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VALVE WITH SAMPLING AND PURGE PORTS

BACKGROUND OF THE DISCLOSURE

Field of the Disclosure

5 [0001] The present disclosure relates to valves for controlling fluid flow, and, more particularly to valves with sampling and/or purge ports.

Description of Related Art

[0002] Extracorporeal blood circulation is a critical component of modern medical care. Various types of extracorporeal blood circulation systems, such as extracorporeal membrane
10 oxygenation (ECMO) machines, heart-lung machines, cardiopulmonary bypass machines, pump-assisted lung protection machines, and dialysis machines, may be used to perform cardiac and/or respiratory support to an individual whose own heart and/or lungs are/is unable to sustain life. During installation of such systems, connection of such systems to a patient, and throughout the course of operation, access to the fluid circuits of the systems may be
15 required or desirable to perform various functions. For example, fluid circuit may need to be purged of air to prevent air injection into the patient. In some instances, it may be necessary or desirable to draw blood from the fluid circuit for analysis. These and other functions may be performed via valves that can be opened and closed to provide selective access to the fluid circuits.

20 [0003] While conventional valves may be able to provide the necessary access to fluid circuits, they also have inherent disadvantages that may pose risks to patients. In particular, the structure of conventional valves includes obstruction which blood impacts when flowing through the valve. Conventional valves have increased hemolysis through edges/corners resulting from an integration of a port in the blood path. Conventional valves also have
25 increased risk of clotting of blood resulting from “dead zones” in the blood path in which the blood is stagnant in the “normal” situation when the valve is closed. Conventional purge ports also include purge ports that are press fit into the housing. Thus, sterilization gases cannot reach parts of the stop cock or purge port, which are later, in the application, exposed to blood. Such impacts can rupture red blood cells, leading to conditions such as hemolysis. Further,
30 obstructions in conventional valves may cause unwanted coagulation of blood in the valve.

SUMMARY OF THE DISCLOSURE

[0004] In view of the foregoing, there exists a need for valves for use in extracorporeal circulation systems which allow for sampling, purging, and like functions, while eliminating

negative effects on the blood. Accordingly, embodiments of the present disclosure are directed a valve for use in an extracorporeal blood circulation system. The valve includes a valve port defining a valve lumen, an access port extending at an angle from the valve lumen and defining an access lumen in fluid communication with the valve lumen, and a valve element disposed in the valve port. The valve element is movable between a closed position in which the valve element engages a sidewall of the valve lumen to prevent fluid flow through the access lumen, and an open position in which the valve element is retracted relative to the closed position to allow fluid to flow through the valve lumen and into the access lumen.

[0005] In some embodiments, the valve port has a tapered sidewall narrowing in a direction toward the main lumen, and the valve element includes a tapered pin configured to seal against the tapered sidewall in the closed position.

[0006] In some embodiments, the tapered sidewall has a taper angle in a range of 3° to 15°.

[0007] In some embodiments, the tapered sidewall acts as a stop preventing the tapered pin from protruding into the main lumen.

[0008] In some embodiments, in the closed position of the valve element, a distal end of the valve element is substantially flush with an inner sidewall of a main fluid path component to which the valve may be fluidly connected.

[0009] In some embodiments, the valve element includes a knob for adjusting the valve element between the closed position and the open position.

[0010] In some embodiments, the valve port included a threaded section, and a proximal end of the valve element is threaded to engage the threaded section of the valve port.

[0011] In some embodiments, the threaded section includes a threaded insert connected to the valve port.

[0012] In some embodiments, the valve port extends at angle of approximately 90° from a main fluid path component to which the valve may be fluidly connected.

[0013] In some embodiments, the access port extends at angle from the valve port in a range of approximately 30° to approximately 90°.

[0014] In some embodiments, the access port includes a luer fitting.

[0015] In some embodiments, the valve further includes a seal disposed in the valve port for preventing fluid flow between the valve element and a sidewall of the valve port.

[0016] In some embodiments, the extracorporeal blood circulation system is selected from a group consisting of an ECMO machine, a heart-lung machine, a cardiopulmonary bypass machine, a pump-assisted lung protection machine, and a dialysis machine.

[0017] Other embodiments of the present disclosure are directed to an extracorporeal blood circulation system, including a fluid path component and a valve. The valve includes a main fluid path component defining a longitudinal axis and a main lumen extending parallel to the longitudinal axis, a valve port extending at an angle from the main lumen, the valve port defining a valve lumen in fluid communication with the main lumen, an access port extending at an angle from the valve lumen and defining an access lumen in fluid communication with the valve lumen, and a valve element disposed in the valve port. The valve element is movable between a closed position in which the valve element engages a sidewall of the valve lumen to prevent fluid flow from the main lumen to the access lumen, and an open position in which the valve element is retracted relative to the closed position to allow fluid to flow from the main lumen, through the valve lumen, and into the access lumen. The main fluid path component is disposed internally in a fluid path of the fluid path component.

[0018] In some embodiments, the fluid path component includes at least one of an oxygenator and a heat exchanger.

[0019] In some embodiments, the valve port has a tapered sidewall narrowing in a direction toward the main lumen, and the valve element includes a tapered pin configured to seal against the tapered sidewall in the closed position.

[0020] In some embodiments, wherein the tapered sidewall has a taper angle in a range of 3° to 15°.

[0021] In some embodiments, the tapered sidewall acts as a stop preventing the tapered pin from protruding into the main lumen.

[0022] In some embodiments, in the closed position of the valve element, a distal end of the valve element is substantially flush with an inner sidewall of the main fluid path component.

[0023] In some embodiments, the valve element includes a knob for adjusting the valve element between the closed position and the open position.

[0024] In some embodiments, the valve port includes a threaded section, and a proximal end of the valve element is threaded to engage the threaded section of the valve port.

[0025] In some embodiments, the threaded section includes a threaded insert connected to the valve port.

[0026] In some embodiments, the valve port extends at angle of approximately 90° from the main fluid path component.

[0027] In some embodiments, the access port extends at angle from the valve port in a range of approximately 30° to approximately 90°.

[0028] In some embodiments, the access port includes a luer fitting.

[0029] In some embodiments, the valve further includes a seal disposed in the valve port for preventing fluid flow between the valve element and a sidewall of the valve port.

