(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 December 2015 (10.12.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/187943 A1

(51) International Patent Classification:
A61M 1/00 (2006.01)

(21) International Application Number:
PCT/US2015/034190

(22) International Filing Date:
4 June 2015 (04.06.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/008,433 5 June 2014 (05.06.2014) US

(71) Applicant: **PURACATH MEDICAL, INC.** [US/US]; 201 San Anotonio Circle, Suite 105, Mountain View, CA 94040 (US).

(72) Inventors: **MURPHY-CHUTORIAN, Douglas**; 201 San Antonio Circle, Suite 105, Mountain View, CA 94040 (US). **KERMODE, James, R.**; 201 San Antonio Circle, Suite 105, Mountain View, CA 94040 (US). **LANCE, Justin, A.**; 201 San Antonio Circle, Suite 105, Mountain View, CA 94040 (US). **RASOOLY, Julia, A.**; 201 San Antonio Circle, Suite 105, Mountain View, CA 94040 (US). **RASOOLY, Michael**; 201 San Antonio Circle, Suite 105, Mountain View, CA 94040 (US). **SCHWIMMER, Charles, Martin**; 201 San Antonio Circle, Suite 105, Mountain View, CA 94040 (US).

(74) Agents: **GLENN, Benjamin, W.** et al.; Shay Glenn Llp, 2755 Campus Drive, Suite 210, San Mateo, CA 94403 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, 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, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, 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))*

(54) **Title**: TRANSFER CATHETER FOR ULTRAVIOLET DISINFECTION

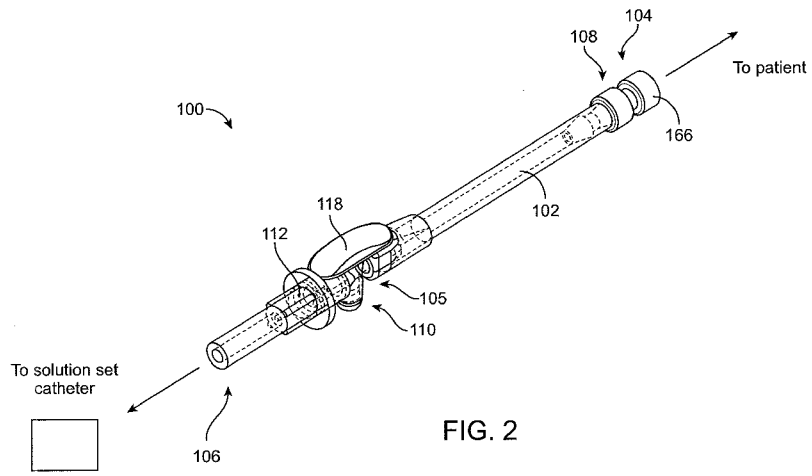


FIG. 2

(57) **Abstract**: Disclosed herein are devices and methods related to UV disinfection of a transfer catheter during peritoneal dialysis. The transfer catheter comprises a first and second end, the second end comprising a transfer valve. The transfer valve body comprises an inlet, outlet, and a flush hole. The valve core comprises a notch configured to allow fluid flow between the various flow paths. The valve core and body are positioned off axis with respect to the fluid flow path. The transfer catheter can allow for a small volume kill zone, which can minimize the amount of UV required to disinfect the catheter.

WO 2015/187943 A1

TRANSFER CATHETER FOR ULTRAVIOLET DISINFECTION

PRIORITY

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/008,433, filed June 5, 2014.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0003] This application relates generally to sterilization of connectors, more particularly connectors used in a medical application, for example during peritoneal dialysis (PD).

BACKGROUND

[0004] Peritoneal dialysis can be used as a treatment for patients with severe chronic kidney disease. Fluid is introduced through a tube in the abdomen and flushed out periodically either while the patients sleeps, in automated peritoneal dialysis or during regular dialysis sessions through the day, as in continuous ambulatory peritoneal dialysis.

[0005] As shown in FIG. 1, a patient undergoing peritoneal dialysis can have an indwelling catheter surgically inserted into the abdomen. A transfer catheter 2 can be attached to the indwelling catheter 4. The transfer catheter can be replaced, in a sterile environment, such as at a clinic, every few months to a year. Between dialysis sessions, the patient wears the transfer catheter against the body. During dialysis sessions, the transfer catheter can be connected to a drain bag to drain fluid present in the abdomen and a fresh dialysate bag to introduce fluid to the abdomen. The drain bag and dialysate bags can be attached in series or can be attached in parallel, using a Y-shaped solution set catheter 6. Prior to each treatment, the patient connects the tip of the transfer catheter to new dialysis tubing using rigorous aseptic techniques to maintain sterility. The same sterile technique must be employed when disconnecting the catheters as well. Once the patient feels confident enough to perform the procedure at home, and after many months of practice, the time to connect and start PD takes 20-30 minutes. The patient and anyone around them must always wear a mask, close doors and windows, turn off fans, and thoroughly wash hands for 2 minutes prior to connecting or disconnecting catheters. If sterility

is compromised at any time, the component being used must be replaced and the whole process started again.

[0006] This is obviously a complicated and time-consuming process that is highly reliant on patient compliance. If a patient fails to adhere to any of the strict steps of the sterilization procedure, he or she faces a greatly increased risk of a serious infection, commonly referred to as peritonitis. This type of internal infection, if not caught early, may lead to sepsis and death of the patient. Typically, peritoneal dialysis (PD) patients experience a 50% chance of infection during the first 12 to 18 months and experience 15% mortality/yr directly related to the infection. In addition to seriously endangering a patient's health, infections in peritoneal dialysis are also very costly to treat. The average total charges from a peritonitis hospital stay are roughly $50,000 dollars and the entire annual cost on the healthcare system is around $1.5 billion. Given that the noncompliance rate for a standard peritoneal dialysis procedure is around 30%, there is a huge need to help reduce the health and financial burdens of infection.

[0007] Ultraviolet (UV) disinfection systems are known in the art. U.S. Patent Nos. 4,882,496; 7,834,328; 4,620,845; 6,461,568 and U.S. Publication Nos. 2005/0013729 and 2007/0274879, the disclosures of which are incorporated by reference herein in their entireties, describe such systems. However, such systems can be cumbersome, making them difficult for a user to use. Additionally, such systems tend to rely on UV disinfection for complete disinfection, which can, in the absence of proper components and connectors, limit the effectiveness of the disinfection.

SUMMARY

[0008] In one aspect, a valve for use in a catheter connection is provided. The valve comprises a valve body comprising a flush hole, an inlet, and an outlet. Fluid flow is permitted between the inlet and the outlet or the outlet and the flush hole. Optionally, the flush hole can be positioned generally between the inlet and the outlet. Optionally, the valve body is generally cylindrical.

[0009] Optionally, the valve comprises a handle connected to the valve core and configured to allow movement of the valve to different flow positions. The valve can comprise a closed position in which the handle is aligned with the inlet and outlet. Optionally, the valve comprises a closed position in which the handle is aligned with the inlet and outlet. The handle can comprise a locking mechanism configured to prevent inadvertent movement of the valve from the closed position. The handle can comprise a notch configured to interact with a trough of the valve. The handle can comprise ribs on its bottom surface configured to interact with ribs on the valve body, the interaction configured to indicate various valve positions to a user. Optionally, the valve core is positioned off axis from a flow path between the inlet and the outlet. The valve

can comprise a first connector connected to the inlet and a second connector connected to the outlet. Optionally, first connector is configured to connect to a transfer catheter. The second connector can be configured to connect to a solution set catheter. Optionally, the valve comprises a cover positioned over the second connector. The cover can be configured to interact with a handle of the valve to maintain the valve in a closed position. Optionally, at least one of the inlet and the outlet has a generally ellipsoid shape. At least one of the inlet and the outlet can have angled walls. Optionally, the valve comprises a closed position in which fluid communication between any of the inlet, the outlet and the flush hole is not permitted; a flush position in which only fluid communication between the outlet and the flush hole is permitted; and a flow position in which only fluid communication between the inlet and the outlet is permitted. The flush hole can be positioned generally equidistant from the inlet and the outlet. Optionally, the flush hole comprises a diameter of about 0.04-0.06 inches. The V-shaped notch can comprise a rounded point. Optionally, the notch comprises a height of about 0.15-0.25 inches; a depth of about 0.15-0.25 inches; and/or a width of about 0.2-0.3 inches. The flush hole can be positioned along the valve body at an approximate midpoint of a height of the V-shaped notch. Optionally, a height of the notch and a diameter of at least one of the inlet and the outlet is about the same. The valve core can comprise a UV opaque material. Optionally, the valve body comprises a UV transparent material.

[0010] In another aspect, a valve for use in a catheter connection is provided. The valve comprises a valve body comprises a flush hole, an inlet, and an outlet. The flush hole can be positioned generally between the inlet and the outlet. The valve body can be generally cylindrical. The valve can comprise a generally cylindrical valve core comprising non-parallel surfaces. The valve core can be positioned off-axis with respect to the inlet and outlet.

[0011] Optionally, the valve further comprises a handle connected to the valve core and configured to allow movement of the valve to different flow positions. The valve can comprise a closed position in which the handle is aligned with the inlet and outlet. The handle can comprise a locking mechanism. Optionally the handle comprises a notch configured to interact with a trough of the valve. The handle can comprise ribs on its bottom surface configured to interact with ribs on the valve body, the interaction configured to indicate various valve positions to a user. Optionally, the valve comprises a first connector connected to the inlet and a second connector connected to the outlet. The first connector can be configured to connect to a transfer catheter. The second connector can be configured to connect to a solution set catheter. Optionally, the valve comprises a cover positioned over the second connector. The cover can be configured to interact with a handle of the valve to maintain the valve in a closed position. At least one of the inlet and the outlet can comprise a generally ellipsoid shape. Optionally at least

one of the inlet and the outlet has angled side walls. The valve can comprise a closed position in which fluid communication between any of the inlet, the outlet and the flush hole is not permitted; a flush position in which only fluid communication between the outlet and the flush hole is permitted; and a flow position in which only fluid communication between the inlet and the outlet is permitted. Optionally, the flush hole is positioned generally equidistant from the inlet and the outlet. The flush hole can comprise a diameter of about 0.04-0.06 inches. Optionally, the notch is generally V-shaped. The V-shaped notch can comprise a rounded point. Optionally the notch comprises a height of about 0.15-0.25 inches; a depth of about 0.15-0.25 inches; and/or a width of about 0.2-0.3 inches. The flush hole can be positioned along the valve body at an approximate midpoint of a height of the notch. Optionally, a height of the notch and a diameter of at least one of the inlet and the outlet is about the same. The valve core can comprise a UV opaque material. Optionally, the valve body comprises a UV transparent material.

[0012] In another aspect, a valve for use in a catheter connection is provided. The valve comprises a valve body comprising a flush hole, an inlet, and an outlet. The valve body can be generally cylindrical. The flush hole can be positioned generally between the inlet and the outlet. Optionally, the valve comprises a valve core comprising a V-shaped notch and optionally generally cylindrical. Fluid flowing within the valve can be exposed to UV radiation.

[0013] Optionally, the valve comprises a handle connected to the valve core and configured to allow movement of the valve to different flow positions. The valve can comprise a closed position in which the handle is aligned with the inlet and outlet. Optionally, the handle comprises a locking mechanism configured to prevent inadvertent movement of the valve from the closed position. The handle can comprise a notch configured to interact with a trough of the valve. Optionally, the handle comprises ribs on its bottom surface configured to interact with ribs on the valve body, the interaction configured to indicate various valve positions to a user. The valve core can be positioned off axis from a flow path between the inlet and the outlet. Optionally, the valve comprises a first connector connected to the inlet and a second connector connected to the outlet. The first connector can be configured to connect to a transfer catheter. The second connector can be configured to connect to a solution set catheter. Optionally, the valve comprises a cover positioned over the second connector. The cover can be configured to interact with a handle of the valve to maintain the valve in a closed position. Optionally, at least one of the inlet and the outlet has a generally ellipsoid shape. Optionally, at least one of the inlet and the outlet has angled side walls. The valve can comprise a closed position in which fluid communication between any of the inlet, the outlet and the flush hole is not permitted; a flush position in which only fluid communication between the outlet and the flush hole is permitted;

and a flow position in which only fluid communication between the inlet and the outlet is permitted. Optionally, the flush hole can be positioned generally equidistant from the inlet and the outlet. The flush hole can comprise a diameter of about 0.04-0.06 inches. Optionally, the V-shaped notch comprises a rounded point. The notch can comprise a height of about 0.15-0.25 inches; a depth of about 0.15-0.25 inches; and/or a width of about 0.2-0.3 inches. Optionally, the flush hole is positioned along the valve body at an approximate midpoint of a height of the V-shaped notch. Optionally, a height of the notch and a diameter of at least one of the inlet and the outlet is about the same. The valve core can comprise a UV opaque material. The valve body can comprise a UV transparent material.

