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Tovar Lopez

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(54) **FLUID PUMPING VENTRICULAR ASSIST
DEVICE AND COMPONENTS WITH STATIC
SEAL**

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(58) **Field of Classification Search**
USPC **600/16**; 623/3.1, 3.18, 3.21
See application file for complete search history.

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Primary Examiner — Joseph Dietrich

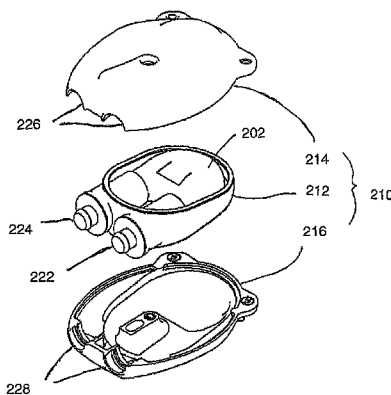
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(57) **ABSTRACT**

A ventricular assist device (VAD) having static seal structure for a pump housing which includes a support structure, a first sealing element, and a second sealing element. The support structure circumscribes a pump chamber and includes a first sealing surface, an opposing second sealing surface, and a fluid transfer end interposed between the sealing surfaces. The support structure provides a fluid flow path running through the fluid transfer end and into the pump chamber via an inlet bore and from the pump chamber back through the fluid transfer end via an outlet bore. The first sealing element is disposed on the first sealing surface, and the second sealing element is disposed on the second sealing surface. The sealing elements are configured for forming sealing interfaces in the pump housing, establishing a static seal that isolates the pump chamber from an environment external to the fluid pump housing.

20 Claims, 13 Drawing Sheets

200



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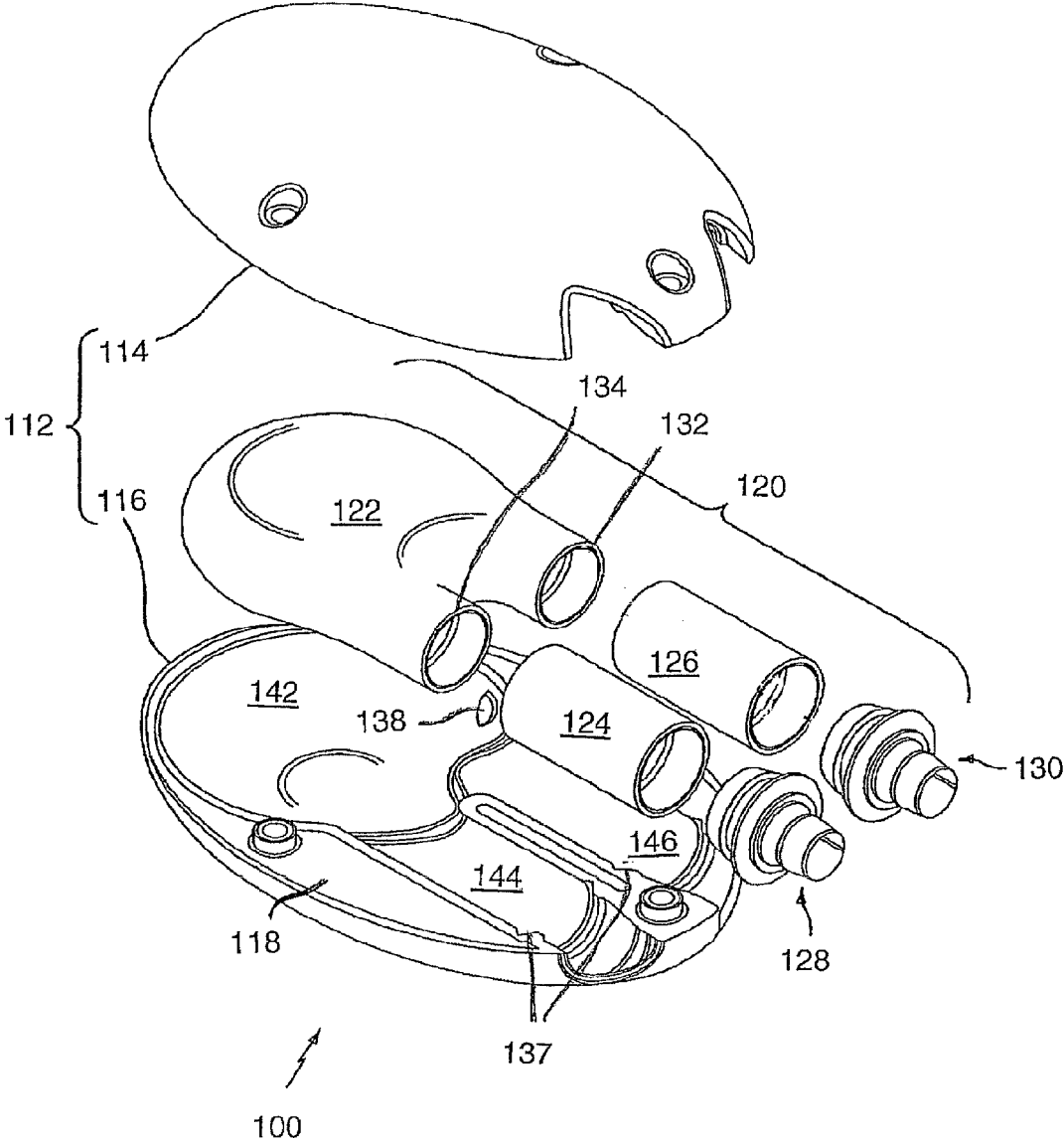


