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(54) MEDICAL FLUID PUMPING SYSTEMS AND RELATED DEVICES AND METHODS

MEDIZINISCHE FLÜSSIGKEITSPUMPSYSTEME SOWIE ZUGEHÖRIGE VORRICHTUNGEN UND VERFAHREN

SYSTÈMES DE POMPAGE DE FLUIDE MÉDICAL ET DISPOSITIFS ET PROCÉDÉS ASSOCIÉS

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TECHNICAL FIELD

[0001] This disclosure relates to medical fluid pumping systems and related devices and methods.

BACKGROUND

[0002] Dialysis is a treatment used to support a patient with insufficient renal function. The two principal dialysis methods are hemodialysis and peritoneal dialysis.

[0003] During hemodialysis ("HD"), the patient's blood is passed through a dialyzer of a dialysis machine while also passing a dialysis solution or dialysate through the dialyzer. A semi-permeable membrane in the dialyzer separates the blood from the dialysate within the dialyzer and allows diffusion and osmosis exchanges to take place between the dialysate and the blood stream. These exchanges across the membrane result in the removal of waste products, including solutes like urea and creatinine, from the blood. These exchanges also regulate the levels of other substances, such as sodium and water, in the blood. In this way, the dialysis machine acts as an artificial kidney for cleansing the blood.

[0004] During peritoneal dialysis ("PD"), a patient's peritoneal cavity is periodically infused with dialysis solution or dialysate. The membranous lining of the patient's peritoneum acts as a natural semi-permeable membrane that allows diffusion and osmosis exchanges to take place between the solution and the blood stream. These exchanges across the patient's peritoneum, like the continuous exchange across the dialyzer in HD, result in the removal of waste products, including solutes like urea and creatinine, from the blood, and regulate the levels of other substances, such as sodium and water, in the blood.

[0005] Many PD machines are designed to automatically infuse, dwell, and drain dialysate to and from the patient's peritoneal cavity. The treatment typically lasts for several hours, often beginning with an initial drain procedure to empty the peritoneal cavity of used or spent dialysate. The sequence then proceeds through the succession of fill, dwell, and drain phases that follow one after the other. Each phase is called a cycle.

[0006] GB 2101232A describes a positive displacement pump for delivery of blood, or the like, from patients to an extracorporeal circuit, for purification, as in hemodialysis treatments. The pump comprises a single blood chamber attached to inlet and outlet conduits separated from the chamber and each other by low resistance flapper valves. The flapper valves are integral with a flexible diaphragm which forms one side of the blood chamber and are operative to close the outlet valve and to open the inlet valve to fill the blood cavity responsive to withdrawal of the diaphragm from the blood chamber cavity and to reverse each valve upon penetration of the diaphragm into the blood chamber to deliver uniformly small

increments of blood to an artificial kidney or other blood treatment device.

[0007] US 2010/0241062 describes a medical fluid delivery cassette configured for use with a medical fluid pumping system. The cassette includes a base, a membrane attached to the base, and an adhesive disposed on a portion of the membrane overlying a fluid pump chamber of the cassette. The portion of the membrane overlying the fluid pump chamber is moveable such that the volume of the fluid pump chamber can be changed.

SUMMARY

180001 The invention is defined in the appended claims. In one aspect, a medical fluid pumping system includes a medical fluid pumping machine including a piston head that can be linearly displaced and a medical fluid cassette that can be secured to the medical fluid pumping machine. The medical fluid cassette includes a base, a flexible membrane attached to the base in a manner such that the flexible membrane and the base cooperate to at least partially define a fluid pump chamber, and a fastening member attached to the flexible membrane. The fastening member defines a recess configured to receive the piston head of the medical fluid pumping machine, and the fastening member has an engagement surface that engages an engagement surface of the piston head when the piston head is disposed in the recess such that, when the piston head is disposed in the recess and is moved linearly away from the base of the cassette, the engagement surface of the piston head is engaged with the engagement surface of the fastening member and pulls the fastening member and the flexible membrane to which the fastening member is attached away from the base to increase a volume of the fluid pump chamber.

[0010] In another aspect, a medical fluid cassette includes a base, a flexible membrane attached to the base in a manner such that the flexible membrane and the base cooperate to at least partially define a fluid pump chamber, and a fastening member attached to the flexible membrane. The fastening member defines a recess configured to receive a piston head of a medical fluid pumping machine and has an engagement surface that engages the piston head when the piston head is disposed in the recess such that, when the piston head is disposed in the recess and is moved linearly away from the base of the cassette, the piston head engages the engagement surface of the fastening member to pull the fastening member and the flexible membrane to which the fastening member is attached away from the base and increase a volume of the fluid pump chamber.

[0011] In a further aspect, a medical fluid pumping machine includes a piston head that can be linearly displaced and is configured to be disposed within a recess defined by a fastening member of a medical fluid cassette. The piston head has an engagement surface configured to engage an engagement surface of the medical

fluid cassette when the piston head is disposed in the recess such that, when the piston head is disposed in the recess and is moved linearly away from a base of the cassette, the engagement surface of the piston head is engaged with the engagement surface of the fastening member and pulls the fastening member and a flexible membrane to which the fastening member is attached away from the base to increase a volume of a fluid pump chamber defined in the cassette between the flexible membrane and the base.

[0012] In an additional aspect, a medical fluid pumping method includes advancing a piston head into a recessed region of a fastening member of a medical fluid cassette to mechanically connect the piston head to the fastening member, and then reciprocating the piston head to cause the fastening member to alternately retract and advance, which causes fluid to alternately be drawn into a fluid pump chamber of the cassette and forced out of the fluid pump chamber of the cassette.

[0013] Implementations of these aspects can include one or more of the following features.

[0014] In some implementations, the medical fluid cassette can be secured to the medical fluid pumping machine by disposing the medical fluid cassette within a cassette compartment defined by the medical fluid pumping machine.

[0015] In certain implementations, the cassette compartment is defined between a door and a cassette interface of the medical fluid pumping machine.

[0016] In some implementations, the fastening member is substantially centered relative to the fluid pump chamber of the medical fluid cassette.

[0017] In certain implementations, the fastening member includes a substantially dome-shaped member.

[0018] In some implementations, the engagement surface of the fastening member is a surface of a radially inwardly extending projection of the substantially domeshaped member.

[0019] In certain implementations, the projection extends continuously around a perimeter region of the substantially dome-shaped member.

[0020] In some implementations, the fastening member includes a peg extending from a surface of the domeshaped member.

[0021] In certain implementations, the engagement surface of the fastening member is a surface of an enlarged head of the peg.

[0022] In some implementations, the piston head includes a body portion and a contact surface that extends radially beyond a perimeter of the body portion. The contact surface of the piston head is configured to contact a contact surface of the fastening member of the medical fluid cassette when the piston head is inserted into the recess of the fastening member.

[0023] In certain implementations, the contact surfaces are angled at about 30 degrees to about 60 degrees relative to a longitudinal axis of the piston head.

[0024] In some implementations, the contact surface

of the piston head is configured to move radially inwardly when the piston head is inserted into the recess of the fastening member.

[0025] In certain implementations, the contact surface of the piston head is a surface of a latch that is radially moveable relative to a body portion of the piston head.

[0026] In some implementations, the contact surface of the fastening member is configured to deflect radially outwardly when the piston head is inserted into the recess of the fastening member.

[0027] In certain implementations, the contact surface of the fastening member is a surface of a radially inwardly extending projection of the fastening member.

[0028] In some implementations, the piston head includes a latch secured to a body portion of the piston head, the engagement surface of the piston head is a surface of the latch, and the latch has an extended position in which the surface of the latch is positioned radially outward of a perimeter of the body portion.

[0029] In certain implementations, the latch has a retracted position in which the surface of the latch is positioned radially inward of the perimeter of the body portion.
[0030] In some implementations, the piston head further includes a second latch that is secured to the body portion of the piston head and has an extended position in which an engagement surface of the second latch is positioned radially outward of the perimeter of the body portion and a retracted position in which the engagement surface of the latch is positioned radially inward of the perimeter of the body portion.

[0031] In certain implementations, the body portion includes front and rear members, and the latch is positioned in a space defined between the front and rear members.

[0032] In some implementations, the piston head further includes a latch lock having a first angled surface that sits adjacent an associated first angled surface of the latch such that radially inward movement of the latch causes axial movement of the latch lock in a first axial direction.

[0033] In certain implementations, the first angled surfaces are at an angle of about 30 degrees to about 60 degrees relative to a longitudinal axis of the piston head. [0034] In some implementations, the first angled surface of the latch and the first angled surface of the latch lock are at substantially the same angle relative to a longitudinal axis of the piston head.

[0035] In certain implementations, the piston head further includes a spring disposed between the latch lock and the front member to resist the axial movement of the latch lock in the first axial direction.

[0036] In some implementations, the latch and the latch lock are configured such that when a force applied to the latch to move the latch radially inwardly and to move the latch lock axially is released, the spring expands and moves the latch lock in a second axial direction opposite the first axial direction and causes the latch to move radially outwardly.

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[0037] In certain implementations, the latch lock has a second angled surface that sits adjacent an associated second angled surface of the latch such that the axial movement of the latch lock in the second axial direction causes the radially outward movement of the latch.

[0038] In some implementations, the latch defines a slot in which a leg of the latch lock is disposed, and the first and second angled surfaces of the latch lock are surfaces of the leg, and the first and second angled surfaces of the latch are surfaces that define the slot.

[0039] In certain implementations, the piston head includes a body portion and a flange that extends at least partially around a perimeter of the body portion, and the engagement surface of the piston head is a surface of the flange of the piston head.

[0040] In some implementations, the fastening member has a projection that extends at least partially around a perimeter of the recess, and the engagement surface of the fastening member is a surface of the projection of the fastening member.

[0041] In certain implementations, the fastening member is a substantially dome-shaped member.

[0042] In some implementations, the projection extends continuously around the perimeter of the recess.

[0043] In certain implementations, an outer diameter of the flange of the piston head is greater than an inner diameter of the flange of the fastening member, and the piston head and the fastening member are constructed such that at least one of the flanges deflects radially relative to the other of the flanges as the piston head is inserted into the recess of the fastening member to allow the piston head to be disposed within the recess.

[0044] In some implementations, the piston head includes a clamp, the fastening member includes a peg configured to be releasably engaged by the clamp, and the engagement surfaces of the piston head and the fastening member are surfaces of the clamp and the peg, respectively.

[0045] In certain implementations, the clamp is positioned within a bore defined by a body portion of the piston head.

[0046] In some implementations, the clamp includes first and second resilient fingers that are configured to deflect away from one another when the peg is received in the clamp.

[0047] In certain implementations, each of the first and second resilient fingers includes a first projection that extends radially inwardly from a base portion of its respective resilient finger.

[0048] In some implementations, a front surface of the first projection of each of the resilient fingers is angled relative to a longitudinal axis of the piston head to cause the first and second resilient fingers to deflect away from one another as the peg is received in the clamp and slides along the front surface of each first projection.

[0049] In certain implementations, the front surface of the first projection of each of the resilient fingers is angled at about 30 degrees to about 60 degrees relative to the

longitudinal axis of the piston head.

[0050] In some implementations, a rear surface of the first projection of each of the resilient fingers is angled relative to a longitudinal axis of the piston head to cause the first and second resilient fingers to deflect away from one another as the peg is removed from the clamp and slides along the rear surface of each first projection.

[0051] In certain implementations, the rear surface of the first projection of each of the resilient fingers is angled at about 30 degrees to about 60 degrees relative to the longitudinal axis of the piston head.

[0052] In some implementations, each of the first and second resilient fingers further includes a second projection that extends radially inwardly from the base portion of its respective resilient finger and is axially offset from the first projection of its respective finger such that the peg rests between the first and second projections of each of the resilient fingers when the peg is disposed in the clamp.

[0053] In certain implementations, the piston head further includes a shaft, the clamp and the body portion are axially moveable relative to the shaft, and the shaft is configured to deflect the resilient fingers of the clamp away from one another when the piston head and the clamp are retracted a certain distance relative to the shaft.

[0054] In some implementations, a rear surface of the second projection of each of the resilient fingers is positioned to contact the shaft when the body portion of the piston head and the clamp are retracted the certain distance relative to the shaft, and the rear surface of the second projection of each of the resilient fingers is angled relative to a longitudinal axis of the piston head to cause the first and second resilient fingers to deflect away from one another as the body portion of the piston head and the clamp are retracted the certain distance relative to the shaft.

[0055] In certain implementations, the rear surface of the second projection of each of the resilient fingers is angled at about 30 degrees to about 60 degrees relative to the longitudinal axis of the piston head.

[0056] In some implementations, a front surface of the second projection of each of the resilient fingers is substantially perpendicular to the longitudinal axis of the piston head.

[0057] In certain implementations, the piston head and the fastening member are constructed to become mechanically connected when the piston head is moved toward the base of the cassette and to become disconnected when the piston head is moved away from the base of the cassette.

[0058] In some implementations, the piston head is disposed within the recess of the fastening member and the engagement surfaces contact one another when the piston head and the fastening member are mechanically connected.

[0059] In certain implementations, the piston head and the fastening member are constructed to require an axial

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force of about 22.2 N (5.0 lbf) to about 222.4 N (50 lbf) to dispose the piston head within the recess of the fastening member such that the piston head and fastening member become mechanically connected.

[0060] In some implementations, the piston head and the fastening member are constructed to require an axial force of at least 222.4 N (50 pounds) to remove the piston head from the recess of the fastening member such that the piston head and fastening member become disconnected from one another.

[0061] In certain implementations, the medical fluid pumping machine is a dialysis machine.

[0062] In some implementations, the dialysis machine is a peritoneal dialysis machine.

[0063] In certain implementations, the fastening member is constructed to become mechanically connected to the piston head when the piston head is moved toward the base of the cassette and to become disconnected from the piston head when the piston head is moved away from the base of the cassette.

[0064] In some implementations, the medical fluid cassette is a dialysis fluid cassette. In certain implementations, the dialysis fluid cassette is a peritoneal dialysis fluid cassette.

[0065] In some implementations, the piston head is advanced into the recessed region of the fastening member with an axial force of about 22.2 N (5.0 lbf) to about 222.4 N (50 lbf).

[0066] In certain implementations, the medical fluid pumping method further includes, after reciprocating the piston head, retracting the piston head a certain distance to disconnect the piston head from the fastening member of the medical fluid cassette.

[0067] In some implementations, the piston head is retracted out of the recessed region of the fastening member with an axial force of at least 222.4 N (50 pounds). In certain implementations, the medical fluid cassette includes a base, a flexible membrane attached to the base in a manner such that the flexible membrane and the base cooperate to at least partially define the fluid pump chamber, and the fastening member attached to the flexible membrane. The fastening member has an engagement surface that engages an engagement surface of the piston head when the piston head is disposed in the recess such that, when the piston head is disposed in the recess and is moved linearly away from the base of the cassette, the engagement surface of the piston head is engaged with the engagement surface of the fastening member and pulls the fastening member and the flexible membrane to which the fastening member is attached away from the base to increase a volume of the fluid pump chamber and draw fluid into the fluid pump cham-

[0068] Implementations can include one or more of the following advantages.

[0069] In certain implementations, a relatively simple mechanical connection, such as a snap-fit connection, can be used to connect the piston head of the medical

fluid pumping machine to the fastening member of the medical fluid cassette. As a result, the system can be more user-friendly, less expensive, and quieter than certain medical fluid pumping systems that utilize vacuum-based connections between a medical fluid pumping machine and a medical fluid cassette.

[0070] In some implementations, the piston head of the medical fluid pump machine can be automatically mechanically connected to the fastening member of the medical fluid cassette by simply advancing the piston head a certain distance relative to the cassette, and the piston head of the medical fluid pump machine can be automatically mechanically disconnected from the fastening member of the medical fluid cassette by simply retracting the piston head a certain distance relative to the cassette. As a result of these automatic connection and disconnection processes, the operator of the machine need not take manual steps to cause the connection or disconnection of the piston head and the fastening member, which makes the system more user-friendly and reduces the risk of human errors that might negatively affect the treatment.

[0071] In certain implementations, the piston head includes a retractable latch mechanism that allows the piston head and its associated fastening member on the cassette to be mechanically connected and disconnected while reducing (e.g., minimizing) the amount of force required to be applied to the fastening member by the piston head. This arrangement can reduce (e.g., minimize) deformation of the piston head and the fastening member resulting from the connection and disconnection processes and can thus increase the pumping accuracy of the system. In particular, reducing deformation of the piston head and the fastening member can help to ensure that a tight fit is maintained between the piston head and the fastening member and can thus reduce (e.g., minimize) movement, such as slippage, that occurs between the piston head and the fastening member during the pumping process.

