection assembly 700 to bend. Thus, the conduit 712 may allow the fluid collection assembly 700 to be conformed to a shape that generally corresponds to the shape of the vulva and the region about the vulva and to maintain said shape thereby inhibiting or preventing leaks.

[0095] In an embodiment, the valleys 766 remain substantially unoccupied. For example, the porous material 710 may not extend into the valleys 766 which may prevent the porous material 710 from inhibiting the conduit 712 from bending or prevent the conduit 712 from maintaining the shape thereof after the external force is removed. Also, configuring the porous material 710 to not extend into the valleys 766 may allow the porous material 710 to be formed using an extruding process instead of other more complicated processes. In an embodiment, the valleys 766 are occupied by the porous material 710.

[0096] **FIG. 8** is a bottom plan view of a fluid collection assembly 800 that is configured to conform to the vulva and the region about the vulva, according to an

embodiment. Except as otherwise disclosed herein, the fluid collection assembly 800 may be the same or substantially similar to any of the fluid collection assemblies disclosed herein. For example, the fluid collection assembly 800 may include a fluid impermeable barrier 802 defining a bottom surface 870 (*e.g.*, the surface of the fluid impermeable barrier 802 opposite the opening defined by the fluid impermeable barrier 802).

[0097] The fluid collection assembly 800 includes a shape memory material 872. The shape memory material 872 may include a shape memory polymer or a metal (*e.g.*, shape memory metal). Suitable shape memory materials are composed to adopt an intermediate or permanent shape in response to a stimuli. The stimuli may include an external physical force (*e.g.*, bending force), heat, electrical bias, or a magnetic field. While the term “shape memory” is used to describe some of the “shape memory materials” herein, it should be understood that, in some examples, the material modified by the term “shape memory” may not necessarily need to return to a preselected shape upon application of a stimuli, as understood as the classical definition of the “shape memory material.” Rather, at least some of the shape memory materials herein may simply hold a selected shape when bent, set, or cured into a specific shape and/or when cooled in a specific shape, regardless of the stimuli applied thereto after. The shape memory materials may be returned to the original shape or changed to a new shape by application of stimuli. For example, a metal wire bent to a first shape may be utilized as the shape memory material, whereinafter the metal wire may be modified to a second shape via physical force applied thereto or via heating. For example, the shape memory material 872 may include a shape memory alloy (*e.g.*, nitinol), a shape memory polymer, copper, aluminum, steel, iron, or any other suitable material that is bendable and maintains its shape after being bent. In the illustrated embodiment, the shape memory material 872 is a wire exhibiting a general zig-zag shape. The generally zig-zag shape of the shape memory material 872 allows the shape memory material 872 to change the shape of a greater portion of fluid collection assembly 800 than if the shape memory material 872 was a generally straight or curved wire while exhibiting a lesser weight than if the shape memory material 872 was a plate.

[0098] In an embodiment, as illustrated, the shape memory material 872 may be attached to the bottom surface 870 of the fluid impermeable barrier 802. The shape memory material 872 may be attached to the bottom surface 870 via an adhesive or any other suitable attachment technique. When the shape memory material 872 is attached to the bottom surface 870, a coating may be applied to the shape memory material 872 to

prevent the shape memory material 872 from chaffing the individual. In an embodiment, the shape memory material 872 may be disposed in the fluid impermeable barrier 802 or attached to an inner surface of the fluid impermeable barrier 802. In an embodiment, the shape memory material 872 is disposed in or attached to the at least one porous material
5 or the conduit of the fluid collection assembly.

[0099] The composition of the shape memory material 872 and examples of different shape memory materials that may form a leak prevention feature are disclosed in International Application No. WO 2021/016026 filed on July 15, 2020, the disclosure of which is incorporated herein, in its entirety, by this reference.

10 **[00100]** Some conventional fluid collection assemblies include a conduit exhibiting an outer diameter that is greater than about 1 cm that extends through substantially all of the fluid collection assembly. Such conventional fluid collection assemblies may exhibit a fluid reservoir that may hold about 10 milliliters (“ml”) to about 14 ml of bodily fluids and may hold about 24 ml of bodily fluids in the chamber before leaking. Some
15 individuals may discharge more than 24 ml of bodily fluids in the first second of urination which may cause the fluid collection assembly to leak, especially if there is any delay in removing the bodily fluids from the chamber. However, it is currently believed by the inventors that the diameter of the conduit may be decreased without decreasing the amount of bodily fluids that are removed from the chamber thereby increasing the amount
20 of bodily fluids that may be held in the chamber. In other words, the one or more leak prevention features of any of the fluid collection assemblies disclosed herein may include using a conduit exhibiting a diameter that is about 5 mm to about 9 mm, such as in ranges of about 5 mm to about 6 mm, about 5.5 mm to about 6.5 mm, about 6 mm to about 7 mm, about 6.5 mm to about 7.5 mm, about 7 mm to about 8 mm, about 7.5 mm to about
25 8.5 mm, or about 8 mm to about 9 mm. In an example, a fluid collection assembly including a conduit exhibiting an outer diameter of about 9 mm may hold about 2% more bodily fluids before leaking than a substantially similar fluid collection assembly including a conduit exhibiting an outer diameter of about 1 cm (this number inherently depends on the length, diameter, and shape of the fluid collection assembly and the
30 porosity of the porous material). The 2% increase in the amount of bodily fluids that are held in the chamber may be sufficient to prevent the fluid collection assembly from leaking. In an example, a fluid collection assembly including a conduit exhibiting an outer diameter of about 7.5 mm may hold about 5% more bodily fluids before leaking than a substantially similar fluid collection assembly including a conduit exhibiting an

outer diameter of about 1 cm. The 5% increase in the amount of bodily fluids that are held in the chamber may be sufficient to prevent the fluid collection assembly from leaking. In an example, a fluid collection assembly including a conduit exhibiting an outer diameter of about 5 mm may hold about 9% more bodily fluids before leaking than a substantially similar fluid collection assembly including a conduit exhibiting an outer diameter of about 1 cm. The 9% increase in the amount of bodily fluids that are held in the chamber may be sufficient to prevent the fluid collection assembly from leaking.

[00101] In an embodiment, the one or more leak prevention features used in any of the fluid collection assemblies disclosed herein may include pre-moistening the at least one porous material before the fluid collection assemblies receive bodily fluids. Pre-moistening the porous material may include moistening the porous material with a non-bodily fluid, such as water, saline, or another suitable liquid. Pre-moistening the porous material may improve flow of the bodily fluids through the porous material. For example, the flow of the bodily fluids through a dry porous material may be slower than the flow of the bodily fluids through a moistened porous material (*e.g.*, a pre-moistened porous material or a previously used porous material).

[00102] The fluid collection assemblies shown in **FIGS. 1A-8** are examples of female fluid collection assemblies that are configured to collect bodily fluids from females. However, the fluid collection assemblies, systems, and method disclosed herein may include male fluid collection assemblies shaped, sized, and otherwise configured to collection bodily fluids from males (*e.g.*, collect urine from a male urethral opening).

[00103] **FIG. 9A** is an isometric view of a fluid collection assembly 900 according to an embodiment. **FIG. 9B** is a cross-sectional view of the fluid collection assembly 900 of **FIG. 9A** taken along the plane B-B of **FIG. 9A**, according to an embodiment. Referring to **FIG. 9A** and **FIG. 9B**, the fluid collection assembly 900 includes a receptacle 974 and a sheath 976. The receptacle 974 is sized, shaped, and made of a material to be coupled to skin that surrounds the male urethra and have the male urethra positioned therethrough. For example, the receptacle 974 may include an annular base 978 that defines an opening 980 in the receptacle 974. The annular base 978 is sized and shaped to be positioned around the male urethra (*e.g.*, positioned around and/or over the penis) and the opening 980 may be configured to have the male urethra positioned therethrough. The annular base 978 may also be sized, shaped, made of a material, or otherwise configured to be coupled (*e.g.*, adhesively attached, such as with a hydrogel adhesive) to the skin around the male urethral opening (*e.g.*, around the penis). In an example, the annular base 978

may exhibit the general shape or contours of the skin surface that the annular base 978 is selected to be coupled with. The annular base 978 may be flexible thereby allowing the annular base 978 to conform to any shape of the skin surface. The annular base 978 may include a laterally extending flange 955. The receptacle 974 also defines a hollowed region that is configured to receive (*e.g.*, seal against) the sheath 976. For example, the
5 receptacle 974 may include a longitudinally extending flange 957 that extends upwardly from the annular base 978. The longitudinally extending flange 957 may be tall enough to prevent the sheath 976 from being accidentally removed from the receptacle 974 (*e.g.*, at least 0.25 cm tall, 1 cm tall, at least 9 cm tall, or at least 5 cm tall). The receptacle 974
10 is located at a proximal region 932 (with respect to a wearer) of the fluid collection assembly 900.