[0030] In some embodiments, the extracorporeal blood circulation system is selected from a group consisting of an ECMO machine, a heart-lung machine, a cardiopulmonary bypass machine, a pump-assisted lung protection machine, and a dialysis machine.

[0031] In another embodiment, a valve for use in an extracorporeal blood circulation system, may include a valve port defining a valve lumen in fluid communication with the main lumen, a valve element disposed in the valve port, wherein the valve element defines a fluid path channel and is configured to be movable between: a closed position in which the valve element engages a sidewall of the valve lumen to prevent fluid flow through the access lumen; and an open position in which the valve element is retracted relative to the closed position to allow fluid to flow through the valve lumen and into the access lumen; and an access port formed on a proximal end of the valve element and defining an access lumen in fluid communication with the valve lumen.

[0032] In another embodiment, the access port comprises a luer lock.

[0033] In another embodiment, the fluid path channel extends from a distal end of the valve element to a proximal end of the valve element.

[0034] In another embodiment, the valve port has a tapered sidewall narrowing in a direction toward the main lumen; and wherein the valve element comprises a tapered pin configured to seal against the tapered sidewall in the closed position.

[0035] In another embodiment, the tapered sidewall has a taper angle in a range of 3° to 15°.

[0036] In another embodiment, the tapered sidewall acts as a stop preventing the tapered pin from protruding into a main path fluid component to which the valve may be fluidly connected.

[0037] In another embodiment, in the closed position of the valve element, a distal end of the valve element is substantially flush with an inner sidewall of a main fluid path component to which the valve may be fluidly connected.

[0038] In another embodiment, a seal is disposed in the valve port for preventing fluid flow between the valve element and a sidewall of the valve port.

[0039] In another embodiment, the extracorporeal blood circulation system is selected from a group consisting of an ECMO machine, a heart-lung machine, a cardiopulmonary bypass machine, a pump-assisted lung protection machine, and a dialysis machine.

[0040] Further details and advantages of the various non-limiting examples described in detail herein will become clear upon reviewing the following detailed description of the various non-limiting examples in conjunction with the accompanying drawing figures.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0041] FIG. 1 is a perspective view of a valve in accordance with an embodiment of the present disclosure;

[0042] FIG. 2 is a cross-sectional view of the valve of FIG. 1, taken along line A-A, in an open position;

10 [0043] FIG. 3 is a cross-sectional view of the valve of FIG. 1, taken along line A-A, in a closed position;

[0044] FIG. 4 is a cross-sectional view of the valve of FIG. 1, taken along line A-A, in the open position;

15 [0045] FIG. 5 is a perspective view of an oxygenator assembly in accordance with an embodiment of the present disclosure.

[0046] FIG. 6 is a perspective view of a valve in accordance with an embodiment of the present disclosure with the valve in a closed position.

[0047] FIG. 7 is a perspective view of the valve of FIG. 6 in an open position.

[0048] FIG. 8 is a cross-sectional view of the valve of FIG. 6 in the closed position.

20 [0049] FIG. 9 is a cross-sectional view of the valve of FIG. 6 in the open position.

[0050] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, the present disclosure is generally directed to an extracorporeal circulation system and a fluid heating pump assembly for use in such a system.

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DETAILED DESCRIPTION

[0051] For purposes of the description hereinafter, the terms “upper”, “lower”, “right”, “left”, “vertical”, “horizontal”, “top”, “bottom”, “lateral”, “longitudinal”, and derivatives thereof shall relate to the disclosure as it is oriented in the drawing figures. Spatial or directional terms, such as “left”, “right”, “inner”, “outer”, “above”, “below”, and the like, are not to be
30 considered as limiting as the disclosed embodiments can assume various alternative orientations.

[0052] As used herein, the singular form of “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise.

[0053] All numbers used in the specification and claims are to be understood as being modified in all instances by the term “about”. The terms “approximately”, “about”, and “substantially” mean a range of plus or minus ten percent of the stated value.

[0054] As used herein, the term “at least one of” is synonymous with “one or more of”. For example, the phrase “at least one of A, B, and C” means any one of A, B, and C, or any combination of any two or more of A, B, and C. For example, “at least one of A, B, and C” includes one or more of A alone; or one or more of B alone; or one or more of C alone; or one or more of A and one or more of B; or one or more of A and one or more of C; or one or more of B and one or more of C; or one or more of all of A, B, and C. Similarly, as used herein, the term “at least two of” is synonymous with “two or more of”. For example, the phrase “at least two of D, E, and F” means any combination of any two or more of D, E, and F. For example, “at least two of D, E, and F” includes one or more of D and one or more of E; or one or more of D and one or more of F; or one or more of E and one or more of F; or one or more of all of D, E, and F.

[0055] It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply examples of the disclosure. Hence, specific dimensions and other physical characteristics related to the examples disclosed herein are not to be considered as limiting.

[0056] The terms “first”, “second”, and the like are not intended to refer to any particular order or chronology, but refer to different conditions, properties, or elements.

[0057] The term “at least” is synonymous with “greater than or equal to”. The term “not greater than” is synonymous with “less than or equal to”.

[0058] It is to be understood that the disclosure may assume alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary aspects of the disclosure. Hence, specific dimensions and other physical characteristics related to the examples disclosed herein are not to be considered as limiting.

[0059] Referring now to FIGS. 1-4, the present disclosure is directed to a valve 100 for controlling flow, and particularly for allowing sampling and/or purging of fluid. The valve 100 may be used in any fluid flow system, but may be particularly suited for use in an extracorporeal blood circulation system such as an ECMO machine, a heart-lung machine, a cardiopulmonary bypass machine, a pump-assisted lung protection machine, and a dialysis machine. The valve 100 includes a main fluid path component 110 through which fluid flows within the valve 100.

The main fluid path component 110 defines a longitudinal axis 112 extending from a first end 120 of the fluid path component 110 to a second end 122 of the fluid path component 110. A main lumen 114 defined by an inner sidewall 124 of the main fluid path component 110 extends parallel to the longitudinal axis 112. In use, fluid may flow through the main lumen 114 in the general direction of the longitudinal axis 112 between from the first end 120 to the second end 122, and vice versa. In some embodiments, flow through the main fluid path component 110 is bidirectional meaning that the first end 120 may serve as an inlet and/or an outlet, and, likewise, the second end 122 may serve as an inlet and/or an outlet. Thus, the valve 100 may be installed in a fluid flow system in either orientation with respect to the flow direction of fluid. Each of the first end 120 and the second end 122 of the main fluid path component 110 may include a connector, such as a luer lock, bayonet connector, slip fitting, or the like for suitable for connection to adjacent components of the system.

