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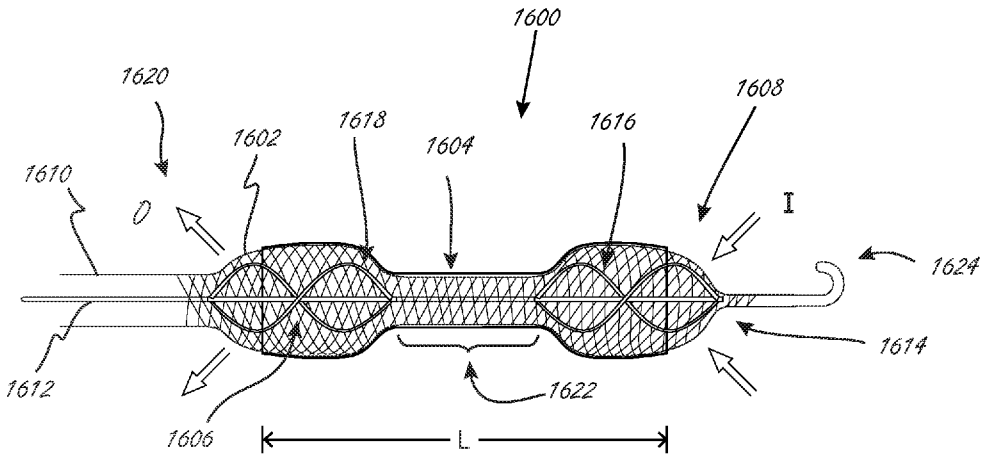


Fig. 1

(57) Abstract: Devices for moving blood within a patient, and methods of doing so. The devices can include a pump portion that includes an impeller and a housing around the impeller, as well as a fluid lumen. The impeller can be activated to cause rotation of the impeller and thereby move fluid within the fluid lumen.

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INTRAVASCULAR FLUID MOVEMENT DEVICES, SYSTEMS, AND METHODS OF USE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This applications claims priority to the following U.S. Provisional Patent Applications, the disclosures of which are fully incorporated by reference herein for all purposes: App. No. 62/585,155, filed November 13, 2017; App. No. 62/607,878, filed December 19, 2017; and App. No. 62/634,769, filed February 23, 2018.

INCORPORATION BY REFERENCE

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

BACKGROUND

[0003] Patients with heart disease can have severely compromised ability to drive blood flow through the heart and vasculature, presenting for example substantial risks during corrective procedures such as balloon angioplasty and stent delivery. There is a need for ways to improve the volume or stability of cardiac outflow for these patients, especially during corrective procedures.

[0004] Intra-aortic balloon pumps (IABP) are commonly used to support circulatory function, such as treating heart failure patients. Use of IABPs is common for treatment of heart failure patients, such as supporting a patient during high-risk percutaneous coronary intervention (HRPCI), stabilizing patient blood flow after cardiogenic shock, treating a patient associated with acute myocardial infarction (AMI) or treating decompensated heart failure. Such circulatory support may be used alone or in with pharmacological treatment.

[0005] An IABP commonly works by being placed within the aorta and being inflated and deflated in counterpulsation fashion with the heart contractions, and one of the functions is to attempt to provide additive support to the circulatory system.

[0006] More recently, minimally-invasive rotary blood pumps have been developed that can be inserted into the body in connection with the cardiovascular system, such as pumping arterial blood from the left ventricle into the aorta to add to the native blood pumping ability of the left side of the patient's heart. Another known method is to pump venous blood from the right ventricle to the pulmonary artery to add to the native blood pumping ability of the right side of the patient's heart. An overall goal is to reduce the workload on the patient's heart muscle to

stabilize the patient, such as during a medical procedure that may put additional stress on the heart, to stabilize the patient prior to heart transplant, or for continuing support of the patient.

[0007] The smallest rotary blood pumps currently available can be percutaneously inserted into the vasculature of a patient through an access sheath, thereby not requiring surgical intervention, or through a vascular access graft. A description of this type of device is a percutaneously-inserted ventricular support device.

[0008] There is a need to provide additional improvements to the field of ventricular support devices and similar blood pumps for treating compromised cardiac blood flow.

