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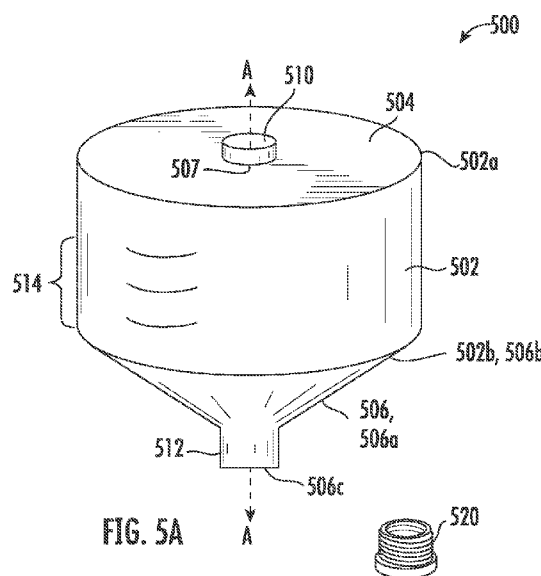
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(54) Title: EXUDATE COLLECTION CONTAINER



(57) Abstract: Various implementations include an exudate collection container that comprises a tubular shaped flexible wall having a first end and a second end that is compressible along its central axis, a first end wall coupled to the first end, and a second end wall coupled to the second end. One of the tubular shaped flexible wall or the second end wall defines a funnel shaped portion. The funnel shaped portion has a first opening coupled to the flexible wall or the second end wall and a second opening that is opposite and spaced apart from the first opening along a central axis of the funnel shaped portion. The first opening is larger than the second opening, and the second opening of the funnel shaped portion defines an outlet conduit for allowing exudate and air to exit the chamber.

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EXUDATE COLLECTION CONTAINER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/527,521, filed June 30, 2017, U.S. Provisional Application No. 62/568,067, filed October 4, 2017, and U.S. Provisional Application No. 62/649,764, filed March 29, 2018, the disclosures of which are hereby incorporated herein by reference in their entirety.

BACKGROUND

[0002] Known exudate closed drain systems include grenade, pancake, or columnar shaped flexible containers that attach to the end of a surgical drainage tube.

[0003] For example, FIG. 1 illustrates a grenade shaped flexible container, which may be referred to as a Jackson-Pratt drain. The closed drain 10 is manually squeezed to provide suction to a surgical drainage tube and remove exudate from a wound in fluid communication with the surgical drainage tube. Exudate moves through the drainage tube and into the closed drain 10. The closed drain 10 defines an opening and a rigid, plastic lip 14 that extends over the opening. The rigid, plastic lip 14 defines two ports 12a, 12b, which are located beside each other. One port 12a connects to the surgical drainage tube, and the other port 12b has an attached cap (or lid) 16 and is used for emptying exudate and air from the closed drain 10. The port 12a includes a one-way valve that prevents exudate from traveling back through the surgical drainage tube.

[0004] To empty exudate from the closed drain 10, medical staff open (or remove) the cap/lid 16 and invert the closed drain 10 over a separate measurement device (e.g., a 30mL common medicine cup). The exudate is measured in the measurement device and then disposed of in a nearby sink, toilet, or drain.

[0005] The rigid lip 14 that defines the two ports of the closed drain hinders the ability to fully empty exudate from the closed drain 10. Exudate is trapped behind a wall created by the rigid lip 14. As a result, measurements of wound exudate are inaccurate. Inaccurate wound drainage measurements potentially lead to misinformed clinical decisions about when to remove surgical drains.

[0006] FIG. 2 illustrates a HEMOVAC drain by Zimmer, which is a cylindrically shaped flexible drain 20. The drain 20 has a cylindrically shaped flexible wall 21 and two, firm planar shaped end walls 23a, 23b that define a chamber. Three metal springs are disposed between the two end walls 23a, 23b in the chamber and bias the end walls 23a, 23b apart from each other. One of the end walls 23a of the drain 20 defines a drainage tube port 22a and an outlet port 22b. A plug 26 is engaged with the outlet port 22b to prevent exudate from leaking from the drain 20, and the

plug 26 is removed to allow exudate or air to be emptied from the drain 20 through the outlet port 22b. As shown, the plug 26 is coupled to the drainage tube port 22a by a tether. To provide suction to a surgical drainage tube coupled to the drainage tube port 22a, the end walls 23a, 23b of the drain 20 are manually squeezed together while the plug 26 is disengaged from the outlet port 22b. After the walls 23a, 23b are pushed together and air is forced out of the chamber, the plug 26 is engaged into the outlet port 22b and the walls 23a, 23b are allowed to move apart from each other, which creates a suction through the drainage tube port 22a. The suction causes exudate to flow through the drainage tube and into the chamber of the drain 20. To empty exudate from the chamber of the drain 20, medical staff uncouple the plug 26 from the outlet port 22b and invert the drain 20 over a separate measurement device (e.g., a 30mL common medicine cup). The end walls 23a, 23b are then pushed toward each other to urge the exudate from the chamber of the drain 20. The exudate is measured in the measurement device and then disposed of in a nearby sink, toilet, or drain.

[0007] However, in each of these drains 10, 20, some of the exudate may get trapped in or adjacent the ports 12a, 12b, 22a, 22b which requires the medical staff to further manipulate the drain 10 (e.g., by shaking and rotating) to urge the exudate from the chamber. Even with the additional manipulation, some of the exudate cannot be removed from the chamber. As a result, measurements of wound exudate are inaccurate. Inaccurate wound drainage measurements potentially lead to misinformed clinical decisions about when to remove surgical drains. In addition, manipulation of the drain 10, 20 to urge the exudate from the chamber may also increase the risk that a health care provider would be exposed to the exudate.

[0008] Physicians may evaluate exudate amounts every 8 hours in determining the clinical necessity of surgical drains. The threshold for removing drains may depend on the drain having less than 30mL of total output in a 24-hour period. Thus, if known closed drains are retaining 1-10mL of fluid (depending on viscosity), these closed drains are impeding the accuracy of clinical decisions, which can lead to infections for patients.

[0009] Thus, there is a need for exudate collection containers that can be more fully emptied easily and consistently.

SUMMARY

[0010] Various implementations include an exudate collection container that comprises a tubular shaped flexible wall having a first end and a second end, a first end wall, and a second end wall. The first and second ends of the tubular shaped flexible wall are spaced apart and opposite each other along a central axis that extends through the first and second ends. The first end wall is coupled to the first end of the flexible wall, and the second end wall is coupled to the second

end of the flexible wall. One of the tubular shaped flexible wall or the second end wall defines a funnel shaped portion. The funnel shaped portion has a first opening coupled to the flexible wall or the second end wall and a second opening that is opposite and spaced apart from the first opening along a central axis of the funnel shaped portion. The first opening has a larger diameter than the second opening. The tubular shaped flexible wall, the first end wall, and the second end wall define a chamber for receiving and storing exudate. One of the first end wall, second end wall, or tubular shaped flexible wall defines an inlet conduit for receiving exudate into the chamber. The second opening of the funnel shaped portion defines an outlet conduit for allowing exudate and air to exit the chamber. And, the tubular shaped flexible wall is compressible along its central axis.

[0011] In some implementations, the container further includes an annular ring disposed in the chamber adjacent the second end of the tubular shaped flexible wall and the second end wall. In some implementations, the container further includes at least one spring disposed in the chamber between an annular surface of the annular ring and the first end wall. The spring biases the first end wall away from the second end wall along the central axis of the tubular shaped flexible wall. In some implementations, the annular ring is a first annular ring, and the container further comprises a second annular ring that has an annular surface that faces the annular surface of the first annular ring. The second annular ring is disposed in the chamber adjacent the first end of the tubular shaped flexible wall and the first end wall, and the at least one spring is disposed within the chamber between the annular surfaces of the first annular ring and the second annular ring.

[0012] In some implementations, the inlet conduit extends from and is integrally formed with the first end wall. In some implementations, the inlet conduit extends from and is integrally formed with the second end wall.

[0013] In some implementations, the container further comprises a threaded cap for selectively coupling with at least one of the inlet or outlet conduit. In some implementations, the threaded cap comprises a valve. The valve is selectively opened to allow fluid flow through the respective outlet or inlet conduit in one direction.

[0014] In some implementations, the container further comprises an inlet threaded cap and an outlet threaded cap. The inlet threaded cap is for coupling with the inlet conduit, and the outlet threaded cap is for coupling with the outlet conduit.

[0015] In some implementations, the flexible wall comprises a resiliently deformable material. For example, in some implementations, the resiliently deformable material is silicone rubber. And, in some implementations, the funnel shaped portion comprises a resiliently

deformable material. For example, in some implementations, the resiliently deformable material of the funnel shaped portion is silicone rubber.

[0016] In some implementations, the tubular shaped flexible wall and the funnel shaped portion are translucent or transparent. In some implementations, the tubular shaped flexible wall comprises a plurality of indicia. Each indicia is associated with a volume of fluid within the chamber.

[0017] In some implementations, the tubular shaped flexible wall and the funnel shaped portion are integrally formed from one material.

[0018] In some implementations, the tubular shaped flexible wall and the funnel shaped portion are formed separately and fused together.

[0019] In some implementations, the tubular shaped flexible wall and the first end wall are formed separately and fused together.

[0020] In some implementations, the second end wall and the funnel shaped portion are integrally formed from one material.

[0021] In some implementations, the second end wall and the funnel shaped portion are separately formed and fused together.

[0022] In some implementations, the second end wall comprises at least one protrusion that extends from the second end wall into the chamber. The protrusion is free of any recessed portions, and a first end of a spring is engaged around the protrusion. In some implementations, the protrusion comprises a conically shaped portion. And, in some implementations, the protrusion comprises a cylindrically shaped portion. In some implementations, the first end wall comprises at least one hollow cylindrically shaped protrusion that extends from the first end wall into the chamber and is axially aligned with the at least one protrusion extending from the second end wall. A second end of the spring is disposed within the at least one hollow cylindrically shaped protrusion.

[0023] In some implementations, the first end wall comprises at least one hollow cylindrically shaped protrusion that extends from the first end wall into the chamber, and a second end of a spring is disposed within the at least one hollow cylindrically shaped protrusion.

[0024] In some implementations, the outlet conduit comprises a coupling surface for sealingly coupling the outlet conduit to a second collection device. In some implementations, the coupling surface is an outer surface of the outlet conduit and defines threads that extend outwardly from the outer surface. In some implementations, the coupling surface is an inner surface of the outlet conduit and defines threads that extend inwardly from the inner surface. In some implementations, the coupling surface comprises a standard male or female Luer lock connector

coupled to the outlet conduit. In some implementations, the coupling surface comprises one or more protrusions extending outwardly from an outer surface of the outlet conduit. In some implementations, the coupling surface comprises one or more protrusions extending outwardly from an outer surface of the outlet conduit. In some implementations, the one or more protrusions comprise one or more annular rings. In some implementations, the coupling surface defines one or more recesses that extend inwardly from an outer surface of the outlet conduit. In some implementations, the coupling surface defines one or more recesses that extend outwardly from an inner surface of the outlet conduit.

[0025] In some implementations, the container comprises at least one spring disposed in the chamber between the end walls. The spring biases the end walls apart from each other, and after the end walls are compressed toward each other and cause air to flow out of the chamber, a region of low-pressure is created within the chamber when the walls expand back to a non-compressed state, which creates suction that urges exudate into the chamber via the inlet conduit.

[0026] In some implementations, the walls are compressible toward each other for urging exudate out of the chamber via the outlet conduit.

[0027] In various implementations, an exudate collection system comprises an exudate collection container and a second collection device. The exudate collection container comprises a tubular shaped flexible wall having a first end and a second end, a first end wall, and a second end wall. The first and second ends of the tubular shaped flexible wall are spaced apart and opposite each other along a central axis that extends through the first and second ends. The first end wall is coupled to the first end of the flexible wall, and the second end wall is coupled to the second end of the flexible wall. One of the tubular shaped flexible wall or the second end wall define a funnel shaped portion. The funnel shaped portion has a first opening coupled to the flexible wall or the second end wall and a second opening that is opposite and spaced apart from the first opening along a central axis of the funnel shaped portion. The first opening has a larger diameter than the second opening. The tubular shaped flexible wall, the first end wall, and the second end wall define a chamber for receiving and storing exudate. One of the first end wall, second end wall, or tubular shaped flexible wall defines an inlet conduit for receiving exudate into the chamber. The second opening of the funnel shaped portion defines an outlet conduit for allowing exudate and air to exit the chamber. And, the tubular shaped flexible wall is compressible along its central axis.