[0060] The valve 100 further includes a valve port 130 extending from the main fluid path component 110. The valve port 130 has an inner sidewall 132 defining a valve lumen 134 extending parallel to a valve axis 136. The valve lumen 134, in an open position of the valve 100, is in fluid communication with the main lumen 114 of the main fluid path component 110. An angle θ between the longitudinal axis 112 and the valve axis 136 may be approximately 90° . It is also contemplated that the valve axis 136 may be at a different angle other than 90° . A valve element 140 is disposed in the valve lumen 134 and is configured to translate along the valve axis 136. The valve element 140 may be in the form of a pin having a tapered distal end 142. The inner sidewall 132 of the valve port 130 may be tapered such that the valve lumen 134 is frusto-conical in shape. The taper of the inner sidewall 132 may be complementary to the shape of the tapered distal end 142 of the valve element 140, so that engagement between the inner sidewall 132 and the distal end 142 forms a substantially fluid-tight seal when the valve element 140 is in the closed position shown in FIG. 3.

[0061] The valve 100 further includes an access port 150 extending from the fluid path component the valve port 130. As will be described herein, the access port 150 may be used to take or add fluid samples from the main lumen 114 and/or to purge the main lumen 114. The access port 150 defines an access lumen 152 extending along an access axis 154. The access lumen 152, in an open position of the valve 100, is in fluid communication with the valve lumen 134. The access axis 154 may extend at an angle β from the valve axis 136, wherein the angle β in a range of approximately 20° to 70° , in some embodiments about 45° . In another example, the angle β is in the range of approximately 30° to 90° . The access port 150 may

include a fitting 156, such as a luer fitting, for connection to another component such as a syringe.

[0062] The valve element 140 is movable between two states, namely a closed position illustrated in FIG. 3 and an open position illustrated in FIGS. 2 and 4. As previously described, in the closed position, the valve element 140 forms a substantially fluid-tight seal with the inner sidewall 132 of the valve port 130. In particular, the tapered distal end 142 of the valve element 140 engages the complementary taper of the inner sidewall 132 to create a substantially fluid-tight interface. The taper angles of the valve element 140 and the inner sidewall 132 may be, in some embodiments, in a range of approximately 1° to approximately 15°. In another example, the taper angle of the valve element 140 and the inner sidewall 132 may be 3° to 15°. In the closed position, the valve element 140 extends over an opening 158 between the valve lumen 134 and the access lumen 152, thereby preventing fluid from flowing from the main lumen 114 into the valve lumen 134 and ultimately to the access lumen 152. Also in the closed position, an end face 144 of the valve element 140 is substantially flush with the sidewall 124 of the main fluid path component 110 to provide a smooth transition across which fluid can flow through the main lumen 114. The taper of the inner sidewall 132 may act as a stop or limit that prevents the valve member 140 from protruding into the main lumen 114 significantly beyond the sidewall 124 of the main fluid path component 110. The flush, smooth transition between the sidewall 124 of the main fluid path component 110 and the end face 144 is free of protruding edges that could cause unwanted coagulation of the fluid (e.g. blood) flowing in the main lumen 114 and/or impacts that could potentially lead to conditions such as hemolysis.

[0063] To utilize the valve 100 for sampling or purging, the valve element 140 is moved from the closed position illustrated in FIG. 3 to the open position illustrated in FIGS. 2 and 4. In the open position, the end face 144 of the valve element 140 is retracted away from the sidewall 124 of the main lumen 114 to allow fluid flow into the valve lumen 134. The end face 144 is spaced apart from the sidewall 124 such that fluid can flow from the main lumen 114 into valve lumen 134, through the opening 158, and ultimately to the access lumen 152. With the valve element 140 retracted in this position, the fluid-tight engagement between the tapered distal end 142 and the inner sidewall 132 is no longer present, so fluid could potentially flow between the inner sidewall 132 and the valve element 140. To prevent this, one or more seals 160 (e.g. and O-rings) are disposed around the valve element 140.

[0064] Referring again to FIGS. 1-4, the valve element 140 may be threaded into the valve port 130 such that rotating the valve element 140 moves the valve element 140 along (i.e. parallel to) the valve axis 134. In particular, rotating the valve element 140 in one direction

moves the valve element 140 from the open position (*see* FIGS. 2 and 4) to the closed position (*see* FIG. 3), while rotating the valve element 140 in an opposite direction moves the valve element 140 from the closed position to the open position. The valve element 140 may include a knob 148 to facilitate manually rotating the valve element 140 by a clinician.

5 [0065] The valve element 140 may include an external threaded portion 146 located proximally of the distal end 142. The external threaded portion 146 engages a complementary internal threaded portion 172 of the valve port 130. In particular, the internal threaded portion 172 may be provided on a threaded insert 170 disposed in the valve port 130. The threaded insert 170 may be connected to the valve port 130 via a press fit, snap fit, adhesive, weld, or
10 the like. In addition to allowing rotation of the valve element 140, the threaded insert 170 may also retain the seal 160 in position in the valve port 130. It is also contemplated that the valve element 140 could be moved by a spring of a magnetic, electric, or pneumatic actuator.

[0066] To take a sample of the fluid within the main lumen 114, the clinician connects a syringe (or other collection device) to the fitting 156 of the outlet port 150, moves the valve
15 element 140 to the open position (*see* FIGS. 2 and 4) so that fluid in the main lumen 114 can flow into the access lumen 152, as described above. The clinician then draws fluid into the collection device connected to the access port 150, and returns the valve element 140 to the closed position (*see* FIG. 3).

[0067] To purge the valve 100 and connected fluid components, the clinician connects a
20 syringe (or other collection device) to the fitting 156 of the outlet port 150, moves the valve element 140 to the open position (*see* FIGS. 2 and 4) so that air in the main lumen 114 can flow into the access lumen 152. The clinician then draws air into the collection device connected to the access port 150, and returns the valve element 140 to the closed position (*see* FIG. 3) once all air has been removed.