[0014] In another aspect, a method of catheter line disinfection is provided. The method comprises connecting an end of a first catheter to an end of a second catheter first end, the end of the first catheter comprising a transfer valve comprising a valve body comprising an inlet configured to fluidly communicate with the first catheter, an outlet configured to fluidly communicate with the second catheter, and a flush hole positioned between the inlet and the outlet; flushing fluid from the second catheter through the flush hole while sealing off fluid communication with the inlet; and flowing fluid between the inlet and the outlet while sealing off fluid communication with the flush hole.

[0015] Optionally, flushing fluid from the second catheter through the flush hole comprises flushing dead volume within the valve and the second catheter. The dead volume can be about 0.3 cm^3 – 1 cm^3 or about 0.3 cm^3 – 2 cm^3. Optionally, the second catheter is a solution set catheter connected to a drain bag and a dialysate bag. Optionally, flushing fluid from the second catheter through the flush hole comprises flushing dialysate from the dialysate bag to the flush hole. The method can comprise moving the transfer valve from a closed position to a flush position prior to flushing fluid from the second catheter through the flush hole while sealing off fluid communication with the inlet. Optionally, the method comprises moving the transfer valve from a flush position to a flow position prior to flowing fluid between the inlet and the outlet while sealing off fluid communication with the flush hole. Optionally, flushing fluid from the second catheter through the flush hole while sealing off fluid communication with the inlet comprises flushing about 3 cm^3 of fluid out of the flush hole. The method can comprise placing the transfer valve in a UV applicator. Optionally, the method comprises irradiating the transfer valve with UV light. The method can comprise removing a cap from the outlet prior to connecting the outlet to the second catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0017] FIG. 1 is an illustration of a conventional peritoneal dialysis setup.

[0018] FIG. 2 is an illustration of an embodiment of a transfer catheter.

[0019] FIG. 3 is an illustration of an embodiment of a cover.

[0020] FIG. 4A is an illustration of a side view of an embodiment of a transfer valve including the valve handle.

[0021] FIGS. 4B-4D are illustrations of top and bottom views of embodiments of a valve handle.

[0022] FIG. 4E is an illustration of an embodiment of a transfer catheter.

[0023] FIG. 4F is an illustration of an end view of an embodiment of a transfer catheter.

[0024] FIG. 4G is an illustration of an embodiment of a valve handle.

[0025] FIGS. 4H-4J are illustrations of embodiments of a valve rib.

[0026] FIG. 5 is an illustration of an embodiment of a valve body.

[0027] FIG. 6 is an illustration of an embodiment of a valve core.

[0028] FIG. 7 is an illustration of a bottom view of an embodiment of a transfer valve.

[0029] FIG. 8 is an illustration of a valve core key.

[0030] FIGS. 9A and 9B are illustrations of embodiments of a hemispherical dome of a transfer valve.

[0031] FIGS. 10A and 10B are illustrations of embodiments of a strain relief of a transfer catheter.

[0032] FIG. 11 illustrates an embodiment of a first end of a transfer catheter.

[0033] FIGS. 12A-D illustrate an embodiment of a method of using the transfer catheter.

DETAILED DESCRIPTION

[0034] Embodiments of the transfer catheter disclosed herein can be used by peritoneal dialysis (PD) patients. The transfer catheter can be attached to the patient's indwelling catheter 4. The transfer catheter can comprise a valve at the end away from the patient's indwelling catheter. During a peritoneal dialysis session, the patient can connect the transfer catheter to the solution set catheter(s). The patient can use the valve on the transfer catheter to flush away any residual fluid within the valve or fluid which may be sequestered by a non UV-transmissive

solution set catheter. The connection between the transfer catheter and the solution set catheter, including the valve, can then be sterilized through exposure to UV light. It has been found that flushing the catheter line in combination with UV sterilization can provide more effective disinfection than UV sterilization alone. Features of the transfer catheter, as will be disclosed in more detail hereinafter, can allow for a minimal volume of fluid to be disinfected or exposed to UV light. Minimizing the volume needed to be disinfected allows for the transfer catheter and valve to comprise a small volume kill zone, and can allow for the transfer catheter and valve to comprise a small size and low profile, which can increase patient comfort while wearing the transfer catheter, for example, between dialysis sessions. Additionally, minimizing the volume to be disinfected can allow for less UV light required for disinfection, which can allow for smaller/fewer UV bulbs and power sources, which in turn, can allow for a smaller UV light applicator. Minimizing the size of the UV applicator can increase patient comfort and convenience.

[0035] FIG. 2 illustrates an embodiment of a transfer catheter 100 that can be used like the transfer catheter 2 of FIG. 1. The transfer catheter comprises a tubular body 102, a first end 104, and a second end 106. The transfer catheter 100 comprises a first connector 108 positioned at or near the first end 104, and a transfer valve 110 positioned at or near the second end 106. The transfer catheter 100 is shown disconnected from the indwelling catheter, and has a cap 166 at the first end.

[0036] The transfer valve 110 is connected to the tubular body 102 at a first end via a first connector 105 and has a second connector 112 at its second end. The first connector 105 can be for example, a barb connection, as best seen in FIG. 9B. Other connections are also possible. The second connector 112 can be a Luer fitting. The second connector 112 can comprise threads (e.g., ISO standard, full height, partial diameter threads). A Luer fitting can help ensure compatibility of the transfer catheter 100 with connectors from other systems. Other connectors are also possible (e.g., barb swagelock, slip, etc.).

[0037] Referring now to FIG. 3, the connector 112 may include a cover 114. The cover can be configured to mate with the connector 112. For example, the cover 114 can comprise threads 115 configured to mate with threads 111 (shown in FIG. 4A) on the connector 112, as shown in FIG. 3. The threads can comprise ISO Standard thread pitch (e.g., double-start thread pitch). In some embodiments, at least a portion of the threads (e.g., portion 116) comprise a shallower (e.g., shallower than standard thread depth, shallower than the connector 112 thread depth) thread depth. The cover 114 comprising a shallower thread depth can help ensure that the cover 114 strips before stripping the mating part (e.g., the connector 112) when the cover 114 is over

torqued. The cover 114 can comprise grooves 113 which can be used to aid grip in attaching and removing the cover.

[0038] The cover 114 can be configured to be UV transparent (e.g., UV-C transparent). UV transparency can allow components underlying the cover 114 (e.g., the connector 112) to be distributed non-sterile and subsequently disinfected by the user. In some embodiments, the cover 114 comprises a UV-transparent material (e.g., cyclic olefin copolymer (COC) (e.g., Topas®)). Other materials are also possible (e.g., Mitsui chemicals TPX). The cover 114 can comprise a smooth outer surface, which can discourage over-torqueing and improve patient comfort while wearing the transfer catheter. The cover 114 can also comprise a smooth end (e.g., hemispherically shaped). This shape can allow the cover 114 to be comfortable to wear against a patient's skin.

[0039] Moving to FIG. 4A, the length and diameter of the cover can be selected to interact with the transfer valve 110. For example, the length and/or diameter of the cover can be selected to allow the cover to act as a handle lock to prevent the transfer valve 110 from rotating. The cover can be sized and shaped to interact with a feature 130 on the valve handle 118 and prevent the valve handle from rotating, as shown in FIGS. 4H-J. The cover 114 can fit close beneath the handle 118, as shown in FIGS. 4A-C, H-J and 6, so the bottom surface 117 of the cover prevents the transfer valve 110 from rotating from the closed position. In this manner, while a patient is wearing the transfer catheter between dialysis sessions, the cover can help ensure the valve 110 stays in a closed position, maintaining the cleanliness of portions of the transfer catheter 100. Other locking mechanisms are also possible.

[0040] As mentioned above, the transfer valve 110 comprises a handle 118. The handle can comprise an underlying rigid skeleton 120 (e.g., a rigid plastic skeleton), as shown in FIG. 4B, beneath a soft overmold 122 (e.g., a soft plastic overmold), as shown in FIG. 4C. This combination can allow the handle 118 to be robust, while still being comfortable to wear against the body. A skeleton 120 can permit the use of less material when manufacturing the handle 118, which can reduce cost. The skeleton 120 can also be used to adjust structure of the handle 118, for example, to optimize patient comfort. In some embodiments, the skeleton 120 can protrude through the overmold 122 to aid in grip. The soft overmold can also make the handle easier to grip, especially when the user's hands are wet. Adding texture to the overmold can also enhance ease of gripping the handle 118. The underlying skeleton 120 can have a smooth bottom 124, as shown in FIG. 4D. In some embodiments, the bottom surface 124 can include one or more rib elements (e.g., rib 130) or other features. Because the portion beneath the handle 118 can be difficult to clean, a smooth surface can help prevent accumulation of contaminants beneath the handle 118.

[0041] The handle 118 long axis can be configured to align with the tubular body 102 in the closed position, as shown in FIGS. 4A-4E. Traditionally, valve handles will not be aligned with the inlet/outlet when in a closed position, and will instead be aligned with the flow path when in a flow position. This closed position alignment can make the handle 118 comfortable to wear against the patient's body, as the handle 118 will not be protruding as far from the tubular body 102 as it would with a different alignment. The alignment can also allow for the handle 118 to be longer without affecting patient comfort. A long valve handle 118 can be easier for a user to operate. The valve handle 118 can be longer than a typical stopcock. As noted above, this increased length can provide more leverage to a user when operating the handle, and can make use more comfortable. A handle 118 with a greater surface area can also be more comfortable for a user to wear against skin than a handle 118 with a smaller protrusion against the skin.

[0042] In some embodiments, the valve core can be positioned off-axis from the tubular body 102, as described in more detail below. In such embodiments, the handle 118 can be centered on the tubular body 102 instead of the valve core, as shown in FIGS. 4F and 7. Centering the handle 118 on the tubular body 102 instead of the core can improve comfort to the user wearing the catheter 100 as such positioning minimizes protrusions poking into the user's skin.

[0043] The handle 118 can be atraumatic and ergonomic, for example, comprising an ellipsoid shape. Such a design can enhance comfort of a user wearing the handle 118 against the body. The shape of the handle 118 is also configured to blend into other components of the valve (e.g., valve core, cap, strain relief), which can help to minimize pinch points and enhance comfort.

[0044] The handle 118 can comprise a feature configured to interact with a component of the valve 110, which can serve to provide tactile user feedback of handle 118 position (e.g., closed position). The interaction can also encourage the handle 118 to stay in a closed position. For example, as shown in FIG. 4G, the handle 118 can comprise a notch 126 positioned beneath the handle configured to interface with a trough 128 on a component (e.g., strain relief) of the valve 110 beneath the handle 118.

[0045] As noted above, the handle 118 can comprise a feature configured to interact with the cover 114 to maintain the handle 118 in a particular position (e.g., a closed position). For example, as shown in FIGS. 4A-D, 4H-J and 6, the handle 118 can comprise a rib 130 on the bottom surface 124, at the front portion of the handle. The rib 130 can be generally perpendicular to the tubular body 102 axis and comprise a generally flat face. In some embodiments, the rib is at an angle other than 90° to the tubular body 102 axis. In some embodiments, the rib 130 does not have a generally flat face. The cover 114 being positioned

adjacent to or abutting the rib 130 can prevent the handle 118 from rotating. This feature can be used to help maintain the valve 110 in a closed position when the cover is positioned on the catheter 100. Maintaining a closed position in the valve 110 can help ensure the cleanliness of the valve and integrity of the transfer catheter in between dialysis sessions. A closed valve position ensures no communication between any of the ports.

[0046] Moving to FIGS. 4I and 4J, the rib 130 on the handle 118 can also interface with ribs on the valve body 140 at various points along the valve rotation path. FIGS. 4I and 4J illustrate side views of the rib 130 from either side of the valve 110. For example, the rib 130 can be configured to interact with ribs 136, 138 positioned at about 45° CW and about 90° CCW from the rib 130 in the closed position. The rib 130 can prevent over-rotation of the valve 110. In some embodiments, the 45° CW position rib 136 ensures communication only between the valve flush hole 150 and the second end 106. The rib 136 or other locking feature can be positioned other than about 45° from the closed position. In some embodiments, the 90° CCW position rib 138 ensures communication only between first end and the second end. Positioning the flush hole 150 within 45° from the closed position can help allow for the flush hole 150 or the first through hole 146 to be securely sealed off in the various positions. Other interaction mechanisms are also possible (e.g., track mechanisms, etc.). Restraining valve stem movement to these positions can increase safety of the valve mechanisms. The various valve handle 118 positions are shown in more detail in FIGS. 12A-D.