[0028] The second collection device receives exudate from the first exudate collection container. The second collection device has an inlet that has a second coupling surface. The first coupling surface of the outlet conduit and the second coupling surface of the inlet are engagable

for creating a sealed coupling through which exudate in the chamber is transferrable to the second collection device.

[0029] In some implementations, the first coupling surface is an outer surface of the outlet conduit and defines threads that extend outwardly from the outer surface, and the second coupling surface is an inner surface of the inlet of the second collection device that defines threads that extend inwardly and mate with the threads extending from the outer surface of the outlet conduit.

[0030] In some implementations, the first coupling surface is an inner surface of the outlet conduit and defines threads that extend inwardly from the inner surface, and the second coupling surface is an outer surface of the inlet of the second collection device that defines threads that extend outwardly and mate with the threads extending inwardly from the inner surface of the outlet conduit.

[0031] In some implementations, the first coupling surface comprises one of a standard male or female Luer lock connector coupled to the outlet conduit, and the second coupling surface comprises the other of the standard female or male Luer lock connector for engaging the standard male or female Luer lock connector coupled to the outlet conduit.

[0032] In some implementations, the first coupling surface comprises one or more annular rings extending outwardly from an outer surface of the outlet conduit, and the second coupling surface comprises one or more protrusions extending inwardly from an inner surface of the inlet for engaging the one or more annular rings.

[0033] In some implementations, the first coupling surface comprises one or more annular rings that extend inwardly from an inner surface of the outlet conduit, and the second coupling surface comprises one or more protrusions that extend outwardly from an outer surface of the inlet, wherein the one or more protrusions engage the one or more annular rings.

[0034] In some implementations, the first coupling surface defines one or more recesses that extend radially outwardly from an inner surface of the outlet conduit, and the second coupling surface comprises one or more protrusions that extend radially outwardly from an outer surface of the inlet of the second collection device, wherein the recesses receive the protrusions.

[0035] In some implementations, the first coupling surface defines one or more recesses extending radially inwardly from an outer surface of the outlet conduit, and the second coupling surface comprises one or more protrusions that extend radially inwardly from an inner surface of the inlet of the second collection device, wherein the recesses receive the protrusions.

[0036] In some implementations, the second collection device comprises a wall and the wall defines marks associated with a volume within the second collection device.

BRIEF DESCRIPTION OF DRAWINGS

[0037] Example features and implementations are disclosed in the accompanying drawings. However, the present disclosure is not limited to the precise arrangements and instrumentalities shown. Additionally, elements in the drawing figures are not necessarily drawn to scale.

[0038] FIG. 1 illustrates a known exudate collection device.

[0039] FIG. 2 illustrates another known exudate collection device.

[0040] FIG. 3 illustrates an exudate collection container according to one implementation.

[0041] FIG. 4 illustrates an exudate collection container according to another implementation.

[0042] FIG. 5A illustrates an exudate collection container according to one implementation.

[0043] FIG. 5B illustrates a cross sectional view of the container in FIG. 5A along the axis A-A.

[0044] FIG. 6 illustrates an exudate collection container according to another implementation.

[0045] FIG. 7A illustrates a perspective view of an exudate collection container according to another implementation.

[0046] FIG. 7B illustrates a side view of the second end wall of the container shown in FIG. 7A.

[0047] FIG. 7C illustrates a side view of the first end wall of the container shown in FIG. 7A.

[0048] FIG. 7D illustrates a cross sectional view of the first end wall of the container shown in FIG. 7A through the C-C line shown in FIG. 7C.

[0049] FIG. 7E illustrates a plan view of the first end wall of the container shown in FIG. 7A.

[0050] FIG. 8 illustrates an exudate collection container according to another implementation.

[0051] FIG. 9 illustrates an outlet conduit of an exudate collection container that includes a standard male Luer lock connector, according to one implementation.

[0052] FIG. 10 illustrates an outlet conduit of an exudate collection container that includes a standard female Luer lock connector, according to one implementation.

[0053] FIG. 11 illustrates an outlet conduit of an exudate collection container having a plurality of annular rings extending radially outwardly from an outer surface of the outlet conduit, according to one implementation.

[0054] FIG. 12 illustrates an outlet conduit of an exudate collection container having a plurality of annular rings extending radially inwardly from an inner surface of the outlet conduit, according to one implementation.

[0055] FIGS. 13A-13D illustrate various implementations of second collection devices.

[0056] FIG. 14 illustrates an external surface of an end wall of an exudate collection container according to one implementation.

DETAILED DESCRIPTION

[0057] Various implementations include an exudate collection container includes a tubular shaped flexible wall having a first end and a second end. The first end and the second end are spaced apart and opposite each other along a central axis extending through the ends. A first end wall is coupled to the first end of the flexible wall, and a second end wall is coupled to the second end of the tubular shaped flexible wall. The tubular shaped flexible wall, the first end wall, and the second end wall define a chamber for receiving and storing exudate. One of the first end wall, the second end wall, or the tubular shaped flexible walls defines an inlet conduit for receiving exudate into the chamber. And, one of the flexible wall or the second end wall of the container defines a funnel shaped portion that extends away from the flexible wall or the second end wall, respectively. The funnel shaped portion has a first opening coupled to the flexible wall or the second end wall and a second opening that is opposite and spaced apart from the first opening along a central axis of the funnel shaped portion. The first opening has a larger diameter than the second opening of the funnel shaped portion. The outlet conduit of the container includes the second opening of the funnel shaped portion through which exudate and air exit the chamber. The end walls are biased apart from each other and are compressible toward each other. Compression of the walls toward each other causes air or exudate to flow through the outlet conduit. To create a low-pressure region in the chamber, the outlet conduit is sealed after air is urged out of the chamber (e.g., using a plug or cap), and the low-pressure region is created as the end walls move back to their non-compressed positions, which creates suction that urges exudate to flow through the inlet conduit into the chamber. Sealing the outlet conduit also prevents exudate from leaking from the chamber.

[0058] In various implementations, an exudate collection system comprises the exudate collection container and a second collection device. The second collection device receives exudate from the first exudate collection container. The second collection device has an inlet that has a

second coupling surface. The first coupling surface of the outlet conduit and the second coupling surface of the inlet are engagable for creating a sealed coupling through which exudate in the chamber is transferrable to the second collection device. The second collection device allows the exudate to be more accurately measured and/or more safely disposed of, according to some implementations.

[0059] In some implementations, the outlet conduit includes a first coupling surface for coupling the outlet conduit to a second coupling surface of the inlet of the second collection device. In some implementations, the first coupling surface is an outer surface of the outlet conduit that defines one or more protrusions (e.g., helical threads, annular or semi-annular rings, tabs) that extend radially outwardly from the outer surface. In some implementations, the first coupling surface is an inner surface of the outlet conduit that defines one or more protrusions (e.g., helical threads, annular or semi-annular rings, tabs) that extend radially inwardly from the inner surface. And, in some implementations, the first coupling surface comprises a standard male (or female) Luer lock connector that is coupled to the outlet conduit. As another example, the first coupling surface comprises one or more annular rings that extend radially outwardly from an outer surface of the outlet conduit and that are axially spaced apart from each other. As another example, the one or more annular rings may extend radially inwardly from an inner surface of the outlet conduit.

[0060] In addition, other implementations include an exudate collection device that includes a flexible wall defining a chamber for receiving and storing exudate, an inlet conduit for receiving exudate into the chamber, and an outlet conduit for allowing exudate and air to exit from the chamber. The flexible wall comprises a resiliently deformable material that is biased into an expanded, or non-compressed, state and is compressible. Upon compression, air is urged out of the chamber through the outlet conduit, and the outlet conduit is sealed. After being compressed, the tendency of the wall to expand to a non-compressed state creates a region of low-pressure within the chamber, which creates suction that urges exudate into the chamber via the inlet conduit. Compression of the wall also urges exudate out of the chamber via the outlet conduit when the outlet conduit is not sealed. The flexible wall and inlet and outlet conduits are coupled together such that the transition between the inlet conduit and the surface of the chamber defined by the flexible wall and the transition between the outlet conduit and the surface of the chamber defined by the flexible wall is smooth. The smooth transitions prevent exudate from damming or ditching or becoming otherwise trapped at the transitions. In some implementations, the flexible wall and the inlet and outlet conduits are formed integrally from the resiliently deformable material during one or more molding processes. In other implementations, the flexible wall and inlet and outlet conduits are separately formed and coupled together (e.g., by fusing them) such that the transitions

between each of them and the surface of the chamber defined by the flexible wall is smooth and allows for the flexible wall to be fully collapsed. By allowing for a more complete evacuation of exudate from the bulb, a more accurate measurement of wound output may be made, which allows for more accuracy in clinical decision making. Furthermore, this increased accuracy can lead to earlier removal of the drainage tube, which can decrease the risk of infection for the patient.

[0061] FIG. 3 illustrates an exudate collection device according to one implementation. The collection device 100 includes a flexible wall 102 that defines a chamber 103 for receiving and storing exudate, an inlet conduit 104 for receiving exudate into the chamber 103, and an outlet conduit 106 for allowing exudate and air to exit from the chamber 103. The flexible wall 102, the inlet conduit 104, and the outlet conduit 106 are formed such that there is a smooth transition between the surface of the chamber 103 defined by the flexible wall 102 and the inlet conduit 104 and between the surface of the chamber 103 defined by the flexible wall 102 and the outlet conduit 106, which prevents the formation of material that can cause damming or ditching for trapping exudate. The smooth transition also allows more of or the entire wall 102 to be compressed. For example, in some implementations, the flexible wall 102 and the inlet 104 and outlet conduits 106 are formed integrally from one resiliently deformable material during one or more molding processes. Alternatively, the flexible wall 102 and inlet 104 and outlet conduits 106 may be formed separately and coupled together (e.g., by fusing them) such that the transition are smooth and do not cause damming or ditching or otherwise traps exudate and do not prevent the wall 102 from being compressed.

[0062] The resiliently deformable material of the flexible wall 102 is biased into an expanded, or non-compressed, state and is compressible. To provide suction to the inlet conduit 104, the material of the wall 102 is compressed to urge air out of the chamber through the outlet conduit 106. After being compressed, the outlet conduit 106 is sealed, and the tendency of the wall 102 to expand into a non-compressed state creates a region of low-pressure within the chamber, which creates suction that causes exudate to flow into the chamber via the inlet conduit 103. Sealing the outlet conduit 106 prevents exudate from flowing through the outlet conduit 106 during collection and concentrates the suction caused by the expansion of the wall 102 to the inlet conduit 103. To empty exudate from the chamber, the outlet conduit 106 is unsealed, and the wall 102 is compressed to urge the exudate out of the chamber 103 through the outlet conduit 106.

[0063] The flexible wall 102 shown in FIG. 3 is bulb-shaped, but the flexible wall may be shaped differently in other implementations. For example, in some implementations, the flexible wall may have any shape that does not include any sharp corners or pockets that could trap exudate.

[0064] In addition, as noted above, the flexible wall 102 and the inlet 104 and outlet conduits 106 may be made of a resiliently deformable elastomer material. Example resiliently deformable elastomer materials include natural polyisoprene (i.e., natural rubber), synthetic polyisoprene, polybutadiene, chloroprene rubber, polychloroprene, (e.g. Neoprene, Baypren, etc.), copolymers of isobutylene and isoprene, halogenated butyl rubbers, styrene-butadiene rubber, copolymers of butadiene and acrylonitrile, hydrogenated nitrile rubbers (e.g., Therban and Zetpol), ethylene propylene rubber, ethylene propylene diene rubber, epichlorohydrin rubber, polyacrylic rubber, silicone rubber, fluorosilicone rubber, fluoroelastomers (e.g., Viton, Tecnoflon, Fluorel, Aflas, and Dai-El), perfluoroelastomers (e.g., Tecnoflon, Kalrez, Chemraz, and Perlast), polyether block amides, chlorosulfonated polyethylene, and ethylene-vinyl acetate copolymers. And, in some implementations, such as shown in FIG. 3, the flexible material is transparent (or translucent, in some implementations), and indicia, such as marks 114, are provided on the flexible wall 102. The marks 114 are associated with a volume of exudate within the chamber.

[0065] The flexible wall 102 and inlet conduit 104 define an inlet opening 107 in fluid communication with the chamber 103, and the flexible wall 102 and outlet conduit 106 define an outlet opening 109 in fluid communication with the chamber 103. In the implementation shown in FIG. 1, the inlet opening 107 and the outlet opening 109 are separately defined and spaced apart from each other. And, the inlet conduit 104 and the outlet conduit 106 extend from the openings 107, 109, respectively. The inlet conduit 104 and the outlet conduit 106 extend from the flexible wall 102 adjacent each other. For example, in the implementation shown in FIG. 3, the inlet opening 107 and the outlet opening 109 are defined adjacent one end of the bulb-shaped flexible wall 102, and the inlet conduit 104 and the outlet conduit 106 extend from the respective openings 107, 109 from that end of the bulb-shaped flexible wall 102.