Fig. 1
Prior Art

200

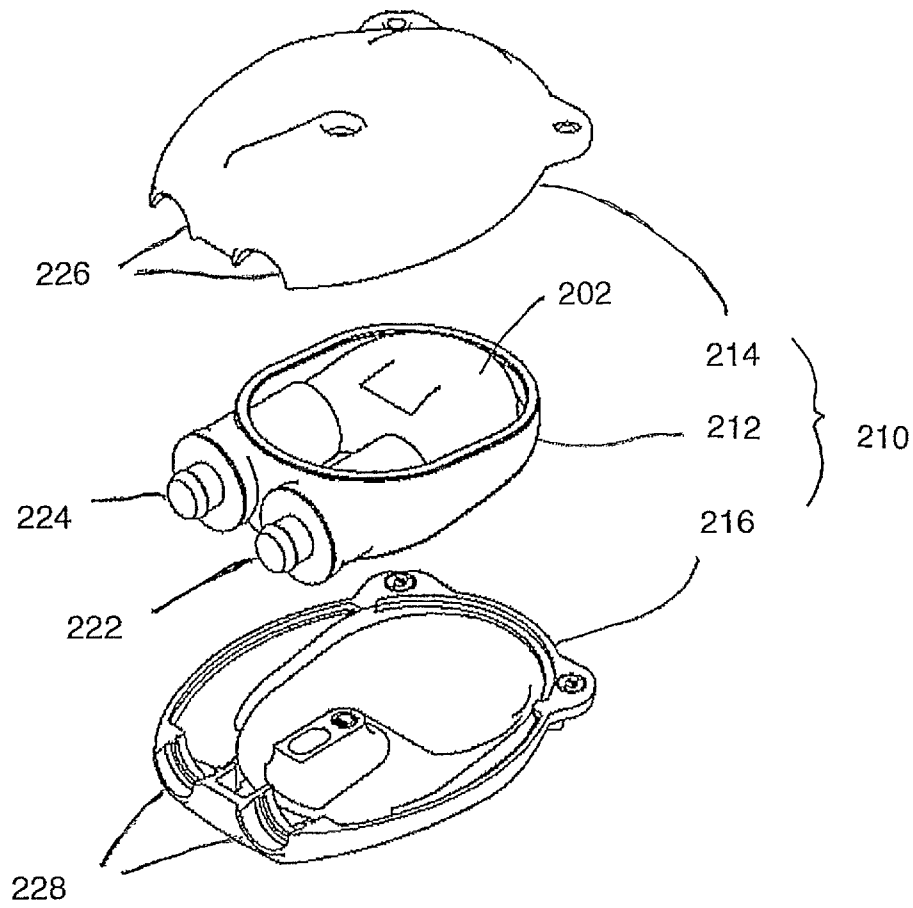


Fig. 2

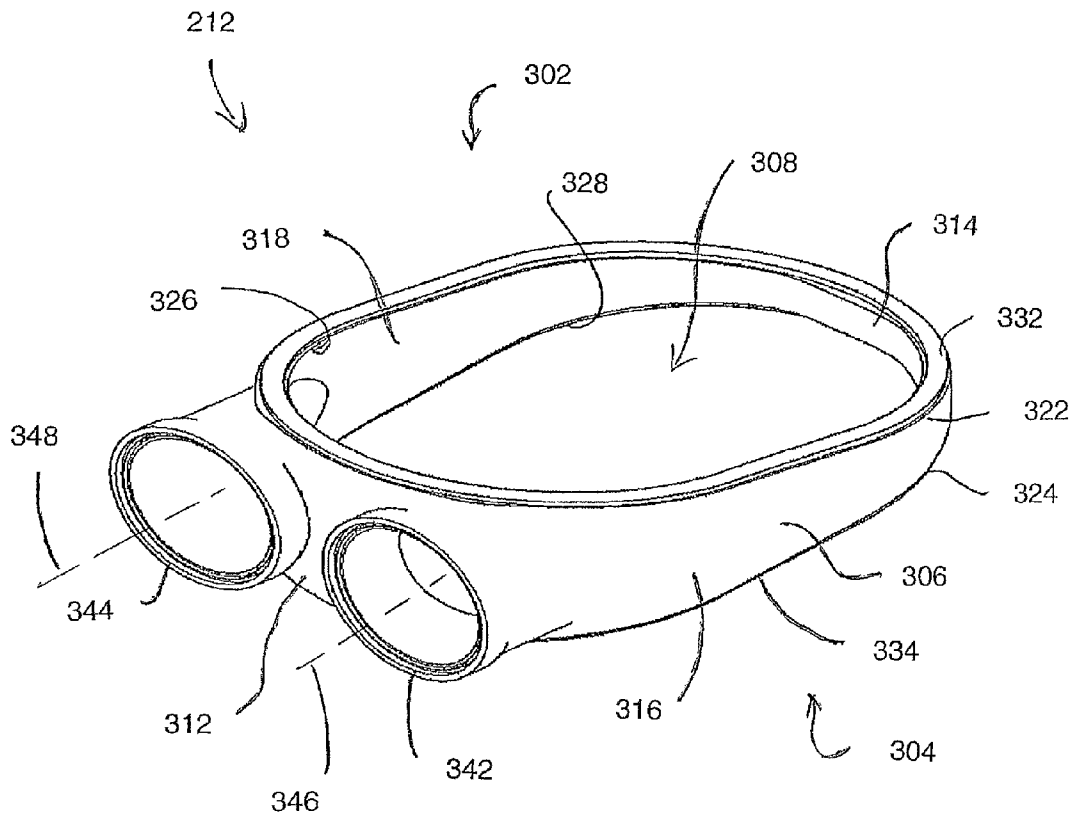


Fig. 3

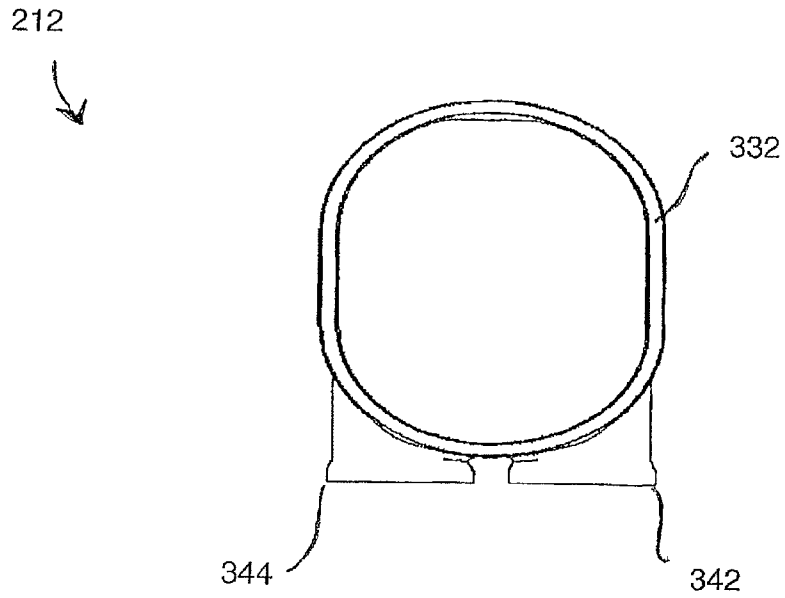


Fig. 4

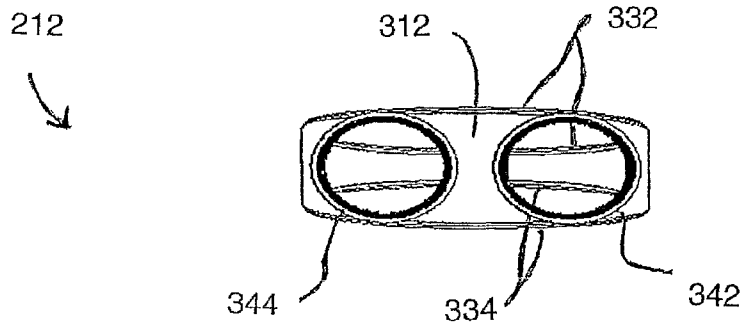


Fig. 5

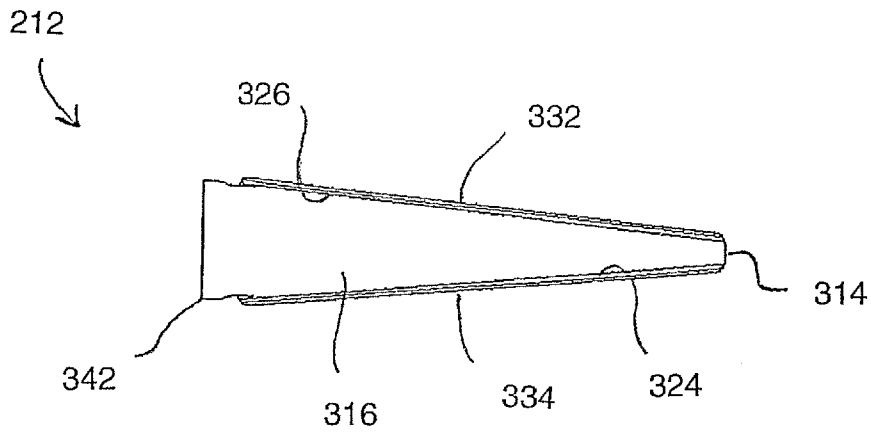


Fig. 6

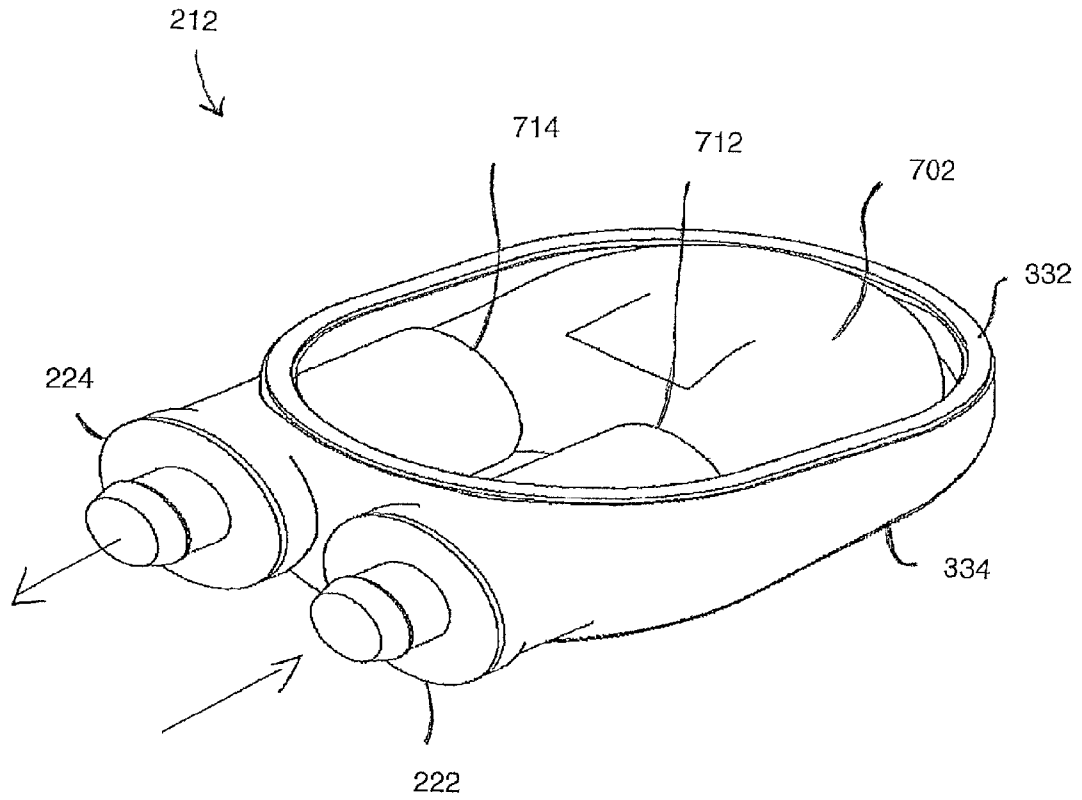


Fig. 7

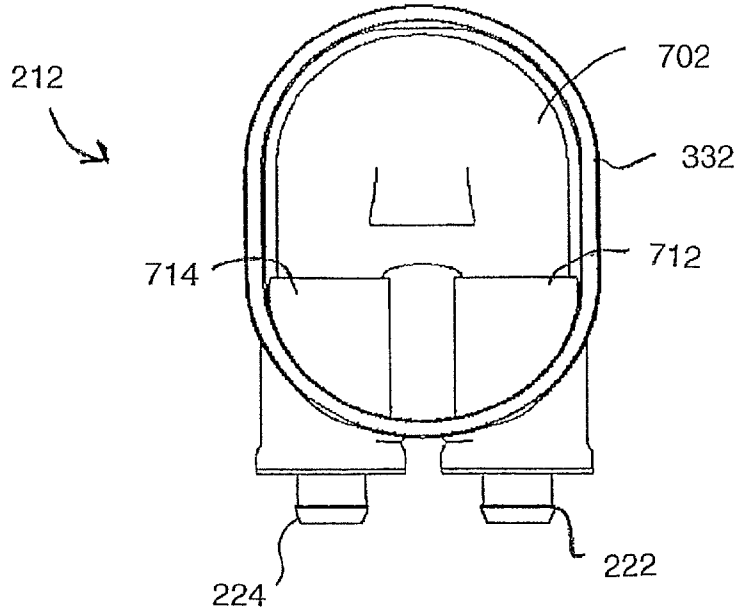


Fig. 8

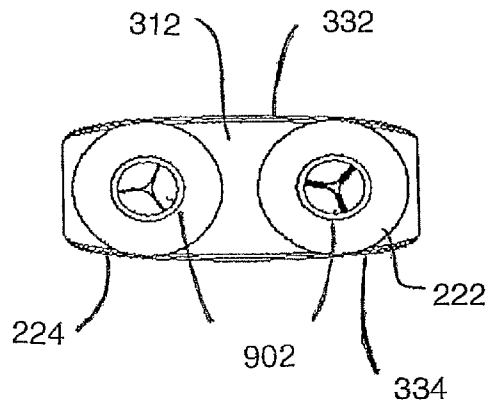


Fig. 9

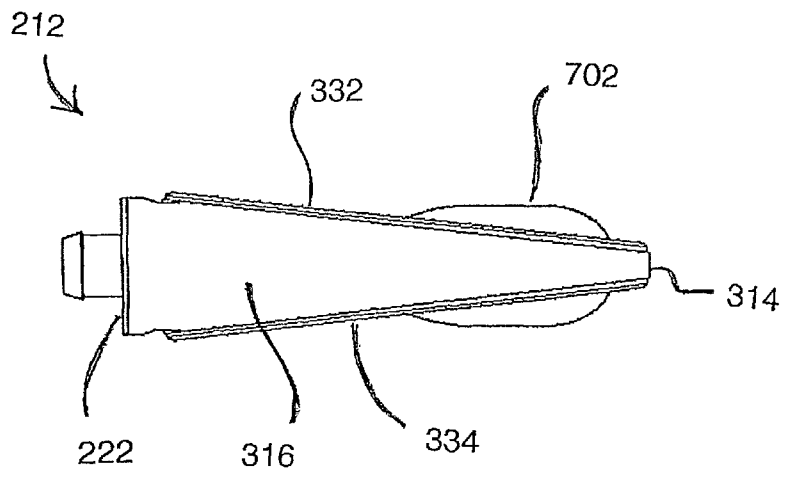


Fig. 10

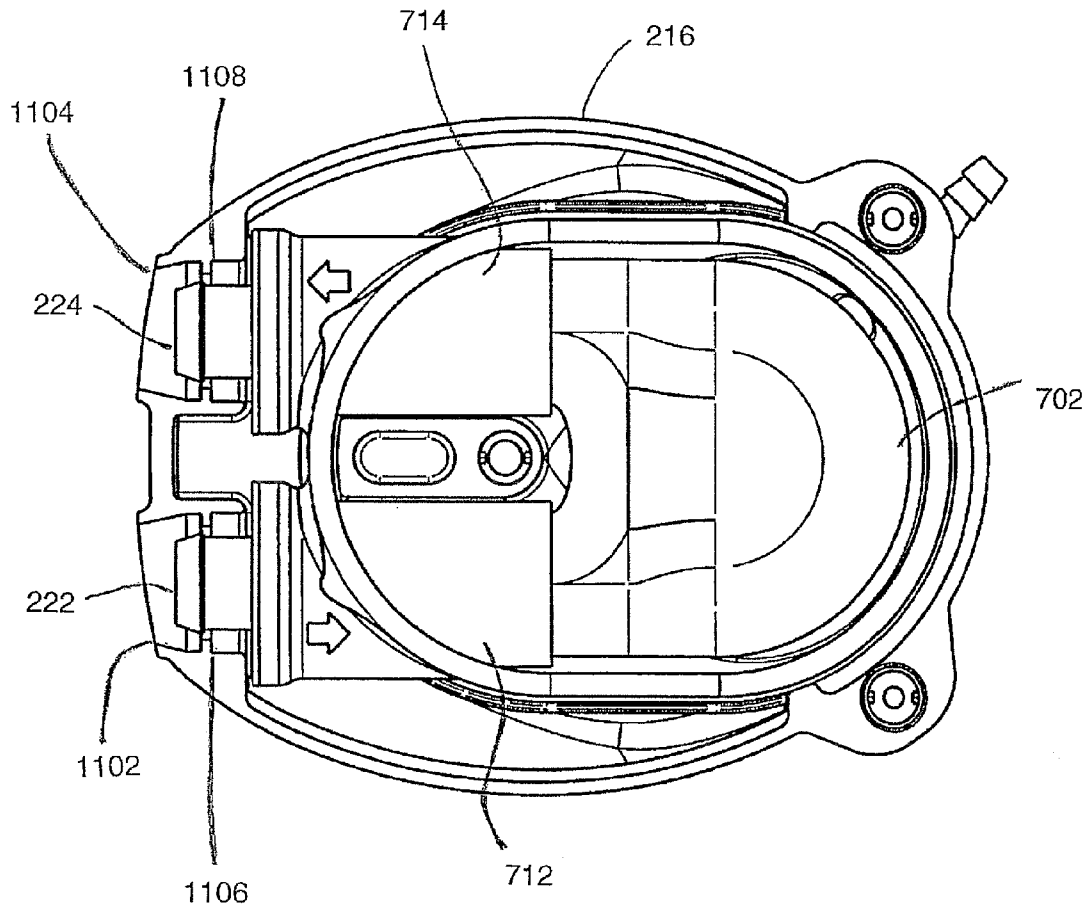


Fig. 11

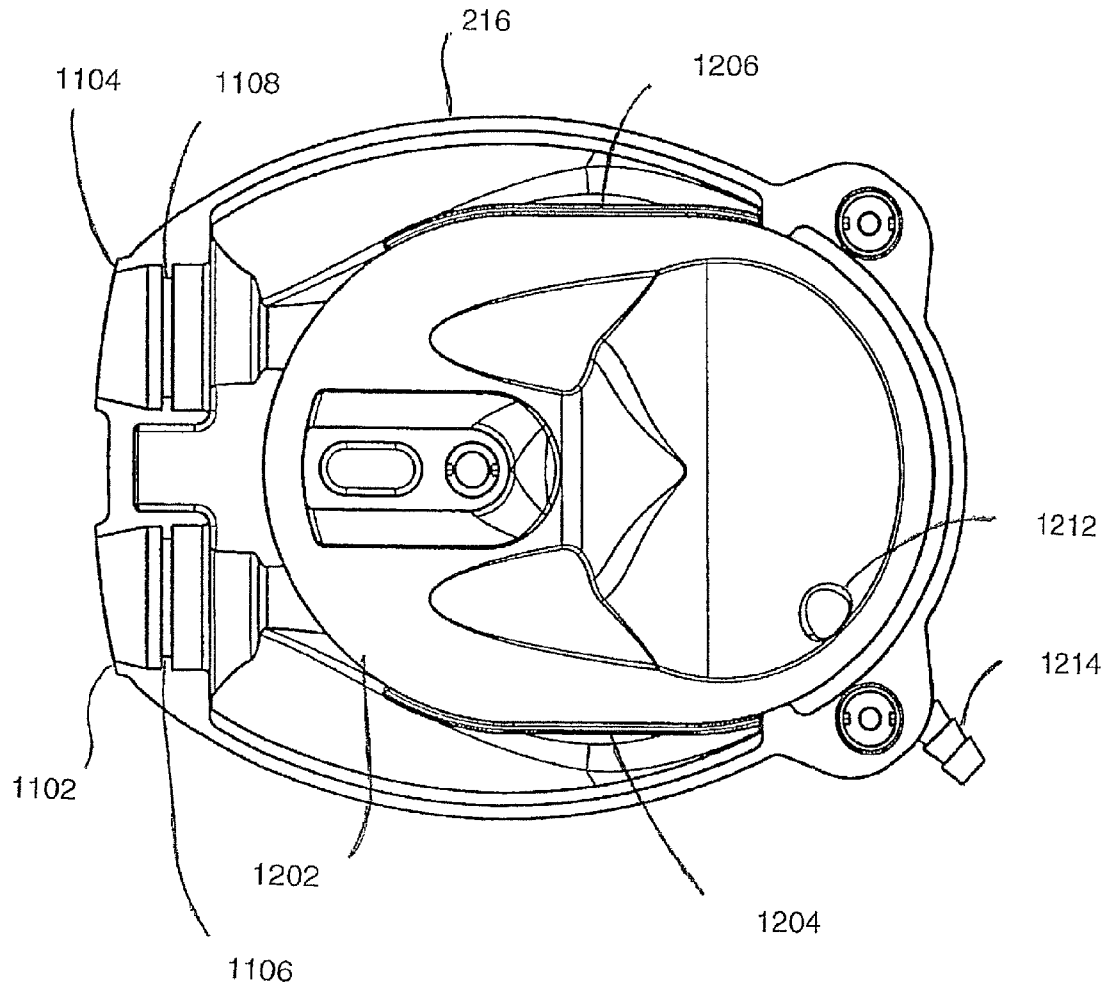


Fig. 12

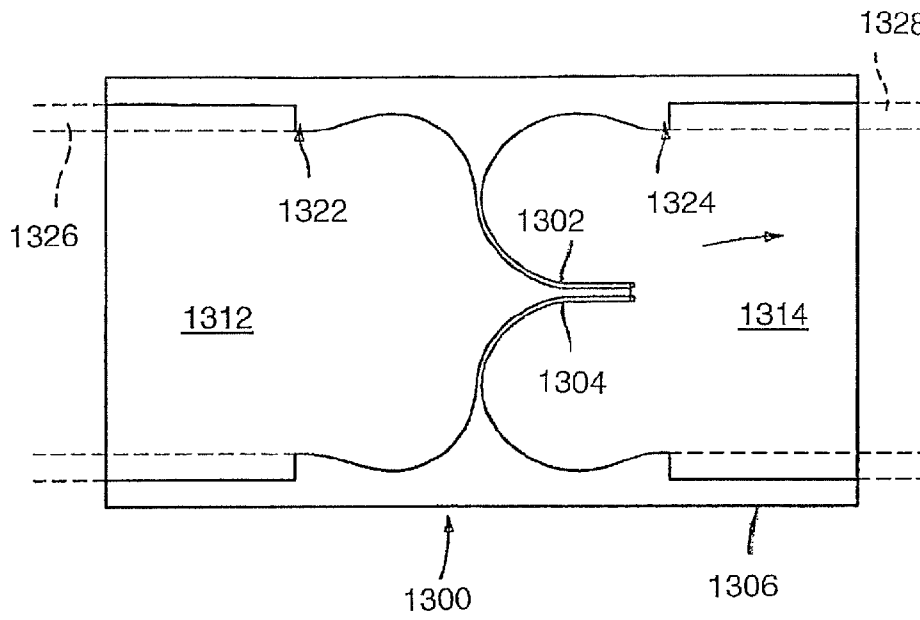


Fig. 13

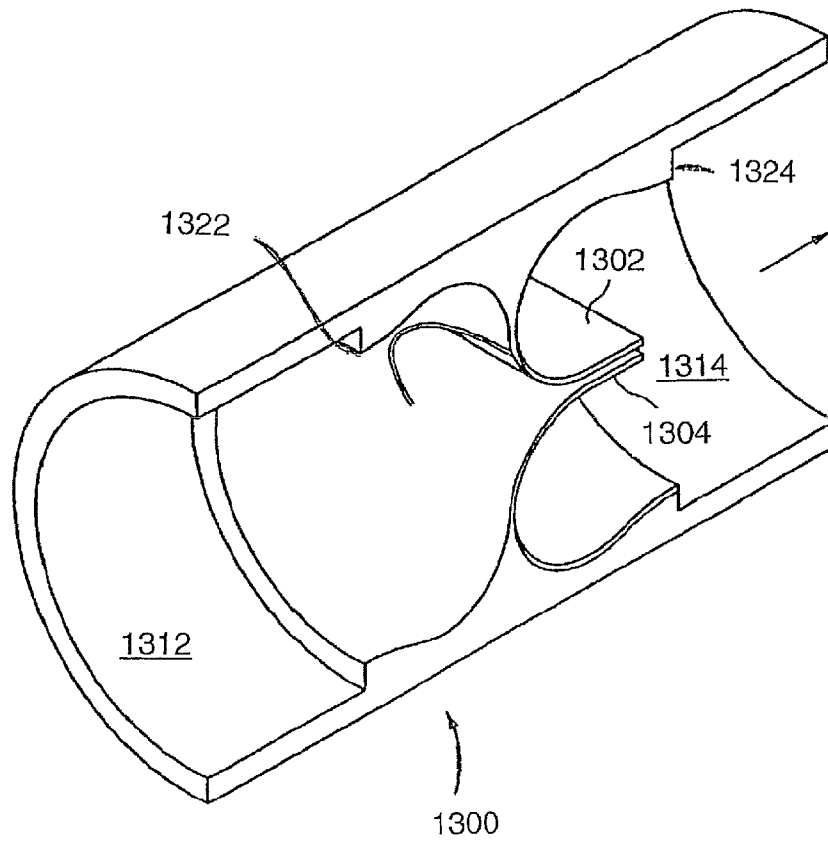


Fig. 14

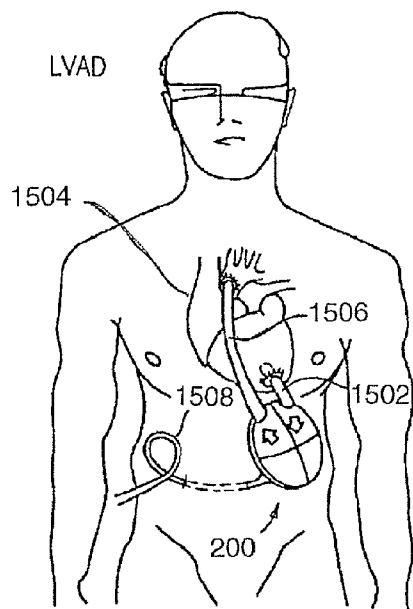


Fig. 15

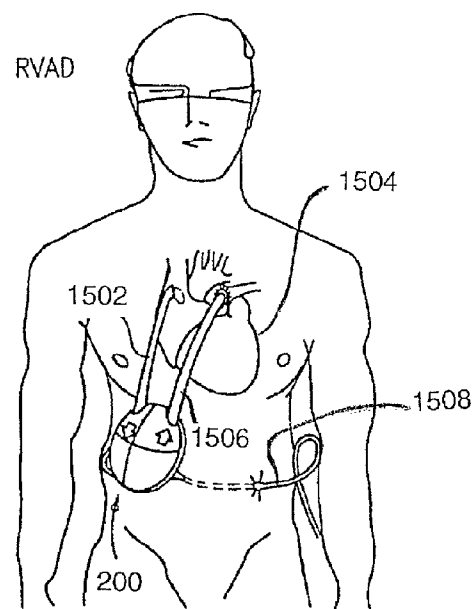


Fig. 16

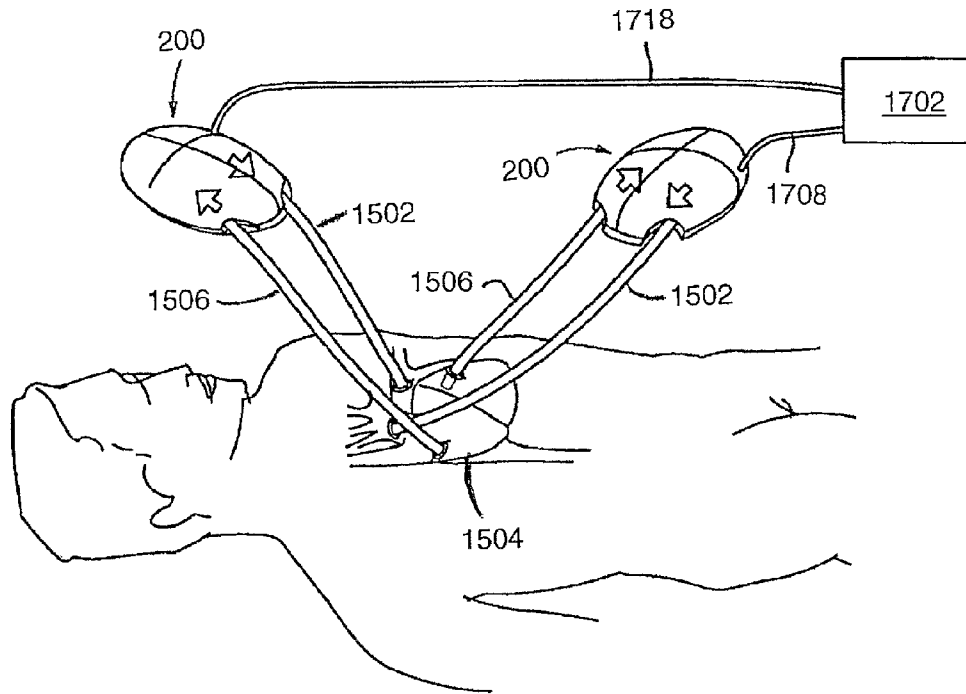


Fig. 17

FLUID PUMPING VENTRICULAR ASSIST DEVICE AND COMPONENTS WITH STATIC SEAL

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional App. Ser. No. 61/040,615, titled "Device For Hermetically Sealing A Ventricular Assist Device Chamber," filed on Mar. 28, 2008, which application is incorporated by reference in its entirety into this application.

TECHNICAL FIELD

The present invention generally relates to static seals and enclosures and devices utilizing static seals. As one particular example, the present invention relates to fluid pumping devices utilizing static seals such as ventricular assist devices.