[0047] The valve body 140 is positioned beneath the handle 118, as shown in FIGS. 4A, C, D, F and 10A. The valve body 140 can be generally cylindrical. The valve body 140 is in fluid communication with the first end 104 and the second end 106 of the transfer catheter 100. The valve body includes a first through hole 146 allowing fluid communication between the valve 110 and the first end 104 (not shown) through first connector 108 (e.g., a barb). The valve body 140 can be formed integrally with or attached to the first connector 108. The valve body also includes a second through hole 148 allowing fluid communication between the valve 110 and the second end 106 (not shown) through second connector 112. The valve body 140 can be formed integrally with or attached to the second connector 112. The through holes 146, 148 can have generally ellipsoid shapes and angled side walls 145 (shown in more detail in FIG. 6) that taper inwards from the outer wall of the valve body 140 to the inside of the valve body 148. Such non parallel surfaces can provide for a taper lock connection such as a Luer connector. In some embodiments, the through holes 146, 148 have generally the same shape and configuration. In some embodiments, the through holes 146, 148 have different shapes and configurations.

[0048] The valve body 140 comprises a flush hole 150 positioned between the first through hole 146 and the second through hole 148, as shown in FIG. 5. The valve 110 can have three

positions: 1.) Closed, in which communication is not allowed between any of the holes 146, 148, 150; 2.) Flush, in which communication is allowed between the second through hole 148 and the flush hole 150; and 3.) Flow, in which communication is allowed between the first through hole 146 and the second through hole 148. In some embodiments, in the flush position, the valve core seals off the first through hole 146, so no flow is allowed to the patient side of the catheter. In some embodiments, in the flow position, no flow is allowed to the flush hole 150. Positioning the flush hole generally orthogonal to the flow path can allow for the flush position to exclude the first through hole 146 and the flow position to exclude the flush hole 150.

[0049] The flush hole 150 is shown positioned generally equidistant from through holes 146, 148. In some embodiments, the flush hole can be positioned closer to one of the through holes than the other. The flush hole 150 is shown positioned, in a vertical direction, generally centrally within the flow path. In other embodiments, the flush hole 150 can be positioned higher or lower than the position shown in FIG. 5.

[0050] The flush hole 150 is a small hole with a diameter of about 0.050 inches. In some embodiments, the diameter of the flush hole 150 can be about 0.040-about 0.060 inches. The hole size can be selected to optimize flow through the hole 150. The flush hole 150 allows for the flushing of the dead volume within valve 110 and the solution set catheter. In some embodiments, the connector of the solution set catheter (e.g., Baxter UltraBag) may not be UV-transparent. In such embodiments, flushing any residual fluid away from the connector and out of the line can help promote thorough disinfection of the fluid line. The volume of fluid flushed can be selected based on the residual or dead volume within the solution set catheter and the valve. In some embodiments, the dead volume can be as low as about 0.3 cm^3. In some embodiments, the dead volume is about 0.3 cm^3 – 1 cm^3. In some embodiments, the dead volume is about 0.3 cm^3- 0.6 cm^3. In some embodiments, the dead volume is about 0.3 cm^3 – 2 cm^3. In some embodiments, the dead volume is about 1-2 cm^3. In some embodiments, the dead volume can be less than or equal to about 2 cm^3. In some embodiments, the volume flushed can be about 3 cm^3 to allow for about a 10X margin of safety. Other volumes are also possible. For example, in some embodiments, the volume flushed can be about 1 cm^3 to about 5 cm^3; about 2 cm^3 to about 4 cm^3; greater than 5 cm^3; etc.

[0051] The flush hole 150 can be used to flush fresh dialysate solution to the atmosphere instead of a separate drain container as the flush solution will comprise sterile dialysate. Any microorganisms within the dead volume are already present in the patient environment. As such, the flush solution can be safe to spill to the atmosphere. The flush solution can also be easy to clean after exiting the flush hole as only a small volume of solution is flushed. In some

embodiments, the amount of fluid flushed can be caught in something as absorbent and small as a tissue.

[0052] The sidewalls 151 of the flush hole 150 can be tapered which can allow for molding. Tapering the walls of the flush hole 150 can also minimize parallel surfaces which are not optimized for UV disinfection as the UV light may be parallel to both surfaces. The wall edges can be sharp or rounded.

[0053] A valve core 142 is positioned within the valve body. The valve 110 allows fluid flow through the valve via a notch 144 or depression cut out of the valve core 142, as shown in FIGS. 5 and 6. The notch 144 can be generally V-shaped. More particularly, the notch can be shaped as a sideways V when viewing the valve core 142 in a vertical orientation, with the open side of the V on the outer side of the valve core 142. The top surface 141 and the bottom surface 143 of the notch 144 taper towards one another as shown in FIG. 5. The point of the V or innermost surface 147 of the notch 144 can be rounded, as shown in FIGS. 5 and 6. The innermost surface 147 can comprise a circular radius. In some embodiments, the innermost surface 147 can comprise a different radius (e.g., elliptical). In other embodiments, the notch may come to a point. Other shapes are also possible. For example, the notch can be generally hemispherical, partially spherical, cylindrical, parabolic, slit-shaped, etc. Certain notch shapes, like a V-shape, can minimize parallel surfaces within the notch. Minimizing parallel surfaces can enhance UV disinfection effectiveness as parallel surfaces may not receive sufficient UV flux to properly disinfect the area. For example, parallel surfaces may not allow complete disinfection or disinfection in a timely manner. Valves with slits or grooves are known in the art. However, such valves are not optimized for UV disinfection as they have parallel walls not suited for UV disinfection. Because the UV light from external sources may be parallel to the parallel walls, it can be more difficult to ensure that parallel walls have been disinfected.

[0054] The valve core 142 can have a diameter of about 0.26 inches. In some embodiments, the diameter of the valve core 142 is about 0.2-0.3 inches.

[0055] The notch can be about 0.2 inches tall (direction along the height of the valve core 142). In some embodiments, the notch is about 0.15-.25 inches tall. The notch can be about 0.2 inches deep (direction into interior of valve core 142). In some embodiments, the notch is about 0.15-.25 inches deep. The notch can be about 0.26 inches wide (direction across valve core 142). In some embodiments, the notch is about 0.2-0.3 inches wide.

[0056] The flush hole 150 can be positioned in the valve body 140 so that it is at the approximate midpoint of the height of the notch 144, as shown in FIG. 5. Positioning the flush hole 150 at this level can help optimize fluid flow during the flush. Positioning the flush hole 150 higher or lower can create more space for accumulation of fluids and contaminants. As

such, the flush hole 150 being positioned, in the valve body 140, at the approximate midpoint of the notch 144 can help enhance the effectiveness of the flush.

[0057] In one aspect, the height of the notch 144 is about the same as the diameter of one or both of the through holes 146, 148. A circumference of the notch 144 can be the full size of the valve body 140 through holes 146, 148. Matching the size of the notch 144 and through holes 146, 148 can help eliminate choking of the flow and help prevent the through holes 146, 148 and/or notch 144 from getting plugged. A diameter of the through hole can be about 0.131 inches. In some embodiments, the diameter of the through hole is about 0.10-0.16 inches Providing for fluid flow through the valve 110 via a cut-out in the valve core instead of a through-hole in the valve core can allow for exteriorly applied UV light to disinfect the entire valve flow pathway, even if the valve core comprises non-UV transparent material. A valve core with a through-hole would not allow for fluid within a non-UV transmissive core to be disinfected. In some embodiments, the notch 144 has sharp edges, which can leave the maximum amount of surface area for valve core sealing.

[0058] Moving to FIG. 7, a bottom view of the transfer valve 110 is shown. As noted above, the valve body 140 and valve core 142 are positioned off-axis with respect to the tubular body 102 and the second connector 112 of the valve 110. A valve core comprising a notch that was centered in the fluid flow can impair the structural integrity of the valve core due to the core being positioned largely within the flow. Additionally, a centered valve core with a notch (vs. flow through) can impede flow more significantly than an off-axis valve core.

[0059] Additionally, a notch in the valve core reduces the surface area of the core available for sealing, for a given core diameter. A notch in a centered valve core would more greatly reduce the remaining valve core surface area available for sealing than a notch in an off-axis valve core, assuming the valve body size remains constant. A centered valve core with a notch would require a significantly larger valve body in order to maintain sufficient surface area for sealing various fluid paths. It can be important for the valve core to be able to seal off various flow paths to maintain the sterility of the various components.

[0060] An off-axis valve allows more degrees of rotation between the different valve positions. Requiring a user to rotate the valve a greater amount can help a user to select the right valve position. Ease in selecting the proper valve position can reduce user error in operating the valve.

[0061] As noted above, the off-axis nature of the valve can help allow for the valve to comprise a minimal volume. Minimizing the volume of the valve can minimize the volume to be disinfected. Minimizing the volume to be disinfected can minimize the amount of contaminants and, thus, the amount of UV required to disinfect. Thus, the UV can be on for less time and/or

smaller or fewer bulbs can be used. If less power is required, fewer and/or smaller batteries can be used. Smaller power and/or UV sources can allow the enclosure to be smaller, which can increase comfort and convenience for the patient.

[0062] In some embodiments, the valve body 140 and valve core 142 can comprise different materials. For example, the valve core 142 can comprise molded-in seals in lower cost materials, commonly used for valve cores. Such materials can be softer than the UV transparent valve body. In some embodiments, the valve core 142 comprises or is coated with a UV reflective material, which can further optimize incident radiation on any volume to be disinfected.

[0063] The valve 110 can comprise a system to show a user the position of the valve. The system can comprise a dome 156 with an indicator positioned at the bottom of the valve core 142. In each valve position (flush, flow, and closed), the dome 156 aligns with symbols 168 on the valve body 140 that indicates the position of the valve 110. The indicator system is described in more detail below.

[0064] The valve 110 can comprise a key 154 positioned on the valve core 142, for example, at the bottom of the valve core as shown in FIG. 8. The key 154 can be used to properly align the dome 156. The key 154 can comprise a feature to receive the dome 156, such as an indentation (e.g., V-shaped indentation, U-shaped indentation, etc.) as shown in FIG. 8. The key 154 can help ensure that the dome 156 does not rotate relative to the valve core 142. Features other than a dome are also possible. For example a square or cylindrical feature can also be used.

[0065] As stated above, the dome 156 can be positioned at the bottom of the valve core 142. The dome 156 can help to plug the bottom of the valve core 142, which can help eliminate the accumulation of nooks and crannies, minimizing the amount of contaminants in the valve 110. The dome 156 can have a slightly larger diameter than that of the valve core 142, which can help the dome 156 maintain its position within the core 142. The dome 156 can have a rounded shape, which can provide comfort to the patient while wearing the transfer catheter 100 in between dialysis sessions.

[0066] The dome 156 can include an indicator 158, for example, an embossed arrow as shown in FIGS. 9A and 9B. Alignment of the dome indicator 158 and various symbols 168 on the valve body 140 can allow a user to identify the position of the valve 110. As noted above, a center valve position (valve handle 118 in alignment with the tubular body 102) indicates that the valve 110 is in the off or closed position, as shown in FIG. 9B, in which the indicator 158 is aligned with the X symbol or closed icon 172. Turning the valve to the right, or CW, can move the valve 110 into the flush position where indicator 158 can be aligned with the flush icon 170 (water droplet) shown in FIG. 9B. The valve handle 118 can be rotated about 45° to move the

valve into the flush position. Turning the valve to the left, or CCW, can move the valve into the flow position. In the flow position, the indicator 158 can be aligned with the flow icon, not shown in FIG. 9B. The flow icon can comprise, for example, a triangle shape. The valve handle 118 can be rotated about 90° to move the valve into the flow position.

[0067] The valve 110 can be connected to the tubular body 102 via a connector, such as a barb 160 shown in FIG. 10A. Other connections between the valve 110 and the tubular body 102 are also possible. The connection between the valve 110 and the tubular body 102 can be configured to be fluid-tight in order to keep the interior of the tubular body 102 sterile.

[0068] As noted above, the valve handle 118 can include a notch 126 positioned beneath the handle configured to interface with a trough 128, as shown in FIGS. 4G and 10A. The trough 128 can be positioned on the strain relief 162 of the tubular body 102, shown in FIGS. 7, 4G, and 10A. A side view of the strain relief 162 is shown in FIG. 10A. A cross-sectional view of the strain relief 162 taken at a portion of the strain relief beneath the handle 118 is shown in FIG. 10B. The trough 128 can be positioned on a strain relief 162 positioned beneath the front portion of the handle 118 where the valve 110 interfaces with the tubular body 102. The strain relief 162 can comprise an undersized inner diameter which can provide additional grip on the tubular body 102 positioned over the barb 160. The strain relief 162 can be configured to blend into the overall profile of the valve 110. As shown in FIG. 4G, the strain relief 162 can have rounded surfaces 163. The design of the strain relief 162 can allow for the reduction of pinch points, nooks, and crannies. These features of the strain relief 162 can increase comfort for the user.