[0066] In addition, the container 100 further includes a cap 110 or plug for selectively coupling with the inlet 104 or outlet conduits 106 of the container 100. In some implementations, the cap 110 may form a friction fit with the outer surfaces of the conduits 104, 106, or the plug may form a friction fit with the inner surfaces of the conduits 104, 106. In other implementations, an outer surface of the inlet 104 and/or outlet conduit 106 may define threads for engaging an inner threaded surface of the cap 110. For example, the threads may be formed on the outer surface of the conduits 104, 106 during the molding process for the conduits 104, 106, or after forming of the wall 102 and inlet 104 and outlet conduits 106. In some implementations, the threaded cap 110 or plug is tethered to the wall 102.

[0067] In some implementations, the inlet opening 104 also includes a one-way valve (not shown) that prevents exudate from flowing through the surgical drainage tube toward the patient.

The outlet opening 106 may also include a one-way valve (not shown) that prevents exudate from flowing back into the chamber 103 after exiting the chamber 103 through the outlet opening 106.

[0068] The implementation of the exudate collection container 200 shown in FIG. 4 is similar to the implementation of the container 100 shown in FIG. 3, but the flexible wall 202 defines one opening 207 from which the inlet conduit 204 and the outlet conduit 206 extend. In addition, an outer surface of the outlet conduit 206 shown in FIG. 4 includes a coupling surface 208 that includes a plurality of helical threads 210 that extend radially outwardly from the outer surface. A second collection device, such as a suction-based fluid removal device (e.g., a VACUTAINER tube and tube holder or a syringe), which has an inlet with an inner surface that defines helical threads that extend radially inwardly from the inner surface, is threadingly coupled to the outlet conduit 206 by rotating the inlet of the second collection device around the threads 210. The exudate from the container 200 is then removed from the container 200 through the outlet conduit 206 and into the second collection device, where the exudate may be measured more accurately and without increasing the risk of exposure of the health care worker or environment to exudate. Examples of second collection devices are shown in FIGS. 13A-13D.

[0069] And, in the implementation shown in FIG. 4, the container 200 includes an inlet cap 211 for coupling with the inlet conduit 204 and an outlet cap 212 for coupling with the outlet conduit 206. The inlet and outlet caps 211, 212 may also be attached to the container 200 via tethers. The outlet cap 212 may have a threaded inner surface for coupling with the threads 210 on the outlet conduit 206. The inlet cap 211 may also have a threaded inner surface or outer surface for engaging a threaded outer surface or inner surface, respectively, of the inlet conduit 204. Alternatively, the caps 211, 212 may form friction fit with the respective conduits 204, 206, or have one or more protrusions or recesses for engaging one or more recesses or protrusions of the respective conduits 204, 206. And, in other implementations, the container 200 may include plugs that are received within the inlet and/or outlet conduits.

[0070] The containers 100, 200 described above are more effective at removing exudate than known containers. To evaluate the efficacy of the collection containers as compared to the known collection container, such as the known collection container shown in FIG. 1, each empty collection container 10, 100 was weighed, and the weights of each were recorded. Then, each collection container 10, 100 was filled with approximately 20mL of water and weighed again. Next, the water was urged out of the collection containers 10, 100 by squeezing the containers, such as a medical professional would do in the hospital setting. Then, the containers 10, 100 were weighed again with whatever residual water remained in them. The difference in the weights of

the empty containers were compared with the weights of the containers with whatever residual water remained in them.

[0071] In this water experiment, the known closed drain 10 retained between 0.5 grams and 1.1 grams of residual water. However, the collection container 100 retained between 0.02 grams and 0.2 grams of residual water. Thus, the collection container 100 is between 5.5 and 25 times more effective than the known closed drain 10 for evacuating fluids having a viscosity similar to water.

[0072] To test the efficacy of the collection container 100 with fluids having a higher viscosity than water, the above experiment was repeated with 20 mL of PURELL hand sanitizer, which has a higher viscosity than water. In this experiment, the known closed drain 10 retained 10.899 grams of residual hand sanitizer, and the collection container 100 retained 6.293 grams of residual hand sanitizer. Thus, for a fluid having a viscosity similar to PURELL hand sanitizer, the collection device 100 was 1.7 times more effective than the closed drain 10.

[0073] FIGS. 5A and 5B illustrate an exudate collection container according to one implementation. The collection container 500 includes a tubular shaped flexible wall 502, a first end wall 504, and a second end wall 506 that defines a funnel shaped portion 506a. The flexible wall 502 includes a first end 502a and a second end 502b that are spaced apart along a central axis A-A extending through the first 502a and second ends 502b. The first end wall 504 is coupled to the first end 502a, and the second end wall 506 is coupled to the second end 502b. The flexible wall 502, the first end wall 504, and the second end wall 506 define a chamber 503 for receiving and storing exudate. The funnel shaped portion 506a has a first opening 506b that has a first diameter and a second opening 506c that has a second diameter. The first diameter is larger than the second diameter. The second end 502b of the tubular shaped flexible wall 502 defines the first opening 506b of the funnel shaped portion 106a such that the funnel shaped portion 506a is also the second end wall 506. The first opening 506b and the second opening 506c of the funnel shaped portion 506a are spaced apart along the central axis A-A.

[0074] In the implementation shown in FIGS. 5A and 5B, the first opening 506b of the funnel shaped portion 506a has an inner diameter that substantially matches the inner diameter of the second end 502b of the tubular shaped flexible wall 502. However, in other implementations, such as shown in FIG. 7A-7B, the first opening of the funnel shaped portion 406a may be defined by a stiff, planar shaped second end wall 406 that extends radially inwardly from the second end 402b of the tubular shaped flexible wall 402.

[0075] As used herein, “funnel shaped portion” refers to a portion of the container that tapers radially inwardly toward a central axis of the funnel shaped portion as the surface of the

portion extends away from the chamber of the container. For example, the funnel shaped portion may have a continuously tapering frusto-conical shape, such as shown in FIG. 6, or the funnel shaped portion may have a frusto-conically shaped portion adjacent the second end wall (or the tubular shaped flexible wall) and a cylindrically shaped portion extending from a distal end of the frusto-conically shaped portion, such as is shown in FIGS. 5A-5B, 7A-7E, and 8.

[0076] The first end wall 504 defines an inlet conduit 510 for receiving exudate into the chamber 503, and the funnel shaped portion 506a defines an outlet conduit 512 for allowing exudate and air to exit from the chamber 503. In other implementations, the inlet conduit may be defined on the second end wall or the tubular shaped flexible wall, and the inlet conduit and the funnel shaped portion may be defined on the same or different walls of the container.

[0077] The funnel shaped portion 506a and the outlet conduit 512 are formed such that there is a smooth transition between the outlet conduit 512 and the funnel shaped portion 506a, which prevents the formation of material that can cause damming or ditching for trapping exudate. Furthermore, the second end wall 506 and the flexible wall 502 are coupled together such that there is a smooth transition between the second end wall 506 and the flexible wall 502, which prevents the formation of material that can cause damming or ditching for trapping exudate. In some implementations, the second end wall 506 and the flexible wall 502 are separately formed and fused together. And, in other implementations, the second end wall 506 and the flexible wall 502 are integrally formed.

[0078] In addition, in some implementations, the first end wall 504 and the inlet conduit 510 are formed such that there is a smooth transition between the inlet conduit 510 and the first end wall 504. And, in some implementations, the first end wall 504 and the flexible wall 502 are separately formed and fused together to create a smooth transition.

[0079] In the implementation shown in FIGS. 5A and 5B, the funnel shaped portion 506a and the first end wall 504 are relatively stiff. For example, the funnel shaped portion 506a and the first end wall 504 may be formed of a stiff material, or the funnel shaped portion 506a and the first end wall 504 may include a stiff insert (e.g., a cardboard or metal insert) covered by a polymer material that prevents fluid leakage or absorption by the insert. One or more helical compression springs 540 are disposed between the funnel shaped portion 506a and the first end wall 504. The one or more springs 540 bias the first end wall 504 away from the first opening 506b of the funnel shaped portion 506a along the axis A-A.

[0080] In addition, an inner surface of the outlet conduit 512 is a coupling surface 508 that defines threads 512a that extend radially inwardly from the inner surface. Threads defined on an outer surface of an inlet of a second collection device (e.g., a suction-based fluid removal device,

such as a VACUTAINER tube and tube holder or a syringe) engage with the threads 512a of the outlet conduit 512 to couple the second collection device to the outlet conduit 512. For example, the coupling surface 1311 of the second collection device 1310 shown in FIG. 13C can be engaged with the coupling surface 508 of the exudate collection container 500. The exudate from the container 500 is then removed from the container 500 through the outlet conduit 506 and into the second collection device, where the exudate may be measured more accurately and without increasing the risk of exposure of the health care worker or environment to exudate. However, in other implementations, the inner surface of the outlet conduit 512 is smooth. Examples of second collection devices are shown in FIGS. 13A-13D.

[0081] FIGS. 7A-7E illustrate an implementation of a drain 400 in which the first opening 406b of the funnel shaped portion 406a is defined by a stiff, planar shaped second end wall 406 that extends radially inwardly from the second end 402b of the tubular shaped flexible wall 402. The funnel shaped portion 406a defines an outlet conduit 406c that extends from an external surface of the funnel shaped portion 406a and protrusions 415 that extend into the chamber 403 from an inner surface of the funnel shaped portion 406a. In addition, the first end wall 404 also defines protrusions 417 that extend into the chamber 403 and axially align with the protrusions 415. Ends of each spring 440 engage each set of aligned protrusions 415, 417, and the protrusions 415, 417 prevent non-axial movement of the ends of the spring 440. The protrusions 415 have a cylindrical base portion extending from the second end wall 406 and a conical portion that extends distally from the cylindrical base portion into the chamber 403. The end of each spring 440 fits around each respective protrusion 415. FIG. 7B illustrates a side view of the second end wall 406 shown in FIG. 7A that shows protrusions 415. The protrusions 417 are hollow cylindrical shaped protrusions that extend from the first end wall 404 into the chamber 403, and the other end of each spring 440 is disposed within a recess defined by the hollow cylindrical shaped protrusions 417. FIGS. 7C-7E illustrate various views of the protrusions 417 and the first end wall 404.

[0082] In addition, at least a portion of an outer surface of a cylindrical portion 406d of the funnel shaped portion 406a is a coupling surface 408 that includes threads 412 that extend radially outwardly from the coupling surface 408. Threads defined on an inner surface of an inlet of a second collection device (e.g., a suction-based fluid removal device, such as a VACUTAINER tube and tube holder or a syringe) engage with the threads 412 to couple the second collection device to the coupling surface 408. The exudate from the container 400 is then removed from the container 400 through the outlet conduit 406c and into the second collection device, where the exudate may be measured more accurately and without increasing the risk of exposure of the health care worker or environment to exudate. However, in other implementations, the outer surface of

the cylindrical portion 406d is smooth. Examples of second collection devices are shown in FIGS. 13A-13D.

[0083] In addition, in the implementation shown in FIG. 7A, the inlet opening 410 is defined on the second end wall 406.

[0084] In other implementations (not shown), the protrusions 415 may extend from the planar portion of the second end wall 406. And, in other implementations, the protrusions 417 may include solid cylindrical and/or conical portions around which the end of the spring 440 may be engaged. The cylindrical and conical portions of the protrusions 415 and the solid surface of the protrusions 415 defined by each portion prevent exudate from being trapped by the protrusions 415. In other implementations, the protrusions 415 may only include a conical portion or only include a cylindrical portion.

[0085] In one experiment, the drain shown in FIGS. 7A-7E was 18.53% more effective at eliminating a relatively viscous mixture of PURELL antibacterial gel and paper towel balls (for mimicking clots) than prior art drains.

[0086] In other implementations, such as shown in FIG. 8, the funnel shaped portion 806a may be formed of a flexible material, such as the flexible material of the tubular shaped flexible wall 802. In certain implementations, the drain 800 further includes an annular ring 830 that is disposed adjacent a transition between the first opening 806b of the funnel shaped portion 806a and the second end 802b of the tubular shaped flexible wall 802. The one or more springs 840 are disposed between an annular surface of this annular ring 830 and the first end wall 804. The annular surface of the annular ring 830 is sufficiently stiff to support the one or more springs 80. In some implementations, the annular ring 830 may be covered by the flexible material forming the tubular shaped flexible wall 802 or be disposed within an inner diameter of the tubular shaped flexible wall 802. The annular ring 830 may also be provided in the implementation shown in FIGS. 5A and 5B and described above. The annular ring 830 has an inner diameter that is smaller than the inner diameter of the first opening 806b of the funnel shaped portion 806a and the inner diameter of the second end 802b of tubular shaped flexible wall 802. In some implementations, the annular ring 80 is a resiliently deformable ring, such as a rubber o-ring or square ring. However, in other implementations, the annular ring 830 is formed from a material that is stiffer than rubber and/or is not resiliently deformable.