[0072] In certain implementations, the engagement surface of the latch is angled relative to the longitudinal axis of the piston (e.g., angled at about 60 to about 70 degrees) relative to the longitudinal axis of the piston). This angled arrangement can enable the piston head to be mechanically connected to fastening members of slightly different sizes (e.g., due to tolerances in the manufacturing process). In particular, the angled engagement surface allows the latch to tightly engage slightly differently sized fastening members by expanding radially outward slightly different distances.

[0073] Other aspects, features, and advantages will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

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FIG. 1 is a perspective view of a peritoneal dialysis ("PD") system that includes a PD cycler positioned atop a portable cart.

FIG. 2 is a perspective view of the PD cycler and a PD cassette of the PD system of FIG. 1. A door of the PD cycler is in the open position to show the inner surfaces of the PD cycler that interface with the PD cassette during use.

FIG. 3 is a perspective view of an open cassette compartment of the PD cycler of FIG. 1, showing, among other things, pistons having piston heads that include spring loaded latch mechanisms that can be used to mechanically connect the piston heads to associated dome-shaped members of the PD cassette.

FIG. 4 is a diagrammatic cross-sectional view of the PD cycler of FIG. 1, illustrating the spring loaded latch mechanism of one of its piston heads.

FIG. 5 is an exploded, perspective view of one of the pistons of the PD cycler of FIG. 1.

FIG. 6 is a side view of a latch lock of one of the piston heads of the PD cycler of FIG. 1.

FIG. 7 is a cross-sectional view of the latch lock, taken along line 7-7 in FIG. 6.

FIG. 8 is a plan view of a sliding latch of one of the piston heads of the PD cycler of FIG. 1.

FIG. 9 is a cross-sectional view of the sliding latch, taken along line 9-9 in FIG. 8.

FIG. 10 is an exploded, perspective view of the PD cassette of FIG. 1, which includes dome-shaped fastening members that can be mechanically connected to the piston heads of the PD cycler of FIG. 1.

FIG. 11 is a perspective, cross-sectional view of the fully assembled PD cassette of FIG. 10.

FIG. 12 is a perspective view of the fully assembled PD cassette of FIG. 10, from a flexible membrane and dome-shaped fastening member side of the PD cassette.

FIG. 13 is a perspective view of the fully assembled PD cassette of FIG. 10, from a rigid base side of the PD cassette.

FIG. 14 is a partial perspective view of the PD cassette in the cassette compartment of the PD cycler of the PD system of FIG. 1.

FIGS. 15A-15F are diagrammatic cross-sectional views of the PD system of FIG. 1 with the PD cassette disposed in the cassette compartment of the PD cycler, during different phases of a pumping operation. FIGS. 16 and 17 are cross-sectional views of one of the piston heads of the PD cycler of the PD system of FIG. 1 mechanically connected to one of the domeshaped fastening members of the PD cassette of the PD system of FIG. 1, illustrating horns or projections that extend from a rear surface of the piston head to allow the piston head to be automatically disconnected from the dome-shaped fastening member of the PD cassette.

FIGS. 18 and 19 are double cross-sectional views of one of the piston heads of the PD cycler the PD

system of FIG. 1 mechanically connected to one of the dome-shaped fastening members of the PD cassette of the PD system of FIG. 1, diagrammatically illustrating a process of automatically disconnecting the piston head from the dome-shaped fastening member of the PD cassette.

FIG. 20 is a diagrammatic cross-sectional view of another PD cycler that includes a translatable piston head with a peripheral flange that allows the piston head to be mechanically connected to a domeshaped fastening member of a PD cassette.

FIGS. 21A-21C are diagrammatic cross-sectional views of a PD cassette in the cassette compartment of the PD cycler of FIG. 20, during different phases of a pumping operation.

FIG. 22 is a perspective view of a PD cassette that includes dome-shaped fastening members having pegs that allow the dome-shaped fastening members to be mechanically connected to translatable piston heads of a PD cycler.

FIG. 23 is a diagrammatic side view of a translatable piston head that has a recess containing a clamp with resilient fingers that can engage the peg of one of the dome-shaped fastening members of the PD cassette of FIG. 22 to mechanically connect the piston head to the dome-shaped fastening member of the PD cassette. Internal features of the piston head are shown in dashed lines.

FIG. 24 is a front view of the piston head of FIG. 23. FIG. 25 is a diagrammatic side view of a translatable piston head that has a recess containing a clamp with resilient fingers of a slightly different configuration for engaging the peg of one of the dome-shaped fastening members of the PD cassette of FIG. 22 to mechanically connect the piston head to the dome-shaped fastening member of the PD cassette. Internal features of the piston head are shown in dashed lines.

FIG. 26 is a front view of the piston head of FIG. 25.

DETAILED DESCRIPTION

[0075] This disclosure relates generally to medical fluid pumping systems and related devices and methods. In some cases, a medical fluid pumping system (e.g., a peritoneal dialysis ("PD") system) includes a medical fluid pumping machine (e.g., a PD cycler) having a piston with a piston head that can be mechanically connected to a medical fluid cassette (e.g., a PD fluid cassette). Typically, the cassette includes a flexible membrane and a fastening member (e.g., a dome-shaped fastening member) attached to the membrane. The membrane and the fastening member overlie a recessed region of a rigid base of the cassette to form a fluid pump chamber, and the piston of the medical fluid pumping machine is designed to be mechanically connected to the fastening member of the cassette. With the piston of the medical fluid pumping machine mechanically connected to the

fastening member of the cassette, reciprocation of the piston causes fluid to be alternately drawn into and forced out of the fluid pump chamber by pulling the fastening member and membrane away from the recessed region of the base and then advancing the fastening member and membrane toward the recessed region of the base. As discussed below, in some cases, the piston can be automatically mechanically connected to the fastening member of the cassette by simply moving the piston toward the base of the cassette and into engagement with the fastening member prior to a medical treatment (e.g., PD treatment) and can be automatically disconnected from the fastening member of the cassette by simply moving the piston away from the base of the cassette and out of engagement with the fastening member after completion of the medical treatment.

[0076] Referring to FIG. 1, a PD system 100 includes a PD cycler (also referred to as a PD machine) 102 seated on a cart 104. Referring also to FIG. 2, the PD cycler 102 includes a housing 106, a door 108, and a cassette interface 110 that abuts a disposable PD cassette 112 when the cassette 112 is disposed within a cassette compartment 114 formed between the cassette interface 110 and the closed door 108. A heater tray 116 is positioned on top of the housing 106. The heater tray 116 is sized and shaped to accommodate a bag of dialysis solution (e.g., a 5 liter bag of dialysis solution). The PD cycler 102 also includes a touch screen 118 and additional control buttons 120 that can be operated by a user (e.g., a patient) to allow, for example, set-up, initiation, and/or termination of a PD treatment.

[0077] Dialysis solution bags 122 are suspended from fingers on the sides of the cart 104, and a heater bag 124 is positioned on the heater tray 116. The dialysis solution bags 122 and the heater bag 124 are connected to the cassette 112 via dialysis solution bag lines 126 and a heater bag line 128, respectively. The dialysis solution bag lines 126 can be used to pass dialysis solution from dialysis solution bags 122 to the cassette 112 during use, and the heater bag line 128 can be used to pass dialysis solution back and forth between the cassette 112 and the heater bag 124 during use. In addition, a patient line 130 and a drain line 132 are connected to the cassette 112. The patient line 130 can be connected to a patient's abdomen via a catheter and can be used to pass dialysis solution back and forth between the cassette 112 and the patient during use. The drain line 132 can be connected to a drain or drain receptacle and can be used to pass dialysis solution from the cassette 112 to the drain or drain receptacle during use.

[0078] Fig. 3 shows a more detailed view of the cassette interface 110 and the door 108 of the PD cycler 102. As shown, the PD cycler 102 includes pistons 133A, 133B with piston heads 134A, 134B attached to piston shafts 135A, 135B (piston shaft 135A shown in FIG. 4) that can be axially moved within piston access ports 136A, 136B formed in the cassette interface 110. The piston shafts 135A, 135B are connected to motors that

can be operated to move the piston heads 134A, 134B axially inward and outward within the piston access ports 136A, 136B. As discussed below, when the cassette 112 (shown in FIGS. 2 and 10-13) is positioned within the cassette compartment 114 of the PD cycler 102 with the door 108 closed, the piston heads 134A, 134B of the PD cycler 102 align with pump chambers 138A, 138B of the cassette 112 such that the piston heads 134A, 134B can be mechanically connected to fastening members of the cassette 112 overlying the pump chambers 138A, 138B. As a result of this arrangement, movement of the piston heads 134A, 134B toward the cassette 112 during treatment can decrease the volume of the pump chambers 138A, 138B, and force dialysis solution out of the pump chambers 138A, 138B, while retraction of the piston heads 134A, 134B away from the cassette 112 can increase the volume of the pump chambers 138A, 138B and cause dialysis solution to be drawn into the pump chambers 138A, 138B.

[0079] FIG. 4 is a diagrammatic cross-sectional view of the PD cycler 102, illustrating the piston 133A disposed within the piston access port 136A. FIG. 5 is an exploded, perspective view of the piston 133A. Because the pistons 133A, 133B are structurally and functionally identical, the piston 133B will not be separately described in detail. As shown in FIGS. 4 and 5, the piston 133A includes a piston shaft 135A to which the piston head 134A is attached. The piston head 134A includes a rear member 137A and a front member 139A between which a latch lock 141A, a latch lock spring 143A, and two sliding latches 145A, 147Aare positioned. The rear and front members 137A, 139A are secured together to retain the latch lock 141A, the latch lock spring 143A, and the two sliding latches 145A, 147A in a contained position therebetween. Typically, the rear and front members 137A, 139A are secured together using screws. However, any of various other fastening techniques, such as riveting, welding, adhesive, etc., can alternatively or additionally be used.

[0080] The piston shaft 135A has a reduced diameter front portion 149A that is sized and shaped to fit within a bore formed in a stem 151A of the rear member 137A of the piston head 134A. Typically, the reduced diameter front portion 149A of the piston shaft 135A and the inner surface of the stem 151A have threads on their outer and inner surfaces, respectively, such that the piston head 134A can be secured to the piston shaft 135A by screwing the stem 151A onto the reduced diameter front portion 149A of the piston shaft 135A. This arrangement allows the piston head 134A to be easily removed from the piston shaft 135A for cleaning, repair, or replacement. Any of various other securement techniques, such as clipping, welding, adhesive bonding, etc., can alternatively or additionally be used to secure the piston head 134A to the piston shaft 135A.

[0081] Still referring to FIGS. 4 and 5, a front end region of the latch lock spring 143A sits within a recess 153A formed in the front member 139A of the piston head 134A, while a rear end of the spring 143A contacts a front-facing

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surface of the latch lock 141A. The latch lock 141A includes legs 155A, 157A that fit within slots 169A, 171A of the sliding latches 145A, 147A. The slots 169A, 171A are formed by inner and outer surfaces of the sliding latches 145A, 147A that sit adjacent to and have substantially the same angular orientation as the inner and outer surfaces, respectively, of the legs 155A, 157A.

[0082] The sliding latches 145A, 147A are slidably positioned within spaces 173A, 175A (shown in FIG. 4) formed between the rear and front members 137A, 139A. The spaces 173A, 175A are sized and shaped to allow the sliding latches 145A, 147A to slide radially inward and outward. As described in greater detail below, as the latch lock 141A moves forward relative to the front member 139A and compresses the spring 143A, the inner surfaces of the legs 155A, 157A of the latch lock 141A contact the correspondingly angled adjacent surfaces of the slide latches 145A, 147A. Due to the angles of those adjacent surfaces, the frontward movement of the latch lock 141A causes the sliding latches 145A, 147A to move radially inward. Similarly, upon applying radially inward forces to the sliding latches 145A, 147A, those surfaces of the sliding latches 145A, 147A that lie adjacent to the outer surfaces of the legs 155A, 157A of the latch lock 141A contact and apply radially inward forces to the latch lock 141A. Due to the geometry of those mating surfaces, the radially inward forces applied to the outer surfaces of the legs 155A, 157A of the latch lock 141A cause the latch lock 141A to move forward toward the front member 139A and compress the spring 143A. Upon releasing the radially inward forces being applied to the sliding latches 145A, 147A that cause the latch lock 141A to compress the spring 143A, the spring 143A will expand, causing the latch lock 141A to move rearward and the sliding latches 145A, 147A to move radially outward.

[0083] Referring to FIGS. 5-7, the latch lock 141A includes a u-shaped member 180A that forms the rearwardly extending horns 170A, 172A. The legs 155A, 157A extend frontward from the u-shaped member 180A at an acute angle relative to the longitudinal axis of the piston 133A when the piston 133A is fully assembled. Feet 182A, 184A are positioned near the front ends of the legs 155A, 157A, respectively. The feet 182A, 184A have front surfaces that are substantially perpendicular to the longitudinal axis of the piston 133A. The front surfaces of the feet 182A, 184A can contact the rear-facing surfaces of the front member 139A of the piston head 134A when the latch lock 141A is moved to its fully forward position and the spring 143A is fully compressed. The latch lock 141A also includes a projection 186A (shown in FIG. 7) that extends frontward from a central region of the u-shaped member 180A and is attached to or integrally formed with the inner surfaces of the legs 155A, 157A. The projection 186A supports the rear end of the spring 143A.

[0084] The dimensions of the piston head 134A and its various components will depend on many factors, including the type of cassette with which it is intended to

be used. Referring to FIG. 6, the latch lock 141A has an overall length L₁, which is measured from its frontmost point to its rearmost point along the longitudinal axis of the piston 133A. The length L₁ can be about 1.3 cm (0.5 inch) to about 2.5 cm (1.0 inch) (e.g., 1.9 cm (0.75 inch)). An axial length L₂ of the portion of the latch lock 141A extending forwardly from the inch)). frontmost point of the u-shaped member 180A can be about 0.76 CM (0.3 inch) to about 1 cm (0.4 inch) (e.g., 0.90 cm (0.353 inch)). A length L₃ of the straight segment of each horn 170A, 172A can be about 0.635 cm (0.25 inch) to about 0.89 cm (0.35 inch) (e.g., 0.74 cm (0.291 inch)). A height H₁ of the legs 155A, 157A, measured perpendicular to the longitudinal axis of the piston 133A, can be about 1.3 cm (0.5 inch) to about 2.5 cm (1.0 inch) (e.g., 1.9 cm (0.75 inch)). A distance D₁ between the bottom surface of the top horn 170A and the top surface of the bottom horn 172A can be about 1.27 cm (0.5 inch) to about 3.8 cm (1.5 inch) (e.g., 2.4 cm (0.95 inch)). A distance D₂ between the top surface of the top horn 170A and the bottom surface of the bottom horn 172A can be about 1.9 cm (0.75 inch) to about 3.175 cm (1.25 inch) (e.g., 2.92 cm

[0085] Referring to FIG. 7, angles α_1 and α_2 , measured between the front surfaces of the feet 182A, 184A and the outer and inner surfaces, respectively, of the leg 157A are about 15 to about 75 degrees (e.g., about 30 to about 60 degrees, about 45 degrees). The other leg 155A of the latch lock 141A is a mirror image of the leg 157A. As noted above, the front surfaces of the feet 182A, 184A are approximately perpendicular to the longitudinal axis of the piston 133A (i.e., the horizontal axis as viewed in FIGS. 4 and 7). Thus, the outer and inner surfaces of each of the legs 155A, 157A are angled at about 15 to about 75 degrees (e.g., about 30 to about 60 degrees, about 45 degrees) relative to the longitudinal axis of the piston 133A. A distance D3 from the outer surface of the leg 155A to the outer surface of the leg 157A at the front ends of the legs 155A, 157A can be about 2 cm (0.8) to about 2.5 cm (1.0 inch) (e.g., 2.3 cm (0.904 inch)). A thickness T₁ of the leg 155A, which is substantially the same as the thickness of the leg 157A, is typically slightly smaller (e.g., about 25 to about 51 micrometers smaller) than the slots 169A, 171A of the sliding latches 145A, 147A. The thickness T₁ of the leg 155A can, for example, be about 178 micrometers (0.07 inch) to about 356 micrometers (0.14 inch) (e.g., 287 micrometers (0.113 inch)).