[0069] In some embodiments, the tubular body 102, male luer 164, and cap 166 on the first end 104 of the transfer catheter 100, as shown in FIG. 11, can comprise commercially available components. For example, Qosina parts 11553 and 65702 respectively can be used.

[0070] The valve body 140 can include a feature 131 such as a rib, shown in FIG. 4D. The feature 131 can be configured to interact with a groove (not shown) in the strain relief 162 to prevent the strain relief 162 from rotating about the tubular body 102. Rotation prevention can be important as the strain relief 162 is not symmetric, and rotation can change functionality of the catheter 100.

[0071] In use, when it is time for a dialysis session, a user begins with the transfer valve 110 in the closed position, as shown in the top view of FIG. 12A. The user may then remove the cap 114 and connect the transfer catheter to a solution set catheter, which comprises a Y-connector to a fresh dialysate bag and a drain bag. Alternatively, separate connections to the dialysate and drain bag can be made. The user can turn the valve 110 about 45° CW to the flush position and flush about 3 cm^3 of fresh dialysate out of the flush hole 150. The flush position is shown in a top view in FIG. 12B. After the flush, the user can turn the valve back about 45° CCW to the

closed position, shown in the top view of FIG. 12C. The flush can help ensure any dead volume within the valve and beneath the solution set catheter connector, which may not be UV-transmissive, is flushed out of the tubing. The user can then place the connected transfer catheter 100 and solution set catheter so that the connection between them, including the valve is placed within a UV applicator. The UV applicator can be configured to apply UV light from the valve to the connection point between the transfer catheter and the solution set catheter. The UV can be activated to deliver a desired amount of UV light to the catheters. After UV disinfection, the user can turn the valve about 90° CCW to the flow position and begin the drain and fill portion of the dialysis session. The flow position is shown in the top down view of FIG. 12D. After the dialysis session, the user can return the valve 110 to the closed position and re-cap the transfer catheter 100, as shown in FIG. 12A.

[0072] U.S. Provisional Patent Application No. 62/052,164, filed September 18, 2014, the entire disclosure of which is hereby incorporated by reference herein, provides examples of UV light applicators. In some embodiments, the UV light applicator can comprise a box comprising a UV light source. The box comprises top and bottom halves hinged together. The box can be rectangular, square, ovular, etc. The box can be configured to be clamped over the connection between the transfer catheter and the solution set catheter. The box can include arcuate sections on each half that form apertures for the catheters when the catheters are positioned within the box. The box can be ambidextrous, meaning the box can be configured to receive the transfer catheter on the right side and the solution set catheter on the left side or vice versa. For example, in some embodiments, the solution set catheter connection may comprise a wide shoulder. The box can be configured to receive the shoulder, via a groove, on either the right or left side of the box.

[0073] The box can comprise a curved bottom surface shaped to contour to the thigh of a patient. The box can be sized to receive the transfer catheter disclosed herein. As described above, the transfer catheter can be designed to comprise a small kill zone. As such, the box may only comprise 4 UV lamps and 4 AA batteries as the power source. Such a box can be light enough to rest on the lap of a patient during disinfection or disinfection and dialysis.

[0074] Further embodiments of flushing in combination with UV disinfection of a catheter line connection are disclosed in U.S. Provisional Application No. 61/978,556 (the '556 Application), filed on April 11, 2014, entitled CONNECTOR DISINFECTION SYSTEM, the entire disclosure of which is incorporated herein by reference. In the '556 application, embodiments using non-gravity assisted flush are disclosed. For example, a syringe can be used to draw the flush out of PD fluid path. Embodiments disclosed herein relate to a gravity assisted flush, wherein a position of the dialysate bag causes the dialysate to be flushed to the atmosphere

through the flush hole. It will be appreciated that any of the features or components of the '556 application can be used in combination with any of the features or components described herein. For example, a syringe or other non-gravity assist can be used to draw the flush out of the valve 110 described herein.

[0075] In still further embodiments, the size, shape, and included volume of the valves described herein are selected or optimized to reduce the volume of the valves (e.g., such as the valves described herein and in the '556 application or smaller). Reducing the volume of the valve can reduce the amount of UV used to disinfect and/or reduce the flush volume as the volume of potential contamination is reduced.

[0076] As noted above, it is believed that flushing in combination with UV sterilization can provide superior disinfection as compared to UV sterilization alone. PuraCath Medical and Phoenix deVentures performed a study comparing the effectiveness of flushing a PD fluid path with dialysate, exposing the path to UV light, or a combination of both. In the study, the inside fluid path of the Y-set connector and transfer catheter were inoculated with *Staphylococcus aureus*. After connecting the transfer catheter to the Y-set, the fluid path was either flushed with dialysate, exposed to UV light, or a combination of both methods.

[0077] The study showed a significant reduction in the growth of bacteria in the UV exposure + flush combination group vs. the UV exposure only group. The results indicate that combining a UV light delivery system with flushing, as in the embodiments disclosed herein, may permit a reduction in the risk of peritonitis in PD patients.

[0078] It will be appreciated that while the transfer catheter has been described in connection with peritoneal dialysis, the transfer catheter and/or valve can be used in numerous other applications, medical or otherwise such as with Central Venous Catheters (CVC) or Peripherally Inserted Central Catheter (PICC) either of which can be used for dialysis or other interventions.

[0079] Variations and modifications of the devices and methods disclosed herein will be readily apparent to persons skilled in the art. As such, it should be understood that the foregoing detailed description and the accompanying illustrations, are made for purposes of clarity and understanding, and are not intended to limit the scope of the invention, which is defined by the claims appended hereto. Any feature described in any one embodiment described herein can be combined with any other feature of any of the other embodiment whether preferred or not.

[0080] It is understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and scope of the appended claims. All publications, patents, and patent applications cited herein are hereby incorporated by reference for all purposes.

CLAIMS

What is claimed is:

1. A valve for use in a catheter connection, the valve comprising

a generally cylindrical valve body comprising a flush hole, an inlet, and an outlet, the flush hole positioned generally between the inlet and the outlet;

a generally cylindrical valve core comprising a V-shaped notch,

wherein fluid flow is permitted between the inlet and the outlet or the outlet and the flush hole.

2. The valve of claim 1, further comprising a handle connected to the valve core and configured to allow movement of the valve to different flow positions.

3. The valve of claim 2, wherein the valve comprises a closed position in which the handle is aligned with the inlet and outlet.

4. The valve of claim 2, wherein the handle comprises a locking mechanism configured to prevent inadvertent movement of the valve from the closed position.

5. The valve of any of claims 2 - 4, wherein the handle comprises a notch configured to interact with a trough of the valve.

6. The valve of any of the claims 2 - 5, wherein the handle comprises ribs on its bottom surface configured to interact with ribs on the valve body, the interaction configured to indicate various valve positions to a user.

7. The valve of any of the preceding claims, wherein the valve core is positioned off axis from a flow path between the inlet and the outlet.

8. The valve of any of the preceding claims, further comprising a first connector connected to the inlet and a second connector connected to the outlet.

9. The valve of claim 8, wherein the first connector is configured to connect to a transfer catheter.

10. The valve of claim 8 or 9, wherein the second connector is configured to connect to a solution set catheter.

11. The valve of any of the preceding claims, further comprising a cover positioned over the second connector .

12. The valve of claim 11, wherein the cover is configured to interact with a handle of the valve to maintain the valve in a closed position.

13. The valve of any of the preceding claims, wherein at least one of the inlet and the outlet has a generally ellipsoid shape.

14. The valve of any of the preceding claims, wherein at least one of the inlet and the outlet has angled side walls.

15. The valve of any of the preceding claims, wherein the valve comprises

a closed position in which fluid communication between any of the inlet, the outlet and the flush hole is not permitted;

a flush position in which only fluid communication between the outlet and the flush hole is permitted; and

a flow position in which only fluid communication between the inlet and the outlet is permitted.

16. The valve of any of the preceding claims, wherein the flush hole is positioned generally equidistant from the inlet and the outlet.

17. The valve of any of the preceding claims, wherein the flush hole comprises a diameter of about 0.04-0.06 inches.

18. The valve of any of the preceding claims, wherein the V-shaped notch comprises a rounded point.

19. The valve of any of the preceding claims, wherein the notch comprises a height of about 0.15-0.25 inches.

20. The valve of any of the preceding claims, wherein the notch comprises a depth of about 0.15-0.25 inches.

21. The valve of any of the preceding claims, wherein the notch comprises a width of about 0.2-0.3 inches.

22. The valve of any of the preceding claims, wherein the flush hole is positioned along the valve body at an approximate midpoint of a height of the V-shaped notch.

23. The valve of any of the preceding claims, wherein a height of the notch and a diameter of at least one of the inlet and the outlet is about the same.

24. The valve of any of the preceding claims, wherein the valve core comprise a UV opaque material.

25. The valve of any of the preceding claims, wherein the valve body comprises a UV transparent material.

26. A valve for use in a catheter connection, the valve comprising

a generally cylindrical valve body comprising a flush hole, an inlet, and an outlet, the flush hole positioned generally between the inlet and the outlet;

a generally cylindrical valve core comprising a notch comprising non-parallel surfaces,

wherein the valve core is positioned off-axis with respect to the inlet and outlet.

27. The valve of claim 26, further comprising a handle connected to the valve core and configured to allow movement of the valve to different flow positions.

28. The valve of claim 27, wherein the valve comprises a closed position in which the handle is aligned with the inlet and outlet.

29. The valve of claim 28, wherein the handle comprises a locking mechanism configured to prevent inadvertent movement of the valve from the closed position.

30. The valve of any of claims 27 - 29, wherein the handle comprises a notch configured to interact with a trough of the valve.

31. The valve of any of claims 27 - 30, wherein the handle comprises ribs on its bottom surface configured to interact with ribs on the valve body, the interaction configured to indicate various valve positions to a user.

32. The valve of any of claims 26 - 31, further comprising a first connector connected to the inlet and a second connector connected to the outlet.

33. The valve of claim 32, wherein the first connector is configured to connect to a transfer catheter.

34. The valve of claims 32 or 33, wherein the second connector is configured to connect to a solution set catheter.

35. The valve of any of claims 26 - 34, further comprising a cover positioned over the second connector.

36. The valve of claim 35, wherein the cover is configured to interact with a handle of the valve to maintain the valve in a closed position.

37. The valve of any of claims 26 - 36, wherein at least one of the inlet and the outlet has a generally ellipsoid shape.

38. The valve of any of claims 26 - 37, wherein at least one of the inlet and the outlet has angled side walls.

39. The valve of any of claims 26 - 38, wherein the valve comprises

a closed position in which fluid communication between any of the inlet, the outlet and the flush hole is not permitted;

a flush position in which only fluid communication between the outlet and the flush hole is permitted; and

a flow position in which only fluid communication between the inlet and the outlet is permitted.

40. The valve of any of claims 26 - 39, wherein the flush hole is positioned generally equidistant from the inlet and the outlet.

41. The valve of any of claims 26 - 40, wherein the flush hole comprises a diameter of about 0.04-0.06 inches.

42. The valve of any of claims 26 - 41, wherein the notch is generally V-shaped.

43. The valve of claim 42, wherein the V-shaped notch comprises a rounded point.

44. The valve of any of claims 26 - 43, wherein the notch comprises a height of about 0.15-0.25 inches.

45. The valve of any of claims 26 - 44, wherein the notch comprises a depth of about 0.15-0.25 inches.

46. The valve of any of claims 26 - 45, wherein the notch comprises a width of about 0.2-0.3 inches.

47. The valve of any of claims 26 - 46, wherein the flush hole is positioned along the valve body at an approximate midpoint of a height of the notch.

48. The valve of any of claims 26 - 47, wherein a height of the notch and a diameter of at least one of the inlet and the outlet is about the same.

49. The valve of any of claims 26 - 48, wherein the valve core comprises a UV opaque material.

50. The valve of any of claims 26 - 49, wherein the valve body comprises a UV transparent material.

51. A valve for use in a catheter connection, the valve comprising

a generally cylindrical valve body comprising a flush hole, an inlet, and an outlet, the flush hole positioned generally between the inlet and the outlet;

a generally cylindrical valve core comprising a V-shaped notch, and

wherein fluid flowing within the valve can be exposed to UV radiation.

52. The valve of claim 51, further comprising a handle connected to the valve core and configured to allow movement of the valve to different flow positions.

53. The valve of claim 52, wherein the valve comprises a closed position in which the handle is aligned with the inlet and outlet.