BACKGROUND

In fluid pumping devices requiring the assembly of two or more components together, static seals may be utilized to prevent unwanted fluid leakage or flow at the interface between assembled components. Moreover, such fluid pumping devices may include internal regions that need to be maintained at a certain pressure or at least without the loss of pressure. Static seals may be utilized to prevent fluid leakage and pressure loss. Fluid pumping devices utilizing static seals include Ventricular Assist Devices (VADs), which are utilized as circulatory support devices for patients during or after open heart surgery or as a bridge to heart transplant for cardiac-failure patients. Other circulatory support devices include rotary blood pumps and axial blood pumps.

Typically, circulatory support devices include some type of a pumping unit, or components configured to provide a pumping action, contained in a suitable enclosure. The pumping unit of the circulatory support device may be connected to a patient's heart via cannulae attached to the heart at appropriate locations according to known surgical practices. Particularly in the case of a VAD, the pumping unit may include a flexible blood sac for supporting or replacing heart activity. The blood sac may be attached to an input cannula via a one-way input valve and to an output cannula via a one-way output valve. The enclosure for the blood sac may be provided in the form of two half shells that are coupled together to enclose the blood sac, resulting in an assembled VAD. A sealing element is included at the interface of the two half shells to hermetically seal the interior (containing the blood sac) from the environment external to the assembled VAD. The sealing element is typically constructed from a deformable material, while the half shells are rigid. Upon coupling the half shells together with the deformable sealing element therebetween, the half shells exert pressure on the sealing element. Consequently, the sealing element is compressed and essentially fills in (or conforms to) the interface between the half shells, thereby establishing a static seal. In the case where a flexible blood sac is employed as the pumping unit, one of the half shells may provide a fitting configured for connection to a pneumatic drive unit. The pneumatic drive unit may be operated to provide air or other gas to the interior of the enclosure in pulses (or fluctuating levels of pressure). In response to a pulse of air input, the blood sac is compressed (e.g., collapses, contracts, etc.), thereby pumping blood residing within the blood sac through the output cannula. Between

pulses, the blood sac relaxes or expands to enable blood to fill the blood sac from the input cannula.