[00104] The sheath 976 includes (*e.g.*, may be formed from) a fluid impermeable barrier 902 that is sized and shaped to fit into the hollowed region of the receptacle 974. For example, the sheath 976 may be generally tubular or cup-shaped, as shown. The
15 generally tubular or cup-shaped fluid impermeable barrier 902 may at least partially define the outer surface 920 of the sheath 976. The fluid impermeable barrier 902 may be similar or identical to any of the fluid impermeable barriers disclosed herein, in one or more aspects. For example, the fluid impermeable barrier 902 may be constructed of any of the materials disclosed herein for the fluid impermeable barrier 102. The fluid
20 impermeable barrier 902 at least partially defines the chamber 906. For example, the inner surface 918 of the fluid impermeable barrier 902 at least partially defines the perimeter of the chamber 906. The chamber 906 may be similar or identical to any of the chambers disclosed herein in one or more aspects. For example, the chamber 906 may at least temporarily retain bodily fluids therein. As shown, the fluid collection assembly
25 900 may include at least one porous material 910 therein. The porous material 910 may be similar or identical to any of the porous materials disclosed herein in one or more aspects. For example, the porous material 910 may include one or more of a fluid permeable membrane 922, a fluid permeable support 924, an absorbent layer (not shown), or a leak prevention layer (not shown). The fluid impermeable barrier 902 may also
30 define an opening 904 extending through the fluid impermeable barrier 902 that is configured to have a male urethral opening (*e.g.*, penis) positioned therethrough.

[00105] The sheath 976 and fluid impermeable barrier 902 may also include at least one vacuum relief hole 982 that allows the chamber 906 to remain substantially at atmospheric pressure. The vacuum relief hole 982 may be located at any point on the

sheath 976, such as near or nearer the opening 980. In some examples (not shown), the vacuum relief hole 982 may extend through the cap 984 or be disposed beneath the cap 984. In some examples, the fluid collection assembly 900 may not include the vacuum relief hole 982, such as when a more complete seal as desired for the chamber 906.

5 [00106] The sheath 976 also includes at least a portion of the conduit 912 therein, such as at least partially disposed in the chamber 906 of the conduit 912 only disposed in the fluid outlet 908. For example, the conduit 912 may extend from the sheath 976 at the distal region 934 to a proximal region 932 at least proximate to the opening 980. The proximal region 932 may be disposed near or on the skin around the male urethral
10 opening (*e.g.*, on the penis or pubic area therearound). Accordingly, when a patient lays on their back, bodily fluids (*e.g.*, urine) may aggregate near the opening 980 against the skin of the subject. The bodily fluids may be removed from the chamber 906 via the conduit 912.

[00107] In some examples, the fluid impermeable barrier 902 may be constructed of a
15 material and/or have a thickness that allows the sheath 976 to collapse when placed under vacuum, such as to remove air around a penis in the fluid collection assembly 900 during use. In such examples, the conduit 912 may extend only to or into the distal region 934 in the chamber 906 (*e.g.*, not through to the area adjacent the opening).

[00108] In an example, portions of the chamber 906 may be substantially empty due to
20 the varying sizes and rigidity of the male penis. However, in some examples, the outermost regions of the chamber 906 (*e.g.*, periphery of the interior regions of the sheath 976) may include porous material 910 (*e.g.*, one or more of the fluid permeable membrane 922 and fluid permeable support 924). For example, the porous material 910 may be bonded to the inner surface 918 of the fluid impermeable barrier 902. The porous
25 material 910 may be positioned (*e.g.*, at the distal end of the chamber 906) to blunt a stream of urine from the male urethral opening thereby limiting splashing and/or to direct the bodily fluids to a selected region of the chamber 906. Since the chamber 906 is substantially empty (*e.g.*, substantially all of the chamber 906 forms a reservoir), the bodily fluids are likely to pool at a gravimetrically low point of the chamber 906. The
30 gravimetrically low point of the chamber 906 may be at an intersection of the skin of an individual and the fluid collection assembly 900, a corner formed in the sheath 976, or another suitable location depending on the orientation of the wearer.

[00109] The porous material 910 may include one or more of the fluid permeable membrane 922 or the fluid permeable support 924. The fluid permeable membrane 922

and the fluid permeable support 924 may be similar or identical to any of the fluid permeable membranes or fluid permeable supports as respectively disclosed herein, in one or more aspects such as material make-up or wicking ability. One or more of the fluid permeable membrane 922 or the fluid permeable support 924 may be disposed
5 between the fluid impermeable barrier 902 and a penis inserted into the chamber 906. The fluid permeable membrane 922 may be positioned between the fluid impermeable barrier 902 and a penis inserted into the chamber 906, such as between the fluid permeable support 924 and penis of a wearer as shown. The fluid permeable support 924 may be positioned between the fluid permeable membrane 922 and the fluid impermeable
10 barrier 902. The inner surface 918, optionally including the end of the chamber 906 substantially opposite the opening 904, may be covered with one or both the fluid permeable membrane 922 or the fluid permeable support 924. The fluid permeable support 924 or the fluid permeable membrane 922 may be affixed (*e.g.*, adhered) to the fluid impermeable barrier 902. The fluid permeable support 924 or the fluid permeable
15 membrane 922 may be affixed to each other. In some examples, the porous material 910 only includes the fluid permeable membrane 922 or the fluid permeable support 924.

[00110] In some examples, the fluid collection assembly 900 includes a cap 984 at a distal region 934. The cap 984 defines an interior channel through which the bodily fluids may be removed from the fluid collection assembly 900. The interior channel is in
20 fluid communication with the chamber 906. The cap 984 may be disposed over at least a portion of the distal region 934 of one or more of the fluid impermeable barrier 902 or the porous material 910. The cap 984 may be made of a polymer, rubber, or any other fluid impermeable material. The cap 984 may be attached to one or more of the fluid impermeable barrier 902, the porous material 910, or the conduit 912. The cap 984 may
25 have a laterally extending flange 986 and a longitudinally extending flange 988. The laterally extending flange 986 may cover at least a portion of the distal region 934 of the fluid collection assembly 900. The longitudinally extending flange 988 may laterally extend a distance from the sheath 976. The longitudinally extending flange 972 is sized and configured to receive and fluidly seal against the conduit 912, such as within the
30 interior channel. The conduit 912 may extend a distance within or through the cap 984, such as to the porous material 910, through the porous material 910, or to a point set-off from the porous material 910. In the latter example, as depicted in **FIG. 9B**, the interior channel of the cap 984 may define a reservoir 936 therein.

- [00111] The reservoir 936 is an unoccupied portion of device such as in the cap 984 and is void of other material. In some examples, the reservoir 936 is defined at least partially by the porous material 910 and the cap 984. During use, the bodily fluids that are in the chamber 906 may flow through the porous material 910 to the reservoir 936.
- 5 The reservoir 936 may store at least some of the bodily fluids therein and/or position the bodily fluids for removal by the conduit 912. In some examples, at least a portion of the porous material 910 may extend continuously between at least a portion of the opening of the interior channel and chamber 906 to move any bodily fluid from the opening directly to the reservoir 936.
- 10 [00112] In some examples (not shown), the fluid impermeable barrier 902 may be disposed on or over the cap 984, such as enclosing the cap 984 within the chamber 906.
- [00113] In some examples, the sheath 976 may include at least a portion of the conduit 912 therein, such as at least partially disposed in the chamber 906. For example, the conduit 912 may extend from the sheath 976 to a region at least proximate to the opening
- 15 980. The inlet of the conduit 912 may be positioned adjacent to the annular base 978. The inlet of the conduit 912 may be positioned to be adjacent or proximate to the gravimetrically low point of the chamber 906, such as adjacent to the annular base 978. For example, the inlet may be co-extensive with or offset from the opening 980. In examples, the inlet may be positioned adjacent to the distal region 944 of the sheath 976.
- 20 [00114] The proximal region 932 may be disposed near or on the skin around the male urethral opening (*e.g.*, around the penis) and the inlet of the conduit 912 may be positioned in the proximal region 932. The outlet of the conduit 912 may be directly or indirectly coupled to a vacuum source. Accordingly, the bodily fluids may be removed from the proximal region 932 of the chamber 906 via the conduit 912.
- 25 [00115] The receptacle 974, the sheath 976, the cap 984, and the conduit 912 may be attached together using any suitable method. For example, at least two of the receptacle 974, the sheath 976, the cap 984, or the conduit 912 may be attached together using at least one of an interference fit, an adhesive, stitching, welding (*e.g.*, ultrasonic welding), tape, any other suitable method, or combinations thereof.
- 30 [00116] In some examples (not shown), the fluid collection assembly 900 may have a one piece design, with one or more of the sheath 976, the receptacle 974, and the cap 984 being a single, integrally formed piece.
- [00117] Also as shown, the conduit 912 may be at least partially disposed with the chamber 906 of a fluid collection assembly 900. The conduit 912 may extend from the