[0087] The implementation shown in FIG. 8 also includes a second annular ring 835 that is disposed between the transition between the first end wall 804 and the first opening 802a of the flexible wall 802. The second annular ring 835 may be covered by the flexible material forming the flexible wall 802 or may be disposed within the inner diameter of the flexible wall 802. The

second annular ring 835 has an inner diameter that is smaller than the outer diameter of the first end wall 804 and the inner diameter of the first end 802a of the tubular shaped flexible wall 802. The annular surface of the annular ring 835 that faces the annular surface of the annular ring 830 is sufficiently stiff to support the one or more springs 840. In some implementations, the second annular ring 835 is a compressible, resiliently deformable ring, such as a rubber o-ring or square ring. However, in other implementations, the annular ring 835 is formed from a material that is stiffer than rubber and/or is not resiliently deformable. The one or more springs 840 extend between facing annular surfaces of the annular rings 830, 835 to urge the first 804 and second end walls 806 apart.

[0088] The tubular shaped flexible walls 402, 502, 602, 802 are cylindrically shaped, but the tubular shaped flexible wall may be shaped differently in other implementations, such as any tubular shape that does not include any sharp corners that cannot be collapsed or pockets that could trap exudate (e.g., triangular, rectangular, pentagonal, hexagonal, etc.). In addition, the first end walls 404, 504, 604, 804 are shown as planar, but the first end wall can have any other suitable shape.

[0089] The flexible walls 402, 502, 602, 802 comprise a deformable material. In one implementation, the deformable material is also resiliently deformable in that it is biased into an expanded, or non-compressed, state and is compressible. Upon compression, the tendency of the walls 402, 502, 602, 802 to expand back to a non-compressed state creates a low-pressure region within the chamber, which creates suction that urges exudate into the chamber via the inlet conduit. Compressing the walls 402, 502, 602, 802 also urges exudate out of the chamber via the outlet conduit. In some implementations, the flexible wall is made of one or more resiliently deformable elastomer materials. Example resiliently deformable elastomer materials include natural polyisoprene (i.e., natural rubber), synthetic polyisoprene, polybutadiene, chloroprene rubber, polychloroprene, (e.g. Neoprene, Baypren, etc.), copolymers of isobutylene and isoprene, halogenated butyl rubbers, styrene-butadiene rubber, copolymers of butadiene and acrylonitrile, hydrogenated nitrile rubbers (e.g., Therban and Zetpol), ethylene propylene rubber, ethylene propylene diene rubber, epichlorohydrin rubber, polyacrylic rubber, silicone rubber, fluorosilicone rubber, fluoroelastomers (e.g., Viton, Tecnoflon, Fluorel, Aflas, and Dai-El), perfluoroelastomers (e.g., Tecnoflon, Kalrez, Chemraz, and Perlast), polyether block amides, chlorosulfonated polyethylene, and ethylene-vinyl acetate copolymers. In some implementations, the funnel shaped portion is also made of one or more resiliently deformable elastomer materials.

[0090] And, in some implementations, the material for the flexible wall is transparent (or translucent, in some implementations), and indicia, such as marks 514 shown in FIGS. 5A and 5B,

are provided on the flexible wall. The marks 514 are associated with a volume of exudate within the chamber 503. In addition, in some implementations, the first end wall 504 and/or the second end wall 506 is transparent (or translucent in some implementations), which allows the user to examine the exudate for clots or other material.

[0091] Referring to FIGS. 5A and 5B, the first end wall 504 and the inlet conduit 510 define an inlet opening 507 in fluid communication with the chamber 503, and the funnel shaped portion 506a and the outlet conduit 512 define an outlet opening 509 in fluid communication with the chamber 503. The inlet conduit 510 and the outlet conduit 512 extend from the openings 507, 509, respectively.

[0092] In addition, the container 500 further includes a cap or plug 520 for selectively coupling with the inlet 510 or outlet conduit 512 of the container 500. For example, in some implementations, the plug 520 may form a friction fit with the inner surfaces of the conduits 510, 512, or the cap may form a friction fit with an outer surface of the inlet 510 and/or outlet conduit 512. In other implementations, an inner surface of the inlet 510 and/or outlet conduit 512 may define threads for engaging an outer threaded surface of the plug 520. The threads may be formed on the inner surface of the conduits 510, 512 during the molding process for the conduits 510, 512, or after forming of the first end wall 504 and inlet conduit 510 or after forming the second end wall 506, the funnel shaped portion 506a, and the outlet conduit 512, for example. In some implementations, the cap or plug 520 is tethered to at least one of the walls 502, 504, 506. And, in other implementations, an inlet cap or plug is provided for coupling with the inlet conduit and an outlet cap or plug is provided for coupling with the outlet conduit. The inlet and outer caps or plugs may also be attached to the container via tethers.

[0093] In some implementations, the inlet opening 507 also includes a one-way valve (not shown) that prevents exudate from flowing through the surgical drainage tube toward the patient. The outlet opening 509 may also include a one-way valve (not shown) that prevents exudate from flowing back into the chamber 503 after exiting the chamber 503 through the outlet opening 509.

[0094] FIG. 6 illustrates another implementation of an exudate collection container 600 that is similar to the exudate collection container 500 described above in relation to FIGS. 5A and 5B except that the tubular shaped flexible wall 602 defines a funnel shaped portion 602c, and the second end wall 606 is planar shaped. The one or more springs are disposed between the first end wall 604 and the second end wall 606. For example, the one or more springs may be disposed between the inner surfaces of the walls 604, 606 or between annular surfaces of rings, such as rings (not shown in FIG. 6) that are disposed adjacent the respective transitions between the flexible wall 602 and the end walls 604, 606. The funnel shaped portion 602c has a first opening 607 that

is defined by the flexible wall 602 and a second opening 609 that is opposite and spaced apart from the first opening 607. The openings 607, 609 are spaced apart along a central axis B-B of the funnel shaped portion 602c, which is disposed transversely to the central axis A-A of the tubular shaped flexible wall 602.

[0095] In the implementations shown in FIGS. 4, 5B, and 7A, coupling surfaces 208, 508, 408 define threads that extend from the coupling surfaces. However, in other implementations, other types of protrusions and/or recesses may be defined by the coupling surfaces. For example, as shown in FIG. 11, the coupling surface of an outlet conduit 706 includes one or more annular rings 710 that extend from an outer surface of the outlet conduit 706. In the implementation shown in FIG. 12, the coupling surface includes one or more annular rings 1210 that extend from an inner surface of the outlet conduit 1206. While annular rings are described as a type of protrusion, other types of protrusions may be used, such as one or more semi-annular rings, tabs, or hemispherical protrusions. Furthermore, the protrusions may have a semi-circular shaped cross section as viewed through a plane that bisects the outlet conduit along its central axis. In other implementations, the cross-sectional shape of the protrusions may be semi-spherical, triangular, rectangular, trapezoidal, or other suitable polygonal shape.

[0096] FIG. 14 illustrates an end wall 1106 of an exudate collection container similar to those described above in relation to FIGS. 5A-5B, 7A-7B, and 8. In the implementation shown in FIG. 14, the coupling surface of the outlet conduit 1106c includes one or more flanges 1110 that extend radially outwardly from at least a portion of an external surface of the outlet conduit 1106c. As shown in FIG. 14, the flange 1110 extends from a distal end of the outlet conduit 1106c, but in other implementations, the flange 1110 can be disposed along the axial length of the outlet conduit 1106c. In addition, the flange 1110 includes two portions that are disposed 180° apart from each other, but in other implementations, the flange may include one or more portions that are circumferentially spaced about the external surface of the conduit 1106c. For example, the flange (or portions thereof) may be fully or semi-annular. And, in some implementations, the flange(s) may extend radially inwardly from an inner surface of the outlet conduit 1106c.

[0097] In some implementations, the inlet of a second collection device to be coupled to the outlet conduit of the primary collection device has one or more annular rings extending from the other of the inner surface of the inlet or the outer surface of the inlet of the second collection device, which is pushed axially past the one or more annular rings of the outlet conduit to couple the inlet of the second collection device to the primary collection container. The coupling surface may be coupled with a corresponding coupling surface of a second collection device such that exudate from the exudate collection container may be removed from the exudate collection

container and be more accurately measured and/or more safely disposed of using the second collection device. In other implementations, one or more of the coupling surfaces may include one or more protrusions that engage each other. And, in other implementations, one of the coupling surfaces may include one or more protrusions that engage one or more annular rings extending from the other coupling surface.

[0098] In the implementation shown in FIG. 9, the outlet conduit 906 of the primary collection device includes a standard male Luer lock connector 910, and the inlet of the second collection device includes a standard female Luer lock connector for coupling with the male Luer lock connector 910. And, in the implementation shown in FIG. 10, the outlet conduit 1006 of the primary collection device includes a standard female Luer lock connector 1010, and the inlet of the second collection device includes a standard male Luer lock connector for coupling with the female Luer lock connector 1010.

[0099] Furthermore, in some implementations, an exudate collection system is provided that includes an exudate collection container defining a chamber and comprising an inlet conduit and an outlet conduit (e.g., the exudate collection containers described above in relation to FIGS. 1-12) and a second collection device. The second collection device may include any suitable collection device for coupling with the outlet conduit of the exudate collection device for receiving exudate from the exudate collection container. For example, the second collection device may include a suction-based fluid removal device (e.g., a VACUTAINER tube and tube holder or a syringe). FIGS. 13A-13D illustrate various implementations of second collection devices 1310. For example, FIG. 13A illustrates a syringe (e.g., a MONOJECT syringe by Covidien) having an inlet 1312 that includes a coupling surface 1311 for mating with the coupling surface of the outlet conduit of the exudate collection container. The coupling surface 1311 of the syringe is a male luer lock connector and can be coupled to a female luer lock connector of the outlet conduit of the exudate collection container. However, the coupling surfaces of the inlet of the second collection device and the outlet conduit of the exudate collection container may be, for example, any of the coupling surfaces described above in relation to FIGS. 4, 5A, 7A, and 9-12. FIGS. 13B-13D illustrate other examples of suitable second collection devices 1310. Each of these devices 1310 include a vacuum (or low pressure) tube 1318 and tube holder 1320, such as the VACUTAINER tubes and tube holders produced by Becton Dickinson. The tube holder 1320 of each device 1310 includes the inlet 1312 with the coupling surface 1311 for coupling to the coupling surface of the exudate collection container. A needle 1321 extends through the inlet 1312 and a rubber stopper 1322 disposed at the end of the tube 1318. The exudate in the exudate collection container flows from the exudate collection container through the needle 1321 and into the tube 1318. The interior

of the tube 1318 is a vacuum or has relatively lower pressure than the exudate collection container such that exudate from the exudate collection container flows through the needle 1321 into the tube 1318. The coupling surface 1311 of the inlet 1312 shown in FIG. 13B is a male luer lock connector. The coupling surface 1311 of the inlet 1312 shown in FIG. 13C includes external threads on an external surface of the inlet 1312. And, the coupling surface 1311 of the inlet 1312 shown in FIG. 13D includes two flanges that extend outwardly from the external surface of the inlet 1312 180 degrees apart.

[00100] The coupling between the outlet conduit and the inlet 1312 of the second collection device 1310 creates a closed system for transferring at least a portion of the exudate in the chamber of the exudate collection container to the second collection device 1310. The exudate collection device coupling surface may be coupled with a corresponding coupling surface of a second collection device 1310 such that exudate from the exudate collection container may be removed from the exudate collection container and be more accurately measured and/or more safely disposed of using the second collection device 1310. In some implementations, the second collection device 1310 may include indicia, such as marks, on a wall of the second collection device. For example, as shown in FIG. 13A and 13C-13D, indicia 1314 are provided on wall 1316 of the syringe and tubes. The indicia 1314 are associated with a volume of exudate within the second collection device 1310.

[00101] Certain terminology is used herein for convenience only and is not to be taken as a limitation on the present claims. In the drawings, the same reference numbers are employed for designating the same elements throughout the several figures. A number of examples are provided, nevertheless, it will be understood that various modifications can be made without departing from the spirit and scope of the disclosure herein. As used in the specification, and in the appended claims, the singular forms “a,” “an,” “the” include plural referents unless the context clearly dictates otherwise. The term “comprising” and variations thereof as used herein is used synonymously with the term “including” and variations thereof and are open, non-limiting terms. Although the terms “comprising” and “including” have been used herein to describe various implementations, the terms “consisting essentially of” and “consisting of” can be used in place of “comprising” and “including” to provide for more specific implementations and are also disclosed.