SUMMARY OF THE DISCLOSURE

[0009] One aspect of the disclosure is an intravascular blood pump, comprising: a housing (optionally collapsible) comprising a fluid lumen, the fluid lumen having a distal end (optionally adjacent an inflow) and a proximal end (optionally adjacent an outflow); a distal impeller (optionally collapsible) axially spaced from a proximal impeller (optionally collapsible), at least a portion of the distal impeller and the proximal impeller disposed axially between the distal end and the proximal end of the fluid lumen, wherein the distal impeller has an expanded configuration in an expanded state, and the proximal impeller has an expanded configuration in an expanded state, and wherein the expanded configuration of the distal impeller is different than the expanded configuration of the proximal impeller.

[0010] The distal impeller can have a distal blade and the proximal impeller can have a proximal blade, wherein the distal blade has a different pitch than the proximal blade. The distal blade can be one of a plurality of distal blades, and the proximal blade can be one of a plurality of proximal blades, wherein the plurality of distal blades can have a different pitch than each of the plurality of proximal blades.

[0011] The proximal impeller can be shaped, dimensioned and positioned to provide predominantly centrifugal flow and the distal impeller can be shaped and dimensioned to provide predominantly axial flow.

[0012] The distal impeller and proximal impeller can be adapted and configured to move fluid in the same direction.

[0013] One aspect of the disclosure is an intravascular blood pump, comprising: a housing (optionally collapsible) comprising a fluid lumen, the fluid lumen having a distal end (optionally adjacent an inflow) and a proximal end (optionally adjacent an outflow); a distal impeller (optionally collapsible) axially spaced from a proximal impeller (optionally collapsible), at least a portion of the distal impeller disposed axially between the distal end and the proximal end of the fluid lumen, wherein a proximal end of the proximal impeller is, when the housing is in an

expanded configuration and when the proximal impeller is in an expanded configuration, disposed proximal to the proximal end of the fluid lumen.

[0014] A distal end of the distal impeller can be, when the collapsible housing is in the expanded configuration and when the collapsible distal impeller is in an expanded configuration, disposed no further distally than the distal end.

[0015] One aspect of the disclosure is a method of positioning an intravascular blood pump in a subject, comprising: positioning a pump housing fluid lumen first end in a left ventricle; positioning a distal impeller of the blood pump in the left ventricle; positioning a proximal impeller of the blood pump in an ascending aorta; positioning a pump housing fluid lumen second end in the ascending aorta; positioning at least a portion of a central region of the fluid lumen across an aortic valve, the central region extending between a distal end of the proximal impeller and a proximal end of the distal impeller, creating a flow path between the fluid lumen first end positioned in the left ventricle and the fluid lumen second end positioned in the ascending aorta such that the distal impeller and the proximal impeller can pump blood through the fluid lumen.

[0016] The method can further include creating axial flow at the distal impeller by activating the distal impeller, and creating flow at an outflow that has a centrifugal component and an axial component by activating the proximal impeller.

[0017] One aspect of the disclosure is an intravascular blood pump, comprising: a housing comprising a fluid lumen, the fluid lumen having a distal end and a proximal end; a distal impeller axially spaced from a proximal impeller, at least a portion of the distal impeller and the proximal impeller disposed axially between the distal end and the proximal end of the fluid lumen; and the proximal impeller having a distal end and the distal impeller having a proximal end, wherein a length of the fluid lumen between the distal end of the proximal impeller and the proximal end of the distal impeller is from 1.5 cm to 25 cm, along a longitudinal axis of the housing. In some exemplary embodiments, the distance may be from 2 cm to 20 cm, from 2cm to 15 cm, from 2 cm to 10 cm, from 2 cm to 8 cm, from 2 cm to 7 cm, or from 2 cm to 6 cm.

[0018] The housing can be a collapsible housing, the proximal impeller can be a collapsible impeller, and the distal impeller can be a collapsible impeller.

[0019] The blood pump can further comprise at least one flow diffuser disposed axially between the proximal impeller and the distal impeller, wherein the at least one flow diffuser is configured to reduce swirl of the fluid in the fluid lumen in between the distal impeller and the proximal impeller.

[0020] One aspect of the disclosure is an intravascular blood pump, comprising: a collapsible housing comprising a fluid lumen extending from a fluid lumen first end and a fluid lumen second end; a collapsible distal impeller axially spaced from a collapsible proximal impeller, at least a portion of the collapsible distal impeller and the collapsible proximal impeller disposed axially

between the fluid lumen first end and the fluid lumen second end of the fluid lumen; the proximal impeller having a distal end and the distal impeller having a proximal end; and at least one flow diffuser disposed axially between the proximal impeller distal end and the distal impeller proximal end, wherein the at least one flow diffuser is configured to reduce swirl of the fluid in the fluid lumen in between the distal impeller and the proximal impeller.