54. The valve of claim 53, wherein the handle comprises a locking mechanism configured to prevent inadvertent movement of the valve from the closed position.

55. The valve of any of claims 52 - 54, wherein the handle comprises a notch configured to interact with a trough of the valve.

56. The valve of any of claims 52 - 55, wherein the handle comprises ribs on its bottom surface configured to interact with ribs on the valve body, the interaction configured to indicate various valve positions to a user.

57. The valve of any of claims 51 - 56, wherein the valve core is positioned off axis from a flow path between the inlet and the outlet.

58. The valve of any of claim 51 - 57, further comprising a first connector connected to the inlet and a second connector connected to the outlet.

59. The valve of claim 58, wherein the first connector is configured to connect to a transfer catheter.

60. The valve of claims 58 or 59, wherein the second connector is configured to connect to a solution set catheter.

61. The valve of any of claims 51 - 60, further comprising a cover positioned over the second connector.

62. The valve of claim 61, wherein the cover is configured to interact with a handle of the valve to maintain the valve in a closed position.

63. The valve of any of claims 51 - 62, wherein at least one of the inlet and the outlet has a generally ellipsoid shape.

64. The valve of any of claims 51 - 63, wherein at least one of the inlet and the outlet has angled side walls.

65. The valve of any of claims 51 - 64, wherein the valve comprises

a closed position in which fluid communication between any of the inlet, the outlet and the flush hole is not permitted;

a flush position in which only fluid communication between the outlet and the flush hole is permitted; and

a flow position in which only fluid communication between the inlet and the outlet is permitted.

66. The valve of any of claims 51 - 65, wherein the flush hole is positioned generally equidistant from the inlet and the outlet.

67. The valve of any of claims 51 - 66, wherein the flush hole comprises a diameter of about 0.04-0.06 inches.

68. The valve of any of claims 51 - 67, wherein the V-shaped notch comprises a rounded point.

69. The valve of any of claims 51 - 68, wherein the notch comprises a height of about 0.15-0.25 inches.

70. The valve of any of claims 51 - 69, wherein the notch comprises a depth of about 0.15-0.25 inches.

71. The valve of any of claims 51 - 70, wherein the notch comprises a width of about 0.2-0.3 inches.

72. The valve of any of claims 51 - 71, wherein the flush hole is positioned along the valve body at an approximate midpoint of a height of the V-shaped notch.

73. The valve of any of claims 51 - 72, wherein a height of the notch and a diameter of at least one of the inlet and the outlet is about the same.

74. The valve of any of claim 51 - 73, wherein the valve core comprises a UV opaque material.

75. The valve of any of claims 51 - 74, wherein the valve body comprises a UV transparent material.

76. A method of catheter line disinfection, comprising

connecting an end of a first catheter to an end of a second catheter first end, the end of the first catheter comprising a transfer valve comprising a valve body comprising an inlet configured to fluidly communicate with the first catheter, an outlet configured to fluidly communicate with the second catheter, and a flush hole positioned between the inlet and the outlet;

flushing fluid from the second catheter through the flush hole while sealing off fluid communication with the inlet; and

flowing fluid between the inlet and the outlet while sealing off fluid communication with the flush hole.

77. The method of claim 76, wherein flushing fluid from the second catheter through the flush hole comprises flushing dead volume within the valve and the second catheter.

78. The method of claim 77, wherein the dead volume is about 0.3 cm^3 – 1 cm^3.

79. The method of claim 77, wherein the dead volume is about 0.3 cm^3 – 2 cm^3.

80. The method of any of claims 76 - 79, wherein the second catheter is a solution set catheter connected to a drain bag and a dialysate bag.

81. The method of claim 80, wherein flushing fluid from the second catheter through the flush hole comprises flushing dialysate from the dialysate bag to the flush hole.

82. The method of any of claims 76 - 81 further comprising moving the transfer valve from a closed position to a flush position prior to flushing fluid from the second catheter through the flush hole while sealing off fluid communication with the inlet.

83. The method of any of claims 76 - 82, further comprising moving the transfer valve from a flush position to a flow position prior to flowing fluid between the inlet and the outlet while sealing off fluid communication with the flush hole.

84. The method of any of claims 76 - 83, wherein flushing fluid from the second catheter through the flush hole while sealing off fluid communication with the inlet comprises flushing about 3 cm^3 of fluid out of the flush hole.

85. The method of any of claims 76 - 84, further comprising placing the transfer valve in a UV applicator.

86. The method of any of claims 76 - 85, further comprising irradiating the transfer valve with UV light.

87. The method of any of claims 76 - 86, further comprising removing a cap from the outlet prior to connecting the outlet to the second catheter.