25 [0068] Referring now to FIG. 5, the valve 100 of the present disclosure may be attached to or integrated with another fluid path component 200 (such as an oxygenator, heat exchanger, or the like) of an extracorporeal circulation system 300. In the embodiment shown, the main fluid path component 110 is disposed internally in a fluid path of the component 200, with the access port 150 and at least the knob 148 of the valve element 140 projecting from the
30 component 200 to allow the clinical to actuate the knob 148 and take a fluid sample 200 from the component and/or purge the component 200 via the access port 150.

[0069] With reference to FIGS. 6-9, in another non-limiting embodiment or aspect of the present disclosure, a valve 300 is shown and described. The valve 300 may be fluidly connected to a main fluid path component 110 similar to the valve 100 described above. The valve 300

includes a valve port 330 extending from the main fluid path component 110. The valve port 330 has an inner sidewall 332 defining a valve lumen 334 extending parallel to a valve axis 336. The valve lumen 334, in an open position of the valve 300, is in fluid communication with the main lumen of the main fluid path component 110. A valve element 340 is disposed in the valve lumen 334 and is configured to translate along the valve axis 336. The valve element 340 may be in the form of a pin having a tapered distal end 342. The inner sidewall 332 of the valve port 330 may be tapered such that the valve lumen 334 is frusto-conical in shape. The taper of the inner sidewall 332 may be complementary to the shape of the tapered distal end 342 of the valve element 340, so that engagement between the inner sidewall 332 and the distal end 342 forms a substantially fluid-tight seal when the valve element 340 is in the closed position shown in FIG. 6.

[0070] The valve 300 may include an access port 350 that is formed integral with the valve element 340. The access port 350 may be provided on a proximal end of the valve element 340. In one example, the access port 350 is a male portion of a luer lock.

[0071] The valve element 340 is movable between two states, namely a closed position illustrated in FIGS. 6 and 8 and an open position illustrated in FIGS. 7 and 9. As previously described, in the closed position, the valve element 340 forms a substantially fluid-tight seal with the inner sidewall 332 of the valve port 330. In particular, the tapered distal end 342 of the valve element 340 engages the complementary taper of the inner sidewall 332 to create a substantially fluid-tight interface. The taper angles of the valve element 340 and the inner sidewall 332 may be, in some embodiments, in a range of approximately 1° to approximately 15°. In another example, the taper angle of the valve element 340 and the inner sidewall 332 may be 3° to 15°. In the closed position, the valve element 340 extends over an opening 358 between the valve lumen 334 and the main fluid path component 110, thereby preventing fluid from flowing from the main fluid path component 110 into the valve lumen 334 and ultimately to the access port 350. Also in the closed position, an end face 344 of the valve element 340 is substantially flush with the sidewall 124 of the main fluid path component 110 to provide a smooth transition across which fluid can flow through the main fluid path component 110. The taper of the inner sidewall 332 may act as a stop or limit that prevents the valve member 340 from protruding into the main fluid path component 110 significantly beyond the sidewall 124 of the main fluid path component 110. The flush, smooth transition between the sidewall 124 of the main fluid path component 110 and the end face 344 is free of protruding edges that could cause unwanted coagulation of the fluid (e.g. blood) flowing in the main fluid path component 110 and/or impacts that could potentially lead to conditions such as hemolysis.

[0072] In one non-limiting embodiment or aspect of the present disclosure, the valve element 340 may define a fluid path channel 360 that extends from an opening in the distal end 342 of the valve element 340 to an opposing opening in the proximal end of the valve element 340. When the valve element 340 is in the open position, a fluid path is established between the main fluid path component 110 and the access port 350 since the opening defined in the distal end 342 of the valve element 340 is not flush or in contact with the inner sidewall 332 of the valve port 330.

[0073] Referring again to FIGS. 6-9, the valve element 340 may be threaded into the valve port 330 such that rotating the valve element 340 moves the valve element 340 along (i.e. parallel to) the valve axis 336. In particular, rotating the valve element 340 in one direction moves the valve element 340 from the open position (*see* FIGS. 7 and 9) to the closed position (*see* FIGS. 6 and 8), while rotating the valve element 340 in an opposite direction moves the valve element 340 from the closed position to the open position.

[0074] The valve element 340 may include an external threaded portion 346 located proximally of the distal end 342. The external threaded portion 346 engages a complementary internal threaded portion 372 of the valve port 330. In particular, the internal threaded portion 372 may be provided on a threaded insert 370 disposed in the valve port 330. The threaded insert 370 may be connected to the valve port 330 via a press fit, snap fit, adhesive, weld, or the like. In addition to allowing rotation of the valve element 340, the threaded insert 370 may also retain the seal in position in the valve port 330. It is also contemplated that the valve element 340 could be moved by a spring of a magnetic, electric, or pneumatic actuator.

[0075] While various examples of the present disclosure were provided in the foregoing description, those skilled in the art may make modifications and alterations to these examples without departing from the scope and spirit of the disclosure. For example, it is to be understood that features of various embodiments described herein may be adapted to other embodiments described herein. Accordingly, the foregoing description is intended to be illustrative rather than restrictive. The disclosure described hereinabove is defined by the appended claims, and all changes to the disclosure that fall within the meaning and the range of equivalency of the claims are to be embraced within their scope.

WE CLAIM:

1. A valve for use in an extracorporeal blood circulation system, the valve comprising:
 - 5 a valve port defining a valve lumen;
 - an access port extending at an angle from the valve lumen and defining an access lumen in fluid communication with the valve lumen; and
 - a valve element disposed in the valve port and movable between:
 - a closed position in which the valve element engages a sidewall of the
 - 10 valve lumen to prevent fluid flow through the access lumen; and
 - an open position in which the valve element is retracted relative to the closed position to allow fluid to flow through the valve lumen and into the access lumen.
2. The valve of claim 1, wherein the valve port has a tapered sidewall
15 narrowing in a direction toward the main lumen; and
wherein the valve element comprises a tapered pin configured to seal against the tapered sidewall in the closed position.
3. The valve of claim 2, wherein the tapered sidewall has a taper angle in
20 a range of 3° to 15°.
4. The valve of claim 2, wherein the tapered sidewall acts as a stop preventing the tapered pin from protruding into the main lumen.
5. The valve of claim 1, wherein, in the closed position of the valve
25 element, a distal end of the valve element is substantially flush with an inner sidewall of a main fluid path component to which the valve may be fluidly connected.
6. The valve of claim 1, wherein the valve element comprises a knob for
30 adjusting the valve element between the closed position and the open position.
7. The valve of claim 1, wherein the valve port comprises a threaded section, and

wherein a proximal end of the valve element is threaded to engage the threaded section of the valve port.