[0021] A distance between the distal end of the proximal impeller and the proximal end of the distal impeller is from 1.5 cm to 25 cm, along a longitudinal axis of the collapsible housing. The distance can be from 2cm to 20 cm, or from 2cm to 15 cm, or from 2cm to 10 cm, or from 2cm to 8 cm, or from 2cm to 7 cm, or from 2cm to 6 cm.

[0022] The collapsible housing may have, in an expanded state, a bend formed therein between the proximal impeller distal end and the distal impeller proximal end such that a distal region of the housing distal to the bend is not axially aligned with a proximal region of the housing proximal to the bend along an axis.

[0023] One aspect of the disclosure is an intravascular blood pump, comprising: a collapsible housing comprising a fluid lumen extending from a distal end to a proximal end; a collapsible distal impeller axially spaced from a collapsible proximal impeller, at least a portion of the collapsible distal impeller and the collapsible proximal impeller disposed axially between the distal end and the proximal end of the fluid lumen; the proximal impeller having a distal end and the distal impeller having a proximal end, the housing having, in an expanded state, a bend formed therein between the proximal impeller distal end and the distal impeller proximal end such that a distal region of the housing distal to the bend is not axially aligned with a proximal region of the housing proximal to the bend along an axis.

[0024] The blood pump can also include at least one flow diffuser disposed axially between the proximal impeller and the distal impeller, wherein the at least one flow diffuser is configured to reduce swirl of the fluid in the fluid lumen in between the distal impeller and the proximal impeller.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] Figure 1 is a side view of an exemplary working portion that includes a conduit, a plurality of impellers, an expandable member

[0026] Figure 2 is a side view of an exemplary working portion that includes a conduit, a plurality of impellers, and a plurality of expandable members.

[0027] Figures 3A, 3B, 3C and 3D illustrate an exemplary working portion that includes a conduit, a plurality of impellers, and a plurality of expandable members.

[0028] Figure 4 illustrates an exemplary placement of a working portion, the working portion including a conduit, a plurality of expandable members, and a plurality of impellers.

[0029] Figure 5 illustrates an exemplary working portion.

[0030] Figure 6A illustrates at least a portion of an exemplary medical device that has a pump portion, where at least two different impellers can be rotated at different speeds.

[0031] Figure 6B illustrates at least a portion of an exemplary medical device that has a pump portion, where at least two different impellers can be rotated at different speeds.

[0032] Figure 6C illustrates at least a portion of an exemplary medical device that has a pump portion with at least two impellers with different pitches.

[0033] Figure 7 illustrates at least a portion of an exemplary medical device that has a pump portion.

[0034] Figure 8 illustrates a pump portion with multiple impellers, with a bend formed therein between adjacent impellers.

[0035] Figure 9 illustrates a pump portion with a plurality of impellers.

DETAILED DESCRIPTION

[0036] The present disclosure is related to medical devices, systems, and methods of use and manufacture. Medical devices herein may include a distal working portion adapted to be disposed within a physiologic vessel, wherein the distal working portion includes one or more components that act upon fluid. For example, distal working portions herein may include one or more rotating members that when rotated, can facilitate the movement of a fluid such as blood.

[0037] Any of the disclosure herein relating to an aspect of a system, device, or method of use can be incorporated with any other suitable disclosure herein. For example, a figure describing only one aspect of a device or method can be included with other embodiments even if that is not specifically stated in a description of one or both parts of the disclosure. It is thus understood that combinations of different portions of this disclosure are included herein unless specifically indicated otherwise.

[0038] Figure 1 is a side view illustrating a distal portion of an exemplary intravascular fluid pump, including pump portion 1600, wherein pump portion 1600 includes proximal impeller 1606 and distal impeller 1616, both of which are in operable communication with drive cable 1612. Pump portion 1600 is in an expanded configuration in Figure 1, but is adapted to be collapsed to a delivery configuration so that it can be delivered with a lower profile. The impellers can be attached to drive cable 1612. Drive cable 1612 is in operable communication with an external motor, not shown, and extends through elongate shaft 1610. The phrases "pump portion" and "working portion" (or derivatives thereof) may be used herein interchangeably unless indicated to the contrary. For example without limitation, "pump portion" 1600 can also be referred to herein as a "working portion."

[0039] Pump portion 1600 also includes expandable member 1602, which in this embodiment has a proximal end 1620 that extends further proximally than a proximal end of proximal impeller 1606, and a distal end 1608 that extends further distally than a distal end 1614 of distal impeller 1616. Expandable member 1602 is disposed radially outside of the impellers along the axial length of the impellers. Expandable member 1602 can be constructed in a manner and made from materials similar to many types of expandable structures that are known in the medical arts to be able to collapsed and expanded, examples of which are provided herein. Examples of suitable materials include, but are not limited to, polyurethane and polyurethane elastomers.