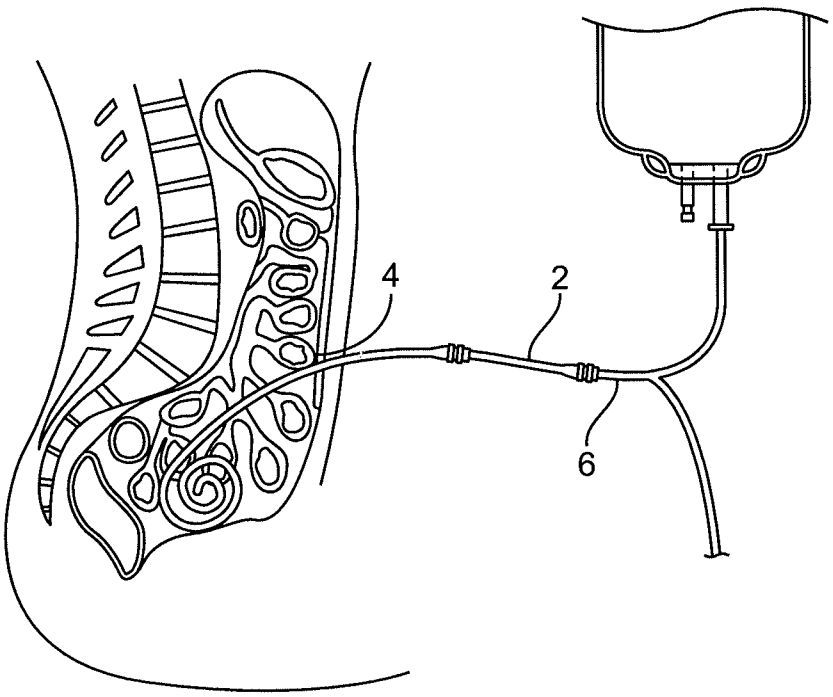


FIG. 1

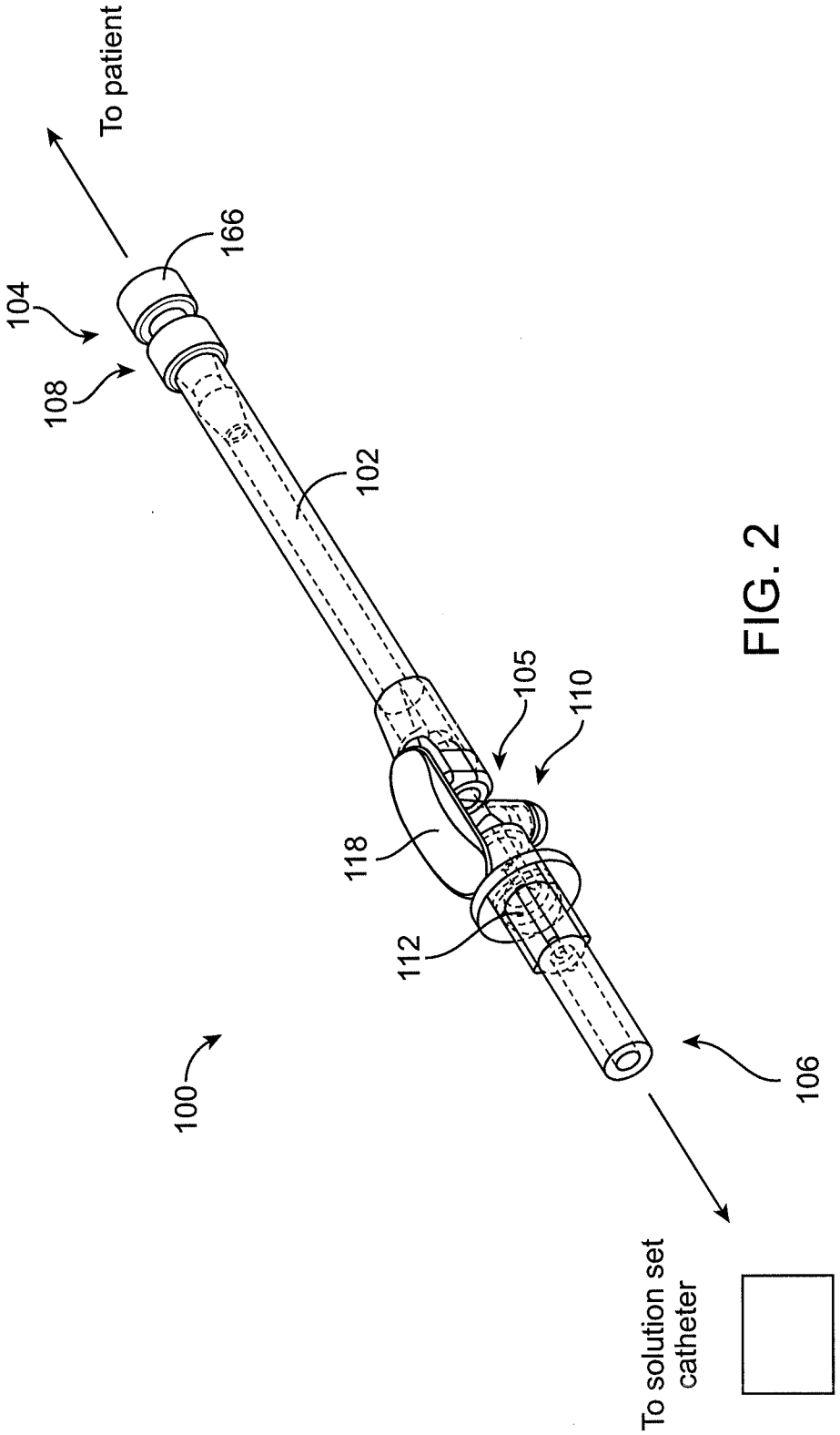

To patient
166
104
108
102
105
110
118
112
100
106
To solution set
catheter

FIG. 2

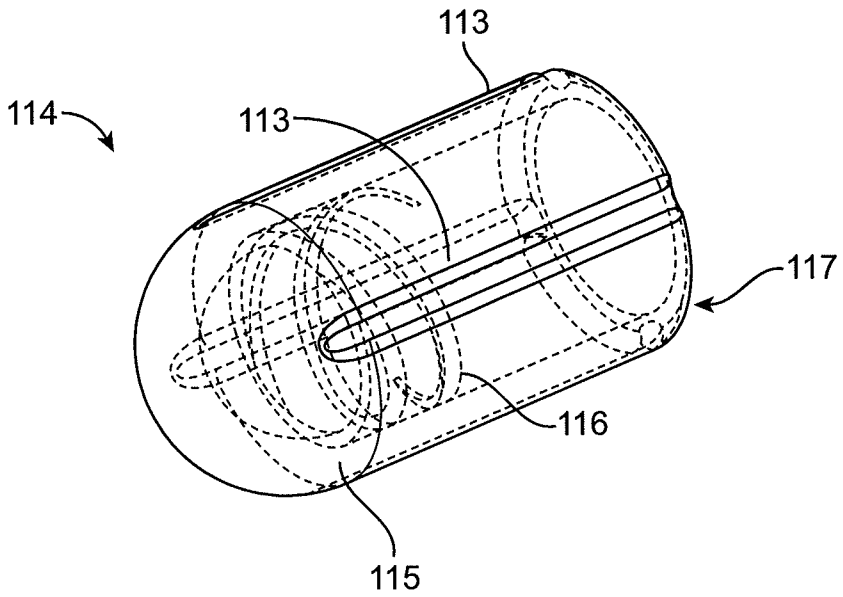


FIG. 3

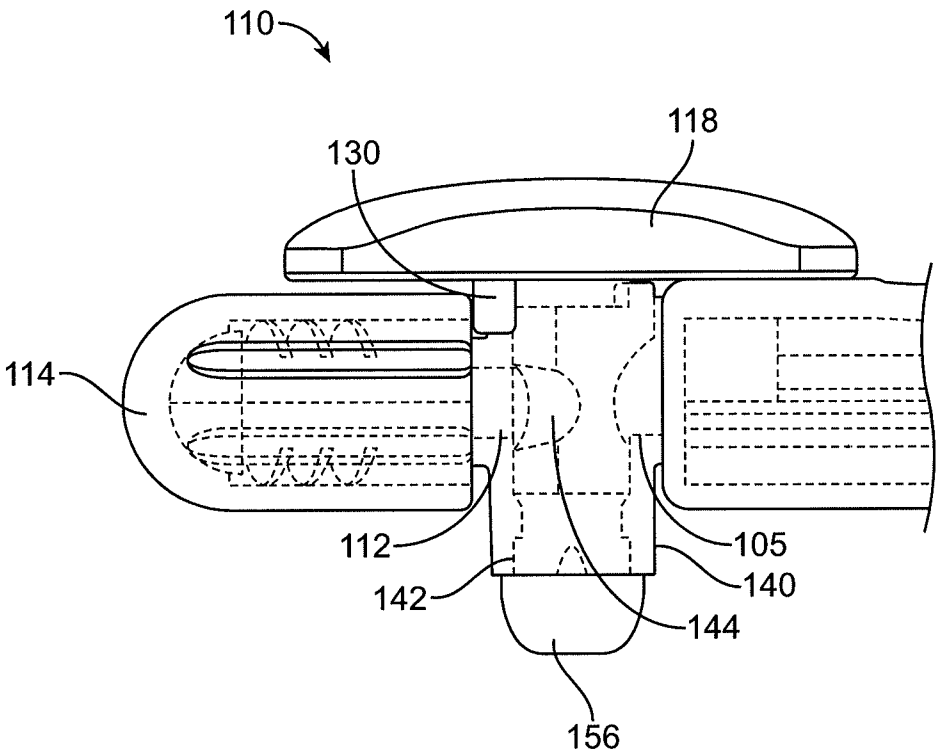


FIG. 4A

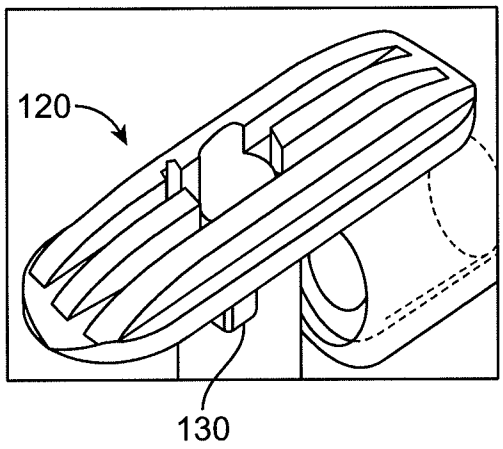


FIG. 4B

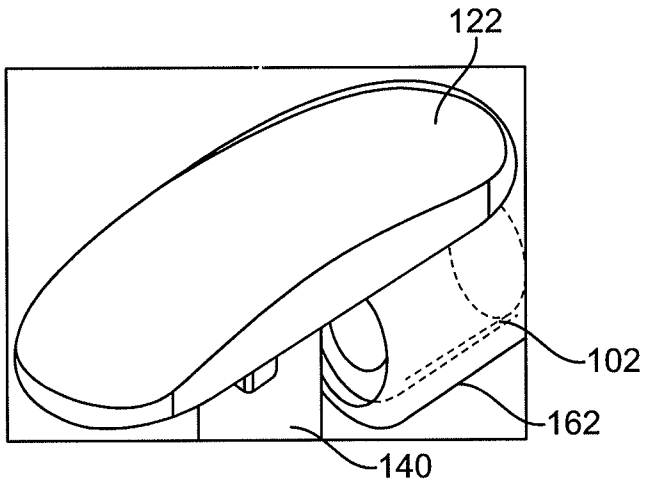


FIG. 4C

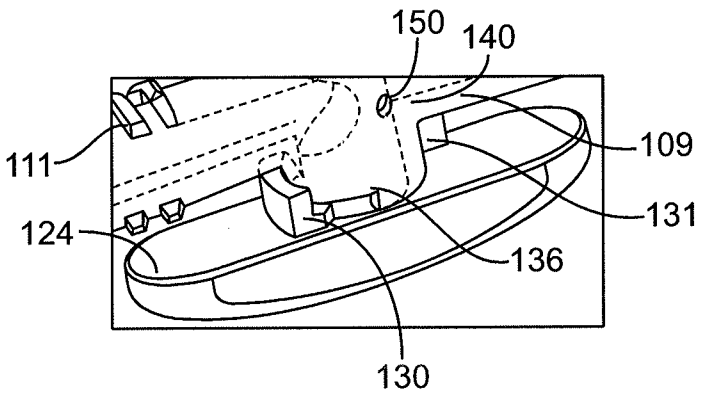


FIG. 4D

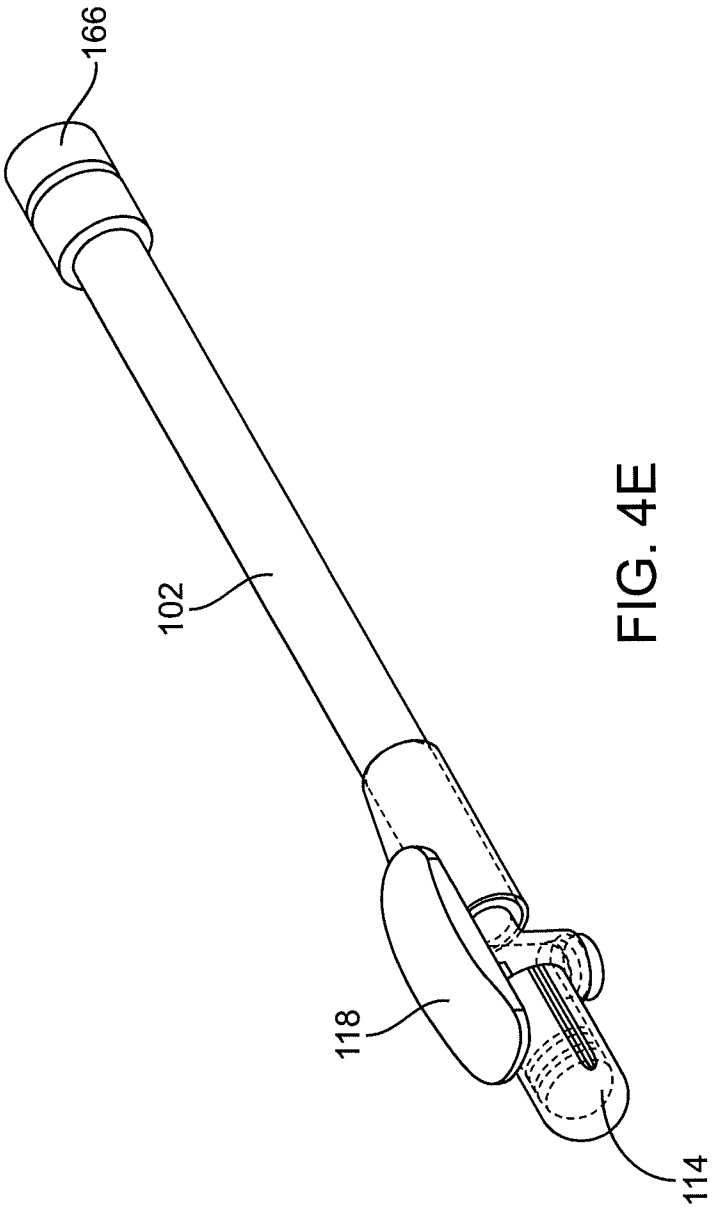


FIG. 4E

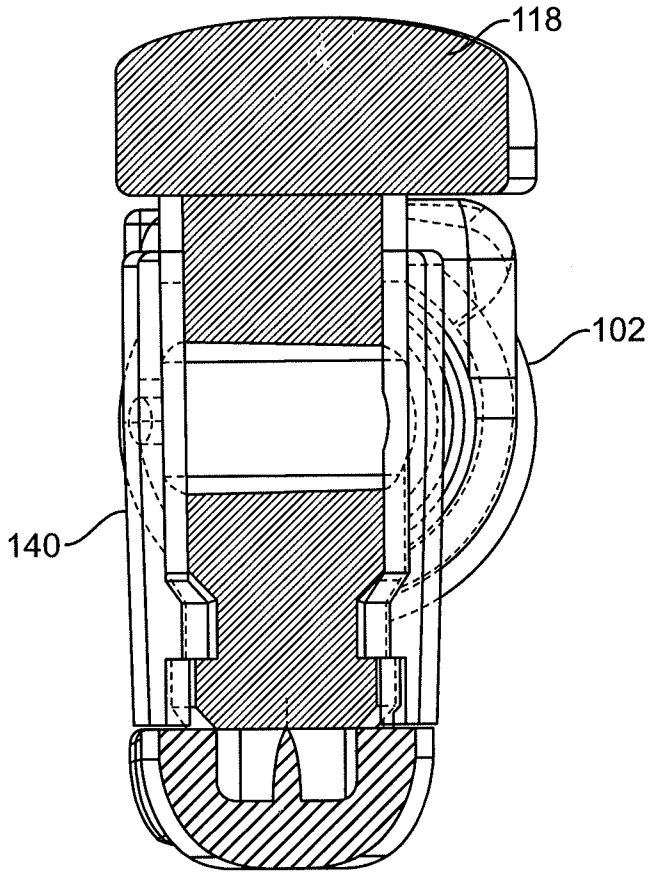


FIG. 4F

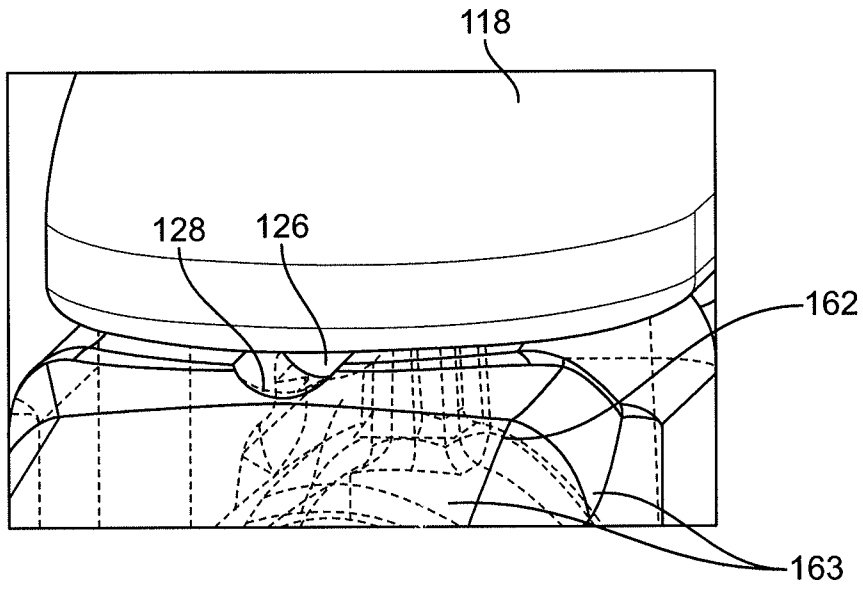


FIG. 4G

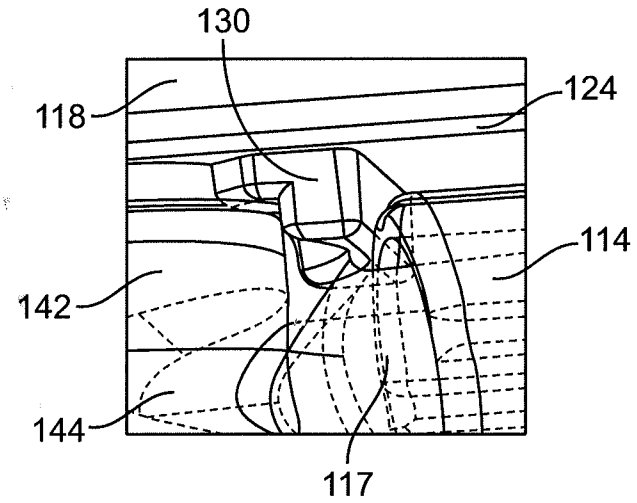


FIG. 4H

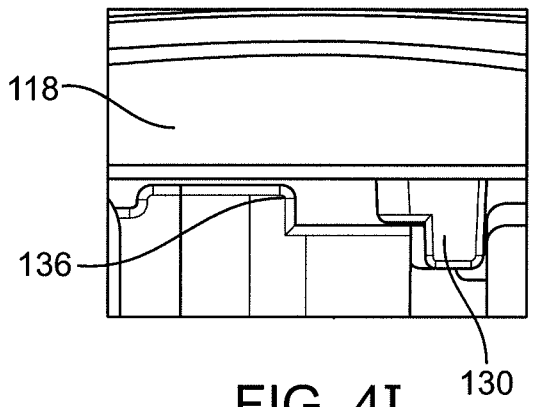


FIG. 4I

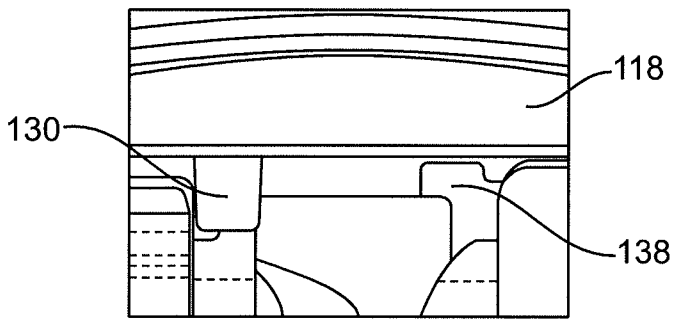


FIG. 4J

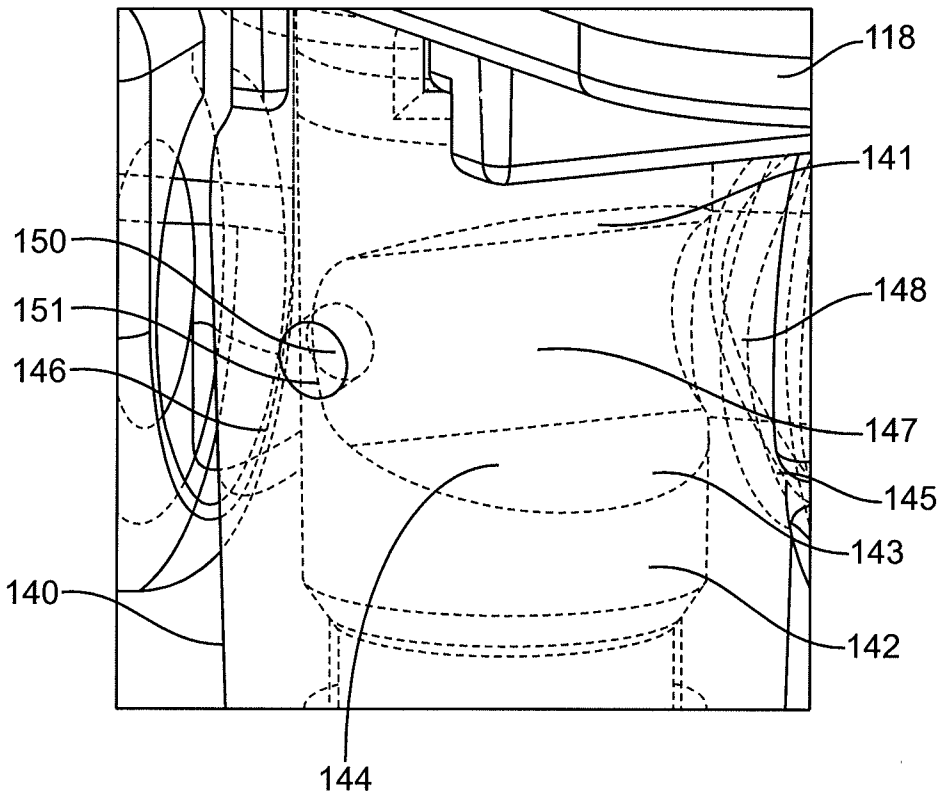


FIG. 5

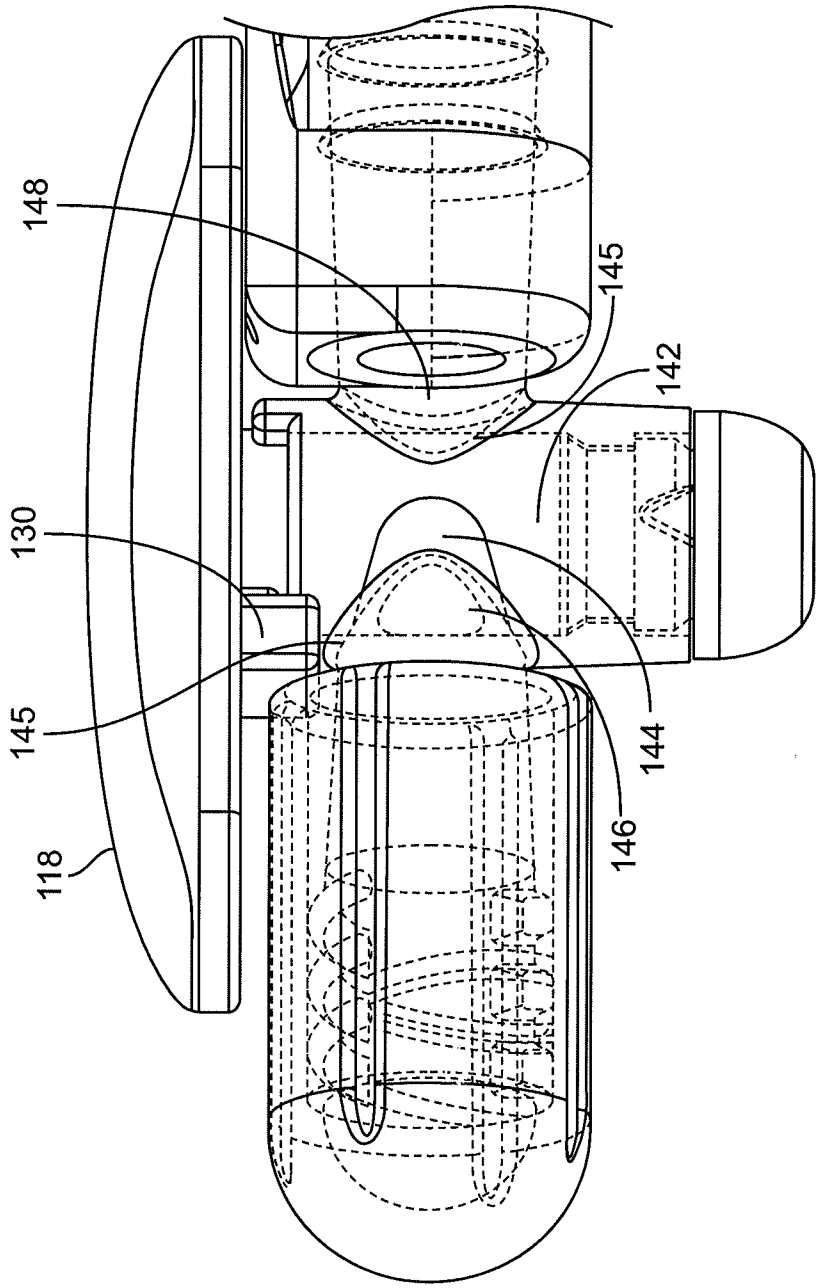


FIG. 6

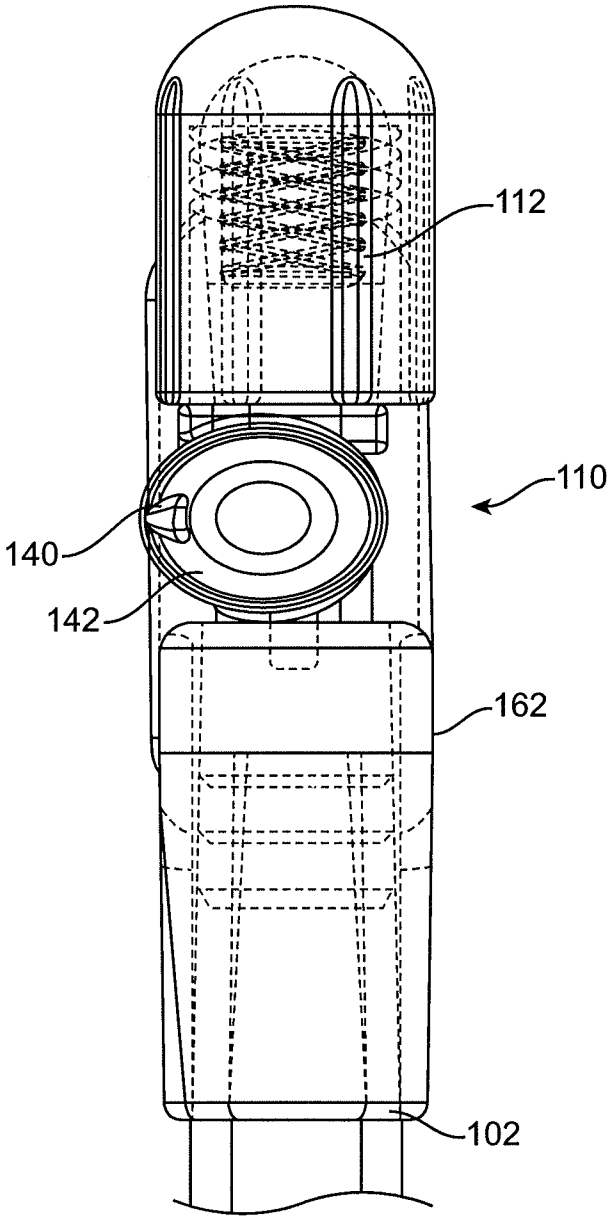


FIG. 7

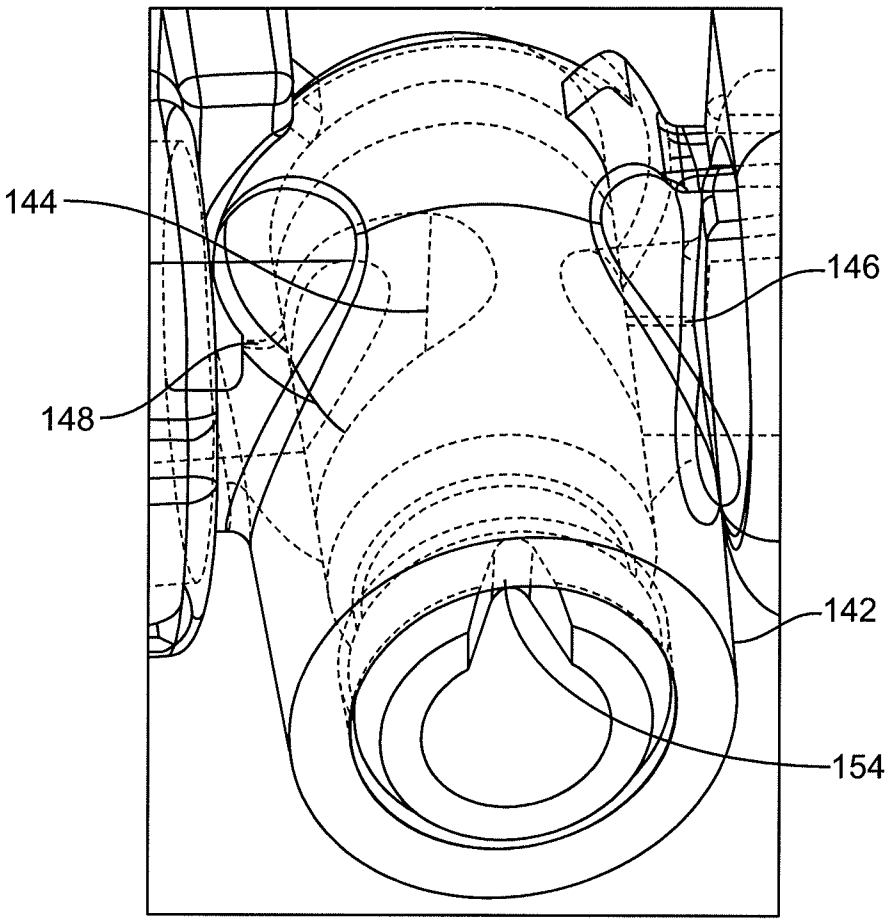


FIG. 8

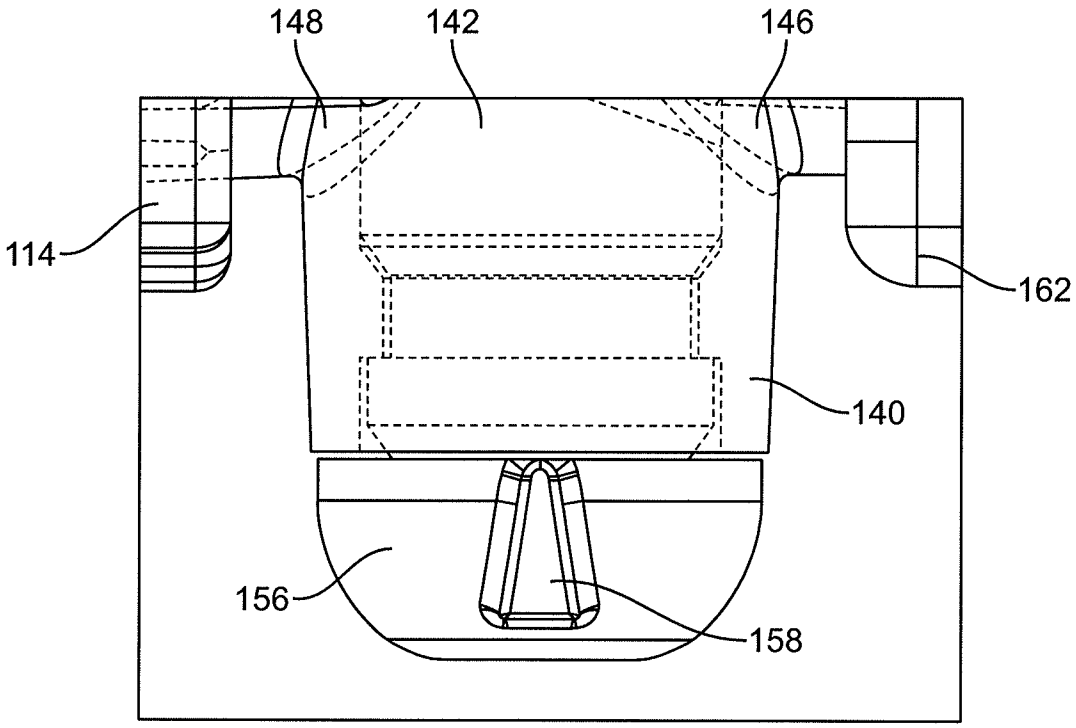


FIG. 9A

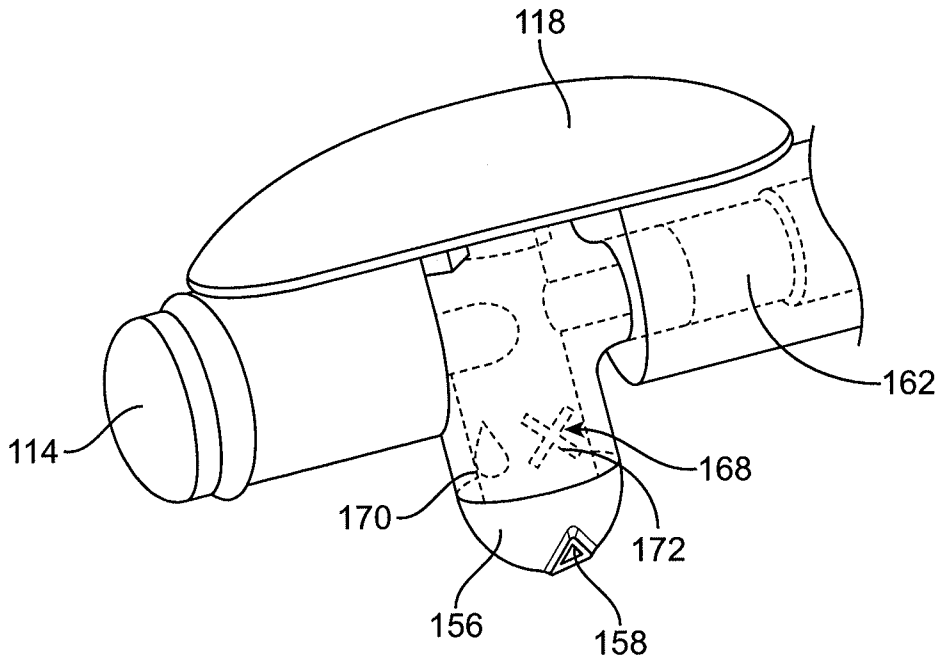


FIG. 9B

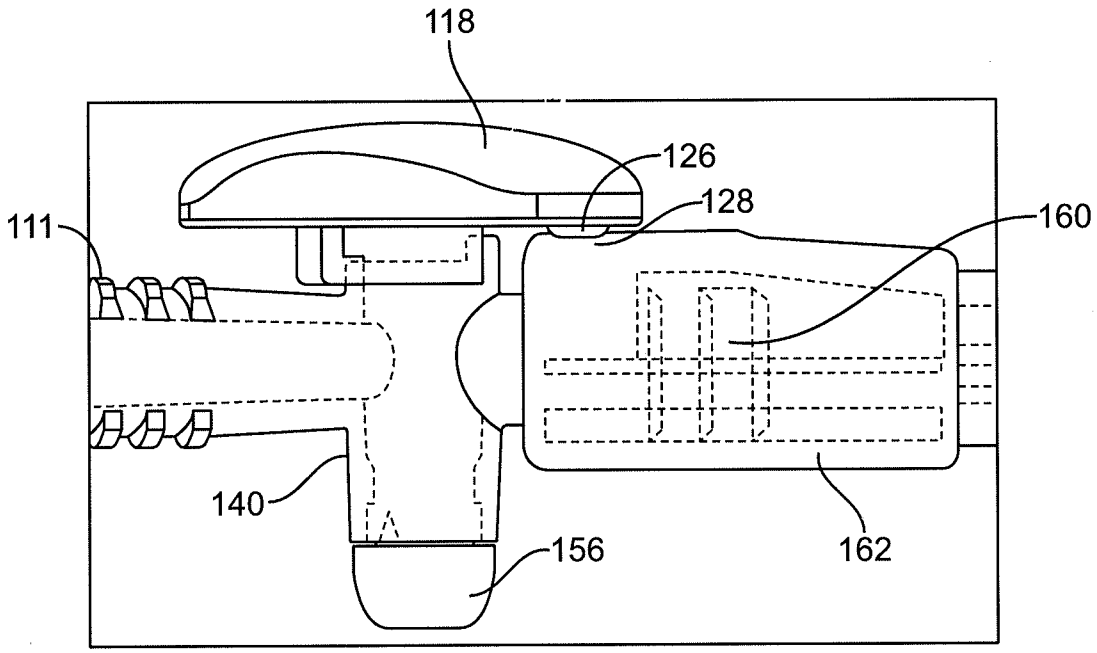


FIG. 10A

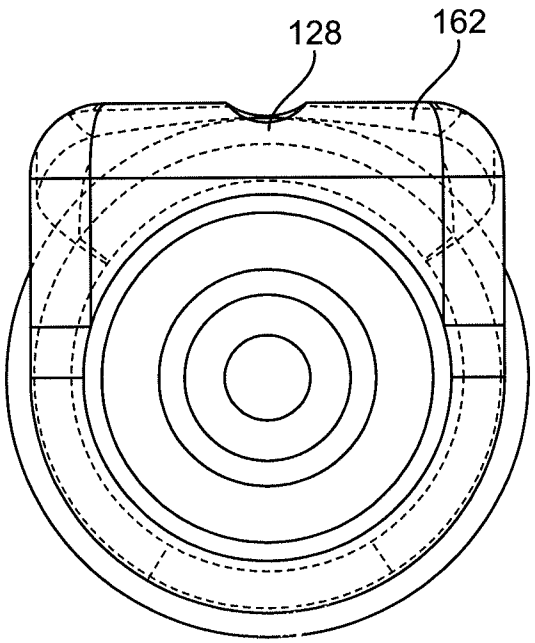


FIG. 10B

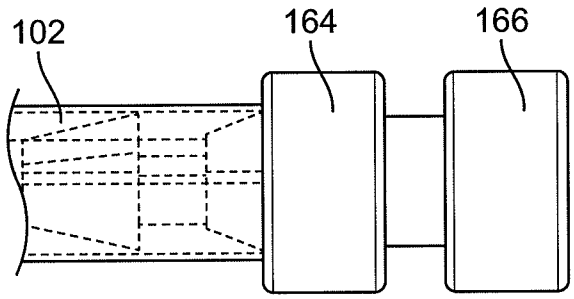
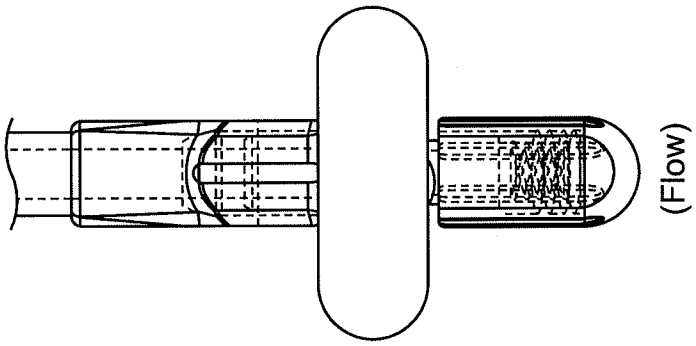
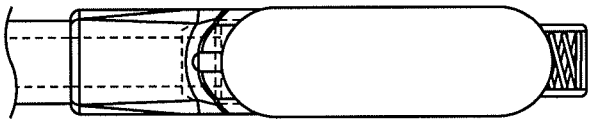


FIG. 11



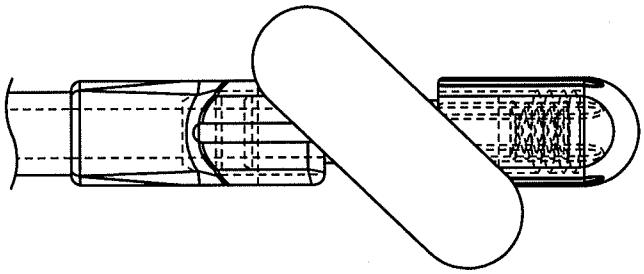
(Flow)

FIG. 12D



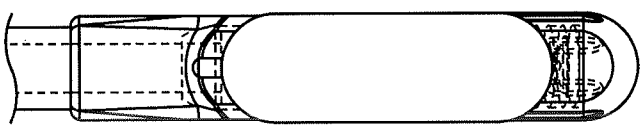
(Closed without cover)

FIG. 12C



(Flush)

FIG. 12B



(Closed with cover)

FIG. 12A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/34190

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/00 (2015.01)
CPC - A61M 39/225
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)