[00102] A number of implementations have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the claims. Accordingly, other implementations are within the scope of the following claims.

[00103] Disclosed are materials, systems, devices, methods, compositions, and components that can be used for, can be used in conjunction with, can be used in preparation for, or are products

of the disclosed methods, systems, and devices. These and other components are disclosed herein, and it is understood that when combinations, subsets, interactions, groups, etc. of these components are disclosed that while specific reference of each various individual and collective combinations and permutations of these components may not be explicitly disclosed, each is specifically contemplated and described herein. For example, if a device is disclosed and discussed each and every combination and permutation of the device, and the modifications that are possible are specifically contemplated unless specifically indicated to the contrary. Likewise, any subset or combination of these is also specifically contemplated and disclosed. This concept applies to all aspects of this disclosure including, but not limited to, steps in methods using the disclosed systems or devices. Thus, if there are a variety of additional steps that can be performed, it is understood that each of these additional steps can be performed with any specific method steps or combination of method steps of the disclosed methods, and that each such combination or subset of combinations is specifically contemplated and should be considered disclosed.

CLAIMS

1. An exudate collection container, the exudate collection container comprising:
 - a tubular shaped flexible wall having a first end and a second end, the first and second ends being spaced apart and opposite each other along a central axis that extends through the first and second ends;
 - a first end wall coupled to the first end of the flexible wall; and
 - a second end wall coupled to the second end of the flexible wall,wherein one of the tubular shaped flexible wall or the second end wall define a funnel shaped portion, the funnel shaped portion having a first opening coupled to the flexible wall or the second end wall and a second opening that is opposite and spaced apart from the first opening along a central axis of the funnel shaped portion, the first opening having a larger diameter than the second opening,
 - wherein:
 - the tubular shaped flexible wall, the first end wall, and the second end wall define a chamber for receiving and storing exudate,
 - one of the first end wall, second end wall, or tubular shaped flexible wall defines an inlet conduit for receiving exudate into the chamber,
 - the second opening of the funnel shaped portion defines an outlet conduit for allowing exudate and air to exit the chamber, and
 - the tubular shaped flexible wall is compressible along its central axis.
2. The container of claim 1, further comprising an annular ring disposed in the chamber adjacent the second end of the tubular shaped flexible wall and the second end wall.
3. The container of claim 2, further comprising at least one spring disposed in the chamber between an annular surface of the annular ring and the first end wall, the spring biasing the first end wall away from the second end wall along the central axis of the tubular shaped flexible wall.

4. The container of claim 3, wherein the annular ring is a first annular ring, and the container further comprises a second annular ring having an annular surface that faces the annular surface of the first annular ring, the second annular ring being disposed in the chamber adjacent the first end of the tubular shaped flexible wall and the first end wall, and the at least one spring is disposed within the chamber between the annular surfaces of the first annular ring and the second annular ring.
5. The container of claim 1, wherein the inlet conduit extends from and is integrally formed with the first end wall.
6. The container of claim 1, wherein the inlet conduit extends from and is integrally formed with the second end wall.
7. The container of claim 1, further comprising a threaded cap for selectively coupling with at least one of the inlet or outlet conduit.
8. The container of claim 7, wherein the threaded cap comprises a valve, the valve being selectively opened to allow fluid flow through the respective outlet or inlet conduit in one direction.
9. The container of claim 1, further comprising an inlet threaded cap and an outlet threaded cap, the inlet threaded cap for coupling with the inlet conduit, and the outlet threaded cap for coupling with the outlet conduit.
10. The container of claim 1, wherein the flexible wall comprises a resiliently deformable material.
11. The container of claim 10, wherein the resiliently deformable material is silicone rubber.
12. The container of claim 1, wherein the funnel shaped portion comprises a resiliently deformable material.
13. The container of claim 12, wherein the resiliently deformable material is silicone rubber.

14. The container of claim 1, wherein the tubular shaped flexible wall and the funnel shaped portion are translucent or transparent.
15. The container of claim 14, wherein the tubular shaped flexible wall comprises a plurality of indicia, each indicia associated with a volume of fluid within the chamber.
16. The container of claim 1, wherein the tubular shaped flexible wall and the funnel shaped portion are integrally formed from one material.
17. The container of claim 1, wherein the tubular shaped flexible wall and the funnel shaped portion are formed separately and fused together.
18. The container of claim 1, wherein the tubular shaped flexible wall and the first end wall are formed separately and fused together.
19. The container of claim 1, wherein the second end wall and the funnel shaped portion are integrally formed from one material.
20. The container of claim 1, wherein the second end wall and the funnel shaped portion are separately formed and fused together.
21. The container of claim 1, wherein the second end wall comprises at least one protrusion that extends from the second end wall into the chamber, the at least one protrusion being free of any recessed portions, and a first end of a spring is engaged around the protrusion.
22. The container of claim 21, wherein the protrusion comprises a conically shaped portion.
23. The container of any one of claim 21 or 22, wherein the protrusion comprises a cylindrically shaped portion.

24. The container of claim 21, wherein the first end wall comprises at least one hollow cylindrically shaped protrusion that extends from the first end wall into the chamber and is axially aligned with the at least one protrusion extending from the second end wall, wherein a second end of the spring is disposed within the at least one hollow cylindrically shaped protrusion.
25. The container of claim 1, wherein the first end wall comprises at least one hollow cylindrically shaped protrusion that extends from the first end wall into the chamber, wherein a second end of a spring is disposed within the at least one hollow cylindrically shaped protrusion.
26. The container of claim 1, wherein the outlet conduit comprises a coupling surface for sealingly coupling the outlet conduit to a second collection device.
27. The container of claim 26, wherein the coupling surface is an outer surface of the outlet conduit and defines threads that extend outwardly from the outer surface.
28. The container of claim 26, wherein the coupling surface is an inner surface of the outlet conduit and defines threads that extend inwardly from the inner surface.
29. The container of claim 26, wherein the coupling surface comprises a standard male or female Luer lock connector coupled to the outlet conduit.
30. The container of claim 26, wherein the coupling surface comprises one or more protrusions extending outwardly from an outer surface of the outlet conduit.
31. The container of claim 26, wherein the coupling surface comprises one or more protrusions extending outwardly from an outer surface of the outlet conduit.
32. The container of any one of claims 30-31, wherein the one or more protrusions comprise one or more annular rings.
33. The container of claim 26, wherein the coupling surface defines one or more recesses that extend inwardly from an outer surface of the outlet conduit.

34. The container of claim 26, wherein the coupling surface defines one or more recesses that extend outwardly from an inner surface of the outlet conduit.

35. The container of claim 1, further comprising at least one spring disposed in the chamber between the end walls, wherein the spring biases the end walls apart from each other, and wherein after the end walls are compressed toward each other and cause air to flow out of the chamber, a region of low-pressure is created within the chamber when the walls expand back to a non-compressed state, which creates suction that urges exudate into the chamber via the inlet conduit.

36. The container of claim 35, wherein the walls are compressible toward each other for urging exudate out of the chamber via the outlet conduit.

37. An exudate collection system, the system comprising:

an exudate collection container comprising:

a tubular shaped flexible wall having a first end and a second end, the first and second ends being spaced apart and opposite each other along a central axis that extends through the first and second ends;

a first end wall coupled to the first end of the flexible wall; and

a second end wall coupled to the second end of the flexible wall,

wherein one of the tubular shaped flexible wall or the second end wall define a funnel shaped portion, the funnel shaped portion having a first opening coupled to the flexible wall or the second end wall and a second opening that is opposite and spaced apart from the first opening along a central axis of the funnel shaped portion, the first opening having a larger diameter than the second opening,

wherein:

the tubular shaped flexible wall, the first end wall, and the second end wall define a chamber for receiving and storing exudate,

one of the first end wall, second end wall, or tubular shaped flexible wall defines an inlet conduit for receiving exudate into the chamber,

the second opening of the funnel shaped portion defines an outlet conduit for allowing exudate and air to exit the chamber, and

the tubular shaped flexible wall is compressible along its central axis; and

a second collection device for receiving exudate from the first exudate collection container, the second collection device having an inlet, the inlet having a second coupling surface,
wherein the first coupling surface of the outlet conduit and the second coupling surface of the inlet are engagable for creating a sealed coupling through which exudate in the chamber is transferrable to the second collection device.

38. The exudate collection system of claim 37, wherein the first coupling surface is an outer surface of the outlet conduit and defines threads that extend outwardly from the outer surface, and the second coupling surface is an inner surface of the inlet of the second collection device and defines threads that extend inwardly and mate with the threads extending from the outer surface of the outlet conduit.
39. The exudate collection system of claim 37, wherein the first coupling surface is an inner surface of the outlet conduit and defines threads that extend inwardly from the inner surface, and the second coupling surface is an outer surface of the inlet of the second collection device and defines threads that extend outwardly and mate with the threads extending inwardly from the inner surface of the outlet conduit.
40. The exudate collection system of claim 37, wherein the first coupling surface comprises one of a standard male or female Luer lock connector coupled to the outlet conduit, and the second coupling surface comprises the other of the standard female or male Luer lock connector for engaging the standard male or female Luer lock connector coupled to the outlet conduit.
41. The exudate collection system of claim 37, wherein the first coupling surface comprises one or more annular rings that extend outwardly from an outer surface of the outlet conduit, and the second coupling surface comprises one or more protrusions that extend inwardly from an inner surface of the inlet for engaging the one or more annular rings.

42. The exudate collection system of claim 37, wherein the first coupling surface comprises one or more annular rings that extend inwardly from an inner surface of the outlet conduit, and the second coupling surface comprises one or more protrusions that extend outwardly from an outer surface of the inlet, wherein the one or more protrusions engage the one or more annular rings.
43. The exudate collection system of claim 37, wherein the first coupling surface defines one or more recesses that extend radially outwardly from an inner surface of the outlet conduit, and the second coupling surface comprises one or more protrusions that extend radially outwardly from an outer surface of the inlet of the second collection device, wherein the recesses receive the protrusions.
44. The exudate collection system of claim 37, wherein the first coupling surface defines one or more recesses that extend radially inwardly from an outer surface of the outlet conduit, and the second coupling surface comprises one or more protrusions that extend radially inwardly from an inner surface of the inlet of the second collection device, wherein the recesses receive the protrusions.
45. The exudate collection system of claim 37, wherein the second collection device comprises a wall and the wall defines marks associated with a volume within the second collection device.