[0086] Referring now to FIGS. 5, 8, and 9, the sliding latch 145A includes a lead-in surface or front angled surface 188A that first contacts the dome-shaped member 161A as the piston head 134A is being mechanically connected to the dome-shaped member 161A, as described below. The sliding latch 145A also includes a lead-out surface or rear angled surface 190A that contacts the dome-shaped member 161A as the piston head 134A is being disconnected from the dome-shaped member 161A. The outer edge of the rear angled surface 190A

and the outer edge of a central portion of the sliding latch 145A from which the rear angled surface 190A extends are arched. These outer edges can have radii of curvature that approximate the radius of curvature of the inner surface of the dome-shaped member 161A. The sliding latch 145A further includes a cut-out portion 192A that is located adjacent the slot 169A and is sized and shaped to receive a portion of the projection 186A extending from the latch lock 141A when the piston head 134A is fully assembled.

[0087] Referring to FIG. 8, in some implementations, the sliding latch 145A has an overall length L_3 of about 2.29 cm (0.9 inch) to about 2.8 cm (1.1 inch) (e.g., 2.48 cm (0.975 inch) or 2.5 cm (0.985 inch)). and/or an overall width W_1 of about 1.65 cm (0.65 inch) to about 1.78 cm (0.7 inch (e.g., 1.7 cm (0.67 inch)). The slot 169A of the sliding latch 145A is typically slightly larger than the leg 155A of the latch lock 141A, which is disposed in the slot 169A when the piston head 134A is fully assembled. The slot 169A can, for example, have a length L_4 of about 1.78 cm (0.7 inch) to about 2.3 cm (0.9 inch) (e.g., 2.0 cm (0.8 inch)). As shown in FIG. 9, the slot 169A can have a width W_2 of about 250 micrometers 0.1 inch) to about 381 micrometers (0.15 inch) (e.g. 318 micrometers (0.125 inch)) or 343 micrometers (0.135 inch)).

[0088] Still referring to FIG. 9, the rear angled surface 190A can have a width W₃ of 381 micrometers (0.15 inch) to 508 micrometers (e.g., 434 micrometers (0.171 inch)). about. The front angled surface 188A is arranged at an angle α_3 of about 15 degrees to about 75 degrees (e.g., about 30 degrees to about 60 degrees, 45 degrees) relative to a plane that is perpendicular to the longitudinal axis of the piston 133A. Thus, the front angled surface 188A is angled at about 15 degrees to about 75 degrees (e.g., about 30 degrees to about 60 degrees, 45 degrees) relative to the longitudinal axis of the piston 133A. The rear angled surface 190A is arranged at an angle α_A of about 15 degrees to about 45 degrees (e.g., 20 degrees, 25 degrees, or 30 degrees) relative to a plane that is perpendicular to the longitudinal axis of the piston 133A. Thus, the rear angled surface 190A is angled at about 45 degrees to about 75 degrees (e.g., 60 degrees, 65 degrees, or 70 degrees) relative to the longitudinal axis of the piston 133A. The inner and outer surfaces of the sliding latch 145A that define the slot 169A are arranged at angles α_5 , α_6 , measured relative to the longitudinal axis of the piston 133A, that are typically approximately the same as the angles at which the inner and outer surfaces of the leg 155A of the latch lock 141A are arranged. The angles α_5 , α_6 can, for example, be about 15 degrees to about 75 degrees (e.g., about 30 degrees to about 60 degrees, 45 degrees).

[0089] The latch lock spring 143A typically has a spring rate of about 38 pounds per inch to about 67 pounds per inch and typically provides sufficient resistance to prevent radial inward forces of about 6.7 N (1.5 lbf) to about 42 N (9.5 lbf) applied to the sliding latches 145A, 147A from compressing the spring and causing the sliding

latches 145A, 147A to move radially inward.

[0090] The piston head 134A and piston shaft 135A can be formed of various different polymers, metals, and/or alloys. The rear member 137A, the front member 139A, and the latch lock 141A are typically formed of materials that are relatively rigid, resistance to wear, and have a relatively low coefficient of friction. Examples of suitable materials for these components include polyoxymethylene (e.g., Delrin), aluminum, steel, bronze, brass, and PTFE. However, other metals and plastics having relatively low coefficients of friction can alternatively or additionally be used. The sliding latches 145A, 147A are similarly typically formed of materials that are relatively rigid, resistance to wear, and have a relatively low coefficient of friction. In some implementations, the sliding latches 145A, 147A are formed of a polytetrafluoroethylene-coated 6061 aluminum alloy. Other examples of materials from which the sliding latches 145A, 147A can be formed include steel, bronze, brass, POM, and PTFE. However, it will be appreciated that certain other metals and plastics can alternatively or additionally be used.

[0091] The various components of the piston head 134A and the piston shaft 135A can be formed using any of various different techniques, including machining techniques molding techniques, and/or casting techniques. [0092] Referring back to FIG. 3, the PD cycler 102 also includes multiple inflatable members 142 positioned within inflatable member ports 144 in the cassette interface 110. The inflatable members 142 align with depressible dome regions 146 of the cassette 112 (shown in FIGS. 10-13) when the cassette 112 is positioned within the cassette compartment 114 of the PD cycler 102. While only one of the inflatable members 142 is labeled in FIG. 3, it should be understood that the PD cycler 102 includes an inflatable member associated with each of the depressible dome regions 146 of the cassette 112. The inflatable members 142 act as valves to direct dialysis solution through the cassette 112 in a desired manner during use. In particular, the inflatable members 142 bulge outward beyond the surface of the cassette interface 110 and into contact with the depressible dome regions 146 of the cassette 112 when inflated, and retract into the inflatable member ports 144 and out of contact with the cassette 112 when deflated. By inflating certain inflatable members 142 to depress their associated dome regions 146 on the cassette 112, certain fluid flow paths within the cassette 112 can be occluded. Thus, PD solution can be pumped through the cassette 112 by actuating the piston heads 134A, 134B, and can be guided along desired flow paths within the cassette 112 by selectively inflating and deflating the inflatable members

[0093] Still referring to FIG. 3, locating pins 148 extend from the cassette interface 110 of the PD cycler 102. When the door 108 is in the open position, the cassette 112 can be loaded onto the cassette interface 110 by positioning the top portion of the cassette 112 under the

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locating pins 148 and pushing the bottom portion of the cassette 112 toward the cassette interface 110. The cassette 112 is dimensioned to remain securely positioned between the locating pins 148 and a spring loaded latch 150 extending from the cassette interface 110 to allow the door 108 to be closed over the cassette 112. The locating pins 148 help to ensure that proper alignment of the cassette 112 within the cassette compartment 114 is maintained during use.

[0094] The door 108 of the PD cycler 102, as shown in FIG. 3, defines cylindrical recesses 152A, 152B that substantially align with the pistons 133A, 133B when the door 108 is in the closed position. When the cassette 112 (shown in FIGS. 10-13) is positioned within the cassette compartment 114, hollow projections 154A, 154B of the cassette 112, inner surfaces of which partially define the pump chambers 138A, 138B, fit within the recesses 152A, 152B. The door 108 further includes a pad that is inflated during use to compress the cassette 112 between the door 108 and the cassette interface 110. With the pad inflated, the portions of the door 108 forming the recesses 152A, 152B support the projections 154A, 154B of the cassette 112 and the planar surface of the door 108 supports the other regions of the cassette 112. The door 108 can counteract the forces applied by the inflatable members 142 and thus allows the inflatable members 142 to actuate the depressible dome regions 146 on the cassette 112. The engagement between the door 108 and the hollow projections 154A, 154B of the cassette 112 can also help to hold the cassette 112 in a desired fixed position within the cassette compartment 114 to further ensure that the pistons 133A, 133B align with the fluid pump chambers 138A, 138B of the cassette

[0095] FIG. 10 is an exploded, perspective view of the cassette 112, FIG. 11 is a perspective, cross-sectional view of the fully assembled cassette 112, and FIGS. 12 and 13 are perspective views of the assembled cassette 112, from the membrane side and from the rigid base side, respectively. Referring to FIGS. 10-12, the cassette 112 includes a flexible membrane 140 attached to a periphery of the tray-like rigid base 156. Rigid dome-shaped fastening members 161A, 161B are positioned within recessed regions 162A, 162B of the base 156. The domeshaped members 161A, 161B are sized and shaped to receive the piston heads 134A, 134B of the PD cycler 102. In certain implementations, the dome-shaped members 161A, 161B have a diameter, measured from the outer edges of flanges 164A, 164B, of about 3.8 cm (1.5 inches) to about 6.35 cm (2.5 inches) (e.g., about 5.1 cm. (2.0 inches)) and take up about two-thirds to about threefourths of the area of the recessed regions 162A, 162B. The annular flanges 164A, 164B of the rigid domeshaped members 161A, 161B are attached in a liquidtight manner to portions of the inner surface of the membrane 140 surrounding substantially circular apertures 166A, 166B formed in the membrane 140. The apertures 166A, 166B expose the rigid dome-shaped members 161A, 161B such that the piston heads 134A, 134B are able to directly contact and mechanically connect to the dome-shaped members 161A, 161B during use.

[0096] The annular flanges 164A, 164B of the domeshaped members 161A, 161B, as shown in FIG. 11, form annular projections 168A, 168B that extend radially inward and annular projections 176A, 176B that extend radially outward from the side walls of the dome-shaped members 161A, 161B. When the piston heads 134A, 134B are mechanically connected to the dome-shaped members 161A, 161B, the radially inward projections 168A, 168B engage the rear angled surfaces of the sliding latches 145A, 147A of the piston heads 134A, 134B to firmly secure the dome-shaped members 161A, 161B to the piston heads 134A, 134B. Because the membrane 140 is attached to the dome-shaped members 161A, 161B, movement of the dome-shaped members 161A, 161B into and out of the recessed regions 162A, 162B of the base 156 (e.g., due to reciprocating motion of the pistons 133A, 133B) causes the flexible membrane 140 to similarly be moved into and out of the recessed regions 162A, 162B of the base 156. This movement allows fluid to be forced out of and drawn into the fluid pump chambers 138A, 138B, which are formed between the recessed regions 162A, 162B of the base 156 and the portions of the dome-shaped members 161A, 161B and membrane 140 that overlie those recessed regions 162A,

[0097] Referring to FIGS. 10 and 12, raised ridges 167 extend from the substantially planar surface of the base 156 towards and into contact with the inner surface of the flexible membrane 140 when the cassette 112 is compressed between the door 108 and the cassette interface 110 of the PD cycler 102 to form a series of fluid passageways 158 and to form the multiple, depressible dome regions 146, which are widened portions (e.g., substantially circular widened portions) of the fluid pathways 158, as shown in FIG. 12. The fluid passageways 158 fluidly connect the fluid line connectors 160 of the cassette 112, which act as inlet/outlet ports of the cassette 112, to the fluid pump chambers 138A, 138B. As noted above, the various inflatable valve members 142 of the PD cycler 102 act on the cassette 112 during use. During use, the dialysis solution flows to and from the pump chambers 138A, 138B through the fluid pathways 158 and dome regions 146. At each depressible dome region 146, the membrane 140 can be deflected to contact the planar surface of the base 156 from which the raised ridges 167 extend. Such contact can substantially impede (e.g., prevent) the flow of dialysis solution along the region of the pathway 158 associated with that dome region 146. Thus, the flow of dialysis solution through the cassette 112 can be controlled through the selective depression of the depressible dome regions 146 by selectively inflating the inflatable members 142 of the PD cycler 102.

[0098] Still referring to FIGS. 10 and 12, the fluid line connectors 160 are positioned along the bottom edge of

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the cassette 112. As noted above, the fluid pathways 158 in the cassette 112 lead from the pumping chambers 138A, 138B to the various connectors 160. The connectors 160 are positioned asymmetrically along the width of the cassette 112. The asymmetrical positioning of the connectors 160 helps to ensure that the cassette 112 will be properly positioned in the cassette compartment 114 with the membrane 140 of the cassette 112 facing the cassette interface 110. The connectors 160 are configured to receive fittings on the ends of the dialysis solution bag lines 126, the heater bag line 128, the patient line 130, and the drain line 132. One end of the fitting can be inserted into and bonded to its respective line and the other end can be inserted into and bonded to its associated connector 160. By permitting the dialysis solution bag lines 126, the heater bag line 128, the patient line 130, and the drain line 132 to be connected to the cassette, as shown in FIGS. 1 and 2, the connectors 160 allow dialysis solution to flow into and out of the cassette 112 during use.

[0099] The rigidity of the base 156 helps to hold the cassette 112 in place within the cassette compartment 114 of the PD cycler 102 and to prevent the base 156 from flexing and deforming in response to forces applied to the projections 154A, 154B by the dome-shaped members 161A, 161B and in response to forces applied to the planar surface of the base 156 by the inflatable members

[0100] The base 156 and the dome-shaped members 161A, 161B of the cassette 112 can be formed of any of various relatively rigid materials. In some implementations, these components of the cassette 112 are formed of one or more polymers, such as polypropylene, polyvinyl chloride, polycarbonate, polysulfone, and other medical grade plastic materials. In certain implementations, these components can be formed of one or more metals or alloys, such as stainless steel. These components of can alternatively be formed of various different combinations of the above-noted polymers and metals. These components of the cassette 112 can be formed using any of various different techniques, including machining, molding, and casting techniques.

[0101] As noted above, the membrane 140 is attached to the periphery of the base 156 and to the annular flanges 164A, 164B of the dome-shaped members 161A, 161B. The portion of the membrane 140 overlying the remaining portions of the base 156 are typically not attached to the base 156. Rather, these portions of the membrane 140 sit loosely atop the raised ridges 165A, 165B, and 167 extending from the planar surface of the base 156. Any of various attachment techniques, such as adhesive bonding and thermal bonding, can be used to attach the membrane 140 to the periphery of the base 156 and to the dome-shaped members. The thickness and material(s) of the membrane 140 are selected so that the membrane 140 has sufficient flexibility to flex toward the base 156 in response to the force applied to the membrane 140 by the inflatable members 142. In certain implementations, the membrane 140 is about 0.100 micron to about 0.150 micron in thickness. However, various other thicknesses may be sufficient depending on the type of material used to form the membrane 140.

[0102] Any of various different materials that permit the membrane 140 to deflect in response to movement of the inflatable members 142 without tearing can be used to form the membrane 140. In some implementations, the membrane 140 includes a three-layer laminate. In certain implementations, for example, inner and outer layers of the laminate are formed of a compound that is made up of 60 percent Septon® 8004 thermoplastic rubber (i.e., hydrogenated styrenic block copolymer) and 40 percent ethylene, and a middle layer is formed of a compound that is made up of 25 percent Tuftec® H1062(SEBS: hydrogenated styrenic thermoplastic elastomer), 40 percent Engage® 8003 polyolefin elastomer (ethylene octene copolymer), and 35 percent Septon® 8004 thermoplastic rubber (i.e., hydrogenated styrenic block copolymer). The membrane can alternatively include more or fewer layers and/or can be formed of different materials.

[0103] As shown in FIG. 14, before treatment, the door 108 of the PD cycler 102 is opened to expose the cassette interface 110, and the cassette 112 is positioned with its dome-shaped members 161A, 161B aligned with the pistons 133A, 133B of the PD cycler 102 and with its membrane 140 adjacent to the cassette interface 110. In order to ensure that the dome-shaped members 161A, 161B align with the pistons 133A, 133B, the cassette 112 is positioned between the locating pins 148 and the spring loaded latch 150 extending from the cassette interface 110. The asymmetrically positioned connectors 160 of the cassette act as a keying feature that reduces the likelihood that the cassette 112 will be installed with the membrane 140 and dome-shaped members 161A, 161B facing in the wrong direction (e.g., facing outward toward the door 108). Additionally or alternatively, the locating pins 148 can be dimensioned to be less than the maximum protrusion of the projections 154A, 154B such that the cassette 112 cannot contact the locating pins 148 if the membrane 140 is facing outward toward the door 108. The pistons 133A, 133B are typically retracted into the piston access ports 136A, 136B during installation of the cassette 112 to avoid interference between pistons 133A, 133B and the dome-shaped members 161A, 161B and thus increase the ease with which the cassette 112 can be positioned within the cassette compartment 114. [0104] FIGS. 15A-15F are diagrammatic cross-sectional views of the PD system 100 with the PD cassette 112 disposed in the cassette compartment 114 of the PD cycler 102, during different phases of a pumping operation used to draw dialysis solution into the pump chamber 138A and to force dialysis solution out of the pump chamber 138A. The technique for pumping solution to and from the other pump chamber 138B is identical and thus is not separately described in detail.

[0105] FIG. 15A shows the cassette 112 positioned

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within the cassette compartment 114 shortly after installation. As shown, the cassette 112 is positioned adjacent to the cassette interface 110 and the door 108 is closed over the cassette 112 such that the cassette 112 is contained within the cassette compartment 114 between the door 108 and the cassette interface 110. The piston head 134A is retracted into the piston access port 136A such that the piston head 134A does not interfere with the cassette 112 during its installation. With the cassette 112 positioned in the cassette compartment 114, the inflatable pad within the door 108 is inflated to compress the cassette 112 between the door 108 and the cassette interface 110. This compression of the cassette 112 holds the projection 154A of the cassette 112 in the recess 152A of the door 108 and presses the membrane 140 tightly against the raised ridges 167 extending from the planar surface of the rigid base 156 to form the enclosed fluid pathways 158 and dome regions 146 (shown in FIG. 12).