distal region 944 to the proximal region 932. For example, the conduit 912 may extend through the cap 984 to a point adjacent to the receptacle 974. The conduit 912 is sized and positioned to be coupled to a fluid storage container or the vacuum source (**FIG. 10**). An outlet of the conduit 912 may be operably coupled to the vacuum source, directly or indirectly. The inlet 914 (*e.g.*, open terminal end) of the conduit 912 may be positioned within or adjacent to the chamber 906 such as at a location expected to be at the gravimetrically low point of the fluid collection assembly 900 during use. By positioning the inlet 914 in a location expected to be at the gravimetrically low point of the fluid collection assembly 900 when worn by the user, the bodily fluids introduced into the chamber 906 may be removed via the conduit 912 to prevent pooling or stagnation of the fluid within the chamber 906.

[00118] The fluid collection assembly 900 may include any of the leak prevention features disclosed herein. In an example, as shown, the one or more leak prevent features of the fluid collection assembly 900 may include the porous material 910 having least one additional layer 1052. The additional layer 1052 may be an absorbent layer similar to the absorbent layer 230 of **FIG. 2B** or a leak prevention layer similar to the leak prevention layer 552 of **FIGS. 5A-5C**. In an example, the one or more leak prevent features of the fluid collection assembly 900 may include the chamber 906 completely filled with porous material 910 (except for the portion configured to receive the male penis) such that the chamber 906 does not include a fluid reservoir. In an example, the one or more leak prevent features of the fluid collection assembly 900 may include the conduit 912 at least partially occupied with an additional porous material and, optionally, the additional porous material may extend from the conduit 912 into the fluid reservoir 936. In an example, the one or more leak prevent features of the fluid collection assembly 900 may include the conduit 912 exhibiting a “crinkle” structure or the fluid collection assembly 900 including at least one shape memory material.

[00119] Further examples of fluid collection assemblies that are configured to collect bodily fluids from males are disclosed in U.S. Patent Application No. 16/433,773 filed on June 6, 2019, the disclosure of which is incorporated herein, in its entirety, by this reference.

[00120] In some examples, the vacuum source may be remotely located from the fluid collection assembly 900. In such examples, the conduit 912 may be fluidly connected to the fluid storage container, which may be disposed between the vacuum source and the fluid collection assembly 900.

[00121] During operation, a male using the fluid collection assembly 900 may discharge bodily fluids into the chamber 906. The bodily fluids may pool or otherwise be collected in the chamber 906. At least some of the bodily fluids may be pulled through the interior of the conduit 912 via the inlet. The bodily fluids may be drawn out of the fluid collection assembly 900 via the vacuum/suction provided by the vacuum source. During operation, the aperture 962 may substantially maintain the pressure in the chamber 906 at atmospheric pressure even though the bodily fluids are introduced into and subsequently removed from the chamber 906.

[00122] FIG. 10 is a block diagram of a system 1046 for fluid collection, according to an embodiment. The system 1046 includes a fluid collection assembly 1000, a fluid storage container 1090, and a vacuum source 1092. The fluid collection assembly 1000, the fluid storage container 1090, and the vacuum source 1092 may be fluidly coupled to each other via one or more conduits 112. For example, fluid collection assembly 1000 may be operably coupled to one or more of the fluid storage container 1090 or the vacuum source 1092 via the conduit 1012. The bodily fluids collected in the fluid collection assembly 1000 may be removed from the fluid collection assembly 1000 via the conduit 1012 which protrudes into the fluid collection assembly 1000. For example, an inlet of the conduit 1012 may extend into the fluid collection assembly 1000, such as to a reservoir therein. The outlet of the conduit 1012 may extend into the fluid collection assembly 1000 or the vacuum source 1092. Suction force may be introduced into the chamber of the fluid collection assembly 1000 via the inlet of the conduit 1012 responsive to suction (*e.g.*, vacuum) force applied at the outlet of the conduit 1012.

[00123] The suction force may be applied to the outlet of the conduit 1012 by the vacuum source 1092 either directly or indirectly. The suction force may be applied indirectly via the fluid storage container 1090. For example, the outlet of the conduit 1012 may be disposed within the fluid storage container 1090 and an additional conduit 1012 may extend from the fluid storage container 1090 to the vacuum source 1092. Accordingly, the vacuum source 1092 may apply suction to the fluid collection assembly 1000 via the fluid storage container 1090. The suction force may be applied directly via the vacuum source 1092. For example, the outlet of the conduit 1012 may be disposed within the vacuum source 1092. An additional conduit 1012 may extend from the vacuum source 1092 to a point outside of the fluid collection assembly 1000, such as to the fluid storage container 1090. In such examples, the vacuum source 1092 may be disposed between the fluid collection assembly 1000 and the fluid storage container 1090.

[00124] The fluid collection assemblies 1000 may be similar or identical to any of the fluid collection assemblies disclosed herein in one or more aspects. The fluid collection assembly 1000 may be shaped and sized to be positioned adjacent to a female urethral opening or have a male urethral opening positioned therethrough (*e.g.*, receive a penis therein). For example, the fluid collection assembly 1000 may include a fluid impermeable barrier at least partially defining a chamber (*e.g.*, interior region) of the fluid collection assembly 1000. The fluid impermeable barrier also defines an opening extending therethrough from the external environment. The opening may be positioned adjacent to a female urethral opening or have a male urethral opening positioned therethrough. The fluid collection assembly 1000 may include a fluid permeable membrane disposed within the fluid impermeable barrier. The fluid collection assembly 1000 may include at least one porous material disposed in the chamber such as one or more of a fluid permeable support and a fluid permeable membrane. The fluid collection assembly 1000 includes the shape memory material on or incorporated in one or more components thereof. The shape memory material is sized, shaped, and positioned to retain a selected geometric configuration as disclosed herein. The conduit 1012 may extend into the fluid collection assembly 1000 at a first end (*e.g.*, proximal) region, through one or more of the fluid impermeable barrier, fluid permeable membrane, or the fluid permeable support to a second end (*e.g.*, distal) region of the fluid collection assembly 1000. The conduit 1012 includes an inlet and an outlet, the outlet being fluidly coupled to the fluid storage container and the inlet being positioned in a portion of the chamber selected to be at a gravimetrically low point of the fluid collection assembly 1000 when worn.

[00125] The fluid storage container 1090 is sized and shaped to retain the bodily fluids therein. The fluid storage container 1090 may include a bag (*e.g.*, drainage bag), a bottle or cup (*e.g.*, collection jar), or any other enclosed container for storing bodily fluids such as urine. In some examples, the conduit 1012 may extend from the fluid collection assembly 1000 and attach to the fluid storage container 1090 at a first point therein. An additional conduit 1012 may attach to the fluid storage container 1090 at a second point thereon and may extend and attach to the vacuum source 1092. Accordingly, a vacuum (*e.g.*, suction) may be drawn through fluid collection assembly 1000 via the fluid storage container 1090. The bodily fluids, such as urine, may be drained from the fluid collection assembly 1000 using the vacuum source 1092.

[00126] The vacuum source 1092 may include one or more of a manual vacuum pump, and electric vacuum pump, a diaphragm pump, a centrifugal pump, a displacement pump, a magnetically driven pump, a peristaltic pump, or any pump configured to produce a vacuum. The vacuum source 1092 may provide a vacuum or suction to remove the
5 bodily fluids from the fluid collection assembly 1000. In some examples, the vacuum source 1092 may be powered by one or more of a power cord (*e.g.*, connected to a power socket), one or more batteries, or even manual power (*e.g.*, a hand operated vacuum pump). In some examples, the vacuum source 1092 may be sized and shaped to fit outside of, on, or within the fluid collection assembly 1000. For example, the vacuum
10 source 1092 may include one or more miniaturized pumps or one or more micro pumps. The vacuum sources 1092 disclosed herein may include one or more of a switch, a button, a plug, a remote, or any other device suitable to activate the vacuum source 1092.