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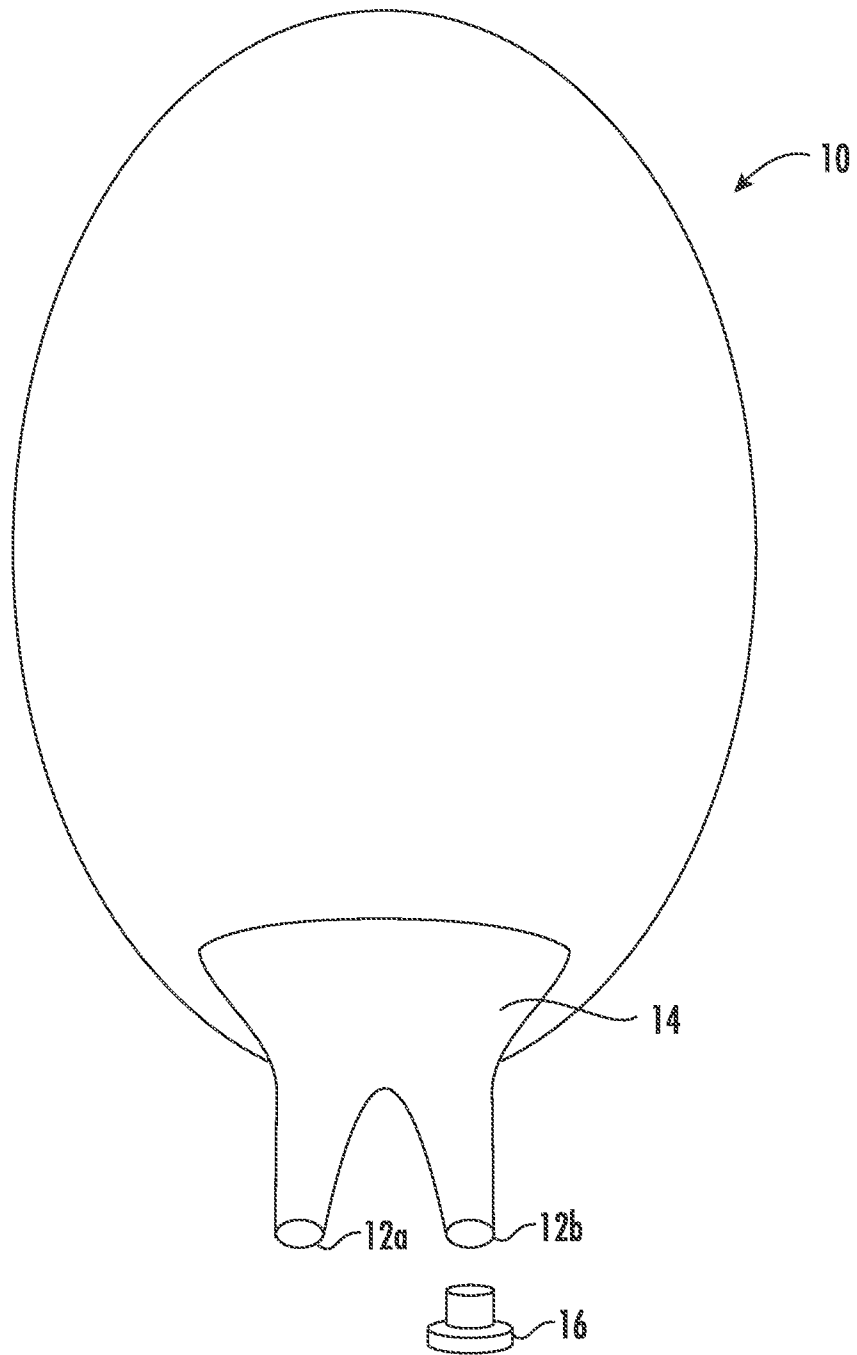
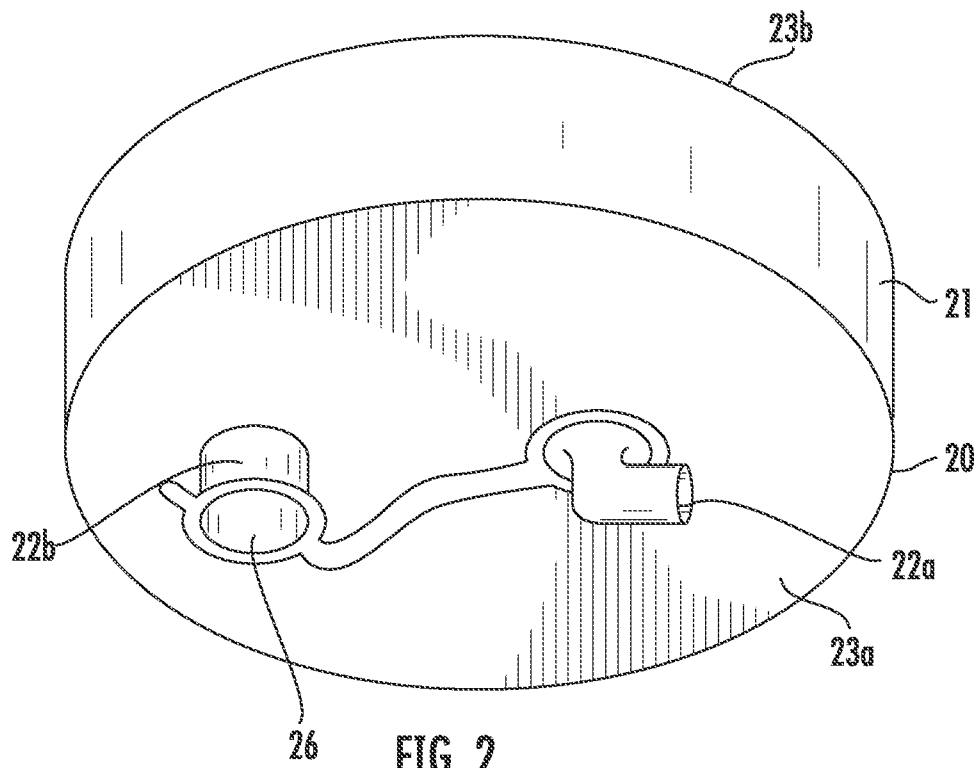
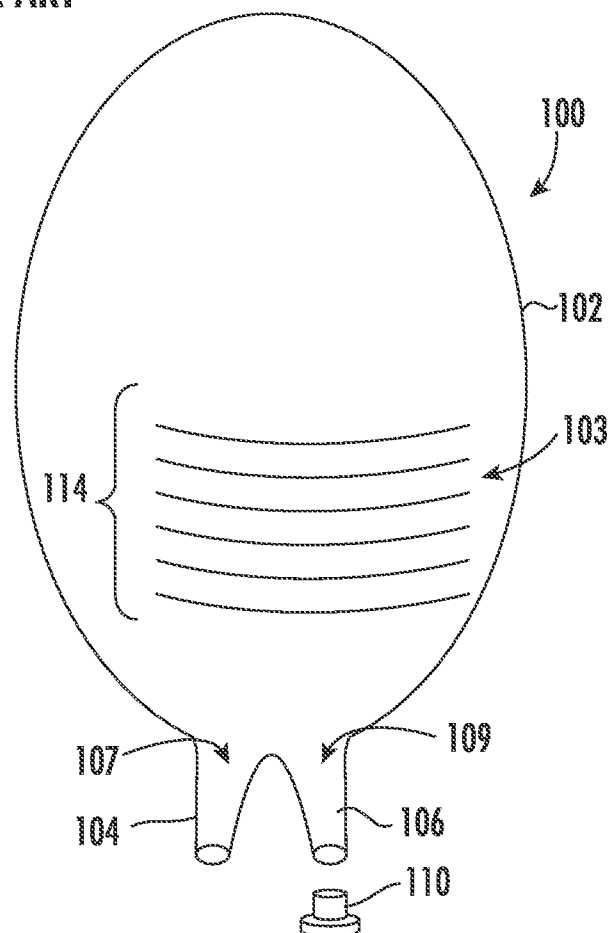


FIG. 1
PRIOR ART

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PRIOR ART



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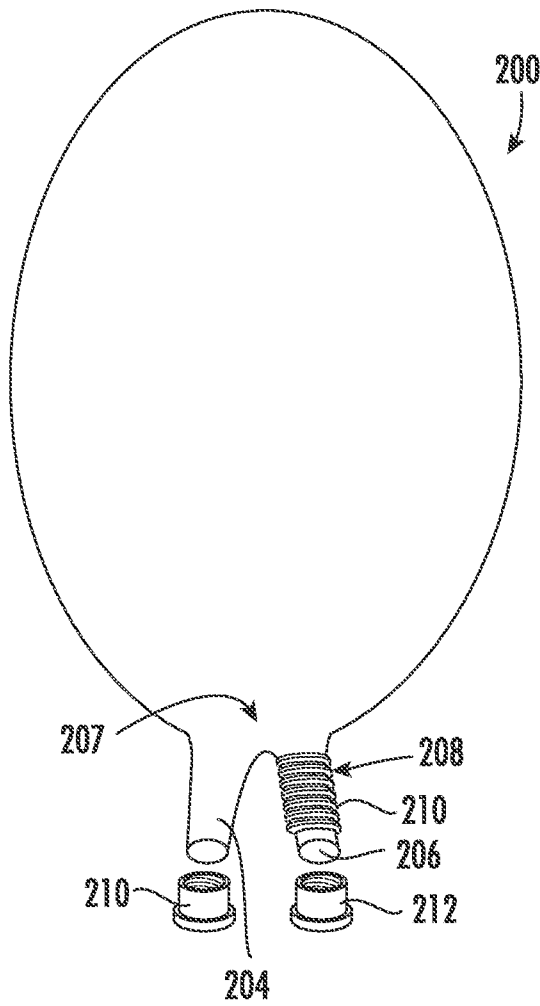


FIG. 4

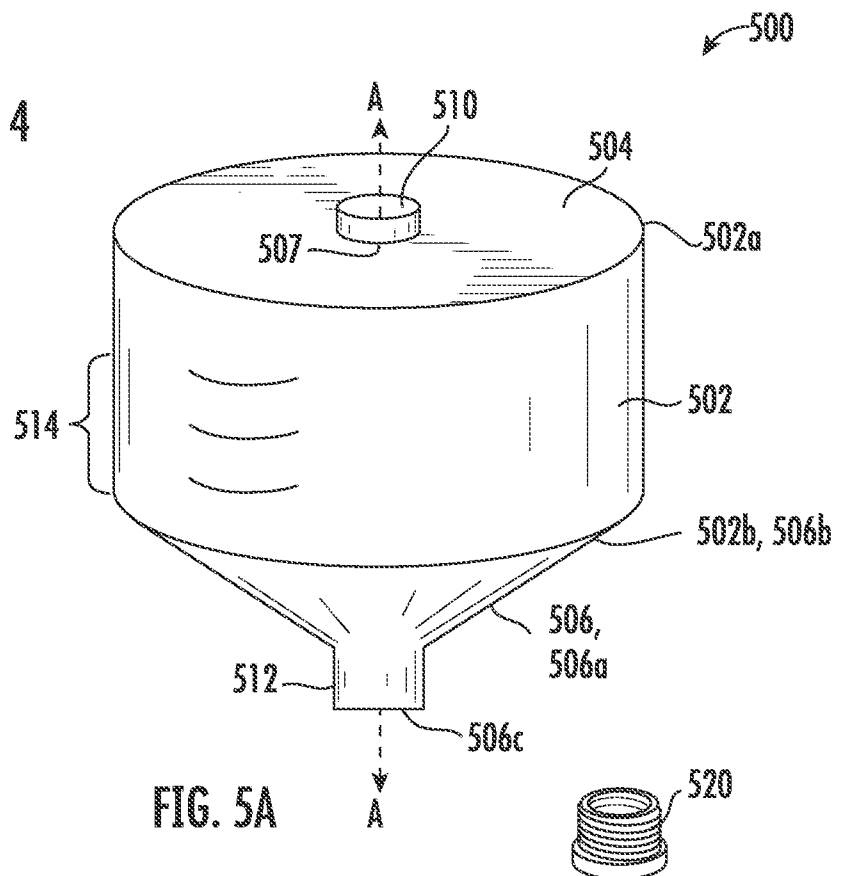


FIG. 5A

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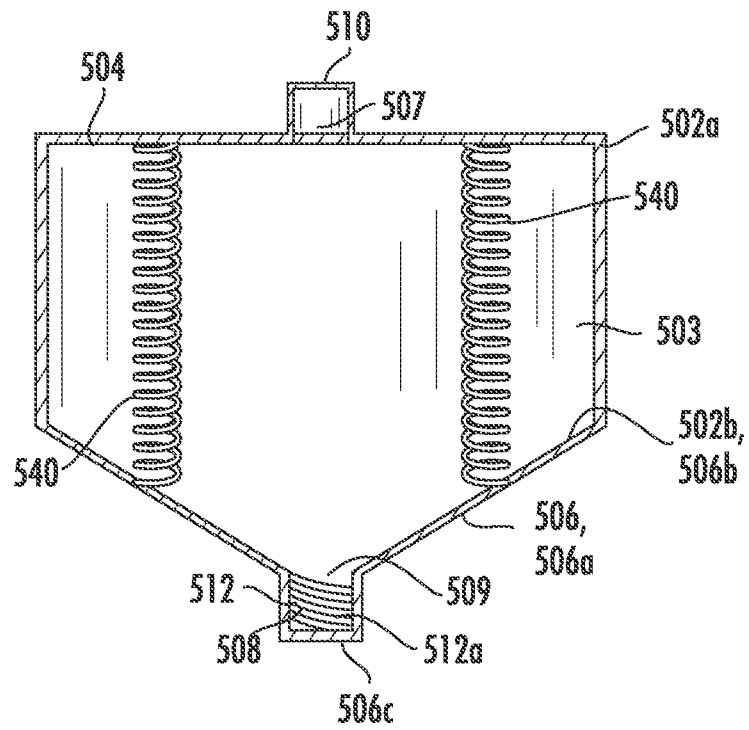