8. The valve of claim 7, wherein the threaded section comprises a threaded insert connected to the valve port.

9. The valve of claim 1, wherein the valve port extends at angle of approximately 90° from a main fluid path component to which the valve may be fluidly connected.

10. The valve of claim 1, wherein the access port extends at angle from the valve port in a range of approximately 30° to approximately 90° .

11. The valve of claim 1, wherein the access port comprises a luer fitting.

12. The valve of claim 1, further comprising a seal disposed in the valve port for preventing fluid flow between the valve element and a sidewall of the valve port.

13. The valve of claim 1, wherein the extracorporeal blood circulation system is selected from a group consisting of an ECMO machine, a heart-lung machine, a cardiopulmonary bypass machine, a pump-assisted lung protection machine, and a dialysis machine.

14. An extracorporeal blood circulation system, comprising:

a fluid path component; and

a valve comprising:

a main fluid path component defining a longitudinal axis and a main lumen extending parallel to the longitudinal axis;

a valve port extending at an angle from the main lumen, the valve port defining a valve lumen in fluid communication with the main lumen;

an access port extending at an angle from the valve lumen and defining an access lumen in fluid communication with the valve lumen; and

a valve element disposed in the valve port and movable between:

a closed position in which the valve element engages a sidewall of the valve lumen to prevent fluid flow from the main lumen to the access lumen; and

an open position in which the valve element is retracted relative to the closed position to allow fluid to flow from the main lumen, through the valve lumen, and
5 into the access lumen,

wherein the main fluid path component is disposed internally in a fluid path of the fluid path component.

15. The system of claim 14, wherein the fluid path component comprises at
10 least one of an oxygenator and a heat exchanger.

16. The system of claim 14, wherein the valve port has a tapered sidewall narrowing in a direction toward the main lumen; and

wherein the valve element comprises a tapered pin configured to seal against
15 the tapered sidewall in the closed position.

17. The system of claim 16, wherein the tapered sidewall has a taper angle in a range of 3° to 15°.

18. The system of claim 16, wherein the tapered sidewall acts as a stop
20 preventing the tapered pin from protruding into the main lumen.

19. The system of claim 14, wherein, in the closed position of the valve element, a distal end of the valve element is substantially flush with an inner sidewall of the
25 main fluid path component.

20. The system of claim 14, wherein the valve element comprises a knob for adjusting the valve element between the closed position and the open position.

21. The system of claim 14, wherein the valve port comprises a threaded section, and
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wherein a proximal end of the valve element is threaded to engage the threaded section of the valve port.

22. The system of claim 21, wherein the threaded section comprises a threaded insert connected to the valve port.

23. The system of claim 14, wherein the valve port extends at angle of approximately 90° from the main fluid path component.

24. The system of claim 14, wherein the access port extends at angle from the valve port in a range of approximately 30° to approximately 90°.

25. The system of claim 14, wherein the access port comprises a luer fitting.

26. The system of claim 14, wherein the valve further comprises a seal disposed in the valve port for preventing fluid flow between the valve element and a sidewall of the valve port.

27. The system of claim 14, wherein the extracorporeal blood circulation system is selected from a group consisting of an ECMO machine, a heart-lung machine, a cardiopulmonary bypass machine, a pump-assisted lung protection machine, and a dialysis machine.

28. A valve for use in an extracorporeal blood circulation system, the valve comprising:

a valve port defining a valve lumen in fluid communication with the main lumen;

a valve element disposed in the valve port, wherein the valve element defines a fluid path channel and is configured to be movable between:

a closed position in which the valve element engages a sidewall of the valve lumen to prevent fluid flow through the access lumen; and

an open position in which the valve element is retracted relative to the closed position to allow fluid to flow through the valve lumen and into the access lumen; and

an access port formed on a proximal end of the valve element and defining an access lumen in fluid communication with the valve lumen.

29. The valve of claim 28, wherein the access port comprises a luer lock.

30. The valve of claim 28, wherein the fluid path channel extends from a distal end of the valve element to a proximal end of the valve element.

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31. The valve of claim 28, wherein the valve port has a tapered sidewall narrowing in a direction toward the main lumen; and

wherein the valve element comprises a tapered pin configured to seal against the tapered sidewall in the closed position.

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32. The valve of claim 31, wherein the tapered sidewall has a taper angle in a range of 3° to 15°.

33. The valve of claim 31, wherein the tapered sidewall acts as a stop preventing the tapered pin from protruding into a main path fluid component to which the valve may be fluidly connected.

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34. The valve of claim 28, wherein, in the closed position of the valve element, a distal end of the valve element is substantially flush with an inner sidewall of a main fluid path component to which the valve may be fluidly connected.

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35. The valve of claim 28, further comprising a seal disposed in the valve port for preventing fluid flow between the valve element and a sidewall of the valve port.

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36. The valve of claim 28, wherein the extracorporeal blood circulation system is selected from a group consisting of an ECMO machine, a heart-lung machine, a cardiopulmonary bypass machine, a pump-assisted lung protection machine, and a dialysis machine.

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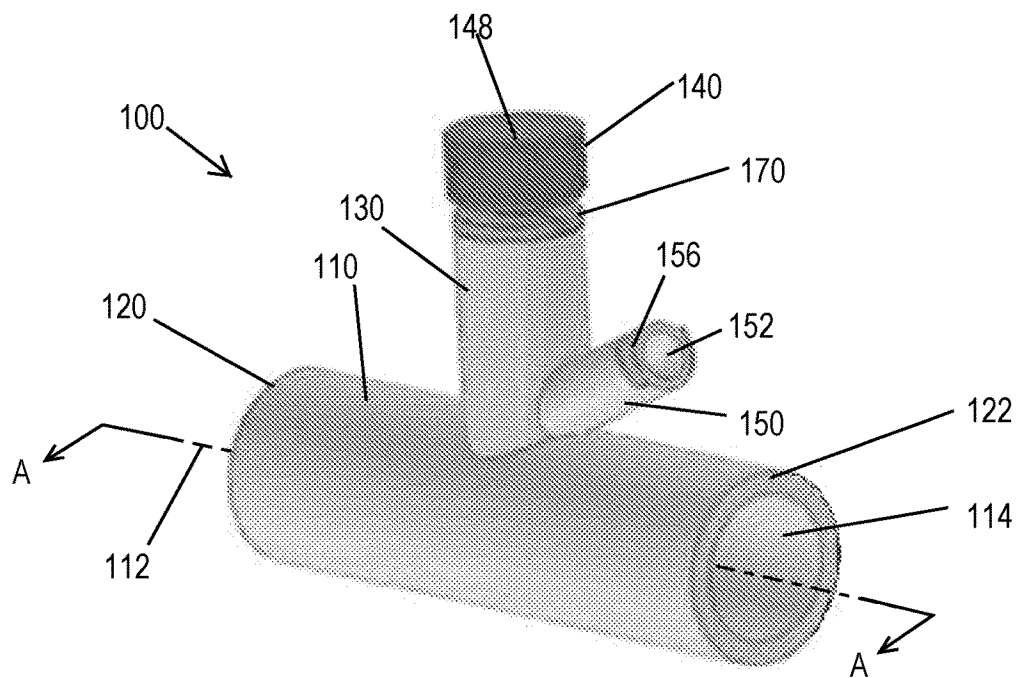