[00127] While various aspects and embodiments have been disclosed herein, other aspects and embodiments are contemplated. The various aspects and embodiments
15 disclosed herein are for purposes of illustration and are not intended to be limiting.

[00128] Terms of degree (*e.g.*, “about,” “substantially,” “generally,” etc.) indicate structurally or functionally insignificant variations. In an example, when the term of degree is included with a term indicating quantity, the term of degree is interpreted to mean $\pm 10\%$, $\pm 5\%$, $+2\%$ or 0% of the term indicating quantity. In an example, when the
20 term of degree is used to modify a shape, the term of degree indicates that the shape being modified by the term of degree has the appearance of the disclosed shape. For instance, the term of degree may be used to indicate that the shape may have rounded corners instead of sharp corners, curved edges instead of straight edges, one or more protrusions extending therefrom, is oblong, is the same as the disclosed shape, etc.

25

CLAIMS

We claim:

1. A fluid collection assembly for capturing one or more bodily fluids from an individual, comprising:
 - 5 a fluid impermeable barrier defining:
 - at least one opening;
 - a chamber in fluid communication with the at least one opening; and
 - at least one fluid outlet;
 - at least one porous material disposed in the chamber;
 - 10 at least one conduit attached to the at least one fluid outlet; and
 - one or more leak prevention features configured to at least inhibit bodily fluids leaking from the chamber.
2. The fluid collection assembly of claim 1, wherein the one or more leak prevention features include the fluid impermeable barrier exhibiting a generally non-
 - 15 cylindrical shape.
3. The fluid collection assembly of claim 2, wherein the fluid impermeable barrier exhibits a generally flat disk-like shape.
4. The fluid collection assembly of claim 2, wherein the fluid impermeable barrier exhibits a generally flat elongated shape.
- 20 5. The fluid collection assembly of claim 2, wherein the fluid impermeable barrier exhibits a concavely curved cross-sectional shape.
6. The fluid collection assembly of any one of claims 1 to 5, wherein the fluid impermeable barrier defines a bulge defining a fluid reservoir extending along the at least one conduit.
- 25 7. The fluid collection assembly of any one of claims 1 to 6, wherein the one or more leak prevention features include the chamber being substantially completely filled with the at least one porous material.
8. The fluid collection assembly of any one of claims 1 to 7, wherein the one or more leak prevention features further includes at least one additional porous material
30 disposed in the at least one conduit
9. The fluid collection assembly of claim 8, wherein:
 - the chamber includes a substantially unoccupied fluid reservoir;
 - the at least one conduit extends from the at least one fluid outlet to or near the

fluid reservoir; and

the at least one additional porous material is disposed in the at least one conduit and a extends from the at least one conduit into the fluid reservoir.

10. The fluid collection assembly of any one of claims 1 to 9, wherein the at
5 least one porous material includes a fluid permeable membrane and a fluid permeable support, and wherein the one or more leak prevention features includes at least one absorbent material disposed between the fluid permeable membrane and the fluid permeable support.

11. The fluid collection assembly of any one of claims 1 to 10, wherein the at
10 least one conduit include an open terminal end and an outlet portion that is disposed in the at least one fluid outlet, the one or more leak prevention features including one or more conduit inlets defined by the at least one conduit, the one or more conduit inlets located between the open terminal end and the outlet portion.

12. The fluid collection assembly of claim 11, wherein the one or more
15 conduit inlets are slots.

13. The fluid collection assembly of any one of claims 11 or 12, wherein at least one of the one or more conduit inlets includes a one-way valve that is configured to allow the bodily fluids to enter an interior of the at least one conduit and substantially prevent the bodily fluids to exiting the interior of the at least one conduit.

14. The fluid collection assembly of any one of claims 11 to 13, wherein the at
20 least one conduit exhibits a length measured from the open terminal end to the outlet portion, and wherein the one or more conduit inlets are spaced from the open terminal end by about 25% to about 40% of the length of the at least one conduit.

15. The fluid collection assembly of any one of claims 11 to 14, wherein the at
25 least one conduit exhibits a length measured from the open terminal end to the outlet portion, and wherein the one or more conduit inlets are spaced from the open terminal end by about 40% to about 60% of the length of the at least one conduit.

16. The fluid collection assembly of any one of claims 11 to 15, wherein the at
30 least one conduit exhibits a length measured from the open terminal end to the outlet portion, and wherein the one or more conduit inlets are spaced from the open terminal end by about 60% to about 99% of the length of the at least one conduit.

17. The fluid collection assembly of any one of claims 1 to 16, wherein one or more leak prevention features includes the at least one conduit including a plurality of conduits, each of the plurality of conduits exhibit an open terminal end and an outlet

portion, and a length of at least some of the plurality of conduits measured from the open terminal end to the outlet portion are different.

18. The fluid collection assembly of any one of claims 1 to 17, wherein the at least one leak prevention feature includes a leak prevention material disposed in the at least one porous material, wherein:

the leak prevention material includes at least one first layer and at least one second layer, each of the at least one first layer and the at least one second layer defining a plurality of void spaces;

wherein at least one of:

the at least one first layer exhibits a first number density of the plurality of void spaces and the at least one second layer exhibits a second number density of the plurality of void spaces that is greater than the first number density; and/or

each of the plurality of void spaces of the at least one first layer exhibits a first average cross-sectional area and each of the plurality of void spaces of the at least one second layer exhibits a second average cross-sectional area that is greater than the first average cross-sectional area of each of the void space.

19. The fluid collection assembly of any one of claims 1 to 18, wherein the at least one leak prevention feature includes one or more peaks and one or more valleys formed in the at least one conduit.

20. The fluid collection assembly of any one of claims 1 to 19, wherein the at least one conduit exhibits an outer diameter that is about 5 mm to about 0.9 mm.

21. The fluid collection assembly of any one of claims 1 to 21, wherein the one or more leak prevention features includes the at least one porous material having at least one non-bodily fluid disposed therein.

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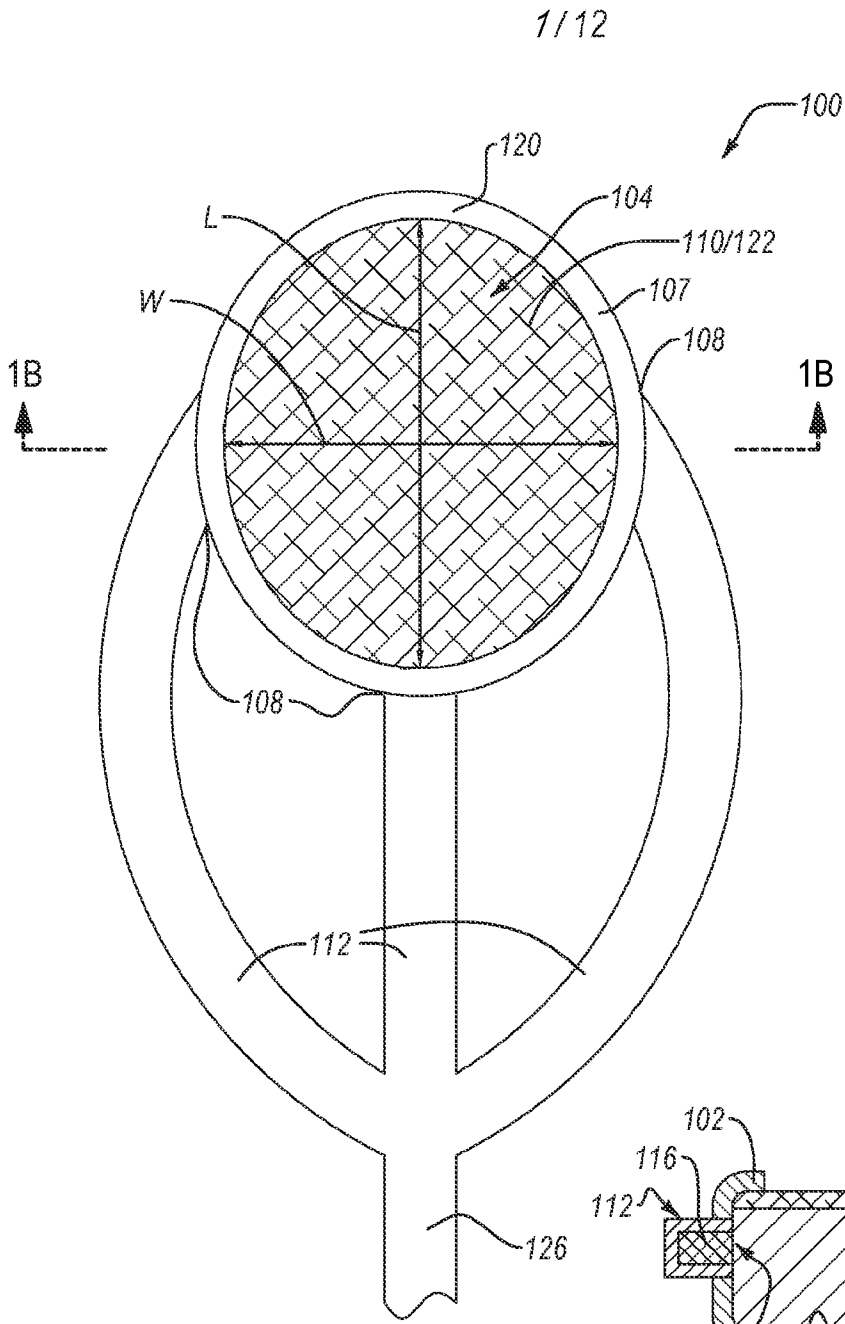