FIG. 1 is an exploded perspective view of a VAD 100 as described in U.S. Pat. No. 7,217,236, commonly assigned to the assignee of the present disclosure and incorporated herein by reference in its entirety into this application. The VAD 100 includes a disposable pumping unit 120 housed within a reusable pump shell 112. The pumping unit 120 includes a disposable blood sac 122 having an inlet 132 and outlet 134 respectively attached to a disposable one-way inlet valve 126 and outlet valve 124. Tubing connectors 130 and 128 are respectively attached to the inlet valve 126 and outlet valve 124 as interfaces to cannulae (not shown). The pump shell 112 includes an upper clamshell half 114 and a lower clamshell half 116. When assembled together, the upper clamshell half 114 and the lower clamshell half 116 define a pump chamber 142 in which the blood sac 122 resides. The lower clamshell half 116 has an air inlet 138 for connection to a pneumatic drive unit (not shown). The pneumatic drive unit provides a pulsed flow of air to the pump chamber 142 via the air inlet 138, thereby alternating the air pressure in the pump chamber 142 between high and low levels. In response, the blood sac 122 alternately contracts and expands such that blood is pumped along a flow path from the input tubing connector 130, to the inlet valve 126, the interior of the blood sac 122, the outlet valve 124, and to the output tubing connector 128.

In the VAD 100 illustrated in FIG. 1, a static, hermetic seal is formed at least in part by a disposable sealing element 118. The sealing element 118 is located along the plane of the interface between the upper clamshell half 114 and the lower clamshell half 116. Stated in another way, the sealing element 118 is located at the assembly plane of the two-piece pump shell 112 where the respective assembly faces of the upper clamshell half 114 and the lower clamshell half 116 meet. The configuration of the VAD 100, however, makes the ability of this sealing element 118 to consistently provide a hermetic seal at the assembly plane without pressure loss challenging. The configuration of the VAD 100 is characterized by the inlet and outlet fluidic lines being located on the same assembly plane as the faces of the upper clamshell half 114 and the lower clamshell half 116. Thus, as shown in FIG. 1, the inlet 132 and outlet 134 of the blood sac 122, the inlet valve 126 and the outlet valve 124, the tubing connectors 130 and 128, and the input and output cannulae (not shown) are all positioned essentially at the assembly plane between the upper clamshell half 114 and the lower clamshell half 116. Moreover, the tubing connectors 130 and 132 are located proximate to each other on the same side of the VAD 100.

Generally, this configuration for the VAD 100 may be considered as optimal for a variety of reasons. For instance, a surgeon can easily visualize and remember which tubing connectors 130 and 132 are being utilized for the input and output directions of blood flow, respectively. If the cannulae are initially connected to the wrong tubing connectors 130 and 132, the surgeon can easily switch the connections. Moreover, the inputs and outputs to the device are easily observable in one location to determine whether the blood sac 122 or one of the valves 124 and 126 has failed. In addition, assembly and disassembly of the VAD 100 for the purpose of replacing the blood sac 122 or the valves 124 and 126 is thought to be facilitated by this configuration. Ease of assembly and disassembly is particularly important during surgery. However, the configuration illustrated in FIG. 1 requires complex geometry, particularly with regard to various surfaces within the interior of the VAD 100. The valves 124 and 126 and tubing connectors 128 and 130 are accommodated by a cylindrical

inlet region **146**, a cylindrical outlet region **144**, and associated grooves, surfaces, edges, and the like. The pump chamber **142** to be hermetically sealed is in open communication with the inlet region **146** and the outlet region **144**. The location of the inlet region **146** and the outlet region **144** are such that there are essentially breaks in the assembly plane of the VAD **100**. The sealing element **118** cannot adequately seal the inlet region **146** and the outlet region **144**. Thus, hermetic sealing of the interior of the VAD **100** relies in part on securing the tubing connectors **128** and **130** to the upper clamshell half **114** and lower clamshell half **116** at locations such as annular shoulders **137** and the like.

In addition, the configuration illustrated in FIG. **1** requires that the assembly faces of the upper clamshell half **114** and lower clamshell half **116** be parallel to ensure pressure is imparted to the sealing element **118** uniformly. This parallelism limits the range of design options for the VAD **100** and results in the VAD **100** being larger and bulkier than necessary, which is particularly disadvantageous when the VAD **100** is intended to be implantable in the patient.

In addition, the blood sac **122**, valves **124** and **126** and the cannulae connected to the valves **124** and **126** via the tubing connectors **130** and **132** are all constructed from a flexible material such as silicone rubber. Hence, these components are unstable during the handling and manipulation required for assembling the components together prior to enclosing them between the upper and lower clamshell halves **114** and **116**. Once filled with fluid, these components are easy to deform, making proper handling and manipulation even more difficult.

Therefore, there is a need for providing a fluid pumping device that provides an improved static seal. There is also a need for providing a fluid pumping device that does not require parallel assembly faces and that is easier to assemble and disassemble. Further, there is a need for improving the stability of a fluid pumping device during assembly and disassembly.

SUMMARY

To address the foregoing problems, in whole or in part, and/or other problems that may have been observed by persons skilled in the art, the present disclosure provides methods, processes, systems, apparatus, instruments, and/or devices, as described by way of example in the various implementations set forth below.

According to one implementation, a static seal structure for a fluid pump housing includes a support structure, a first sealing element, and a second sealing element. The support structure circumscribes a pump chamber. The support structure includes a first sealing side, a second sealing side opposite to the first sealing side, a first opening located at the first sealing side, a second opening located at the second sealing side, a first sealing surface circumscribing the first opening, a second sealing surface circumscribing the second opening, a fluid transfer end interposed between the first sealing side and the second sealing side, a fluid inlet bore formed through the fluid transfer end, and a fluid outlet bore formed through the fluid transfer end. The support structure provides a fluid flow path running through the fluid transfer end and into the pump chamber via the fluid inlet bore and from the pump chamber back through the fluid transfer end via the fluid outlet bore. The first sealing element is disposed on the first sealing surface, and the second sealing element is disposed on the second sealing surface. The first sealing element and the second sealing element are configured for forming sealed interfaces

between the support structure and the fluid pump housing when assembled in the fluid pump housing.

According to another implementation, a fluid pump housing includes a support structure, a first sealing element, a second sealing element, a first housing section and a second housing section. The support structure circumscribes a pump chamber. The support structure includes a first sealing side, a second sealing side opposite to the first sealing side, a first opening located at the first sealing side, a second opening located at the second sealing side, a first sealing surface circumscribing the first opening, a second sealing surface circumscribing the second opening, a fluid transfer end interposed between the first sealing side and the second sealing side, a fluid inlet bore formed through the fluid transfer end, and a fluid outlet bore formed through the fluid transfer end. The support structure provides a fluid flow path running through the fluid transfer end and into the pump chamber via the fluid inlet bore and from the pump chamber back through the fluid transfer end via the fluid outlet bore. The first sealing element is disposed on the first sealing surface, and the second sealing element is disposed on the second sealing surface. The first housing section contacts the first sealing element and covers the first opening, and the second housing section contacts the second sealing element and covers the second opening. The support structure, the first sealing element, the second sealing element, the first housing section, and the second housing section cooperatively fluidly seal the pump chamber from an environment external to the fluid pump housing, with the first sealing element forming a sealed interface between the first housing section and the support structure and the second sealing element forming a sealed interface between the second housing section and the support structure.

According to another implementation, a fluid pump includes a support structure, a first sealing element, a second sealing element, a first housing section, a second housing section, and a pump unit. The support structure circumscribes a pump chamber. The support structure includes a first sealing side, a second sealing side opposite to the first sealing side, a first opening located at the first sealing side, a second opening located at the second sealing side, a first sealing surface circumscribing the first opening, a second sealing surface circumscribing the second opening, a fluid transfer end interposed between the first sealing side and the second sealing side, a fluid inlet bore formed through the fluid transfer end, and a fluid outlet bore formed through the fluid transfer end. The first sealing element is disposed on the first sealing surface, and the second sealing element is disposed on the second sealing surface. The first housing section contacts the first sealing element and covers the first opening, and the second housing section contacts the second sealing element and covers the second opening. The pump unit is disposed in the pump chamber, and includes a pump inlet fluidly communicating with the fluid inlet bore and a pump outlet fluidly communicating with the fluid outlet bore. The support structure, the first sealing element, the second sealing element, the first housing section, and the second housing section cooperatively fluidly seal the pump chamber and the pump unit from an environment external to the fluid pump housing, with the first sealing element forming a sealed interface between the first housing section and the support structure and the second sealing element forming a sealed interface between the second housing section and the support structure.

According to another implementation, a method is provided for forming a static seal in a fluid pump housing. A support structure is seated in a first housing section such that a first sealing element is interposed between a first sealing surface of the support structure and a first inside surface of the

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first housing section. The support structure circumscribes a pump chamber and the first sealing element circumscribes a first opening between the interior space and a first interior of the first housing section. A second housing section is seated on the support structure such that a second sealing element is interposed between a second sealing surface of the support structure and a second inside surface of the second housing section. The second sealing surface is located on a side of the support structure opposite to the first sealing surface and circumscribes a second opening between the interior space and a second interior of the second housing section. The support structure, the first sealing element, the second sealing element, the first housing section, and the second housing section cooperatively fluidly seal the pump chamber from an environment external to the fluid pump housing.