CPC: A61M 39/225 IPC(8): A61M 1/00 (2015.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 604/32; 251/149.2, 208, 209; 137/625.46, 625.47
CPC: A61M 39/223 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google Patents; Google
Search Terms Used: vent*, flush*, drain*, adaptor, adapter, connector, coupler, coupling, manifold, valve, notch, recess, cutout, rotary, rotat*, detent, lock*, handle, offset, catheter, outer, exterior, external, channel, groove

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X – Y	US 4,949,723 A (WALLACE et al) 21 August 1990 (21.08.1990) fig 3B, 3D, c ol 8, ln 16-20	1-3 --- 4-5, 26-30, 51-53
Y	US 5,105,853 A (LIE) 21 April 1992 (21.04.1992) fig 1, 2, col 4, ln 21-26	4-5, 29-30, 54-55
Y	US 2008/0195031 A1 (KITANI et al) 14 August 2008 (14.08.2008) fig 4, para [0048]	26-30
Y	WO 1982/04187 A1 (MONCRIEF et al) 09 December 1982 (09.12.1982) abstract	51-55

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
05 October 2015 (05.10.2015)	02 NOV 2015

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/34190

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 6-25, 31-50, 56-75, 82-87
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-5, 26-30, 51-55 directed to a valve.

Group II: Claims 76-81 directed to a method of catheter line disinfection.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

----Continued on Supplemental Page----

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-5, 26-30, 51-55

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/34190

Continuation of Box III: Observations where unity of invention is lacking

Special Technical Features