FIG. 5B

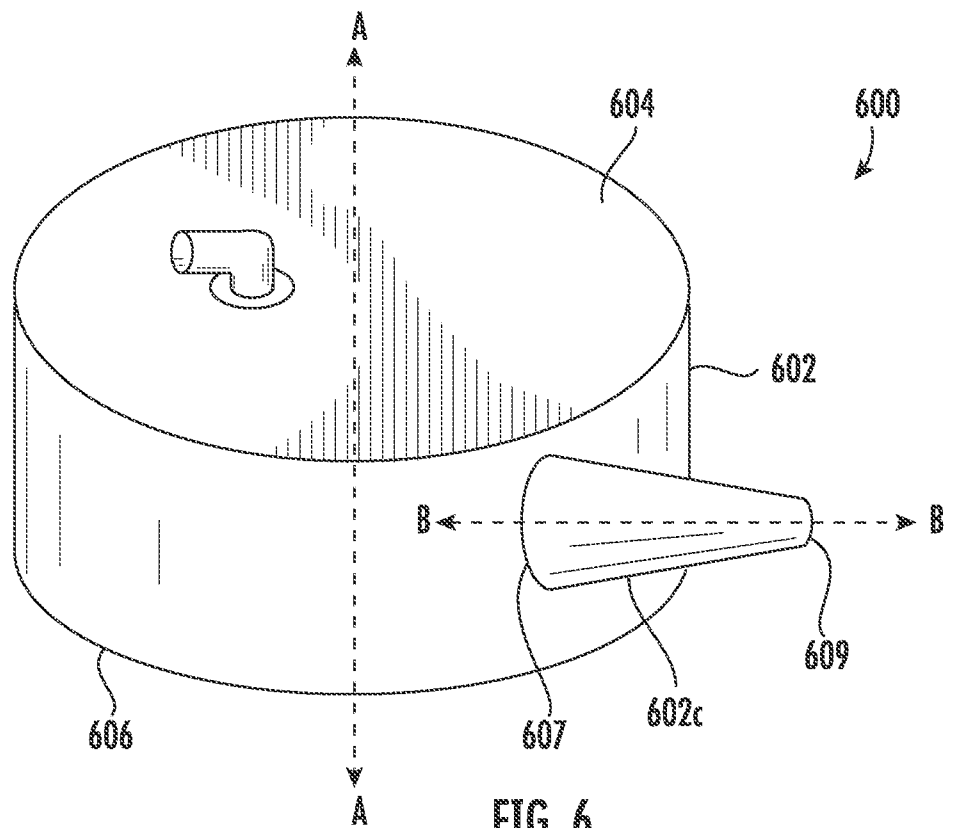


FIG. 6

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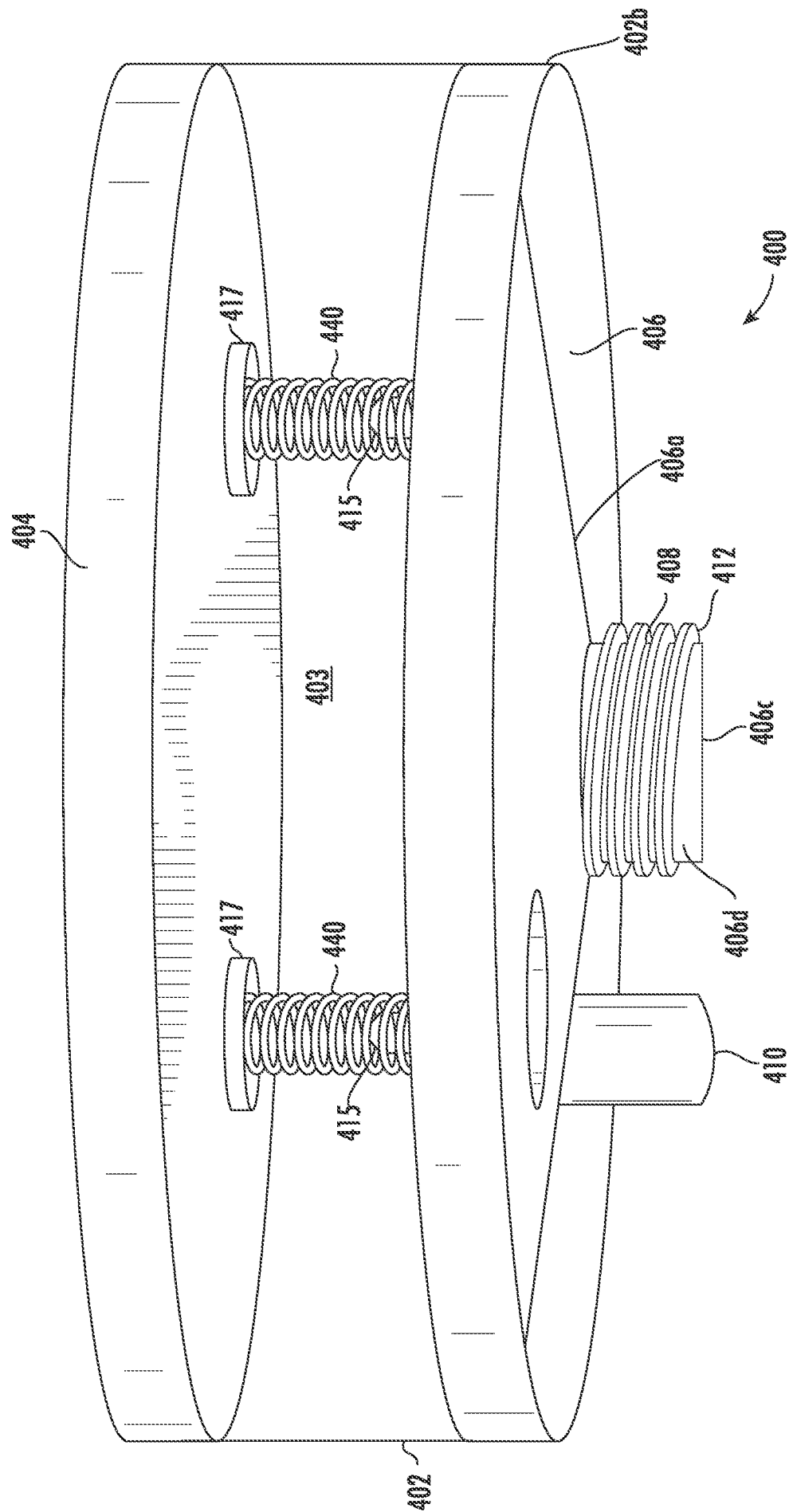


Fig. 7A

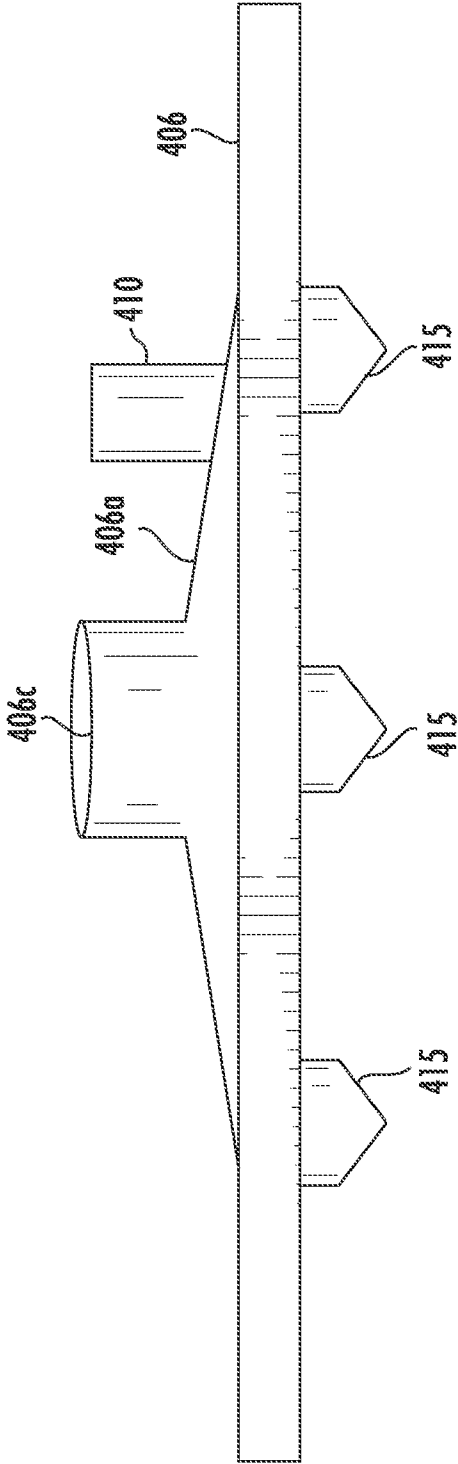


FIG. 7B

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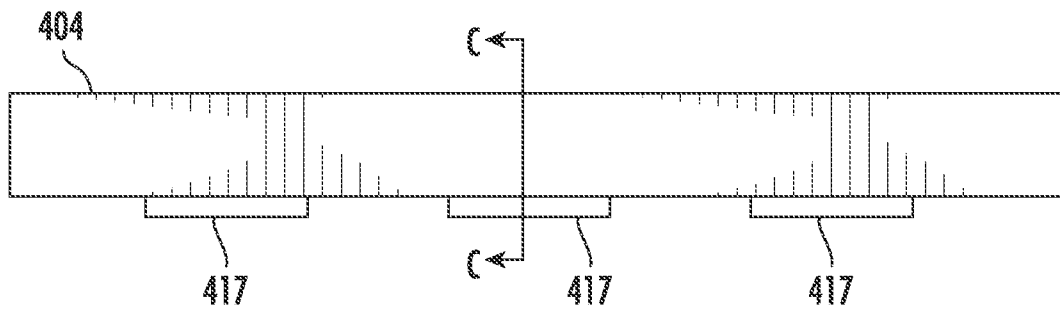


FIG. 7C

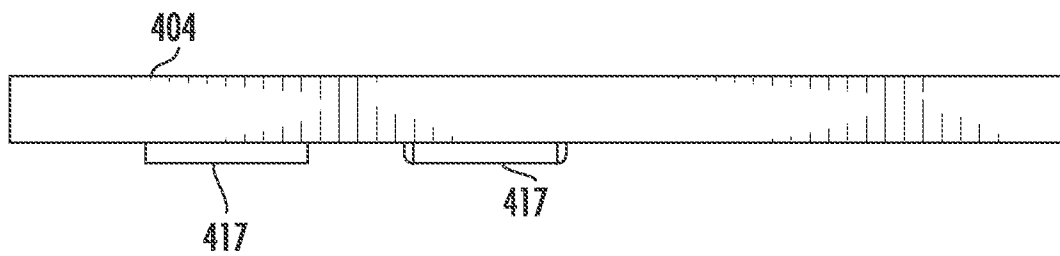


FIG. 7D

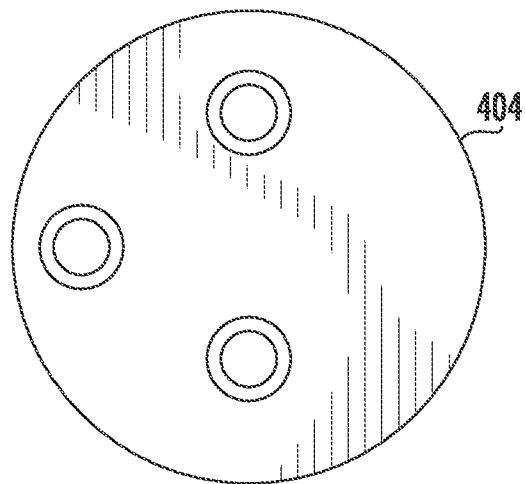


FIG. 7E

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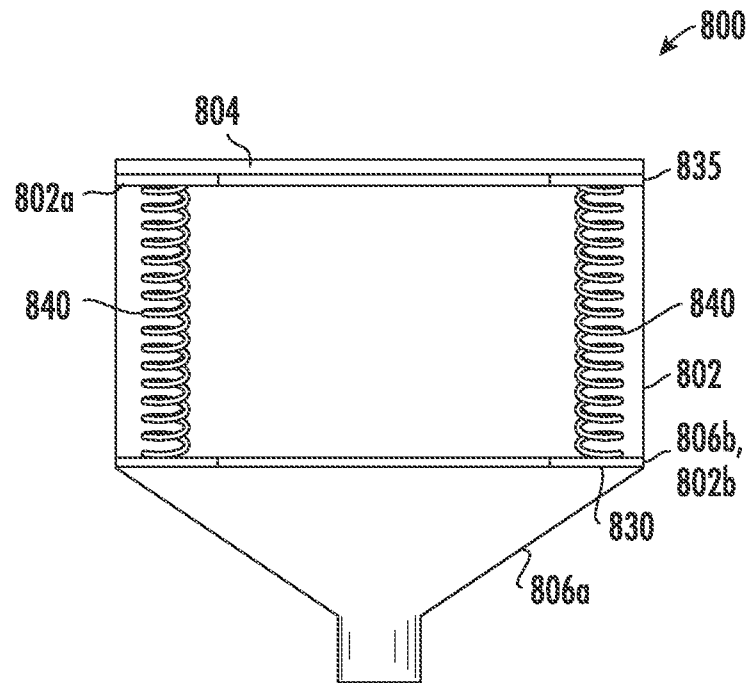