Other devices, apparatus, systems, methods, features and advantages of the invention will be or will become apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems, methods, features and advantages be included within this description, be within the scope of the invention, and be protected by the accompanying claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention can be better understood by referring to the following figures. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. In the figures, like reference numerals designate corresponding parts throughout the different views.

FIG. 1 is an exploded perspective view of a known Ventricular Assist Device (VAD).

FIG. 2 is an exploded perspective view of an example of a fluid pump provided in accordance with the present invention.

FIG. 3 is a perspective view of an example of a static seal structure that may be provided with the fluid pump illustrated in FIG. 2.

FIG. 4 is a plan view from a sealing side of the support structure illustrated in FIG. 3.

FIG. 5 is an elevation view from one end of the support structure illustrated in FIG. 3.

FIG. 6 is an elevation view from a lateral side of the support structure illustrated in FIG. 3.

FIG. 7 is a perspective view of an example of a pump unit of the fluid pump illustrated in FIG. 2 installed with the support structure illustrated in FIG. 3.

FIG. 8 is a plan view from a sealing side of the pump unit and support structure illustrated in FIG. 7.

FIG. 9 is an elevation view from a fluid transfer end of the pump unit and support structure illustrated in FIG. 7.

FIG. 10 is a lateral side of the pump unit and support structure illustrated in FIG. 7.

FIG. 11 is a plan view illustrating the pump unit and support structure seated in a housing section.

FIG. 12 is a plan view illustrating the same housing section as illustrated in FIG. 11 but with the pump unit and support structure removed.

FIG. 13 is a cross-sectional elevation view of an example of a one-way valve that may be utilized in the fluid pump illustrated in FIG. 2.

FIG. 14 is a cross-sectional perspective view of the one-way valve illustrated in FIG. 13.

FIG. 15 illustrates an example of the use of the fluid pump as a Left Ventricular Assist Device (LVAD).

FIG. 16 illustrates an example of the use of the fluid pump as a Right Ventricular Assist Device (RVAD).

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FIG. 17 illustrates an example of the use of two fluid pumps as a Bi-Ventricular Assist Device (BIVAD).

DETAILED DESCRIPTION

FIG. 2 is an exploded perspective view of an example of a fluid pump 200 provided in accordance with the present invention. In the illustrated example, the pump 200 is adapted for use as a Ventricular Assist Device (VAD). As will become evident from the following description, however, the pump 200 is not limited to use as a VAD but rather may be utilized as another type of implantable or non-implantable pump. Moreover, the pump 200 may be adapted for use in non-medical as well as medical purposes. The pump 200 generally includes a pump unit 202 and a pump housing 210 that when assembled encloses and hermetically seals the pump unit 202. The pump unit 202 generally may be any device adapted to admit a volume of fluid into its interior through a pump inlet and discharge the fluid through a pump outlet via a pumping action. The fluid may be a liquid, gas, slurry, suspension, or the like. In the present example of a VAD, the pump unit 202 may be flexible sac adapted for pumping blood. The housing 210 includes a rigid support structure 212 surrounding the pump unit 202, a first housing section 214, and a second housing section 216. The support structure 212 and housing sections 214 and 216 may be constructed from any suitable rigid material such as various types of plastics, and may be fabricated by any suitable molding or machining process.

In assembling the pump 200, the pump unit 202 is placed in the support structure 212 in fluid communication with an inlet tubing connector 222 and an outlet tubing connector 224. The tubing connectors 222 and 224 may be constructed from any suitable rigid material such as various types of plastics and metals (e.g., stainless steel, titanium, etc.). The designation of one particular tubing connector 222 or 224 as being an inlet and the other tubing connector 224 or 222 as being an outlet is arbitrary and given merely by example. The support structure 212 is then placed in sealing contact with the first housing section 214 and the second housing section 216 in a manner described below. The first housing section 214 and the second housing section 216 are then secured together by fasteners or any other suitable means, resulting in a fully hermetically sealed pump 200. The tubing connectors 222 and 224 are secured directly to the support structure 212 and independently of the first housing section 214 and the second housing section 216. The first housing section 214 and the second housing section 216 may include respective surfaces 226 and 228 that form apertures after assembly to provide access to the tubing connectors 222 and 224. Neither the pump unit 202 nor the tubing connectors 222 and 224 need to be sealed to these apertures to maintain a static seal.

FIGS. 3-6 illustrate the support structure 212 utilized to form a static seal for a pump such as the pump 200 illustrated in FIG. 2. Specifically, FIG. 3 is a perspective view, FIG. 4 is a plan view from a sealing side, FIG. 5 is an elevation view from one end, and FIG. 6 is a lateral side view.

Referring to FIG. 3, the support structure generally includes a first sealing side 302, an opposing second sealing side 304, and a wall 306 between the first sealing side 302 and second sealing side 304. In the present context, the wall 306 may include a single, continuous wall, or more than one wall where adjacent walls are adjoined. In either case, the wall 306 circumscribes an interior space 308 sized to receive the pump unit 202 (FIG. 2) and in part defining a sealed chamber of the pump 200. The support structure 212 generally includes a fluid transfer end 312, an end 314 opposite to the fluid transfer end 312, and opposing lateral sides 316 and 318 extending

between the fluid transfer end **312** and the opposing end **314**. The support structure **212** also includes a first sealing surface **322** at the first sealing side **302** and an opposing second sealing surface **324** at the second sealing side **304**. The first sealing surface **322** circumscribes a first opening **326** and the second sealing surface **324** circumscribes a second opening **328**. Each sealing surface **322** and **324** may have a flat or rounded profile and may or may not be provided in the form of a groove. More generally, the first sealing surface **322** is configured to receive a first sealing element **332** and the second sealing surface **324** is configured to receive a second sealing element **334**. The sealing elements **332** and **334** may be constructed of any suitable deformable or elastic material. The sealing elements **332** and **334** may be structured as continuous loops of material. In the present example, the sealing elements **332** and **334** include curved sections at the fluid transfer end **312** and opposing end **314** and straight sections along the lateral sides **316** and **318**. The sealing elements **332** and **334** together with the support structure **212** form a static seal structure.

In one implementation, the support structure **212** and sealing elements **332** and **334** form a multi-piece static seal structure. In this implementation, the sealing elements **332** and **334** are initially physically separate components that are first placed in properly aligned or oriented contact with either the respective sealing surfaces **322** and **324** or the corresponding inside surfaces of the housing sections **214** and **216** prior to assembling the support structure **212** and housing sections **214** and **216** securely together. In another implementation, the support structure **212** and sealing elements **332** and **334** are initially provided as a one-piece static seal structure prior to assembly with the housing sections **214** and **216**. In this implementation, the sealing elements **332** and **334** are initially affixed to the respective sealing surfaces **322** and **324** by any suitable means. As one non-limiting example, the support structure **212** and sealing elements **332** and **334** may all be fabricated together in situ in a double injection manufacturing process. As appreciated by persons skilled in the art, the double injection manufacturing process enables dissimilar polymers or different polymeric components to be joined together. In other implementations, the sealing elements **332** and **334** may be bonded or adhered to the respective sealing surfaces **322** and **324** by any other suitable means that does not impair the deformability or elasticity of the sealing elements **332** and **334**.

Continuing with FIG. 3, an inlet bore **342** and an outlet bore **344** are both formed at the fluid transfer end **312** of the support structure **212** in open communication with the interior space **308**. The designation of one of these bores **342** or **344** as being the inlet and the other bore **344** or **342** as being the outlet is arbitrary and given merely by example. The inlet bore **342** is oriented about an inlet axis **346** along which fluid flows through the fluid transfer end **312** into the pump unit **202** (FIG. 2). The outlet bore **344** is oriented about an outlet axis **348** along which fluid flows from the pump unit **202** and back through the fluid transfer end **312**. The inlet bore **342** and the outlet bore **344** may be configured and positioned such that the inlet axis **346** and the outlet axis **348** are parallel to each other and lie in the same plane, as in the illustrated example. In other implementations, the inlet axis **346** and the outlet axis **348** may be non-parallel. As also shown in FIG. 3, the inlet bore **342** and the outlet bore **344** may be sized to receive tubing connectors **222** and **224** (FIG. 2) of a standard size. The portion of the wall **306** associated with the fluid transfer end **312** is tall enough to accommodate the inlet bore **342** and the outlet bore **344**. However, as shown in FIG. 3 and further in FIG. 6, the first sealing element **332** and the second

sealing element **334** may be non-parallel in accordance with certain implementations of the present invention. In this case, the wall **306** of the support structure **212** along the lateral sides **316** and **318** may taper from the height at the fluid transfer end **312** down to a lesser height at the opposite end **314**.

FIGS. 7-10 illustrate the pump unit **202** installed with the support structure **212**. Specifically, FIG. 7 is a perspective view, FIG. 8 is a plan view from a sealing side, FIG. 9 is an elevation view from the fluid transfer end, and FIG. 10 is an elevation view from a lateral side.