[0106] As shown in FIG. 15B, once the cassette 112 has been installed within the cassette compartment 114 of the PD cycler 102, the piston 133A is advanced to initiate the process of mechanically connecting the piston head 134A of the PD cycler 102 to the dome-shaped member 161A of the cassette 112. The piston 133A can be advanced at a rate of about 2.0 cm (0.8 inch)/minute to about 28 cm (11 inches)/minutes and with an axial force of about 22 N (5 lbf) to about 222 N (50 lbf). As the piston 133A is advanced, the front angled surface 188A of the sliding latch 145A and a front angled surface 191A of the sliding latch 147A contact a rear surface of the annular projection 168A, which extends radially inward from the dome-shaped member 161A. The rear surface of the annular projection 168A is approximately perpendicular to the longitudinal axis of the piston 133A.

[0107] As the piston 133A continues to advance, the dome-shaped member 161A contacts the inner surface of the portion of the rigid base 156 that forms the recessed region 162A, as shown in FIG. 15B. The rigid base 156 prevents further forward movement of the dome-shaped member 161A. The membrane 140, which is attached to the peripheral flange 164A of the dome-shaped member 161A, also stretches and moves into the recessed region 162A due to the advancing piston 133A. Due to the angled geometries of the front angled surfaces 188A, 191A of the sliding latches 145A, 147A and the resistance provided by the rigid base 156 to the forward motion of the dome-shaped member 161A, the sliding latches 145A, 147A are caused to move radially inward (i.e., toward the longitudinal axis of the piston 133A) as the piston head 134A continues to be advanced relative to the domeshaped member 161A. More specifically, the forward motion of the sliding latches 145A, 147A is converted into a combined forward and radially inward motion due to the sliding motion of the front angled surfaces 188A, 191A of the sliding latches 145A, 147A against the rear surface of the annular projection 168A of the dome-shaped member 161A. The radial inward movement of each of the

sliding latches 145A, 147A in turn causes a forward movement of the latch lock 141A due to the mated geometries of the outer surfaces of the legs 155A, 157A of the latch lock 141A and the surfaces of the sliding latches 145A, 147A that are positioned adjacent to and brought into contact with those outer surfaces of the legs 155A, 157A. This forward movement of the latch lock 141A is resisted by the spring 143A.

[0108] FIG. 15C shows the piston head 134A at a point during the connection process at which the sliding latches 145A, 147A have been deflected radially inward a sufficient distance to allow the sliding latches 145A, 147A to pass beyond the annular projection 168A that extends radially inward from the dome-shaped member 161A. In this position, outer peripheral surfaces of the sliding latches 145A, 147A, which are substantially parallel to the longitudinal axis of the piston 133A, contact and slide along an inner surface of the projection 168A of the domeshaped member 161A, which is also substantially parallel to the longitudinal axis of the piston 133A. The spring 143A is further compressed due to the radially inwardly deflected positions of the sliding latches 145A, 147A. [0109] Referring to FIG. 15D, as the sliding latches 145A, 147Apass beyond the projection 168A, the spring 143A is allowed to expand. The expansion of the spring

143A causes the latch lock 141A to move rearward. As a result, the outer surfaces of the legs 155A, 157A of the latch lock 141A contact the correspondingly angled adjacent surfaces of the sliding latches 145A, 147A, causing the sliding latches 145A, 147A to move radially outward underneath the projection 168A of the domeshaped member 161A. The rear angled surfaces 190A, 193A of the sliding latches 145A, 147A ride along the front surface of the projection 168A of the dome-shaped member 161A, which is slightly angled toward the rear of the dome-shaped member 161A (e.g., angled at about 88 degrees relative to the longitudinal axis of the piston head 133A), as the sliding latches 145A, 147A move radially outward. The sliding latches 145A, 147A become wedged beneath the projection 168A as the sliding latches 145A, 147A move radially outward.

[0110] The rear angled surfaces 190A, 193A of the sliding latches 145A, 147A permit the piston head 134A to be firmly locked within dome-shaped members of slightly different sizes. For example, due to imperfect manufacturing techniques, the thickness of the annular projection 168A along the longitudinal axis of the piston 133A may differ slightly (e.g., by about 76 to about 127 micrometers (0.003 to about 0.005 inch) amongst different molded dome-shaped members. The rear angled surfaces of the sliding latches 145A, 147A can help to ensure that a tight fit is achieved with any of those dome-shaped members. [0111] FIG. 15E illustrates the complete mechanical connection between the piston head 134A and the domeshaped member 161A in which the sliding latches 145A, 147A have moved to maximum outwardly displaced positions within the dome-shaped member 161A. In this configuration, the projection 168A of the dome-shaped

member 161A is effectively pinched between the rear member 137A of the piston head 134A and the sliding latches 145A, 147A, resulting in a secure engagement between the piston head 134A and the dome-shaped member 161A. As a result of the secure engagement of the piston head 134A to the dome-shaped member 161A, the amount of slippage of the piston head 134A relative to the dome-shaped member 161A can be reduced (e.g., minimized) and thus precise pumping can be achieved. [0112] As discussed above, as the piston 133A is being mechanically connected to the dome-shaped member 161A, the dome-shaped member 161A is advanced into the recessed region 162A of the rigid base 156 until the dome-shaped member 161A contacts the inner surface of the recessed region 162A of the base 156 of the cassette 112. This movement decreases the volume of the pump chamber 138A formed between the dome-shaped member 161A, the membrane 140, and the recessed region of the base 156, and thus causes any fluid (e.g., priming fluid) within the pump chamber 138A to be forced out of the pump chamber 138A from the fluid pathways 158 of the cassette via the inlet port 185A (shown in FIG.

[0113] Referring to FIG. 15F, after the piston 133A has been mechanically connected to the dome-shaped member 161A, the piston 133A is retracted to draw dialysis solution into the pump chamber 138A. Because the piston head 134A is mechanically connected to the dome-shaped member 161A and the dome-shaped member 161A is attached to the membrane 140 of the cassette 112, the retraction of the piston 133A causes the dome-shaped member 161A and the portion of the membrane 140 attached to the dome-shaped member 161A to move rearwardly. As a result, the volume of the pump chamber 138A is increased and fluid is drawn into the pump chamber 138A.

[0114] Because the volumes of the fluid pump chamber 138A and the piston head 134A are known, the linear distance travelled by the piston 133A can be used to determine the volume of dialysis solution drawn into the fluid pump chamber 138A. The linear distance travelled by the piston 133A can be determined based on the number of revolutions or steps of the motor (e.g., stepper motor) used to drive the piston 133A. Thus, the volume of solution drawn into the fluid pump chamber 138A can be determined based on the number of revolutions or steps of the motor. The tight fit between the piston head 134A and the dome-shaped member 161A ensure the accuracy of the volume of solution determined in this manner.

[0115] After drawing the dialysis solution into the pump chamber 138A, the dialysis solution is forced out of the pump chamber 138A by again advancing the piston 133A and decreasing the volume of the pump chamber 138A. The piston 133A is typically advanced until the domeshaped member 161A contacts or nearly contacts the inner surface of the recessed region of the base 156 so that substantially all of the dialysis solution is forced out

of the fluid pump chamber 138A via the outlet port 187A (shown in FIG. 10).

[0116] This process of drawing dialysis solution into the fluid pump chamber 138A and then forcing the dialysis solution out of the fluid pump chamber 138A is repeated until a desired volume of dialysis solution has been pumped to or from a location (e.g., to or from the patient).

[0117] As noted above, while forcing dialysis solution into and out of the pump chambers 138A, 138B, certain inflatable members 142 of the PD cycler 102 can be selectively inflated to direct the pumped dialysis solution along desired pathways in the cassette 112.

[0118] Referring back to FIGS. 1 and 2, during PD treatment, the patient line 130 is connected to a patient's abdomen via a catheter, and the drain line 132 is connected to a drain or drain receptacle. The PD treatment typically begins by emptying the patient of spent dialysis solution that remains in the patient's abdomen from the previous treatment. To do this, the pump of the PD cycler 102 is activated to cause the pistons 133A, 133B to reciprocate and selected inflatable members 142 are inflated to cause the spent dialysis solution to be drawn into the fluid pump chambers 138A, 138B of the cassette 112 from the patient. The spent dialysis solution is then pumped from the fluid pump chambers 138A, 138B to the drain via the drain line 132.

[0119] After draining the spent dialysis solution from the patient, heated dialysis solution is transferred from the heater bag 124 to the patient. To do this, the motor or motors of the PD cycler 102 is/are activated to cause the pistons 133A, 133B to reciprocate and certain inflatable members 142 of the PD cycler 102 are inflated to cause the warmed dialysis solution to be drawn into the fluid pump chambers 138A, 138B of the cassette 112 from the heater bag 124 via the heater bag line 128. The warmed dialysis solution is then pumped from the fluid pump chambers 138A, 138B to the patient via the patient line 130.

[0120] Once the dialysis solution has been pumped from the heater bag 124 to the patient, the dialysis solution is allowed to dwell within the patient for a period of time. During this dwell period, toxins cross the peritoneum of the patient into the dialysis solution from the patient's blood. As the dialysis solution dwells within the patient, the PD cycler 102 prepares fresh dialysate for delivery to the patient in a subsequent cycle. In particular, the PD cycler 102 pumps fresh dialysis solution from one of the four full dialysis solution bags 122 into the heater bag 124 for heating. To do this, the pump of the PD cycler 102 is activated to cause the pistons 133A, 133B to reciprocate and certain inflatable members 142 of the PD cycler 102 are inflated to cause the dialysis solution to be drawn into the fluid pump chambers 138A, 138B of the cassette 112 from the selected dialysis solution bag 122 via its associated line 126. The dialysis solution is then pumped from the fluid pump chambers 138A, 138B to the heater bag 124 via the heater bag line 128.

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[0121] After the dialysis solution has dwelled within the patient for the desired period of time, the spent dialysis solution is pumped from the patient to the drain. The heated dialysis solution is then pumped from the heater bag 124 to the patient where it dwells for a desired period of time. These steps are repeated with the dialysis solution from two of the three remaining dialysis solution bags 122. The dialysis solution from the last dialysis solution bag 122 is typically delivered to the patient and left in the patient until the subsequent PD treatment.

[0122] While the dialysis solution has been described as being pumped into the heater bag 124 from a single dialysis solution bag 122, dialysis solution can alternatively be pumped into the heater bag 124 from multiple dialysis solution bags 122. Such a technique may be advantageous, for example, where the dialysis solutions in the bags 122 have different concentrations (e.g., different dextrose concentrations) and a desired concentration for treatment is intermediate to the concentrations of the dialysis solution in two or more of the bags 122.

[0123] After completion of the PD treatment, the pistons 133A, 133B are retracted in a manner to disconnect the piston heads 134A, 134B from the dome-shaped members 161A, 161B of the cassette. This process will be described with reference to FIGS. 16-19. Because the piston heads 134A, 134B are substantially identical, the disconnection process will only be described in detail with respect to the piston head 134A. As shown in FIGS. 16 and 17, which are different cross-sectional views of the piston head 134A connected to the dome-shaped member 161A, the horns or projections 170A, 172A of the latch lock 141A extend rearwardly through apertures formed in the rear member 137A of the piston head 134A. The horns 170A,172A have a length such that the horns 170A, 172A extend slightly from the rear surface of the rear member 137A or are flush with the rear surface of the rear member 137A when the latch lock 141A is advanced to its fully forward position and the spring 143A is compressed.

[0124] The horns 170A, 172A can be used to draw the sliding latches 145A, 147A radially inward to allow the piston head 134A to be disconnected from the domeshaped member 161A of the cassette 112. FIG. 18 is a double cross-sectional view of the piston head 134A mechanically connected to the dome-shaped member 161A. As shown in FIG. 18, when the piston head 134A and the dome-shaped member 161A are mechanically connected, the horns 170A, 172A extend through the apertures of the rear member 137A and rearwardly beyond the rear surface of that member. In this position, the spring 143A of the piston head 134A is expanded and holds the latch lock 141 in its rearmost position, causing the horns 170A, 172A to protrude from the apertures of the rear member 137A.

[0125] FIG. 19 is a double cross-sectional view of the piston head 134A in a configuration to be mechanically disconnected from the dome-shaped member 161A. In this configuration, the horns 170A, 172A are pushed into

the apertures of the rear member 137A. As a result, the latch lock 141A is moved to its forward most position and the spring 143A is compressed.

[0126] As the piston 133A is reciprocated during treatment, the horns 170A, 172A are forwardly spaced from a vertically oriented stop or surface 174 (shown in FIGS. 15A-15F) of the PD cycler 102. As a result, the horns 170A, 172A remain in their fully rearwardly extended position throughout the pump process. However, after the treatment has been completed, the piston 133A is retracted a sufficient distance so that the horns 170A, 172A are backed into the stop or surface 174 of the PD cycler 102. Continued retraction of the piston 133A pushes the horns 170A, 172A into the apertures of the rear member 137A and causes the latch lock 141A to move forward relative to the front member 139A, thereby compressing the spring 143A, as shown in FIG. 19. As a result, the inner angled surfaces of the legs 155A, 157A of the latch lock 141A press against the adjacent, similarly angled surfaces of the sliding latches 145A, 147A, causing the sliding latches 145A, 147A to be drawn radially inwardly and disengaging the sliding latches 145A, 147A from the projection 168A (shown in FIGS. 15A-15F) of the domeshaped member 161A. Further retraction of the piston 133A causes the piston head 134A to be backed out of the dome-shaped member 161A of the cassette 112. Alternatively or additionally, the resilience of the stretched membrane 140 can cause the membrane 140 and the dome-shaped member 161A to snap forward and out of contact with the piston head 134A as the sliding latches 145A, 147A become disengaged from the projection 168A of the dome-shaped member 161A.

[0127] After the pistons 133A, 133B have been disconnected from and backed out of the dome-shaped members 161A, 161B of the cassette 112 in the manner described above, the door 108 of the PD cycler is opened and the cassette 112 is removed from the cassette compartment 114 and discarded.

[0128] Because the PD system 100 does not require a vacuum system to draw liquid into the fluid pump chambers 138A, 138B, a substantially airtight seal between the door 108 and the cassette interface 110 is typically not required. Thus, as compared to systems including a vacuum system adapted to retract portions of the cassette membrane overlying pump chambers, the door sealing mechanism of the PD cycler 102 can be simpler and more cost effective. In addition, the reduced use of vacuum pressure relative to certain conventional cyclers can result in quieter operation.

[0129] While certain implementations have been described, other implementations are possible.

[0130] While the piston heads 134A, 134B have been described as including springloaded latch mechanisms with sliding latches 145A, 145B that can be move radially inward and outward to allow those piston heads 134A, 134B to be mechanically connected to the dome-shaped members 161A, 161B of the cassette 112, piston heads of simpler construction that include no such sliding latch-

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es can alternatively be used in some cases. FIG. 20 illustrates a PD cycler 202 including a piston 233A that has one such type of piston head 234A connected to its piston shaft 135A. The PD cycler 202 is essentially the same as the PD cycler 102 described above except the pistons include different types of piston heads than the pistons in the PD cycler 102 described above. Like the PD cycler 102, the PD cycler 202 also includes a second piston that has a substantially identical structure and function to the piston 233A illustrated in FIG. 20 and thus will not be separately described in detail.

[0131] Still referring to FIG. 20, the piston head 234A is a unitary structure that includes a peripheral flange 245A that can be engaged with an annular projection of a dome-shaped member of a cassette in order to mechanically connect the piston head 234A to the cassette and enable a fluid pumping process of the type described above to be carried out. The rear surface of the flange 245A can be arranged at an angle of about 45 degrees to about 75 degrees (e.g., about 60 degrees) relative to the longitudinal axis of the piston. The piston head 234A can be formed using any of the materials and techniques described above with respect to the piston head 134A. Similarly, the piston head 234A can be secured to the piston shaft 135A using any of the attachment techniques discussed above for attaching the piston head 134A to the piston shaft 135A.