FIG. 1

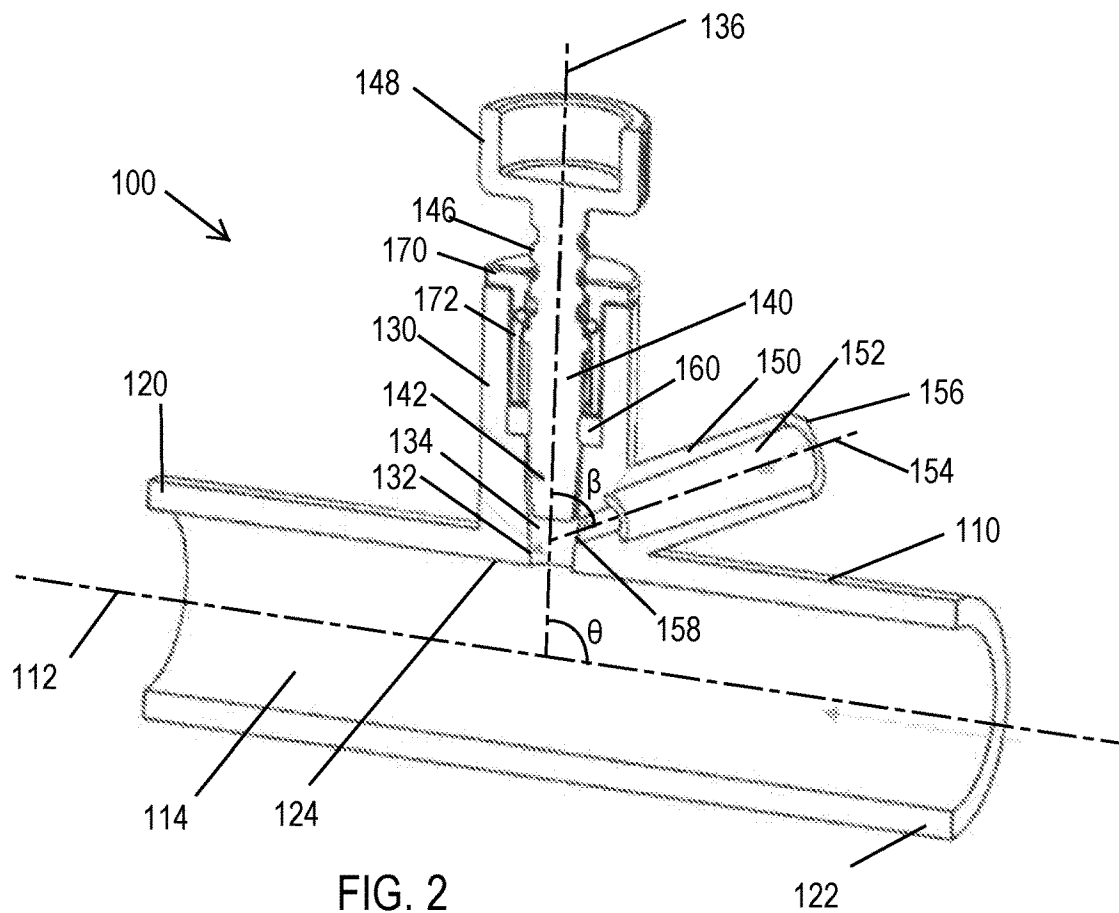


FIG. 2

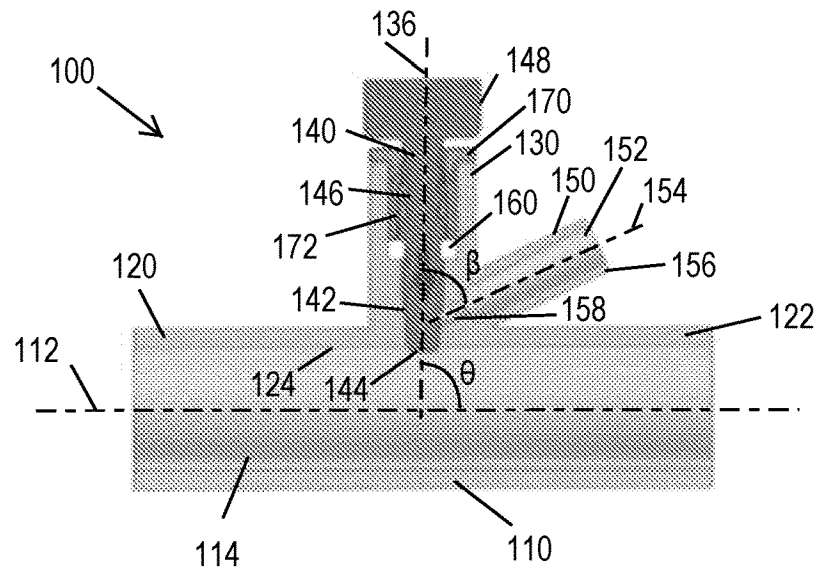


FIG. 3

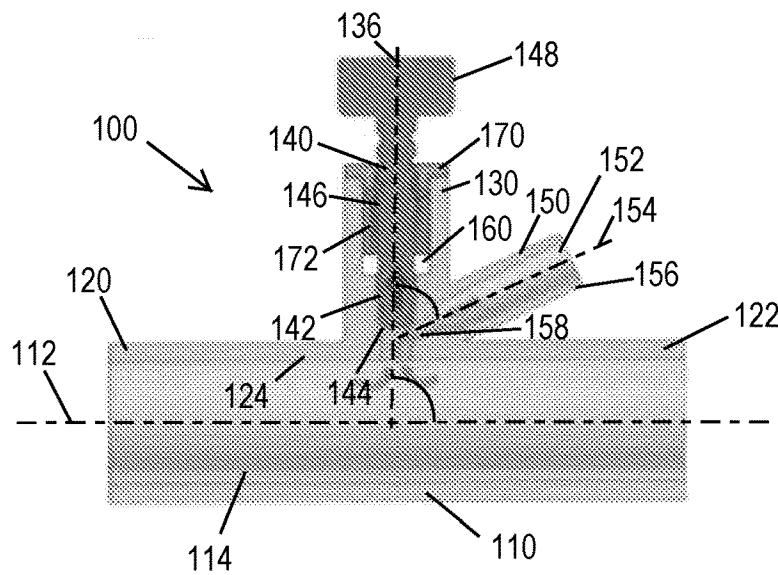


FIG. 4

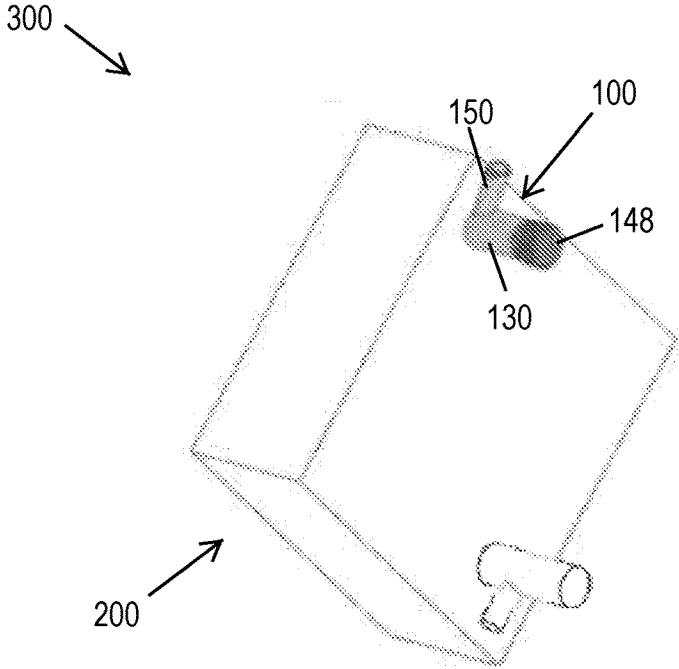


FIG. 5

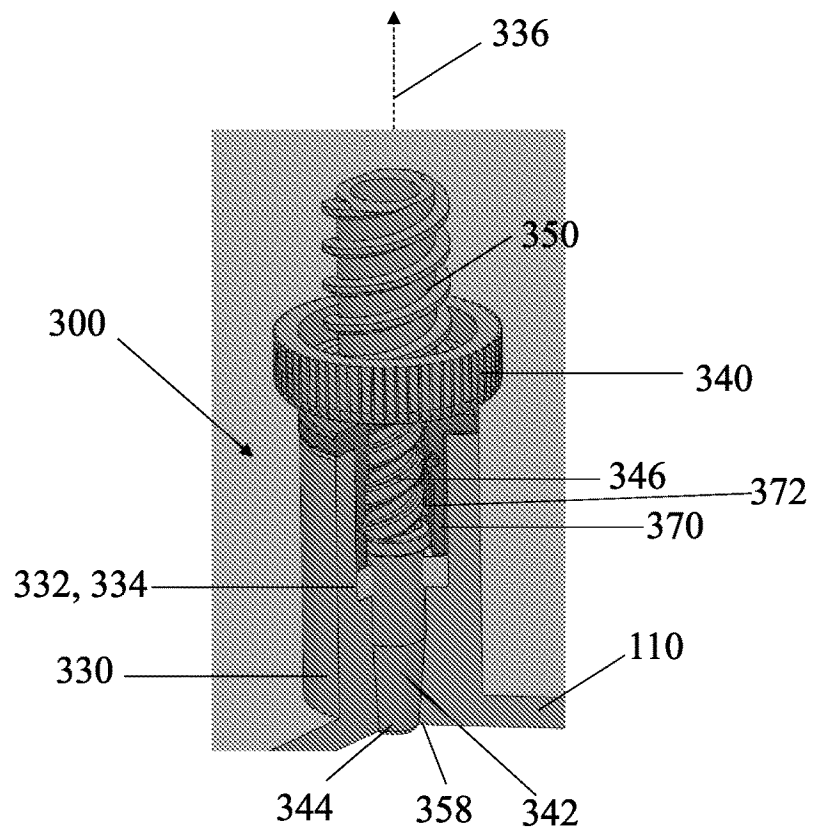


FIG. 6

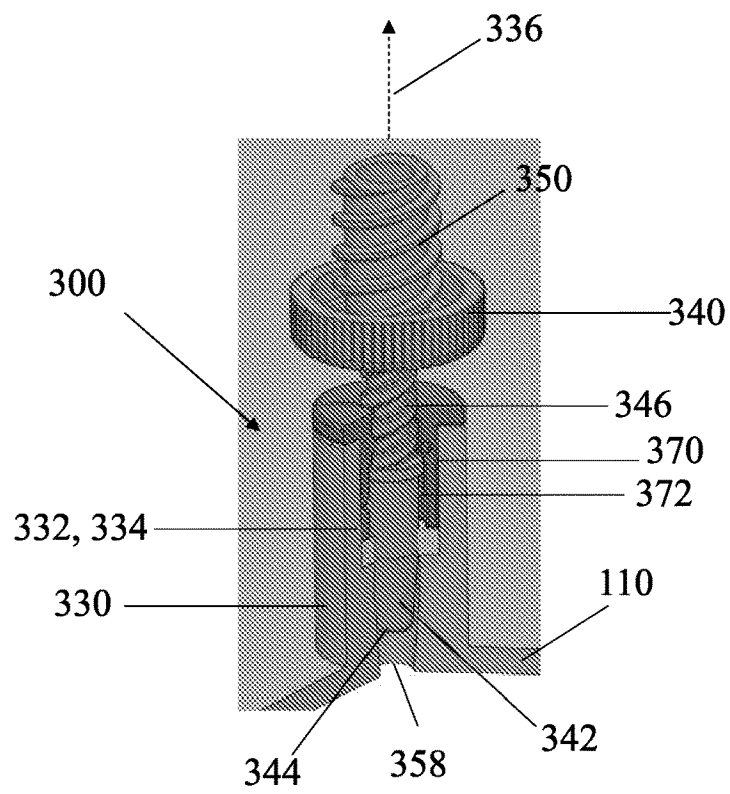


FIG. 7

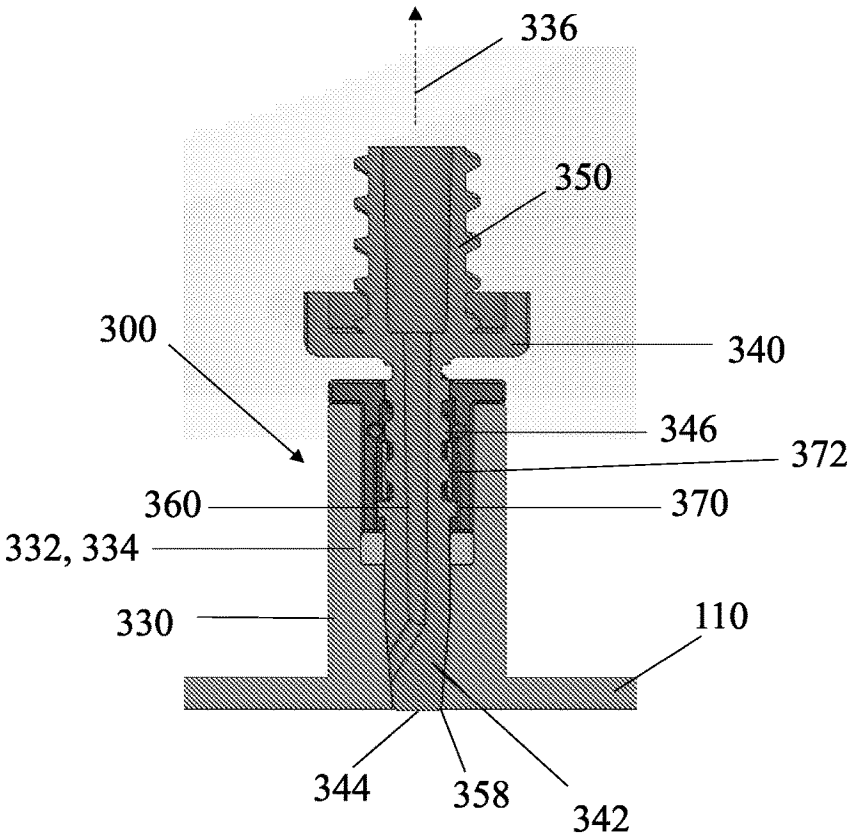


FIG. 8

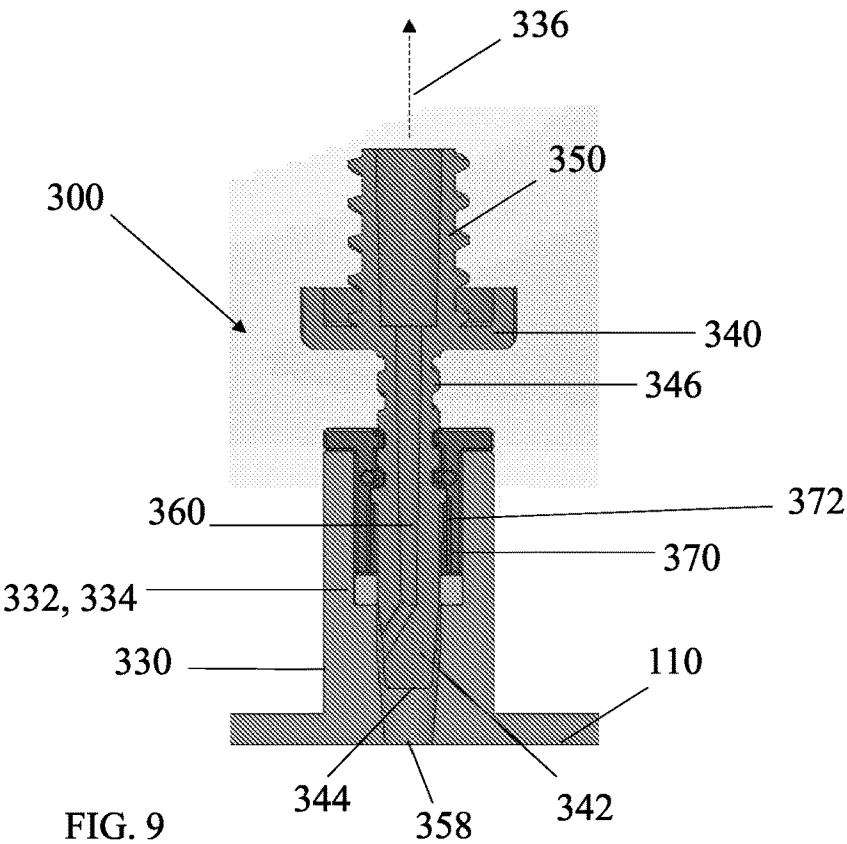


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2024/056817

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M39/22 ADD. A61M39/00 A61M1/14 A61M1/36		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61M Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 414 999 A (BASTA MICHAEL I [US]) 15 November 1983 (1983-11-15) figures 1-4 column 3 - column 7 -----	1 - 27
X	JP H10 314298 A (SENKO MED INSTR MFG) 2 December 1998 (1998-12-02) figures 3a-d -----	1 - 27
X	EP 0 331 526 A1 (SPECTRAMED INC [US]) 6 September 1989 (1989-09-06) figures 2-8 page 7 - page 11 -----	1 - 27
X	US 4 210 178 A (BASTA MICHAEL I [US] ET AL) 1 July 1980 (1980-07-01) figures 6, 7 column 2 - column 3 ----- - / - -	1 - 27
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 23 May 2024		Date of mailing of the international search report 05/06/2024
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Petersheim, Markus

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2024/056817

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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X	US 2014/228815 A1 (HAAG ULRICH [DE] ET AL) 14 August 2014 (2014-08-14) figure 7 paragraph [0083] - paragraph [0108] -----	28-36

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