Referring to FIG. 7, the pump unit **202** generally includes a structural enclosure **702** enclosing a pump interior in fluid communication with a pump inlet and a pump outlet. The specific configuration of the pump unit **202** may depend on the particular application of the pump **200** and the type of fluid to be pumped. In the present example of a VAD, at least a portion of the enclosure **702** of the pump unit **202** is flexible such that the internal volume of the pump unit **202** varies between contraction/expansion cycles of the enclosure **702**. Accordingly, the pump unit **202** may be configured similarly to the flexible blood sac described above in conjunction with FIG. 1. All or a portion of the pump unit **202** may be constructed from a supple elastomer such as silicone, and the pump unit **202** may have a generally rounded profile with no sharp or abrupt edges. Such a configuration is suitable for preventing damage to blood tissue during pumping. A one-way inlet valve **712** is connected to the inlet of the pump unit **202**, and a one-way outlet valve **714** is connected to the outlet of the pump unit **202**. The inlet valve **712** and the outlet valve **714** thus fluidly communicate with the pump interior but are detachable from the pump inlet and pump outlet for replacement, cleaning, or the like. The interior space **308** (FIG. 3) defined by the support structure **212** is large enough to accommodate the inlet valve **712** and the outlet valve **714**. The ends of the inlet valve **712** and outlet valve **714** opposite to the pump unit **202** are attached to the respective tubing connectors **222** and **224**. The inlet valve **712** and outlet valve **714** may be coupled to the pump unit **202** and tubing connectors **222** and **224** by any suitable means such as, for example, friction fit, threading, Luer-type fitting, etc.

The tubing connectors **222** and **224** may be securely mounted to the inlet bore **342** and outlet bore **344** (FIG. 3) in any suitable sealed manner that prevents fluid leakage from the interior space **308** through the inlet bore **342** and outlet bore **344**. In one example, the tubing connectors **222** and **224** may include threads that mate with complementary threads formed on the inside surface of the inlet bore **342** and outlet bore **344**. Because the inlet bore **342** and outlet bore **344** are formed through the one-piece support structure **212**, instead of by assembly of two housing sections together, the tubing connectors **222** and **224** are easily sealed against the inlet bore **342** and outlet bore **344** without risk of leakage.

When the various components are assembled as illustrated in FIG. 7, a fluid flow path is established in which fluid enters the input tubing connector **222** as indicated by an arrow, passes through the fluid transfer end **312** of the support structure **212**, flows through the inlet valve **712** and into the interior of the pump unit **202**, flows out from the pump interior and through the outlet valve **714**, passes back through the fluid transfer end **312**, and exits the output tubing connector **224** as indicated by an arrow. In practice, an input conduit (not shown) may be connected between the input tubing connector **222** and a suitable fluid source, and an output conduit (not shown) may be connected between the output tubing connector **224** and a suitable fluid destination. In the case of a VAD,

the input and output conduits may be medical-grade cannulae attached to a patient's heart according to known surgical procedures.

Various components of the pump 200, such as for example the pump unit 202, valves 712 and 714, cannulae, etc. may be fabricated or treated for specific purposes such as to improve blood compatibility and non-thrombogenicity. As examples, such components may be coated with lubricant, hydrophobic, antibacterial and/or antithrombotic coatings, including but not limited to PTFE coatings, heparin-bonded coatings, fluorinated coatings, triclosan and silver compound coatings, anti-calcification agent-releasing coatings, etc.

Referring to FIGS. 2, 7 and 8, it can be seen that the interior chamber of the pump 200, which includes the interior space 308 (FIG. 3) circumscribed by the support structure 212, is completed upon assembly of the first housing section 214 to the second housing section 216 with the support structure 212 interposed between these two housing sections 214 and 216. During assembly, the first sealing element 332 is properly seated against a complementary interior surface of the first housing section 214, and the second sealing element 334 is properly seated against a complementary interior surface of the second housing section 216. Compression and consequent deformation of the first and second sealing elements 332 and 334 between the support structure 212 and the respective first and second housing sections 214 and 216 results in the interior chamber of the pump 200 being hermetically sealed. The components associated with the inlet and outlet fluidic lines (e.g., the inlet and outlet of the pumping unit 202, the inlet and outlet valves 712 and 714, the inlet and outlet bores 342 and 344 of the support structure, and the tubing connectors 222 and 224) are still located in a position considered advantageous in many implementations, including applications entailing ventricular assistance, i.e., in between two housing sections 214 and 216 that are assembled together to enclose a pump unit 202. Due to the illustrated configuration, however, these components do not break or interfere with the assembly planes associated with the housing sections 214 and 216. In particular, the tubing connectors 222 and 224 are remote from and completely independent of the first and second sealing elements 332 and 334 that serve as the assembly interfaces of the structural components of the pump housing 210. Moreover, as further shown in FIG. 10, the static seal established according to the present invention does not require sealing interfaces to be parallel.

FIG. 9 illustrates that the inlet valve 712 and outlet valve 714 may be configured as one-way valves, such as through the use of two or more flaps or leaflets 902 in each valve 712 and 714 configured for allowing fluid flow in a single direction. A further example of one-way valves is described below in conjunction with FIGS. 13 and 14.

FIG. 10 illustrates an implementation in which the support structure 212 is tapered such that the first sealing element 332 and second sealing element 334 are positioned in a non-parallel relation. In this case, the pump unit 202 may protrude out from the first sealing side 302 and the second sealing side 304 of the support structure 212. The interior profiles of the first and second housing sections 214 and 216 (FIG. 2) may be configured to be just large enough to enclose the pump unit 202 and provide some space for a gas (e.g. air) to be admitted into the interior chamber of the pump 200 for activating the pumping action of the pump unit 202. Because the first sealing element 332 and second sealing element 334 are not required to be parallel, the pump housing 210 does not need to assume a more traditional cylindrical or box-like shape.

Instead, the pump housing 210 can be made smaller and occupy less volume, which is particularly useful in implantable applications.

FIG. 11 is a plan view illustrating the pump unit 202 and support structure 212 seated in a housing section 214 (or 216). The housing sections 214 and 216 may provide openings 1102 and 1104 for accessing the tubing connectors 222 and 224, as well as features such as annular shoulders 1106 and 1108 for facilitating the connection of cannulae or other types of conduits to the tubing connectors 222 and 224. However, the tubing connectors 222 and 224 are not required to be sealingly coupled to these openings 1102 and 1104 to form a static seal. Instead, the tubing connectors 222 and 224 may be securely coupled to the inlet bore 342 and outlet bore 344 of the support structure 212, with the static seal being established by the sealing elements 332 and 334.

FIG. 12 is a plan view illustrating the same housing section 214 (or 216) as illustrated in FIG. 11 but with the pump unit 202 and support structure 212 removed. Each housing section 214 and 216 may include an inside sealing surface 1202 configured for complete, uniform contact with the corresponding sealing element 332 or 334. The inside sealing surface 1202 may have a flat or rounded profile and may or may not be provided in the form of a groove. The inside sealing surface 1202 may be a continuous surface to ensure uniform contact with, and pressure imparted to, the sealing element 332 or 334. As also illustrated in FIG. 12, the housing sections 214 and 216 may include shoulders or ridges 1204 and 1206 proximate to their corresponding inside sealing surfaces 1202 to facilitate seating the rigid support structure 212 (FIG. 11) in an aligned manner that ensures the establishment of a proper sealing interface. As also shown in FIG. 12, at least one of the housing sections may include a gas (e.g., air) port 1212 and associated fitting 1214 for connection to a pneumatic drive unit (not shown). As described earlier, the pneumatic drive unit or equivalent device may be operated to inject a gas into the chamber of the pump 200 in a pulsed manner to activate the pumping action of the pump unit 202 (FIG. 11).

The pump 200 may be easily assembled and disassembled. As an example of assembling the pump 200, the tubing connectors 222 and 224 are secured to the respective inlet bore 342 and outlet bore 344 of the support structure 212. The inlet valve 712 and outlet valve 714 may then be connected to the respective inlet and outlet of the pump unit 202 and to the corresponding tubing connectors 222 and 224. The support structure 212 (with the associated components mounted thereto) may then be placed in contact with the appropriate inside surface 1202 of one of the housing sections 214 and 216, with one of the sealing elements 332 and 334 being interposed between the support structure 212 and the housing section 214 or 216. The other housing section 216 or 214 may then be brought into contact with the opposing sealing side of the support structure 212, with the other sealing element 334 or 332 being interposed between the support structure 212 and the housing section 216 or 214. The housing sections 214 and 216 are then secured or fastened together by any suitable means, thereby compressing the sealing elements 332 and 334 and establishing the fluid-tight, active static seal of the pump 200. Input and output cannulae (to other type of conduits) may be connected to the corresponding tubing connectors 222 and 224 before or after the housing sections 214 and 216 are secured to the support structure 212. In an implementation where one or both of the housing sections 214 and 216 include features adapted to enhance securement of the cannulae to the tubing connectors (e.g., shoulders, edges or the like for effecting a crimping, clamping or locking action), the

cannulae may be connected to the tubing connectors **222** and **224** prior to securing the housing sections **214** and **216** to the support structure **212**. It can also be seen that the support structure **212** provides a rigid component facilitating handling and manipulation of the various components during assembly and disassembly. The support structure **212** may be directly handled by the user when attaching/detaching the inlet valve **712** and outlet valve **714** to/from the pump unit **202** and tubing connectors **222** and **224**, and attaching/detaching the tubing connectors **222** and **224** to/from cannulae.

FIG. **13** is a cross-sectional elevation view and FIG. **14** is a cross-sectional perspective view of an example of a one-way valve **1300** that may be utilized as the inlet and outlet valves described above. It will be understood, however, that various other configurations may be provided for the one-way valves utilized in the presently described implementations. In the present example, the one-way valve **1300** may have a hingeless design in which two or more flexible, elastic flaps or leaflets **1302** and **1304** extend generally toward each other from an inside surface of a main valve body **1306**. The flaps **1302** and **1304** are positioned between an inlet end **1312** and an outlet end **1314** of the one-way valve **1300**. The flaps **1302** and **1304** are shaped such that when the fluid pressure at the inlet end **1312** is greater than the fluid pressure at the outlet end **1314**, the flaps **1302** and **1304** flex away from each other whereby fluid flows from the inlet end **1312** to the outlet end **1314**. When the fluid pressure at the inlet end **1312** is less than the fluid pressure at the outlet end **1314**, the flaps **1302** and **1304** are compressed together whereby fluid is prevented from flowing from the outlet end **1314** back toward the inlet end **1312**. The one-way valve **1300** is configured such that the opening and closing of the flaps **1302** and **1304** is gentle and enables a smooth and continuous flow of fluid in the intended direction and in a manner similar to the action of a natural heart valve. The one-way valve **1300** may be configured without any sharp edges and the material may be a supple elastomer such as, for example, silicone. The one-way valve **1300** may be formed by injection molding or any other suitable method of fabrication. A one-way valve such as illustrated in FIGS. **13** and **14** minimizes or eliminates the risk of damage to blood cells and hence is suitable for flowing blood.