[0132] FIGS. 21A-21C are diagrammatic cross-sectional views of a PD system 200 that includes a PD cassette 212 disposed in the cassette compartment 114 of the PD cycler 202, during different phases of a pumping operation used to draw dialysis solution into a pump chamber 23 8A of the cassette 212 and to force dialysis solution out of the pump chamber 238A of the cassette 212. The cassette 212 is very similar to the cassette 112 described above. However, the cassette 212 includes a rigid dome-shaped member 261A that is shaped slightly differently than the dome-shaped member 161A described above. The technique for pumping solution to and from the other pump chamber of the cassette 212 is identical and thus is not separately described in detail. [0133] As shown in FIG. 21A, once the cassette 212 has been installed within the cassette compartment 114 of the PD cycler 202, the piston 233A is advanced to initiate the process of connecting the piston head 234A of the PD cycler 202 to the dome-shaped member 261A

that extends radially inward from the dome-shaped member 261A and pushes the dome-shaped member 261A into contact with the rigid base 156 of the cassette 212. The front surface of the flange 245A of the piston head 234A and the rear surface of the annular projection 268A of the dome-shaped member 261A are generally arranged to approximately mate with one another. The leading front surface of the flange 245A of the piston head 234A is typically angled rearwardly at about 45 to about

of the cassette 212. As the piston 233A is advanced, the

flange 245A of the piston head 234A contacts the lead-

in chamfer or rear surface of an annular projection 268A

75 degrees (e.g., about 60 degrees) relative to the longitudinal axis of the piston 233A. The rear surface of the annular projection is typically angled frontwardly at about 45 to about 75 degrees (e.g., about 60 degrees) relative to the longitudinal axis of the piston 233A. Due to the geometry and rigidity of the flange 245A of the piston head 234A, advancing the piston head 234A into the dome-shaped member 261A of the cassette 212 causes the peripheral side wall of the cassette 212 from which the projection 268A extends to deflect radially outwardly, allowing the flange 245A to slide past the projection 268A. The dome-shaped member 261A of the cassette 212 is resilient so that the projection 268A snaps back into place behind the flange 245 after the flange 245 slides past the projection 268A. The engagement between the flange 245A and the projection 268A holds the piston head 234A secured to the dome-shaped member 261A of the cassette 212 to permit pumping action to be applied to the cassette 212 by the piston 233A.

[0134] As the piston head 234A is mechanically connected to the dome-shaped member 261A in the manner described above, the volume of the pump chamber 238A formed between the dome-shaped member 261A, the membrane 140 decreases due to the forward movement of the dome-shaped member 261A into the recessed region 162A of the base 156, and thus causes any fluid (e.g., priming fluid) within the pump chamber 238A to be forced out of the pump chamber 238A.

[0135] Referring to FIG. 21C, the piston 233A is then retracted to draw dialysis solution into the pump chamber 238A. Because the piston head 234A is mechanically connected to the dome-shaped member 261A and the dome-shaped member 261A is attached to the membrane 140 of the cassette 212, the retraction of the piston 233A causes the dome-shaped member 261A and the portion of the membrane 140 attached to the dome-shaped member 261A to move rearwardly. As a result, the volume of the pump chamber 23 8A is increased and fluid is drawn into the pump chamber 23 8A.

[0136] After drawing the dialysis solution into the pump chamber 238A, the dialysis solution is forced out of the pump chamber 238A by again advancing the piston 233A and decreasing the volume of the pump chamber 238A. As discussed above, this process of drawing dialysis solution into the fluid pump chamber 238A and then forcing the dialysis solution out of the fluid pump chamber 238A can be repeated until a desired volume of dialysis solution has been pumped to or from a location (e.g., to or from the patient) during a PD treatment.

[0137] To mechanically disconnect the piston head 234A from the dome-shaped member 261A after treatment, the piston 233A is retracted farther than it is retracted during treatment. This retraction causes the rear surface of the peripheral flange of the dome-shaped member 261A to contact the surface 174 of the PD cycler 202 such that the dome-shaped member 261A is prevented from moving any further in the rearward direction. The piston 233A continues to retract such that the piston

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head 234A slides rearwardly relative to the dome-shaped member 261A. The rear surface of the flange 245A of the piston head 234A is typically angled frontwardly at about 60 to about 80 degrees (e.g., about 70 degrees) relative to the longitudinal axis of the piston 233A. The front surface of the annular projection 268A is typically angled rearwardly at about 60 to about 80 degrees (e.g., about 70 degrees) relative to the longitudinal axis of the piston 233A. As a result of the orientation of these surfaces and the inability of the dome-shaped member 261A to move further rearwardly, the rearward motion of the piston head 234A causes the portions of the domeshaped member 261A from which the annular projection 268A extends to deflect radially outwardly. This allows the flange 245A of the piston head 234A to slide past the annular projection 268A resulting in the piston head 234A being mechanically disconnected from the dome-shaped member 261A.

[0138] While the piston head 234A and cassette 212 have been described as being constructed so that the peripheral side walls of the cassette 212 deflect outwardly as the piston head 234A is advanced into and retracted out of the dome-shaped member 261A, they can alternatively or additionally be designed so that wall of the piston head 234A from which the flange 245A extends deflects radially inwardly to allow the flange 245A of the piston head 234A to slide past the projection 268A of the cassette 212.

[0139] While the cassette 212 and the PD cycler 202 described above are designed so that the rear surface of the peripheral flange of the dome-shaped member 261 contacts the surface 174 of the PD cycler 202 during the disconnection process, in certain implementations, the membrane 140 itself may provide sufficient resistance to rearward movement of the dome-shaped member 261A to allow the piston head 234A to be disconnected from the dome-shaped member 261A.

[0140] Other structures for enabling a mechanical connection between piston heads and a cassette can also be used. As shown in FIG. 22, for example, a cassette 312, which is structurally very similar to the cassette 112 described above, includes pegs 368A, 368B that extend from rigid, dome-shaped members 361A, 361B, which are disposed within the recessed regions 162A, 162B of the base 156 of the cassette 112 and are attached to the membrane 140 of the cassette 312 in the same way as the dome-shaped members 161A, 161B of the cassette 112 discussed above. Each of the pegs 368A, 368B includes a stem 370A, 370B attached to the associated dome-shaped member 361A, 361B of the cassette 312 and an enlarged head 372A, 372B attached to or integrally formed with an end of the stem 370A, 370B opposite the dome-shaped members 361A, 361B. As discussed below, the pegs 368A, 368B can engage piston heads of a PD cycler in a manner to mechanically connect the dome-shaped members 361A, 361B to the piston

[0141] FIGS. 23 and 24 illustrate a piston head 334A

that can be secured to the piston shaft 135A of one of the PD cyclers described above and can engage the peg 345A of the cassette 312 to allow a pumping action to be produced in a pump chamber formed between a recessed region of the base 156 of the cassette 312 and the dome-shaped member 361A and membrane 140 when the piston is reciprocated. It will be appreciated that an identical piston head could be secured to the other piston shaft 135B of the PD cycler to enable a similar pumping action to be produced within the pump chamber adjacent the other dome-shaped member 361B. As shown in FIGS. 23 and 24, the piston head 334A includes a bore 336A in which a clamp mechanism 338A including two resilient spring fingers 345A, 347A is contained. Central portions of the spring fingers 345A, 347A can, for example, be attached to a radially inwardly extending annular projection 390A of the piston head 334A. Any of various attachment techniques, such as adhesive bonding, thermal welding, and/or mechanical fastening techniques, can be used to attach the spring fingers 345A, 347A to the annular projection 390A.

[0142] Still referring to FIGS. 23 and 24, the spring finger 345A includes front and rear projections 349A and 351A, respectively, that extend radially inward from a base portion of the finger 345A, and the spring finger 347A includes front and rear projections 353A and 355A, respectively, that extend radially inward from a base portion of the finger 347A. The front projections 349A, 353A have chamfers at their leading, front ends that are angled by about 15 degrees to about 75 degrees (e.g., about 30 degrees to about 60 degrees, about 45 degrees) relative to the longitudinal axis of the piston. To mechanically connect the piston head 334A to the peg 368A the piston head 334A is advanced into the dome-shaped member 361A such that front surfaces of the projections 349A, 353A of the spring fingers 345A, 347A contact the enlarged head 372A of the peg 368A. Due to the angled orientation of the font surfaces of the projections 349A, 353A, continued advancement of the piston head 334A causes the spring fingers 345A, 347A to deflect radially outward and thus spread apart as the projections 349A, 353A slide along the enlarged head 372A of the peg 368A. The spring fingers 345A, 347A spread apart a sufficient distance to allow the enlarged head 372A of the peg 368A to slide forward past the projections 349A, 353A and allow the enlarged head 372A to become fixed within a space formed between the front and rear projections of the spring fingers 345A, 347A. The front surface of each of the rear projections 351A, 355A is substantially perpendicular to the longitudinal axis of the piston such that further advanced of the piston head 334A will not cause the spring fingers 345A, 347A to spread apart when the enlarged head 372A of the peg 368A is disposed in the space between the front and rear projections of the spring fingers 345A, 347A. With the piston head 334A and the peg 368A engaged in this manner, reciprocation of the piston head 334A causes movement of the dome-shaped member 361A and the surrounding

portion of the membrane 140 and thus causes fluid to be pumped into and out of the pump chamber of the cassette 312 in the same manner as described above.

[0143] Like the front surfaces of the front projections 349A, 353A of the spring fingers 345A, 347A, the rear surfaces of the rear projections 351A, 355A are angled at about 15 degrees to about 75 degrees (e.g., about 30 degrees to about 60 degrees, about 45 degrees). An internal shaft 357A sits within an axial bore formed in the piston head 334A positioned behind the bore 336A in which the clamp mechanism 338A is contained. The internal shaft 357A is fixed to the housing of the PD cycler such that the piston head 334A moves relative to the shaft 357A as the piston head 334A reciprocates. To disconnect the piston head 334A from the peg 368A after treatment, the piston head 334A is retracted into the PD cycler a sufficient distance so that the shaft 357A contacts the rear surfaces of the rear projections 351A, 355A of the spring fingers 345A, 347A. This contact, due to the angled orientation of the rear surfaces of the rear projections 351A, 355A, causes the spring fingers 345A, 347A to spread apart. Further retraction of the piston head 334A causes the front projections 349A, 353A to move back beyond the peg 368A.

[0144] FIGS. 25 and 26 illustrate a slightly different piston head 434A that can be secured to the piston shaft 135A of one of the PD cyclers described above and can engage the peg 345A of the cassette 312 to allow a pumping action to be produced in a pump chamber formed between a recessed region of the base 156 of the cassette 312 and the dome-shaped member 361A and membrane 140 when the piston is reciprocated. As shown in FIGS. 25 and 26, the piston head 434A includes a bore 436A in which a clamp mechanism 43 8A including two resilient spring fingers 445A, 447A is contained. Central portions of the spring fingers 445A, 447A are attached to a radially inwardly extending annular projection 490 of the piston head 434A. Any of various attachment techniques, such as adhesive bonding, thermal welding, and/or mechanical fastening techniques, can be used to attach the spring fingers 445A, 447A to the annular projection 490A.

[0145] Still referring to FIGS. 25 and 26, the spring fingers 445A, 447A include projections 449A, 453A that extend radially inward from base portions of the fingers 445A, 447A. The projections 449A, 453A have chamfers at their leading, front ends and their trailing, rear ends that are angled in opposite directions by about 15 degrees to about 75 degrees (e.g., about 30 degrees to about 60 degrees, about 45 degrees) relative to the longitudinal axis of the piston. The piston head 434A is mechanically connected to the cassette 312 in much the same way as the piston head 334A described above. In particular, the piston head 434A is advanced into the dome-shaped member 361A such that front surfaces of the projections 449A, 453A of the spring fingers 445A, 447A contact the enlarged head 372A of the peg 368A and, due to the angled orientation of the font surfaces of

the projections 449A, 453A, cause the spring fingers 445A, 447A to deflect radially outward. The spring fingers 445A, 447A spread apart a sufficient distance to allow the enlarged head 372A of the peg 368A to slide forward past the projections 449A, 453A and into a space formed between the spring fingers 445A, 447A behind the projections 449A, 453A.

[0146] To disconnect the piston head 434A from the peg 368A after treatment, the piston head 434A is retracted into the PD cycler. As the piston head 434A is retracted, a point is reached at which the resistance of the membrane 140 pulling on the dome-shaped member 361A is greater than the force required to spread the fingers 445A, 447A apart. At this point, continued retraction of the piston head 434A causes the chamfered rear surfaces of the projections 449A, 453A to slide axially along the enlarged head 372A of the peg 368A of the cassette 312 of the spring fingers 445A, 447A, causing the spring fingers 445A, 447A to spread apart thereby allowing the peg 368A to be released from the space behind the projections 449A, 453A of the fingers 445A, 447A.

[0147] While the cassette interface 110 of the PD cycler 102 has been described as including locating pins 148 that help to ensure that the dome-shaped members of the cassette are aligned with the pistons 133A, 133B when the cassette is positioned in the cassette compartment 114, other structures or techniques can be used to ensure this alignment. In some implementations, for example, the cassette is placed against the door of the PD cycler with the hollow projections of the cassette disposed in recesses of the PD cycler's door., and the cassette is held in this position by retainer clips attached to the door. Upon closing the door, the pistons of the PD cycler align with the dome-shaped members of the cassette.

[0148] While the door 108 of each of the PD cyclers above has been described as including an inflatable pad that, when inflated, can press the cassette against the cassette interface, the inflatable pad can alternatively be positioned behind the cassette interface such that the cassette interface can be moved toward the door 108 to compress the cassette therebetween. Similarly, as an alternative to an inflatable pad, any of various mechanisms that can be operated to move a surface of the door 108 toward the cassette interface or vice versa can be used

[0149] While the door 108 of the PD cyclers described above are shown as being positioned on a front face of the PD cyclers, the doors can alternatively be positioned at various other locations on the PD cyclers. For example, the doors could be positioned on a top face of the PD cycler such that the cassette is slid into the cassette compartment in a substantially horizontal orientation instead of a substantially vertical orientation. In some implementations, the door and the cassette interface of the PD cycler are positioned at an angle of about 10 to about 35 degrees to vertical when the PD cycler is rested on a

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horizontal surface. It has been found that this configuration makes it easier for the user to load the cassette into the cassette compartment.

[0150] While the cassettes discussed above have two pump chambers, the cassettes can alternatively have more or fewer than two pump chambers.

[0151] While each of the pump chambers of the cassettes described above has been described as including a fluid inlet port and a fluid outlet port, in certain implementations, the pump chambers include a single port that is used as both an inlet and an outlet. In such implementations, the inflatable valve members of the PD cycler that act on the valve portions of the cassettes would be activated and deactivated in a slightly different sequence to allow fluid to be drawn into the pump chamber from a desired location and then to be forced out of the pump chamber to a desired location.

[0152] While certain PD cyclers above have been described as including a touch screen and associated buttons, the PD cyclers can alternatively or additionally include other types of screens and user data entry systems. In certain implementations, for example, the cycler includes a display screen with buttons (e.g., feather touch buttons) arranged on the console adjacent the display screen. Certain buttons can be arranged to be aligned with operational options displayed on the screen during use such that the user can select a desired operational option by pressing the button aligned with that operational option. Additional buttons in the form of arrow buttons can also be provided to allow the user to navigate through the various display screens and/or the various items displayed on a particular screen. Other buttons can be in the form of a numerical keypad to allow the user to input numerical values in order, for example, to input operational parameters. A select or enter button can also be provided to allow the user to select an operational option to which the user navigated by using the arrow keys and/or to allow the user to enter values that the user inputted using the numerical keypad.

[0153] While the mechanically connectable piston heads and cassettes described above have been described as being part of PD systems, these types of piston heads and cassettes can be used in any of various other types of medical fluid pumping systems. Other examples of medical fluid pumping systems in which the piston heads and cassettes described herein can be used include hemodialysis systems, blood perfusion systems, and intravenous infusion systems.

[0154] Similarly, while many of the systems above have been described as being used to pump dialysis solution, other types of dialysis fluids can be pumped through the cassettes. As an example, in the case of cassettes used with hemodialysis machines, blood can be pumped through the cassettes. In addition, priming solutions, such as saline, can similarly be pumped through cassettes using the various different systems and techniques described above. Similarly, as an alternative to dialysis fluids, any of various other types of med-

ical fluids can be pumped through the above-described cassettes depending on the type of medical fluid pumping machines with which the cassettes are used.

Claims

1. A medical fluid cassette (112, 312) comprising:

a base (156),

a flexible membrane (140) attached to the base (156) in a manner such that the flexible membrane (140) and the base cooperate to at least partially define a fluid pump chamber, characterized by a fastening member (161A, 161B, 261A, 361A, 361B) formed of a rigid material and attached to the flexible membrane (140), the fastening member (161A, 161B, 261A, 361A, 361B) defining a recess configured to receive a piston head (134A, 134B, 234A, 434A) of a medical fluid pumping machine and having an engagement surface that engages the piston head (134A, 134B, 234A, 434A) when the piston head is disposed in the recess (162A, 162B) such that, when the piston head is disposed in the recess and is moved linearly away from the base (156) of the cassette, the piston head engages the engagement surface (168A) of the fastening member to pull the fastening member (161A, 161B, 261A, 361A, 361B) and the flexible membrane (140) to which the fastening member is attached away from the base (156) and increase a volume of the fluid pump chamber.