FIG. 1A

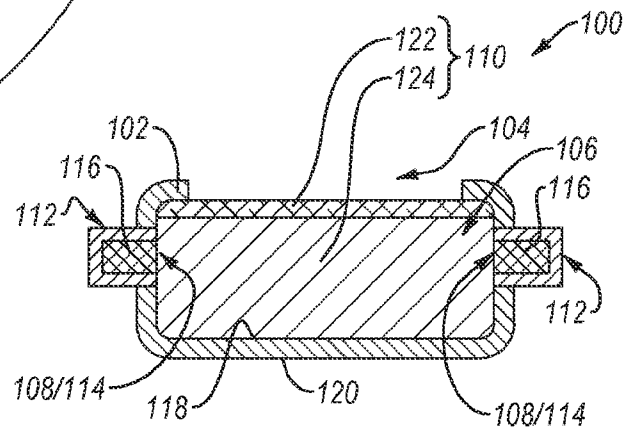
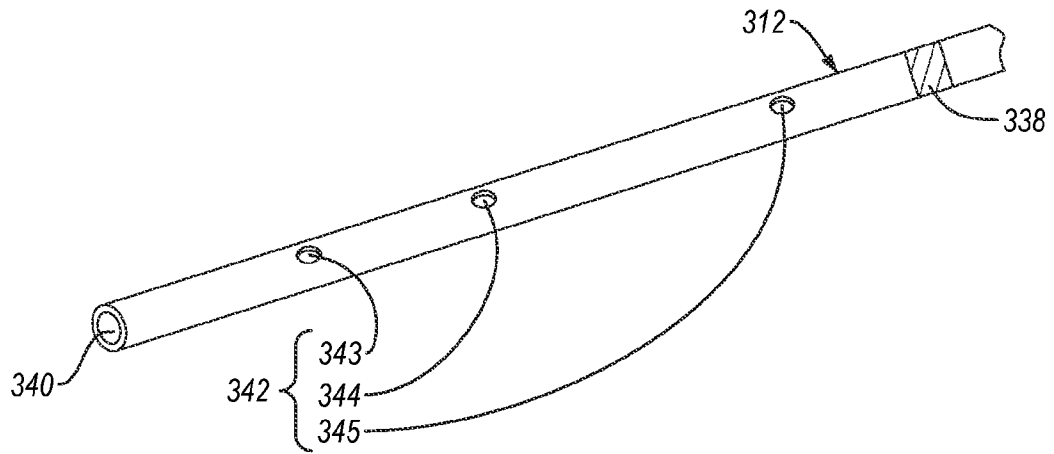
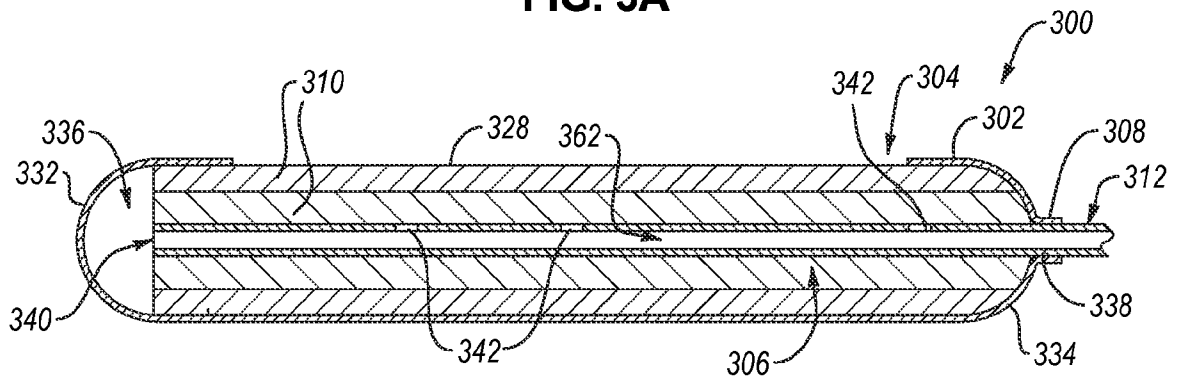
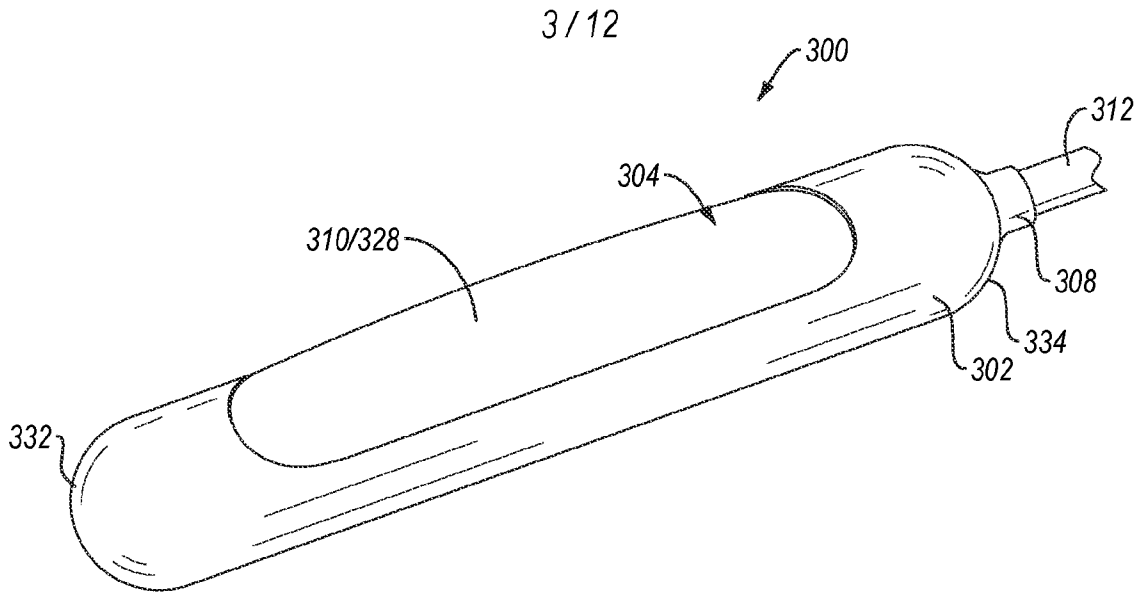