As further illustrated by example in FIG. **13**, the one-way valve **1300** may include inside annular shoulders or surfaces **1322** and **1324** sized to abut the respective ends of an inlet conduit **1326** and an outlet conduit **1328**. It will be appreciated, however, that alternative coupling configurations may be implemented. In a case where the one-way valve **1300** is utilized as an inlet valve, the inlet conduit **1326** may represent an inlet tubing connector and the outlet conduit **1328** may represent the inlet of a pump unit. In a case where the one-way valve **1300** is utilized as an outlet valve, the inlet conduit **1326** may represent the outlet of a pump unit and the outlet conduit **1328** may represent an outlet tubing connector.

FIGS. **15-17** illustrate examples of applications of the pump **200** described above. FIG. **15** illustrates the use of the pump **200** as a Left Ventricular Assist Device (LVAD). A ventricular (or atrial) cannula **1502** is attached to the input tubing connector of the pump **200** and surgically attached to an appropriate site of a patient's heart **1504**, thereby providing a flow path for blood from the heart **1504** into the pump **200**. An arterial cannula **1506** is attached to the output tubing connector of the pump **200** and surgically attached to an appropriate site of the heart **1504**, thereby providing a flow path for blood from the pump **200** into the heart **1504**. A pneumatic line **1508** is interconnected between the pump **200** and a pneumatic drive device or equivalent gas (e.g., air) source **1702** (FIG. **17**) to provide a pulsed flow of gas for

actuating the pump **200** as described above. FIG. **16** illustrates the use of the pump **200** as a Right Ventricular Assist Device (RVAD). FIG. **17** illustrates the use of two pumps **200** as a Bi-Ventricular Assist Device (BIVAD). The two pumps **200** are driven by the pneumatic drive device **1702** via respective pneumatic lines **1708** and **1718**.

FIGS. **15-17** illustrate examples of extracorporeal applications of the pump **200**. It will be appreciated, however, that the pump **200** may be utilized in paracorporeal implementations and as a tethered implant. As noted above, the pump **200** is configured in accordance with the present invention such that its size may be reduced relative to pumps of conventional design, thereby greatly facilitating implantable implementations. The pump **200** may be utilized in a wide variety of circulatory supporting applications, including short-term trans-operative support (e.g., a few hours), acute and post-cardiotomy support (e.g., up to a few weeks), bridge to transplant (e.g., three to six months), bridge to recovery (e.g., several years), and destination therapy (i.e., until death). More generally, the pump **200** may be utilized in various non-medical as well as medical applications for pumping various types of fluids. In addition to the flexible-sac configuration described by example above, other types of pump units may benefit through the use of the static seal provided by the present invention.

In general, terms such as "communicate" and "in . . . communication with" (for example, a first component "communicates with" or "is in communication with" a second component) are used herein to indicate a structural, functional, mechanical, electrical, signal, optical, magnetic, electromagnetic, ionic or fluidic relationship between two or more components or elements. As such, the fact that one component is said to communicate with a second component is not intended to exclude the possibility that additional components may be present between, and/or operatively associated or engaged with, the first and second components.

It will be understood that various aspects or details of the invention may be changed without departing from the scope of the invention. Furthermore, the foregoing description is for the purpose of illustration only, and not for the purpose of limitation—the invention being defined by the claims.

What is claimed is:

1. A static seal structure for a medical device fluid pump housing, comprising:

a support structure circumscribing a pump chamber, the support structure including a first sealing side, a second sealing side opposite to the first sealing side, a first opening located at the first sealing side, a second opening located at the second sealing side, a first sealing surface circumscribing the first opening, a second sealing surface circumscribing the second opening;

a first sealing element disposed on the first sealing surface; and

a second sealing element disposed on the second sealing surface,

wherein the first sealing element and the second sealing element are configured for forming sealed interfaces between the support structure and surfaces of the fluid pump housing when assembled in the fluid pump housing.

2. The static seal structure of claim 1, wherein the support structure further includes a fluid transfer end interposed between the first sealing side and the second sealing side, a fluid inlet bore formed through the fluid transfer end, and a fluid outlet bore formed through the fluid transfer end, wherein the support structure provides a fluid flow path running through the fluid transfer end and into the pump chamber

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via the fluid inlet bore and from the pump chamber back through the fluid transfer end via the fluid outlet bore.

3. The static seal structure of claim 2, wherein the fluid inlet bore is disposed about an inlet axis, and the fluid outlet bore is disposed about an outlet axis parallel to the inlet axis.

4. The static seal structure of claim 2, wherein the fluid inlet bore is disposed about an inlet axis, and the fluid outlet bore is disposed about an outlet axis non-parallel to the inlet axis.

5. The static seal structure of claim 2, further including an inlet tubing connector attached to the fluid inlet bore, and an outlet tubing connector attached to the fluid outlet bore.

6. The static seal structure of claim 1, wherein the first sealing element is parallel to the second sealing element.

7. The static seal structure of claim 1, wherein the first sealing element is non-parallel to the second sealing element.

8. The static seal structure of claim 1, wherein the first sealing element and the second sealing element are each configured as a continuous loop of material.

9. The static seal structure of claim 1, wherein the first sealing surface and the second sealing surface are continuous surfaces.

10. A medical device fluid pump housing, comprising:

a support structure circumscribing a pump chamber, the support structure including a first sealing side, a second sealing side opposite to the first sealing side, a first opening located at the first sealing side, a second opening located at the second sealing side, a first sealing surface circumscribing the first opening, and a second sealing surface circumscribing the second opening;

a first sealing element disposed on the first sealing surface; a second sealing element disposed on the second sealing surface;

a first housing section contacting the first sealing element and covering the first opening; and

a second housing section contacting the second sealing element and covering the second opening,

wherein the support structure, the first sealing element, the second sealing element, the first housing section, and the second housing section cooperatively fluidly seal the pump chamber from an environment external to the fluid pump housing, with the first sealing element forming a sealed interface between the first housing section and the support structure and the second sealing element forming a sealed interface between the second housing section and the support structure.

11. The medical device fluid pump housing of claim 10, wherein the support structure further includes a fluid transfer end interposed between the first sealing side and the second sealing side, a fluid inlet bore formed through the fluid transfer end, and a fluid outlet bore formed through the fluid transfer end, wherein the support structure provides a fluid flow path running through the fluid transfer end and into the pump chamber via the fluid inlet bore and from the pump chamber back through the fluid transfer end via the fluid outlet bore.

12. The medical device fluid pump housing of claim 11, further including an inlet tubing connector attached to the fluid inlet bore, and an outlet tubing connector attached to the fluid outlet bore.

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13. The medical device fluid pump housing of claim 10, wherein a gas inlet is formed in at least one of the first housing section and the second housing section, the gas inlet fluidly communicating with the pump chamber and configured for connection to a gas conduit.

14. The medical device fluid pump housing of claim 10, wherein the second housing section is secured to the first housing section using fasteners so as to form a housing in which the support structure is fitted.

15. A medical device fluid pump, comprising:

a support structure circumscribing a pump chamber, the support structure including a first sealing side, a second sealing side opposite to the first sealing side, a first opening located at the first sealing side, a second opening located at the second sealing side, a first sealing surface circumscribing the first opening, a second sealing surface circumscribing the second opening, a fluid transfer end interposed between the first sealing side and the second sealing side, a fluid inlet bore formed through the fluid transfer end, and a fluid outlet bore formed through the fluid transfer end;

a first sealing element disposed on the first sealing surface; a second sealing element disposed on the second sealing surface;

a first housing section contacting the first sealing element and covering the first opening;

a second housing section contacting the second sealing element and covering the second opening; and

a pump unit disposed in the pump chamber, the pump unit including a pump inlet fluidly communicating with the fluid inlet bore and a pump outlet fluidly communicating with the fluid outlet bore,

wherein the support structure, the first sealing element, the second sealing element, the first housing section, and the second housing section cooperatively fluidly seal the pump chamber and the pump unit from an environment external to the fluid pump housing, with the first sealing element forming a sealed interface between the first housing section and the support structure and the second sealing element forming a sealed interface between the second housing section and the support structure.

16. The medical device fluid pump of claim 15, wherein the pump unit comprises a sac adapted for pumping blood.

17. The medical device fluid pump of claim 15, wherein at least a portion of the pump unit is deformable for establishing a pulsed flow of fluid from the pump inlet to the pump outlet.

18. The medical device fluid pump of claim 15, further including a one-way inlet valve connected to the pump inlet and a one-way outlet valve connected to the pump outlet.

19. The medical device fluid pump of claim 18, wherein the one-way inlet valve and the one-way outlet valve are each configured as a hinge-less valve including a plurality of flexible portions movable between an open position and a closed position.

20. The medical device fluid pump of claim 18, further including an inlet tubing connector interconnecting the fluid inlet bore and the one-way inlet valve, and an outlet tubing connector interconnecting the fluid outlet bore and the one-way outlet valve.

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