[0040] Pump portion 1600 also includes conduit 1604, which is coupled to expandable member 1602, has a length L, and extends axially between the impellers. Conduit 1604 creates and provides a fluid lumen between the two impellers. When in use, fluid move through the lumen provided by conduit 1604. The conduits herein are non-permeable, or they can be semi-permeable, or even porous as long as they can still define a lumen. The conduits herein are also flexible, unless it is otherwise indicated. The conduits herein extend completely around (i.e., 360 degrees) at least a portion of the pump portion. In pump portion 1600, conduit extends completely around expandable member 1602, but does not extend all the way to the proximal end 1602 or distal end 1608 of expandable member 1602. The structure of the expandable member creates at least one inlet aperture to allow for inflow "I," and at least one outflow aperture to allow for outflow "O." Conduit 1604 improves impeller pumping dynamics, compared to those that working portion 1600 would have without the conduit.

[0041] Expandable member 1602 can have a variety of constructions, and made from a variety of materials. For example, expandable member 1602 may be formed similar to expandable stents or stent-like devices, or any other example provided herein. For example without limitation, expandable member 1602 could have an open-braided construction, such as a 24-end braid, although more or fewer braid wires could be used. Exemplary materials for the expandable member include nitinol, cobalt alloys, and polymers, although other materials could be used. Expandable member 1602 has an expanded configuration, as shown, in which the outer dimension (measured orthogonally relative a longitudinal axis of the working portion) of the expandable member is greater in at least a region where it is disposed radially outside of the impellers than in a central region 1622 of the expandable member that extends axially between the impeller. Drive cable 1612 is co-axial with the longitudinal axis in this embodiment. In use, the central region can be placed across a valve, such as an aortic valve. In some embodiments, expandable member 1602 is adapted and constructed to expand to an outermost dimension of 12-24F (4.0-8.0mm) where the impellers are axially within the expandable member, and to an

outermost dimension of 10-20F (3.3-6.7mm) in central region 1622 between the impellers. The smaller central region outer dimension can reduce forces acting on the valve, which can reduce or minimize damage to the valve. The larger dimensions of the expandable member in the regions of the impellers can help stabilize the working portion axially when in use. Expandable member 1602 has a general dumbbell configuration. Expandable member 1602 has an outer configuration that tapers as it transitions from the impeller regions to central region 1622, and again tapers at the distal and proximal ends of expandable member 1602.

[0042] Expandable member 1602 has a proximal end 1620 that is coupled to shaft 1610, and a distal end 1608 that is coupled to distal tip 1624. The impellers and drive cable 1612 rotate within the expandable member and conduit assembly. Drive cable 1612 is axially stabilized with respect to distal tip 1624, but is free to rotate with respect to tip 1624.

[0043] In some embodiments, expandable member 1602 can be collapsed by pulling tension from end-to-end on the expandable member. This may include linear motion (such as, for example without limitation, 5-20mm of travel) to axially extend expandable member 1602 to a collapsed configuration with collapsed outer dimension(s). Expandable member 1602 can also be collapsed by pushing an outer shaft such as a sheath over the expandable member/conduit assembly, causing the expandable member and conduit to collapse towards their collapsed delivery configuration.

[0044] Impellers 1606 and 1616 are also adapted and constructed such that one or more blades will stretch or radially compress to a reduced outermost dimension (measured orthogonally to the longitudinal axis of the working portion). For example without limitation, any of the impellers herein can include one or more blades made from a plastic formulation with spring characteristics, such as any of the impellers described in U.S. Pat. No. 7,393,181, the disclosure of which is incorporated by reference herein for all purposes and can be incorporated into embodiments herein unless this disclosure indicates to the contrary. Alternatively, for example, one or more collapsible impellers can comprise a superelastic wire frame, with polymer or other material that acts as a webbing across the wire frame, such as those described in U.S. Pat. No. 6,533,716, the disclosure of which is incorporated by reference herein for all purposes.

[0045] The inflow and/or outflow configurations of working portion 1600 can be mostly axial in nature.

[0046] Exemplary sheathing and unsheathing techniques and concepts to collapse and expand medical devices are known, such as, for example, those described and shown in U.S. Pat. No. 7,841,976 or U.S. Pat. No. 8,052,749, the disclosures of which are incorporated by reference herein.