- 35 2. The medical fluid cassette (112, 312) of claim 1, wherein the medical fluid cassette can be secured to the medical fluid pumping machine (102) by disposing the medical fluid cassette (112, 312) within a cassette compartment (114) defined by the medical fluid pumping machine.
 - 3. The medical fluid cassette (112, 312) of claim 1, wherein the fastening member (161A, 161B, 261A, 361A, 361B) is substantially centered relative to the fluid pump chamber (138A, 138B) of the medical fluid cassette.
 - 4. The medical fluid cassette (112, 312) of claim 1, wherein the fastening member (161A, 161B, 261A, 361A, 361B) comprises a substantially domeshaped member (161A, 161B, 261A, 361A, 361B).
 - 5. The medical fluid cassette (112, 312) of claim 4, wherein the engagement surface of the fastening member (161A, 161B, 261A) is a surface of a radially inwardly extending projection (168A, 168B, 268) of the substantially dome-shaped member (161A, 161B, 261A).

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- The medical fluid cassette (112, 312) of claim 5, wherein the projection extends continuously around perimeter region of the substantially dome-shaped member.
- 7. The medical fluid cassette (312) of claim 4, wherein the fastening member (361A, 361B) comprises a peg (368A, 368B) extending from a surface of the domeshaped member.
- **8.** The medical fluid cassette (312) of claim 7, wherein the engagement surface of the fastening member is a surface of an enlarged head of the peg (368A, 368B).
- 9. The medical fluid cassette (112, 312) of any one of claims 4-8, wherein the dome-shaped member comprises an annular flange (164A, 164B) that is attached in a liquid-tight manner to portions of an inner surface of the membrane (140) surrounding a substantially circular aperture (166A, 166B) formed in the membrane (140).
- 10. The medical fluid cassette (112, 312) of claim 1, wherein the fastening member is constructed to become mechanically connected to the piston head (134A, 134B, 234A, 434A) when the piston head is moved toward the base of the cassette and to become disconnected from the piston head when the piston head is moved away from the base of the cassette.
- **11.** The medical fluid cassette (112, 312) of claim 1, wherein the medical fluid cassette is a dialysis fluid cassette.
- **12.** The medical fluid cassette (112, 312) of claim 11, wherein the dialysis fluid cassette is a peritoneal dialysis fluid cassette.
- 13. The medical fluid cassette (112, 312) of claim 1, wherein the piston head includes a retractable latch mechanism that allows the piston head and the fastening member to be mechanically connected and disconnected.
- 14. The medical fluid cassette (112, 312) of claim 13, wherein the engagement surface is of the latch mechanism and angled relative to the longitudinal axis of the piston, for example, at about 60 to 70 degrees relative thereto.
- **15.** The medical fluid cassette (112, 312) of claim 13, wherein the latch mechanism is a spring loaded latch mechanism.

Patentansprüche

- 1. Medizinische Fluidkassette (112, 312), umfassend:
- eine Basis (156),
 eine flexible Membran (140), die auf eine solche
 Weise an der Basis (156) befestigt ist, dass die
 flexible Membran (140) und die Basis zusammenarbeiten, um zumindest teilweise eine Flu-

 $idpumpkammer\,zu\,definieren,\,\textbf{gekennzeichnet}\\ \,\textbf{durch}$

ein Befestigungselement (161A, 161B, 261A, 361A, 361B), das aus einem starren Material gefertigt ist und an der flexiblen Membran (140) befestigt ist, wobei das Befestigungselement (161A, 161B, 261A, 361A, 361B) eine Aussparung definiert, die zur Aufnahme eines Kolbenkopfes (134A, 134B, 234A, 434A) einer Maschine zum Pumpen eines medizinischen Fluids ausgelegt ist und eine Einrastfläche aufweist, die den Kolbenkopf (134A, 134B, 234A, 434A) in Eingriff nimmt, wenn der Kolbenkopf in der Aussparung (162A, 162B) angeordnet ist, so dass, wenn der Kolbenkopf in der Aussparung angeordnet ist und linear von der Basis (156) der Kassette weg bewegt wird, der Kolbenkopf die Einrastfläche (168A) des Befestigungselements in Eingriff nimmt, um das Befestigungselement (161A, 161B, 261A, 361A, 361B) und die flexible Membran (140), an der das Befestigungselement befestigt ist, von der Basis (156) weg zu ziehen und ein Volumen der Fluidpumpkammer zu erhöhen.

- 2. Medizinische Fluidkassette (112, 312) nach Anspruch 1, wobei die medizinische Fluidkassette an der Maschine (102) zum Pumpen eines medizinischen Fluids befestigt werden kann, indem die medizinische Fluidkassette (112, 312) in einem von der Maschine zum Pumpen eines medizinischen Fluids definierten Kassettenfach (114) angeordnet wird.
- Medizinische Fluidkassette (112, 312) nach Anspruch 1, wobei das Befestigungselement (161A, 161B, 261A, 361A, 361B) im Verhältnis zur Fluidpumpkammer (138A, 138B) der medizinischen Fluidkassette im Wesentlichen zentriert ist.
- Medizinische Fluidkassette (112, 312) nach Anspruch 1, wobei das Befestigungselement (161A, 161B, 261A, 361A, 361B) ein im Wesentlichen kuppelförmiges Element (161A, 161B, 261A, 361A, 361B) umfasst.
- 55 5. Medizinische Fluidkassette (112, 312) nach Anspruch 4, wobei die Einrastfläche des Befestigungselements (161A, 161B, 261A) eine Oberfläche eines sich radial einwärts erstreckenden Vorsprungs

(168A, 168B, 268) des im Wesentlichen kuppelförmigen Elements (161A, 161B, 261A) ist.

 Medizinische Fluidkassette (112, 312) nach Anspruch 5, wobei sich der Vorsprung kontinuierlich um eine Umfangsregion des im Wesentlichen kuppelförmigen Elements erstreckt.

- Medizinische Fluidkassette (312) nach Anspruch 4, wobei das Befestigungselement (361A, 361B) einen Zapfen (368A, 368B) umfasst, der sich von einer Oberfläche des kuppelförmigen Elements erstreckt.
- Medizinische Fluidkassette (312) nach Anspruch 7, wobei die Einrastfläche des Befestigungselements eine Oberfläche eines vergrößerten Kopfes des Zapfens (368A, 368B) ist.
- 9. Medizinische Fluidkassette (112, 312) nach einem der Ansprüche 4-8, wobei das kuppelförmige Element einen ringförmigen Flansch (164A, 164B) umfasst, der auf flüssigkeitsdichte Weise an Abschnitten einer Innenseite der Membran (140) um eine im Wesentlichen kreisförmige Öffnung (166A, 166B), die in der Membran (140) ausgebildet ist, befestigt ist.
- 10. Medizinische Fluidkassette (112, 312) nach Anspruch 1, wobei das Befestigungselement so konstruiert ist, dass es mechanisch mit dem Kolbenkopf (134A, 134B, 234A, 434A) verbunden wird, wenn der Kolbenkopf zur Basis der Kassette bewegt wird und vom Kolbenkopf gelöst wird, wenn der Kolbenkopf von der Basis der Kassette weg bewegt wird.
- Medizinische Fluidkassette (112, 312) nach Anspruch 1, wobei die medizinische Fluidkassette eine Dialyseflüssigkeitskassette ist.
- **12.** Medizinische Fluidkassette (112, 312) nach Anspruch 11, wobei die Dialyseflüssigkeitskassette eine Peritonealdialyseflüssigkeitskassette ist.
- 13. Medizinische Fluidkassette (112, 312) nach Anspruch 1, wobei der Kolbenkopf einen zurückziehbaren Verriegelungsmechanismus aufweist, der es gestattet, dass der Kolbenkopf und das Befestigungselement mechanisch miteinander verbunden und voneinander gelöst werden.
- **14.** Medizinische Fluidkassette (112, 312) nach Anspruch 13, wobei die Einrastfläche zum Verriegelungsmechanismus gehört und bezüglich der Längsachse des Kolbens abgewinkelt ist, beispielsweise ungefähr 60 bis 70 Grad relativ dazu.
- **15.** Medizinische Fluidkassette (112, 312) nach Anspruch 13, wobei der Verriegelungsmechanismus

ein federgespannter Verriegelungsmechanismus ist.

Revendications

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1. Cassette de fluide médical (112, 312), comprenant:

une base (156),

une membrane flexible (140) attachée à la base (156) de telle manière que la membrane flexible (140) et la base coopèrent afin de définir au moins partiellement une chambre de pompe à fluide, et caractérisée par:

un élément de fixation (161A, 161B, 261A, 361A, 361B) attaché à la membrane flexible (140), l'élément de fixation (161A, 161B, 261A, 361A, 361B) définissant un évidement configuré de manière à recevoir une tête de piston (134A, 134B, 234A, 434A) d'une machine de pompage de fluide médical et présentant une surface d'engagement qui engage la tête de piston (134A, 134B, 234A, 434A) lorsque la tête de piston est disposée dans l'évidement (162A, 162B) de telle sorte que, lorsque la tête de piston est disposée dans l'évidement et est déplacée de façon linéaire à l'écart de la base (156) de la cassette, la tête de piston engage la surface d'engagement (168A) de l'élément de fixation de manière à tirer l'élément de fixation (161A, 161B, 261A, 361A, 361B) et la membrane flexible (140) à laquelle l'élément de fixation est attaché à l'écart de la base (156) et à augmenter un volume de la chambre de pompe à fluide.

- 2. Cassette de fluide médical (112, 312) selon la revendication 1, dans laquelle la cassette de fluide médical peut être fixée à la machine de pompage de fluide médical (102) en disposant la cassette de fluide médical (112, 312) à l'intérieur d'un compartiment de cassette (114) défini par la machine de pompage de fluide médical.
- 3. Cassette de fluide médical (112, 312) selon la revendication 1, dans laquelle l'élément de fixation (161A, 161B, 261A, 361A, 361B) est sensiblement centré par rapport à la chambre de pompe à fluide (138A, 138B) de la cassette de fluide médical.
- 4. Cassette de fluide médical (112, 312) selon la revendication 1, dans laquelle l'élément de fixation (161A, 161B, 261A, 361A, 361B) comprend un élément sensiblement en forme de dôme (161A, 161B, 261A, 361A, 361B).

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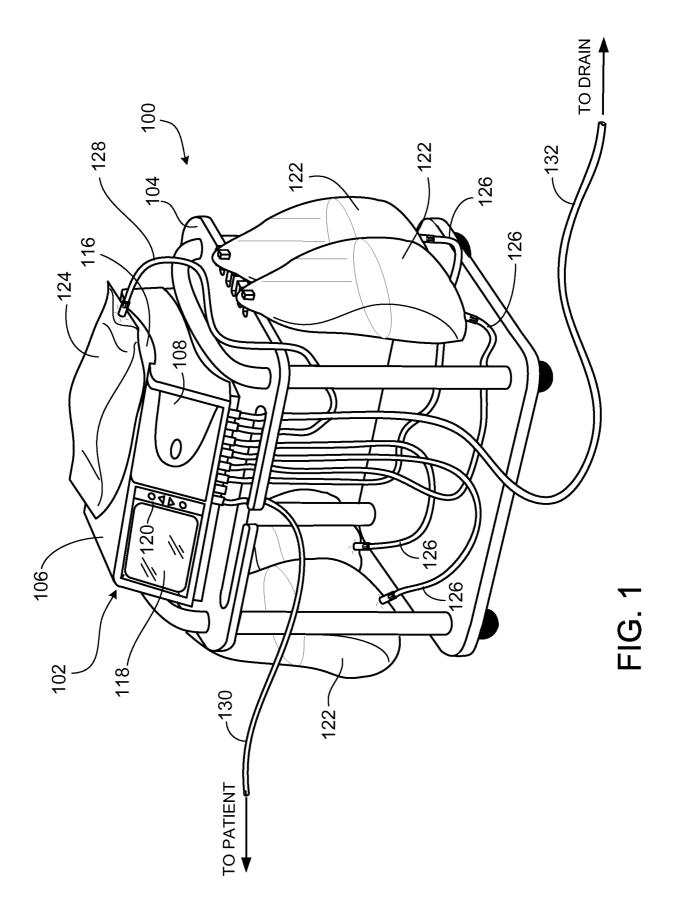
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5. Cassette de fluide médical (112, 312) selon la revendication 4, dans laquelle la surface d'engagement de l'élément de fixation (161A, 161B, 261A) est une surface d'une saillie s'étendant radialement vers l'intérieur (168A, 168B, 268) de l'élément sensiblement en forme de dôme (161A, 161B, 261A).

6. Cassette de fluide médical (112, 312) selon la revendication 5, dans laquelle la saillie s'étend de façon continue autour de la région périmétrique de l'élément sensiblement en forme de dôme.

- 7. Cassette de fluide médical (312) selon la revendication 4, dans laquelle l'élément de fixation (361A, 361B) comprend une goupille (368A, 368B) qui s'étend à partir d'une surface de l'élément sensiblement en forme de dôme.
- 8. Cassette de fluide médical (312) selon la revendication 7, dans laquelle la surface d'engagement de l'élément de fixation est une surface d'une tête agrandie de la goupille (368A, 368B).
- 9. Cassette de fluide médical (112, 312) selon l'une quelconque des revendications 4 à 8, dans laquelle l'élément sensiblement en forme de dôme comprend une bride annulaire (164A, 164B) qui est attachée d'une manière étanche au liquide à des parties d'une surface intérieure de la membrane (140) qui entoure une ouverture sensiblement circulaire (166A, 166B) formée dans la membrane (140).
- 10. Cassette de fluide médical (112, 312) selon la revendication 1, dans laquelle l'élément de fixation est conçu de manière être connecté de façon mécanique à la tête de piston (134A, 134B, 234A, 434A) lorsque la tête de piston est déplacée en direction de la base de la cassette et à être déconnecté de la tête de piston lorsque la tête de piston est déplacée à l'écart de la base de la cassette.
- **11.** Cassette de fluide médical (112, 312) selon la revendication 1, dans laquelle la cassette de fluide médical est une cassette de fluide de dialyse.
- 12. Cassette de fluide médical (112, 312) selon la revendication 11, dans laquelle la cassette de fluide de dialyse est une cassette de fluide de dialyse péritonéale.
- 13. Cassette de fluide médical (112, 312) selon la revendication 1, dans laquelle la tête de piston comprend un mécanisme de verrou rétractable qui permet à la tête de piston et à l'élément de fixation d'être connectés et déconnectés de façon mécanique.
- **14.** Cassette de fluide médical (112, 312) selon la revendication 13, dans laquelle la surface d'engage-

- ment fait partie du mécanisme de verrou et est inclinée par rapport à l'axe longitudinal du piston, par exemple d'environ 60 degrés à 70 degrés par rapport à celui-ci.
- 15. Cassette de fluide médical (112, 312) selon la revendication 13, dans laquelle le mécanisme de verrou est un mécanisme de verrou chargé par ressort.