FIG. 1B



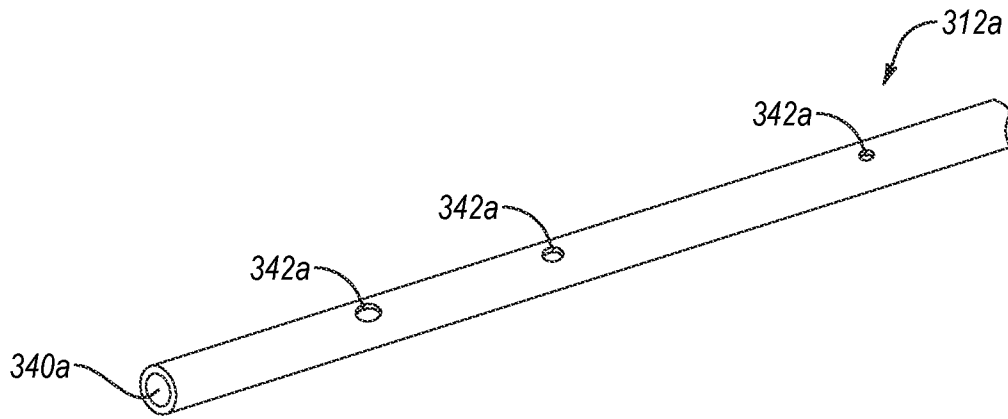


FIG. 3D

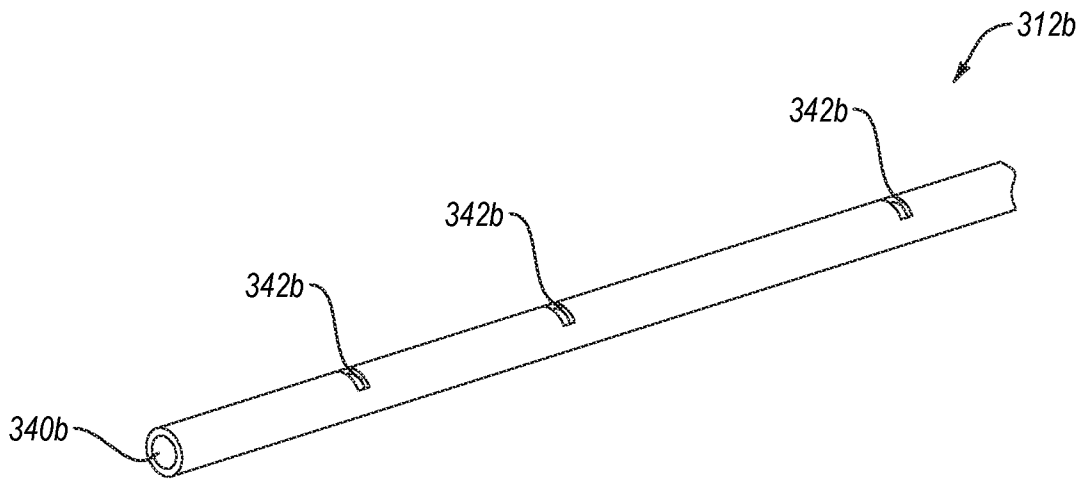


FIG. 3E

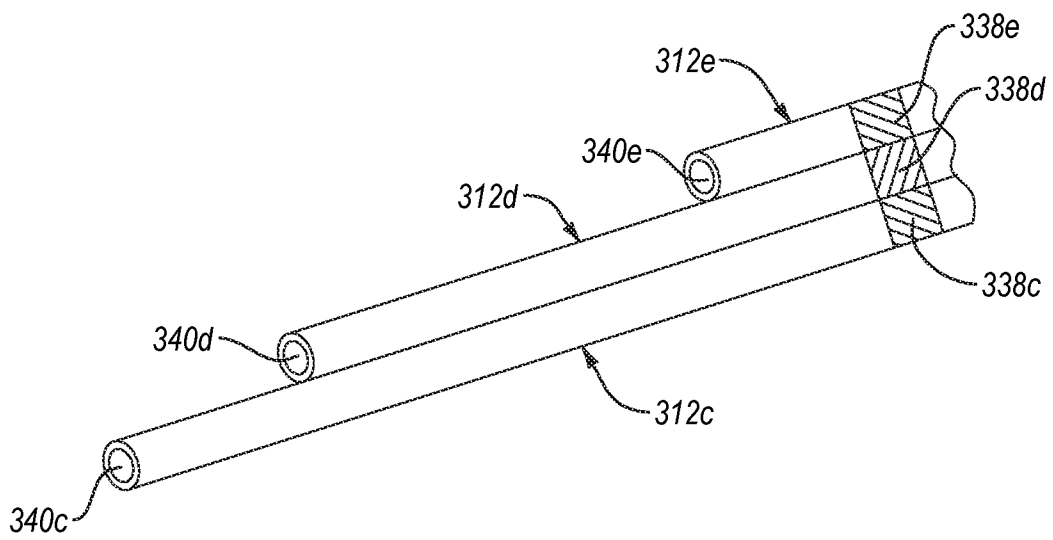


FIG. 3F

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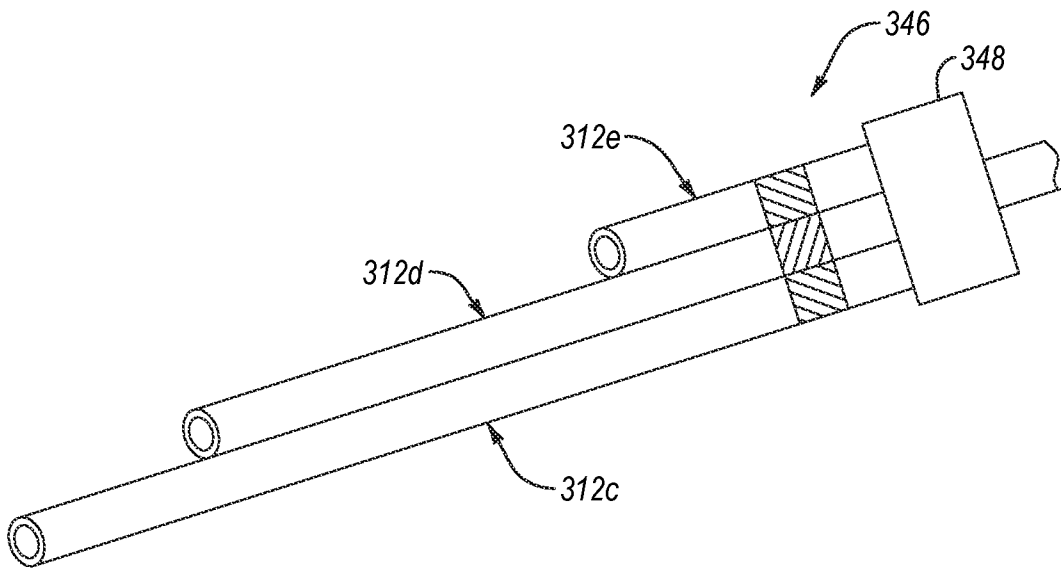