The invention of Group II includes the special technical features of method steps for catheter line disinfection including connecting an end of a first catheter to an end of a second catheter first end, the end of the first catheter comprising a transfer valve; flushing fluid from the second catheter through the flush hole while sealing off fluid communication with the inlet; and flowing fluid between the inlet and the outlet while sealing off fluid communication with the flush hole. not required in Group I.

Common Technical Features

Groups I and II are related as an apparatus (group I) and a method of using the apparatus (group II). The inventions of Groups I-II share the technical features of Claim 1. The apparatus is known in the prior art, as shown in US 4,949,723 A to Wallace, et al. (hereinafter 'Wallace').

Regarding claim 1, Wallace teaches a valve for use in a catheter connection (intended use), the valve comprising
a generally cylindrical valve body (70) comprising a flush hole (84), an inlet (85), and an outlet (87), the flush hole positioned generally between the inlet and the outlet (fig 3D);
a generally cylindrical valve core (74) comprising a notch (98), wherein fluid flow is permitted between the inlet and the outlet or the outlet and the flush hole (fig 3B, col 8, ln 16-20), but does not specifically teach the notch being V -shaped. However, Wallace teaches a notch with a u-shape (fig 3D). It would have been obvious to one of ordinary skill in the art that other shapes would have been used, including a v-shape, in order to optimizing operating parameters of the valve, as selection of an appropriate shape is within the ordinary skill of one in the art.

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

Continuation of Item 4
Claims 6-25, 31-50, 56-75, 82-87 have been held unsearchable because they are not drafted in accordance with the second and third sentences of Rule 6.4(a).