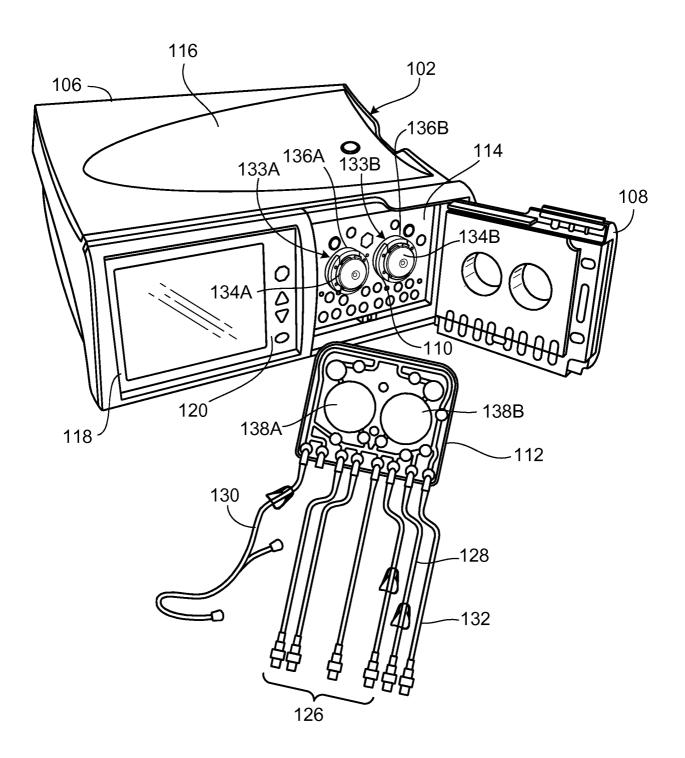
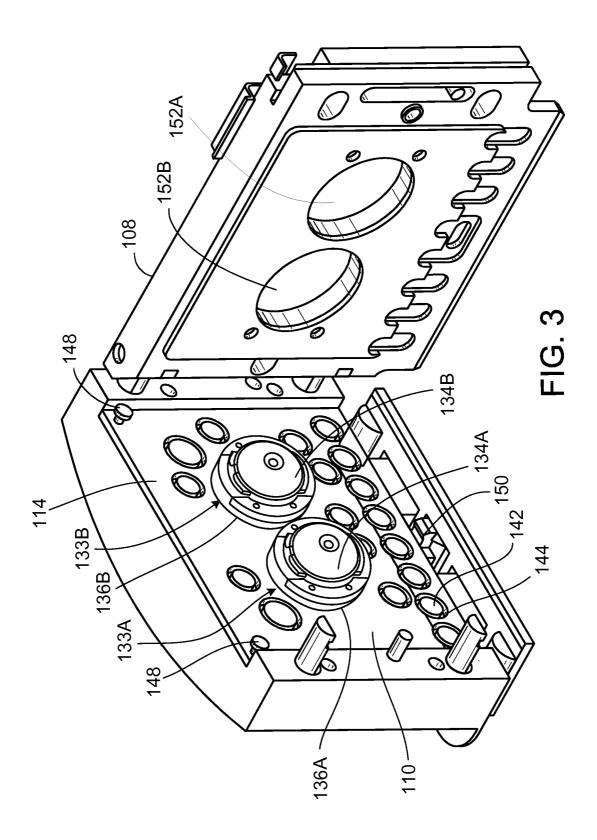


FIG. 2



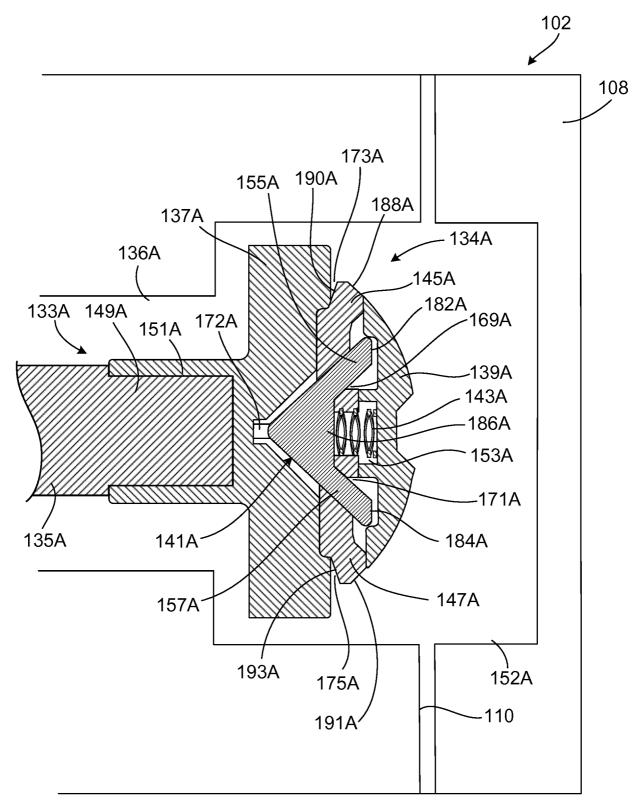
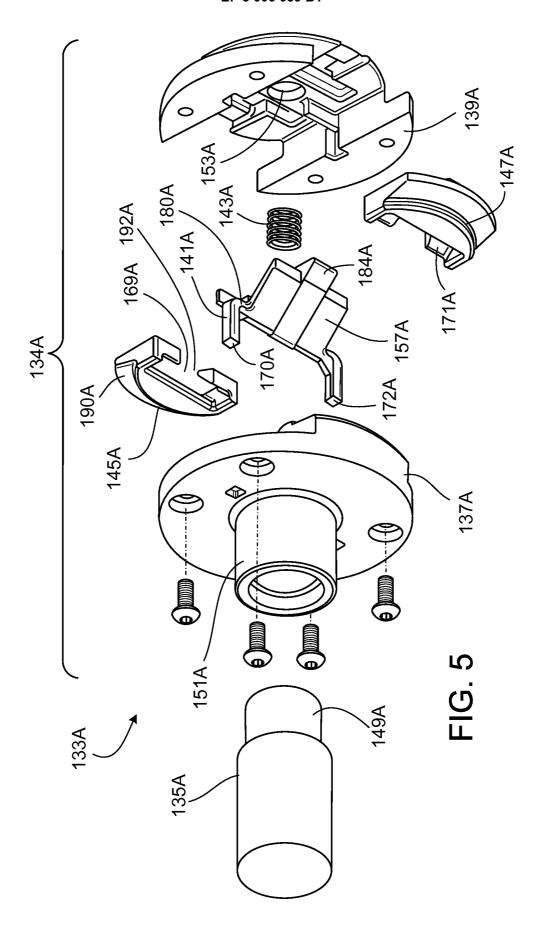
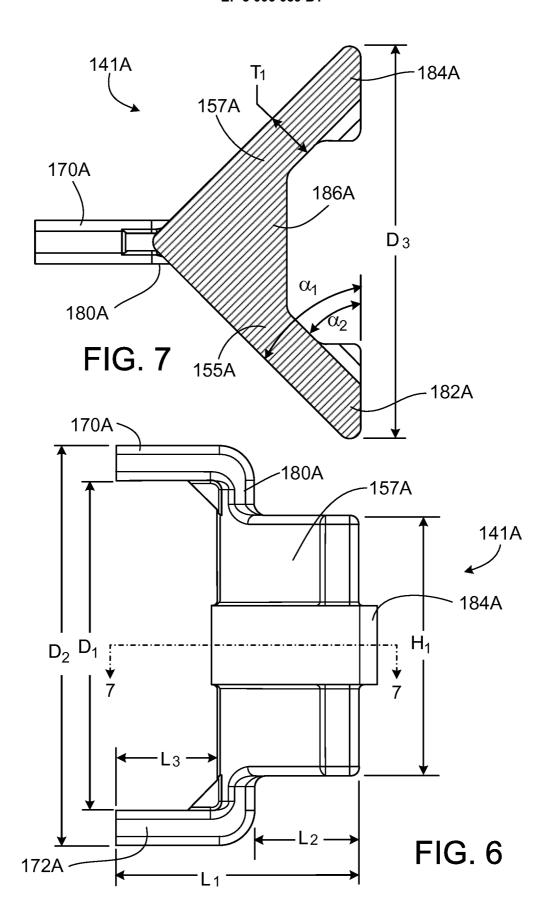
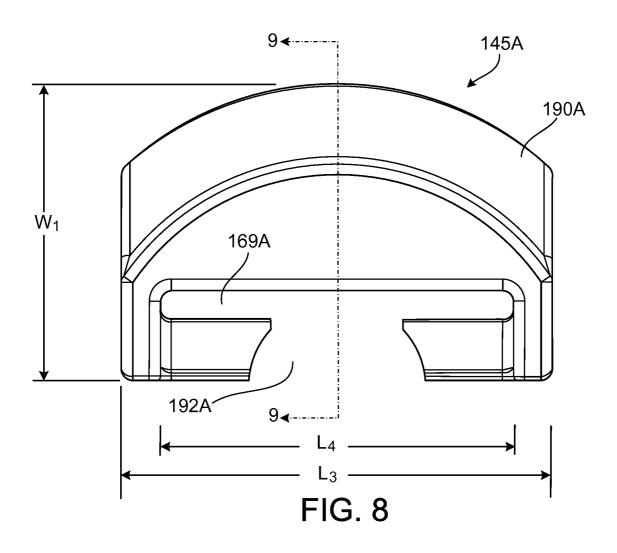
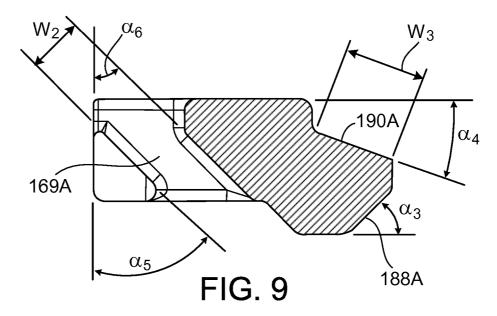


FIG. 4









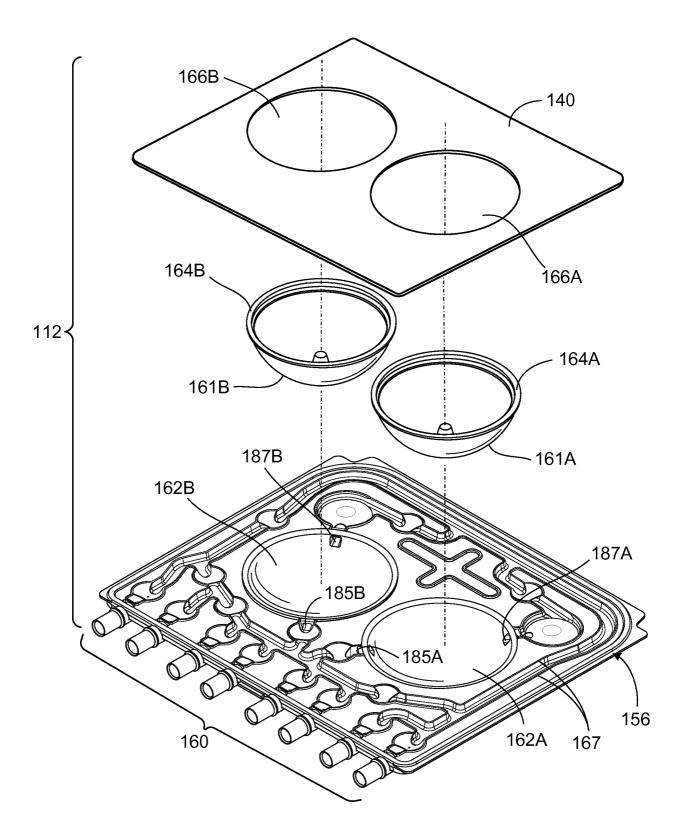
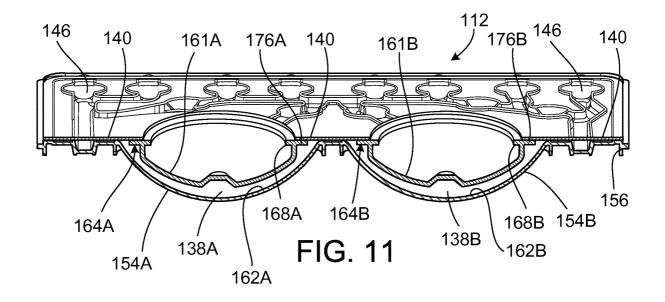
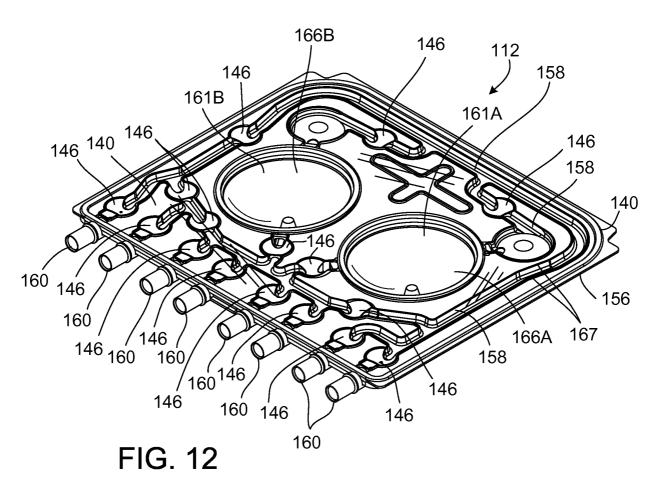