FIG. 3G

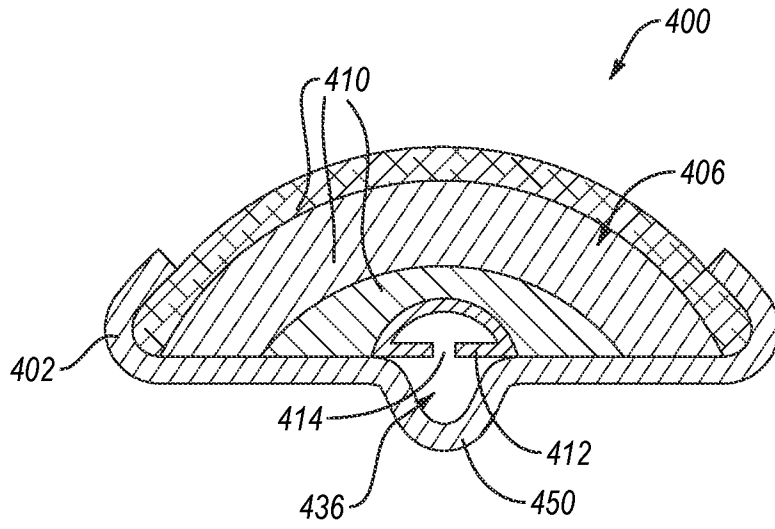


FIG. 4

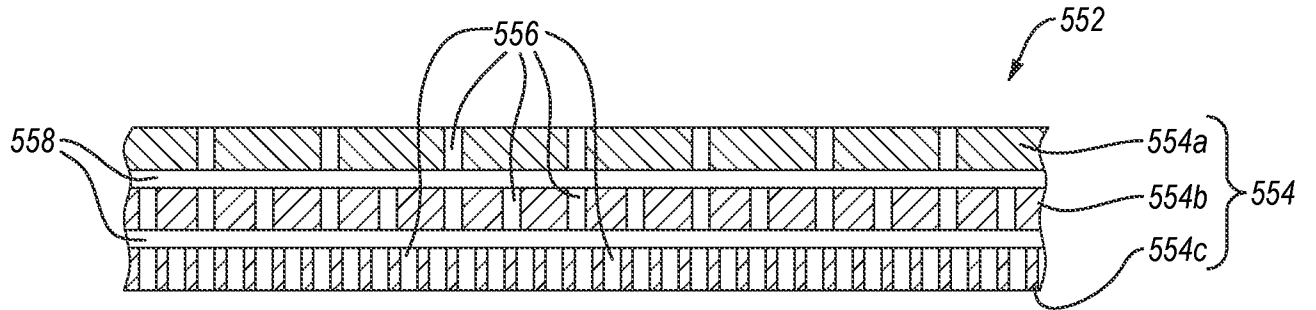


FIG. 5A

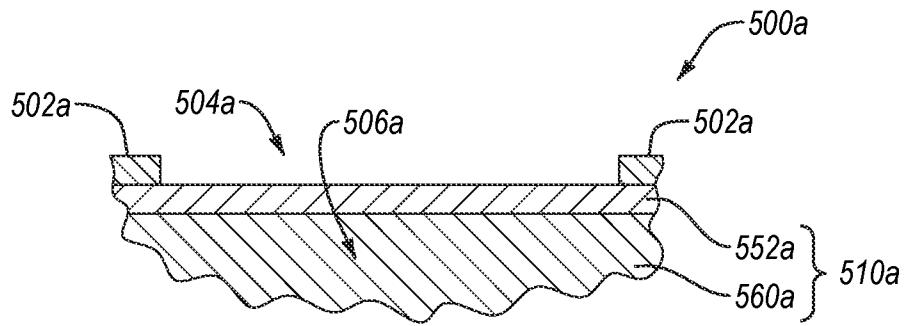


FIG. 5B

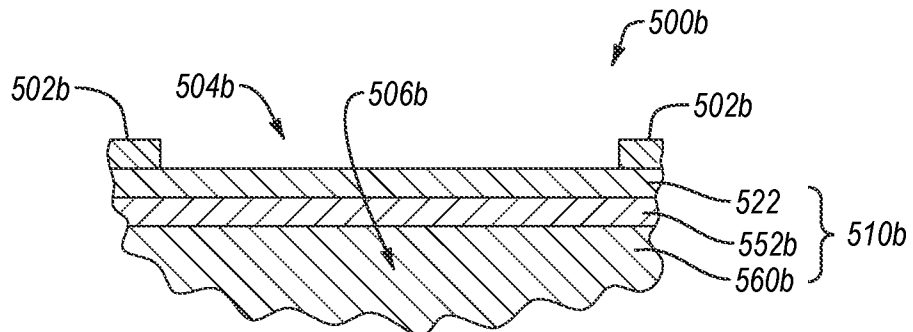


FIG. 5C

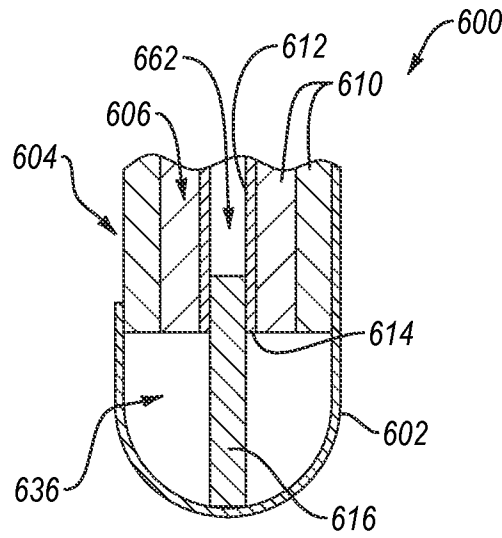


FIG. 6

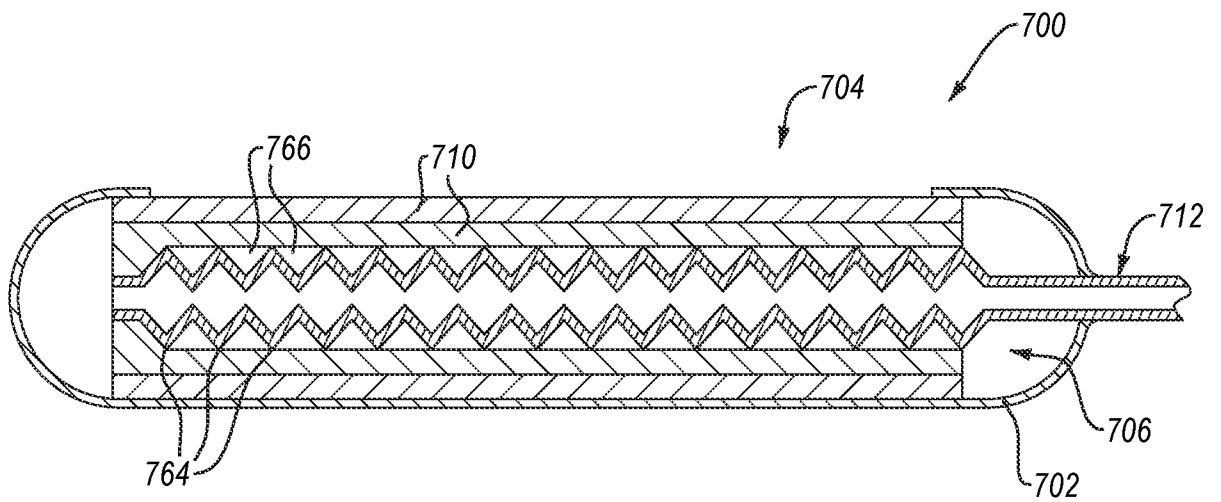


FIG. 7

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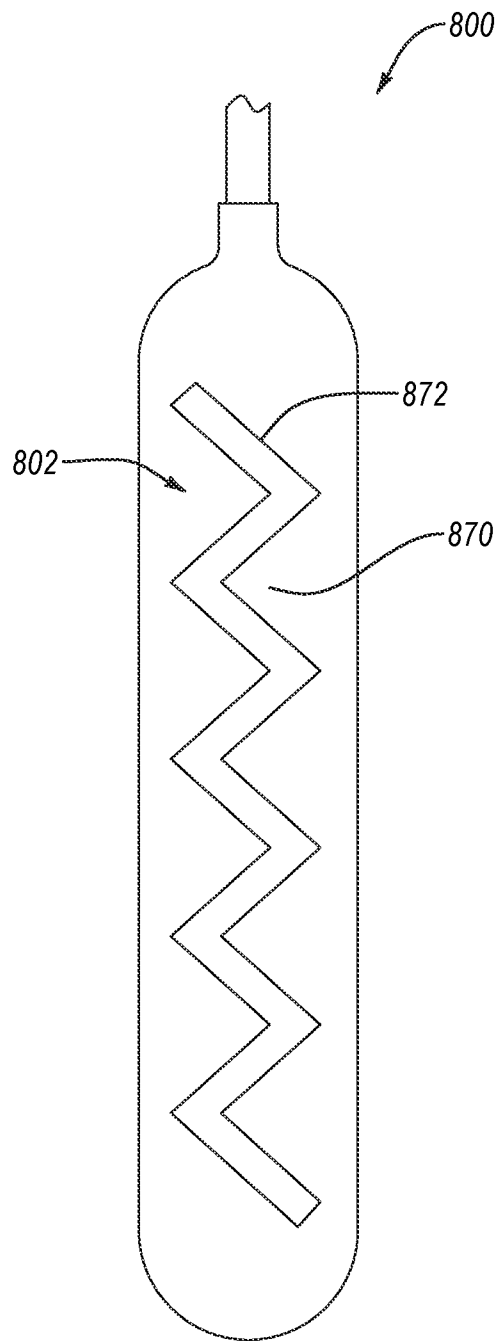