FIG. 8

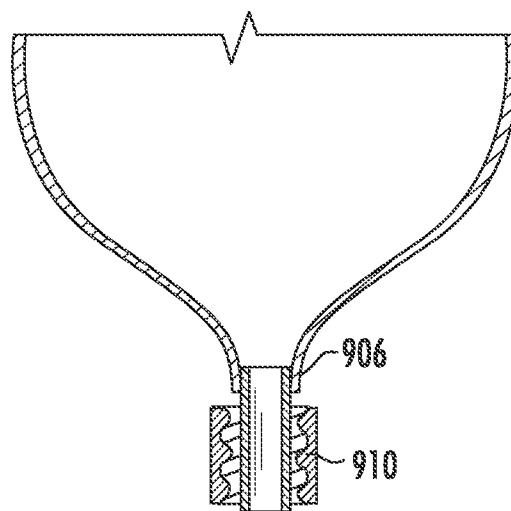


FIG. 9

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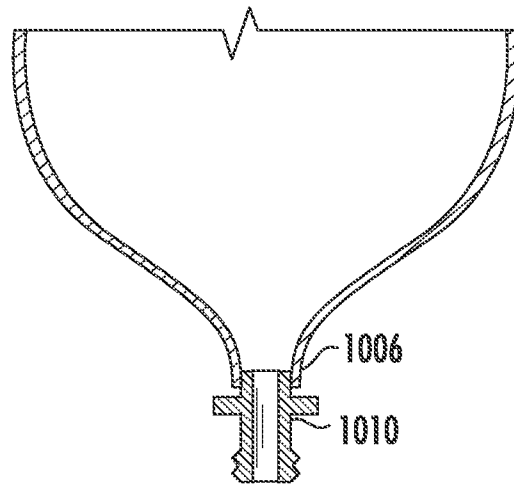


FIG. 10

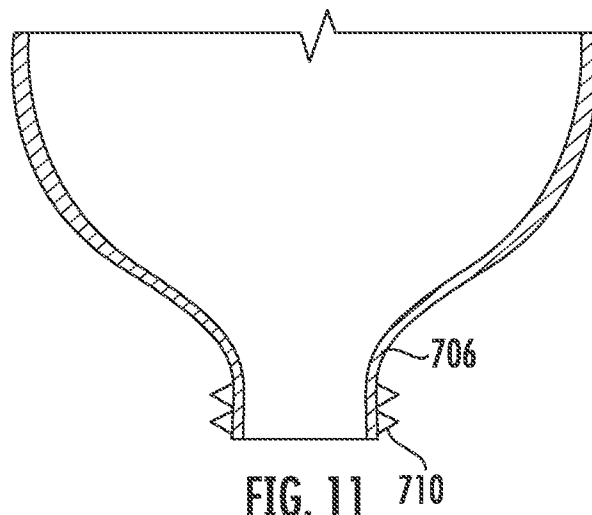


FIG. 11

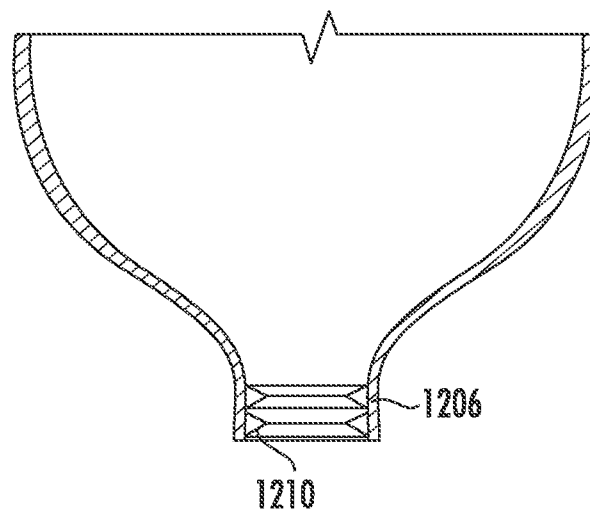
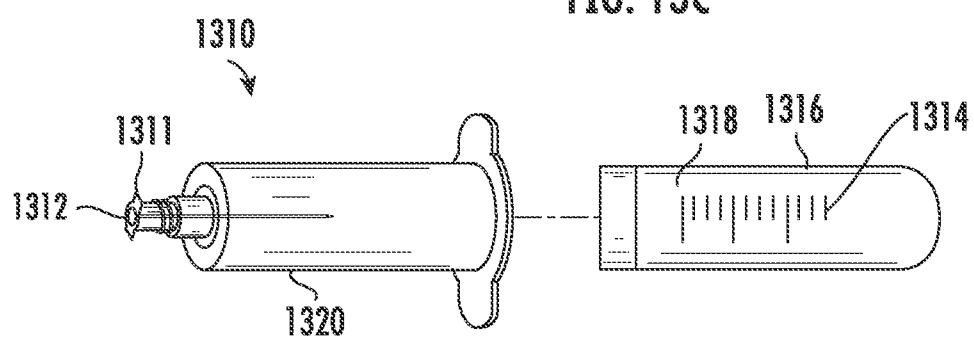
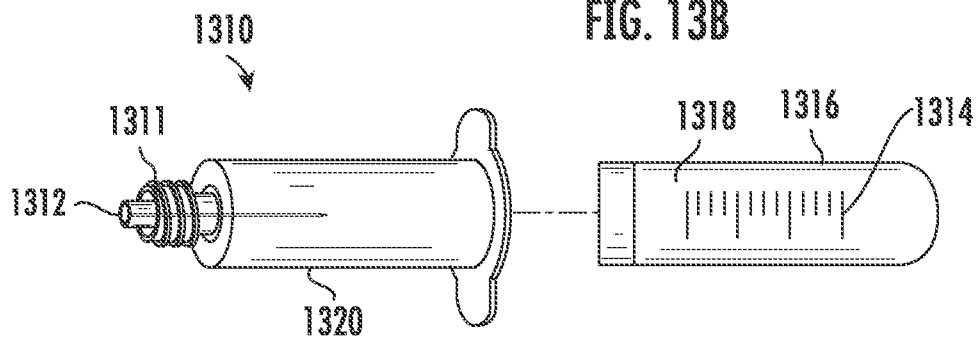
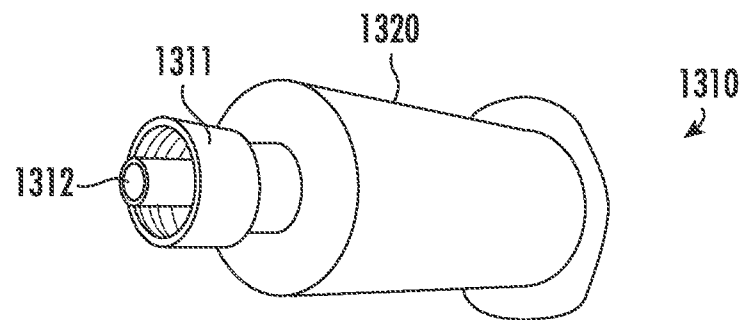
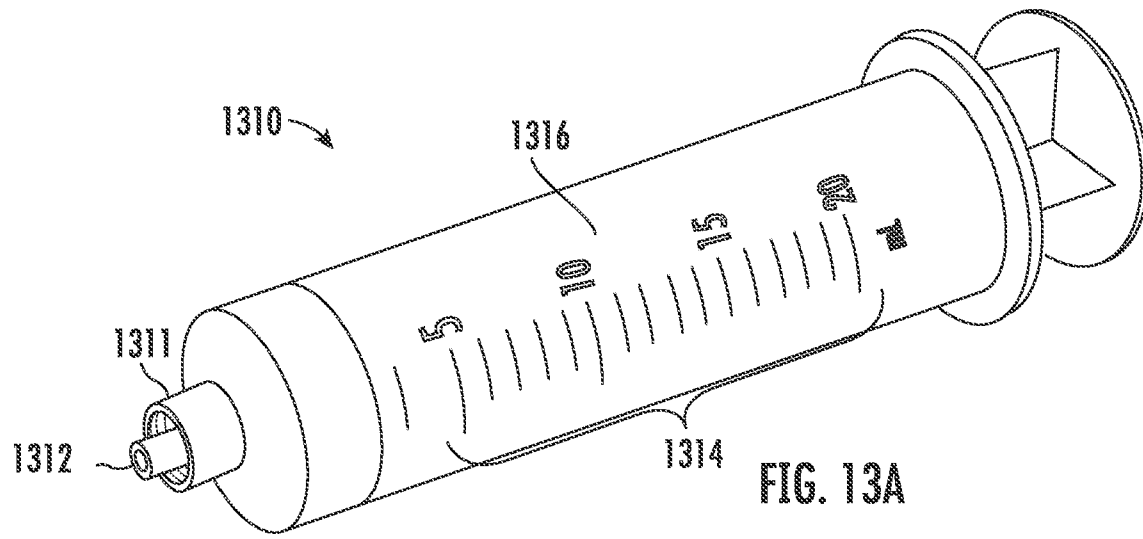


FIG. 12

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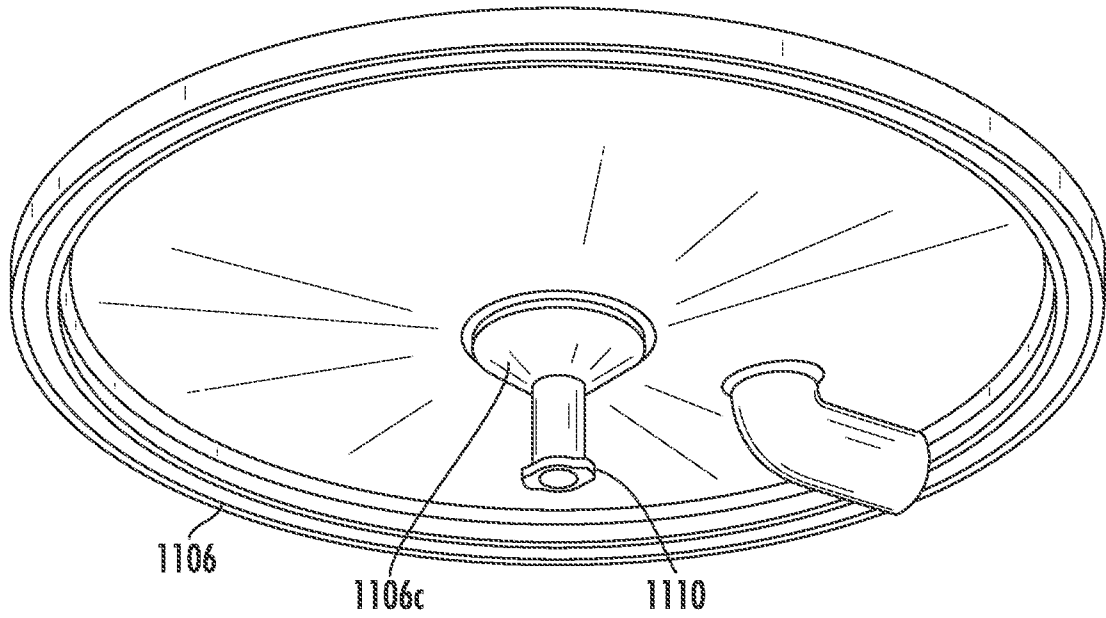


FIG. 14

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2018/040263

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61J 1/14; A61J 1/20; A61M 1/00; A61M 1/02; A61M 1/36; A61M 27/00 (2018.01)

CPC - A61M 1/0001; A61J 1/1418; A61M 1/0003; A61M 1/0005; A61M 1/0011; A61M 1/0017; A61M 1/0049; A61M 1/0056 (2018.08)

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)

See Search History document

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

USPC - 604/317; 604/319; 604/320; 604/321; 604/323; 604/326; 604/542 (keyword delimited)

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---	US 2010/0130957 A1 (SMISSON III et al) 27 May 2010 (27.05.2010) entire document	1, 2, 5, 10-14, 16-20 ---
Y		3, 4, 7, 9, 21-26, 28
Y	KR 10-2016-0027756 A (SU) 10 March 2016 (10.03.2016) entire document	3, 4, 21-25
Y	US 8,366,694 B1 (JORDAN) 05 February 2013 (05.02.2013) entire document	7, 9
Y	US 2012/0016337 A1 (KHALAJ) 19 January 2012 (19.01.2012) entire document	26, 28
A	US 3,713,444 A (BRIDGMAN) 30 January 1973 (30.01.1973) entire document	1-45
A	US 5,409,833 A (HU et al) 25 April 1995 (25.04.1995) entire document	1-45
A	US 2002/0185186 A1 (JULIAR et al) 12 December 2002 (12.12.2002) entire document	1-45

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

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"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

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Date of the actual completion of the international search

14 August 2018

Date of mailing of the international search report

17 SEP 2018

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