FIG. 10





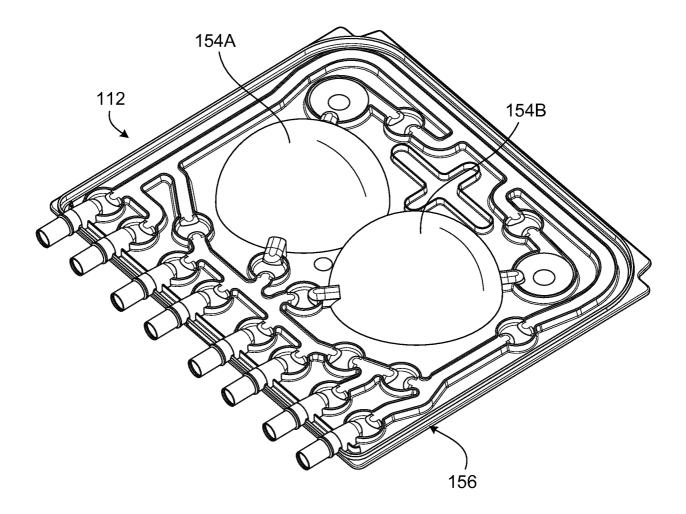


FIG. 13

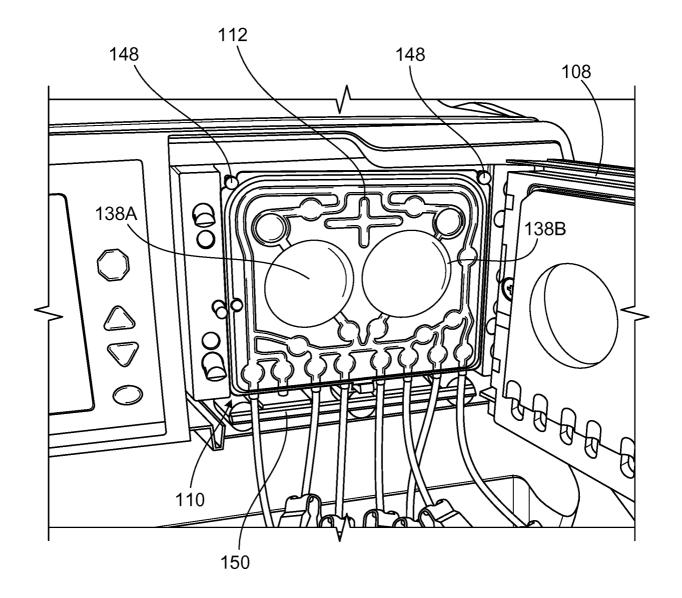


FIG. 14

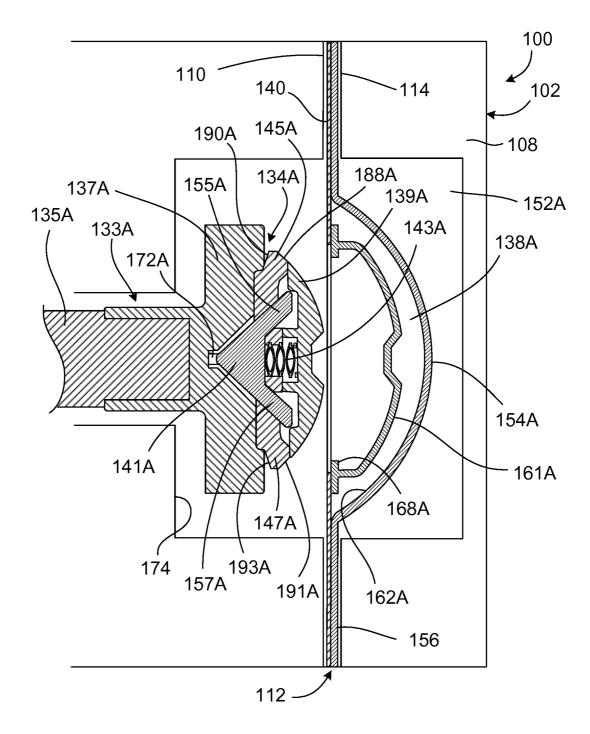


FIG. 15A

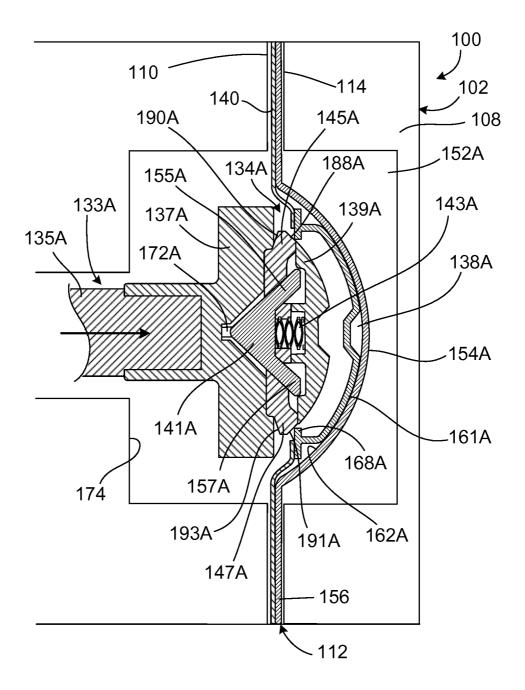


FIG. 15B

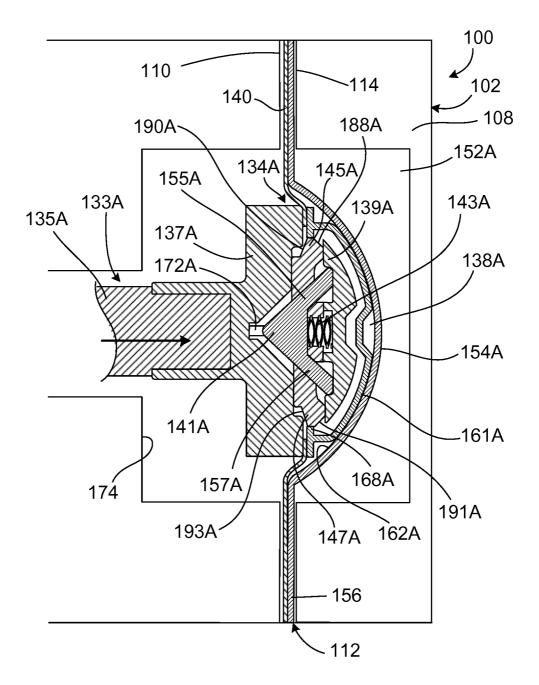


FIG. 15C

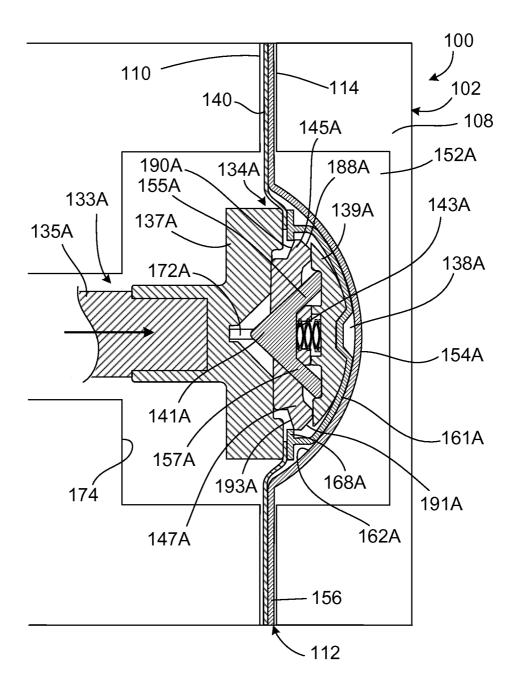


FIG. 15D

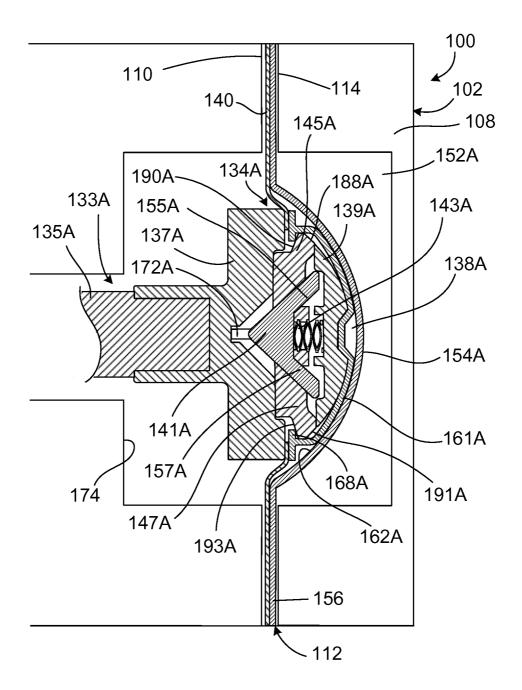


FIG. 15E

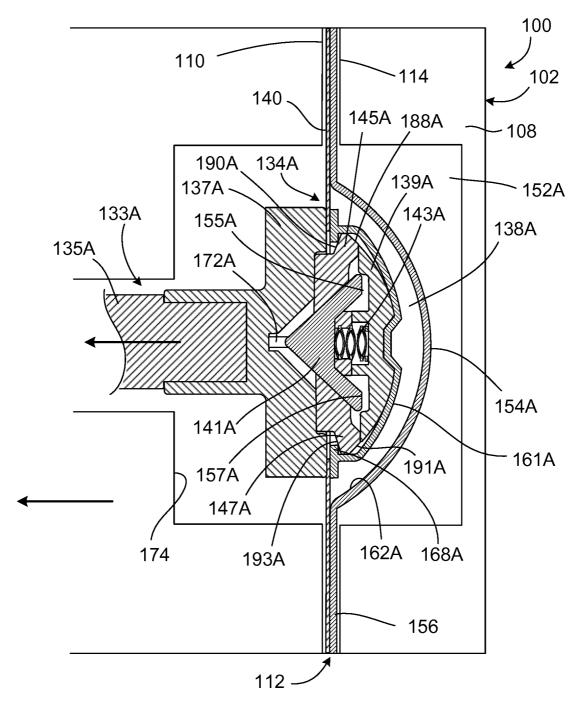
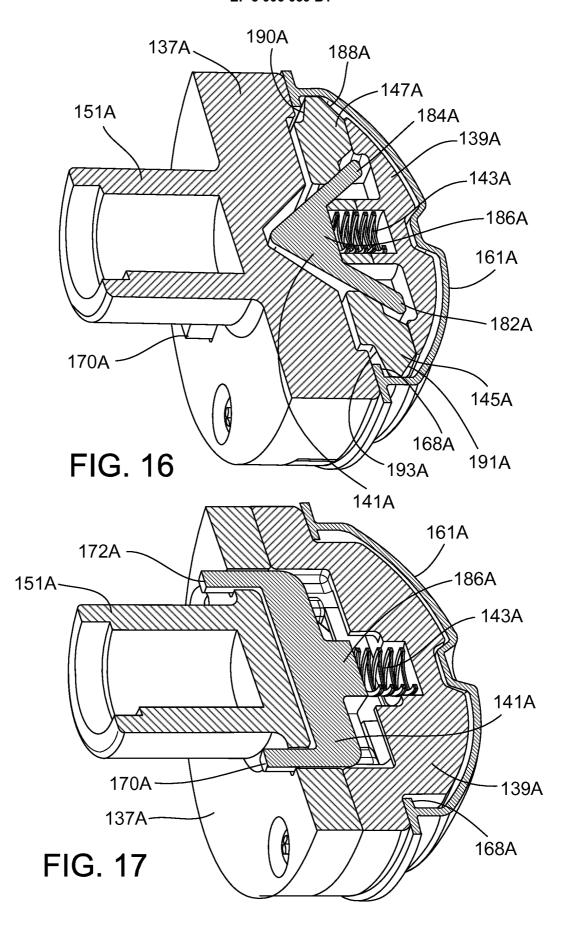
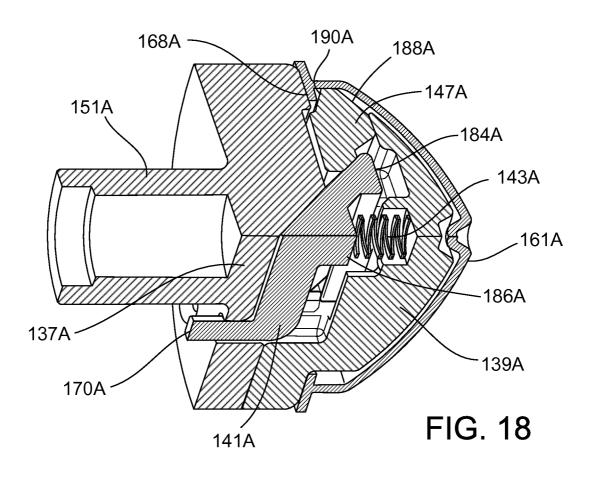
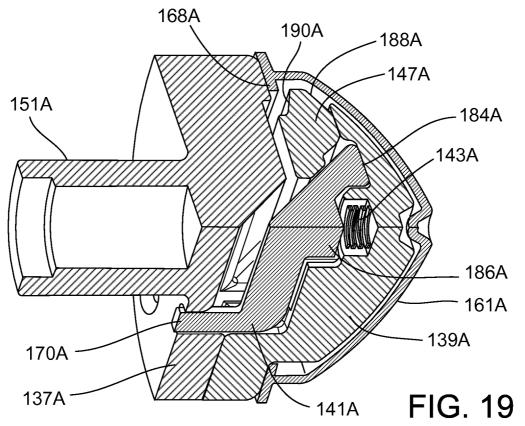


FIG. 15F







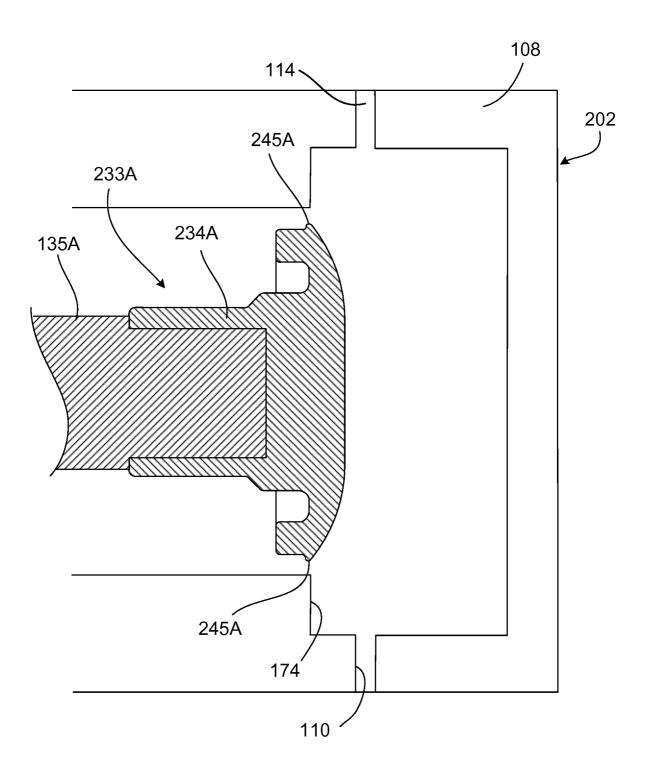
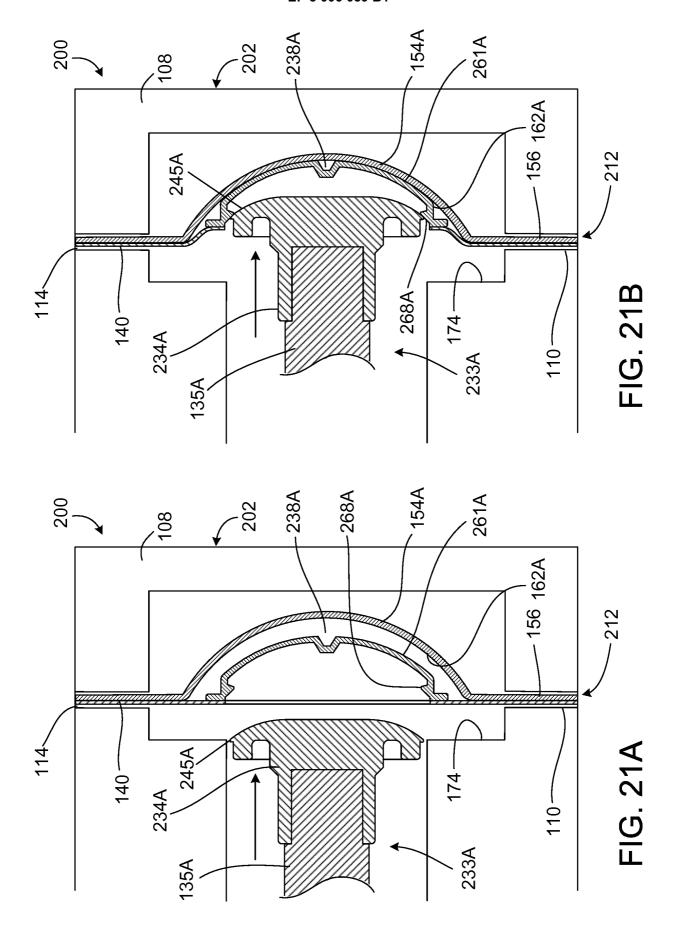


FIG. 20



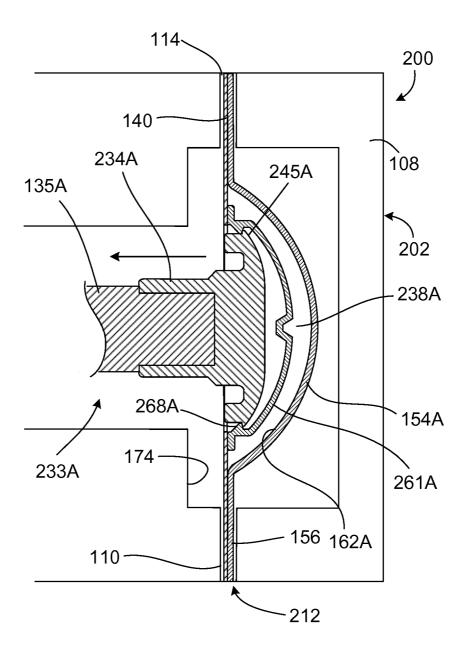


FIG. 21C

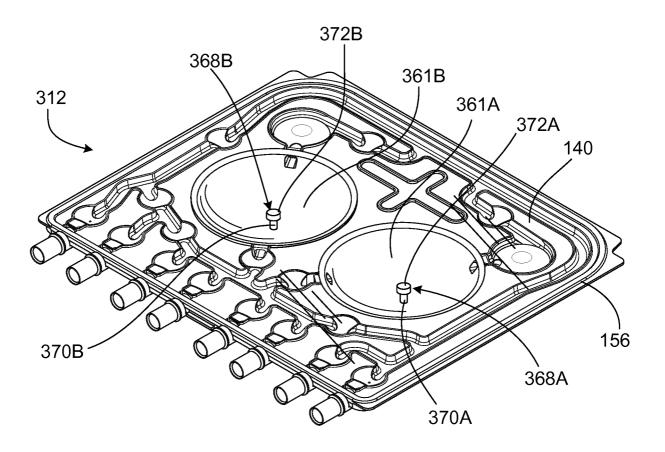
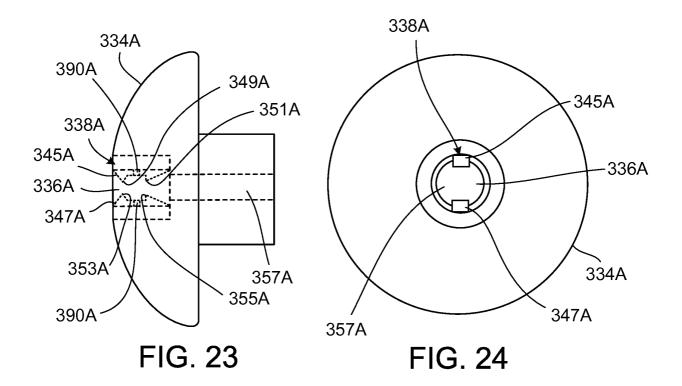
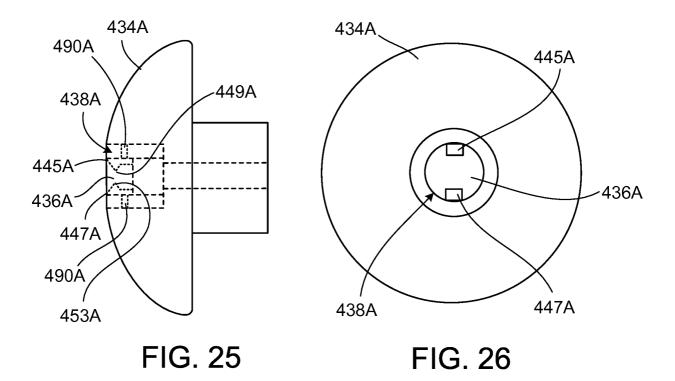


FIG. 22





EP 3 006 059 B1

REFERENCES CITED IN THE DESCRIPTION

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