FIG. 8

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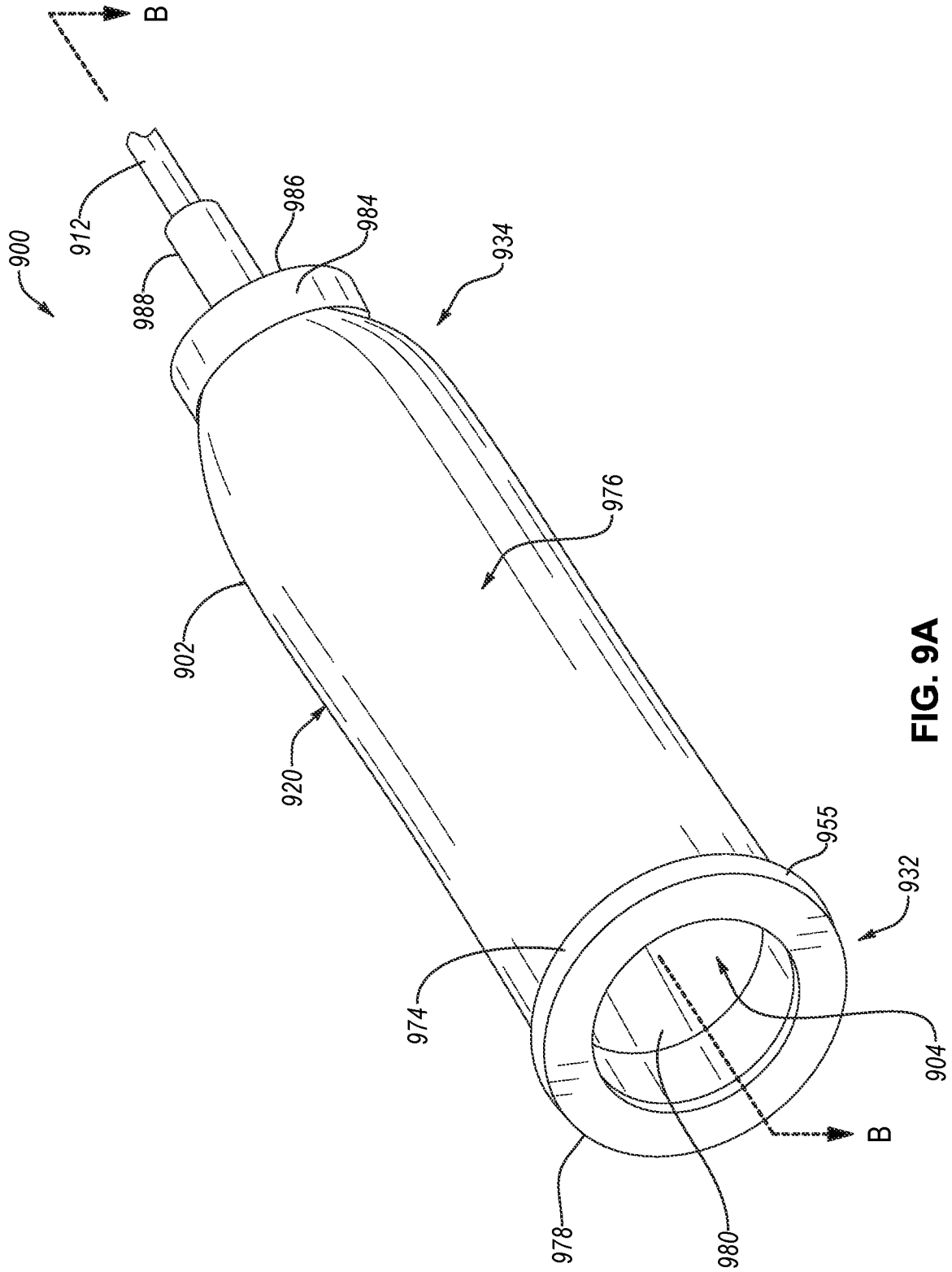


FIG. 9A

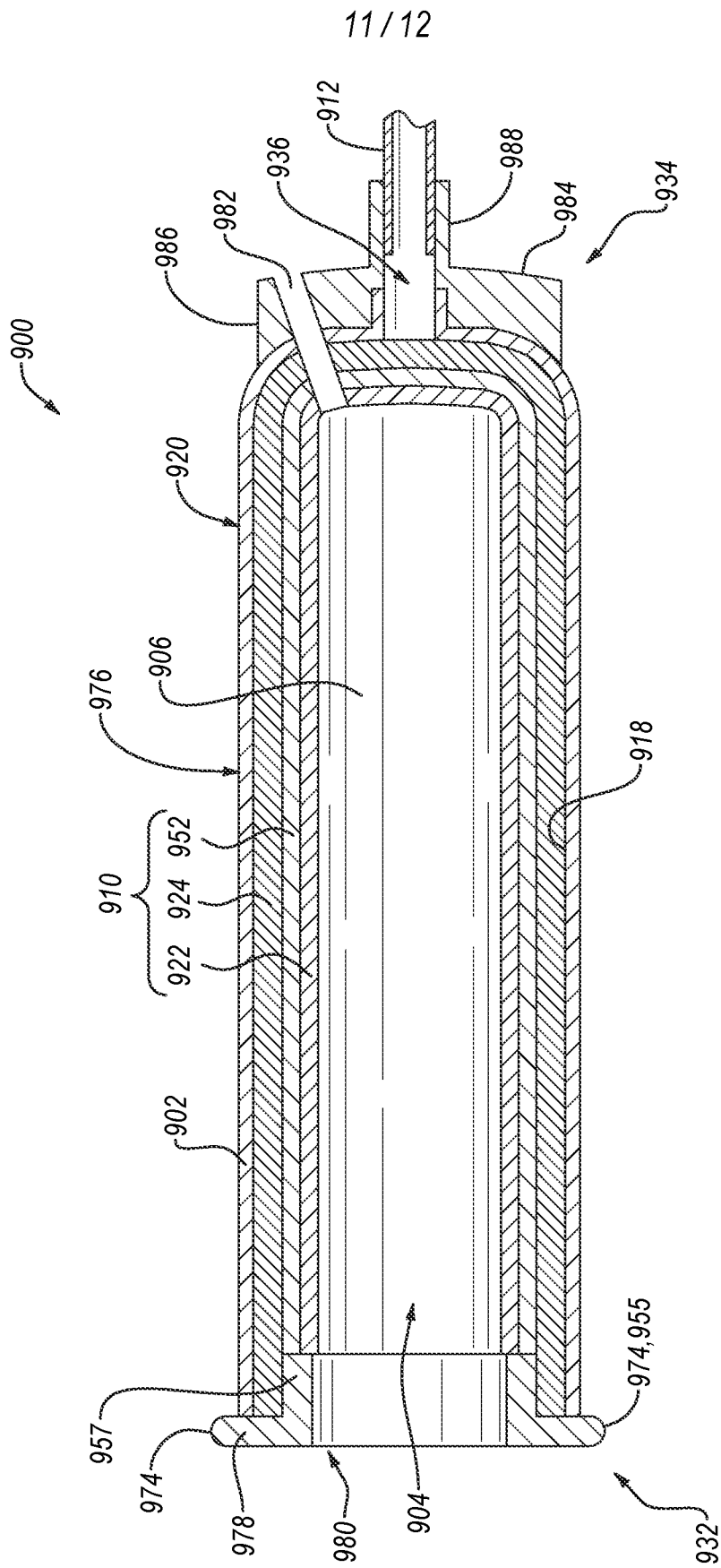


FIG. 9B

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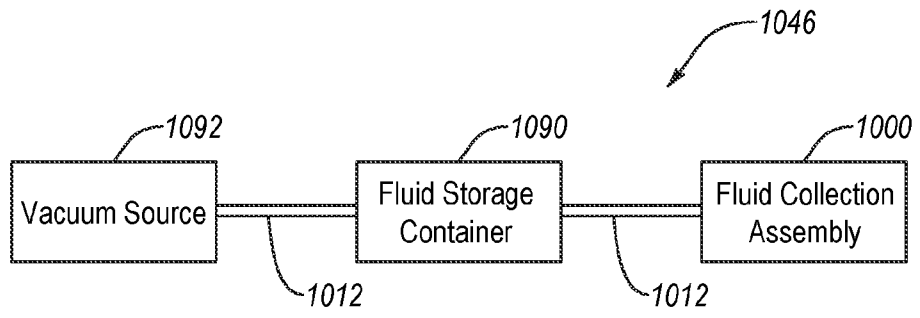


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No PCT/US2021/026607

A. CLASSIFICATION OF SUBJECT MATTER INV. A61F5/453 A61F5/455 A61F5/44 ADD.				
According to International Patent Classification (IPC) or to both national classification and IPC				
B. FIELDS SEARCHED				
Minimum documentation searched (classification system followed by classification symbols) A61F				
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				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X	WO 2019/212950 A1 (PUREWICK CORP [US]) 7 November 2019 (2019-11-07)	1,5, 10-16, 20,21		
Y	figures 1-3 paragraph [0018] paragraph [0021] - paragraph [0048] -----	8,9		
X	US 2018/028349 A1 (NEWTON CAMILLE R [US] ET AL) 1 February 2018 (2018-02-01) figures 1-3, 5-7 paragraph [0018] paragraph [0020] paragraph [0022] - paragraph [0023] paragraph [0026] - paragraph [0028] paragraph [0031] paragraph [0034] - paragraph [0035] paragraph [0037] paragraph [0048] - paragraph [0061] ----- -/--	1-5,20, 21		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.				
* Special categories of cited documents : <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> "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 </td> <td style="width: 50%; border: none; vertical-align: top;"> "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 </td> </tr> </table>			"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
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family			
Date of the actual completion of the international search	Date of mailing of the international search report			
20 July 2021	29/07/2021			
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Harnack, Hanna			

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International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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Information on patent family members

International application No

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