[0047] Figure 2 is a side view illustrating a deployed configuration (shown extracorporally) of a distal portion of an exemplary embodiment of a fluid movement system. Exemplary system 1100 includes working portion 1104 (which as set forth herein may also be referred to herein as a pump portion) and an elongate portion 1106 extending from working portion 1104. Elongate portion 1106 can extend to a more proximal region of the system, not shown for clarity, and that can include, for example, a motor. Working portion 1104 includes first expandable member 1108 and second expandable member 1110, axially spaced apart along a longitudinal axis LA of working portion 1104. Spaced axially in this context refers to the entire first expandable member being axially spaced from the entire second expandable member along a longitudinal axis LA of working portion 1104. A first end 1122 of first expandable member 1108 is axially spaced from a first end 1124 of second expandable member 1110.

[0048] First and second expandable members 1108 and 1110 generally each include a plurality of elongate segments disposed relative to one another to define a plurality of apertures 1130, only one of which is labeled in the second expandable member 1110. The expandable members can have a wide variety of configurations and can be constructed in a wide variety of ways, such as any of the configurations or constructions in, for example without limitation, U.S. Pat. No. 7,841,976, or the tube in 6,533,716, which is described as a self-expanding metal endoprosthetic material. For example, without limitation, one or both of the expandable members can have a braided construction or can be at least partially formed by laser cutting a tubular element.

[0049] Working portion 1104 also includes conduit 1112 that is coupled to first expandable member 1108 and to second expandable member 1110, and extends axially in between first expandable member 1108 and second expandable member 1110 in the deployed configuration. A central region 1113 of conduit 1112 spans an axial distance 1132 where the working portion is void of first and second expandable members 1108 and 1110. Central region 1113 can be considered to be axially in between the expandable members. Distal end 1126 of conduit 1112 does not extend as far distally as a distal end 1125 of second expandable member 1110, and proximal end of conduit 1128 does not extend as far proximally as proximal end 1121 of first expandable member 1108.

[0050] When the disclosure herein refers to a conduit being coupled to an expandable member, the term coupled in this context does not require that the conduit be directly attached to the expandable member so that conduit physically contacts the expandable member. Even if not directly attached, however, the term coupled in this context refers to the conduit and the expandable member being joined together such that as the expandable member expands or collapses, the conduit also begins to transition to a different configuration and/or size. Coupled

in this context therefore refers to conduits that will move when the expandable member to which it is coupled transitions between expanded and collapsed configurations.

[0051] Any of the conduits herein can be deformable to some extent. For example, conduit 1112 includes elongate member 1120 that can be made of one or more materials that allow the central region 1113 of conduit to deform to some extent radially inward (towards LA) in response to, for example and when in use, forces from valve tissue (e.g., leaflets) or a replacement valve as working portion 1104 is deployed towards the configuration shown in figure 2. The conduit may be stretched tightly between the expandable members in some embodiments. The conduit may alternatively be designed with a looseness that causes a greater degree of compliance. This can be desirable when the working portion is disposed across fragile structures such as an aortic valve, which may allow the valve to compress the conduit in a way that minimizes point stresses in the valve. In some embodiments, the conduit may include a membrane attached to the proximal and distal expandable members. Exemplary materials that can be used for any conduits herein include, without limitations, polyurethane rubber, silicone rubber, acrylic rubber, expanded polytetrafluoroethylene, polyethylene, polyethylene terephthalate, including any combination thereof.

[0052] Any of the conduits herein can have a thickness of, for example, .5 - 20 thousandths of an inch (thou), such as 1-15 thou, or 1.5 to 15 thou, 1.5 to 10 thou, or 2 to 10 thou.

[0053] Any of the conduits herein, or at least a portion of the conduit, can be impermeable to blood. In figure 2, working portion 1104 includes a lumen that extends from distal end 1126 of conduit 1112 and extends to proximal end 1128 of conduit 1112. The lumen is defined by conduit 1112 in central region 1113, but can be thought of being defined by both the conduit and portions of the expandable members in regions axially adjacent to central region 1113. In this embodiment, however, it is the conduit material that causes the lumen to exist and prevents blood from passing through the conduit.

[0054] Any of the conduits herein that are secured to one or more expandable members can be, unless indicated to the contrary, secured so that the conduit is disposed radially outside of one or more expandable members, radially inside of one or more expandable members, or both, and the expandable member can be impregnated with the conduit material.

[0055] The proximal and distal expandable members help maintain the conduit in an open configuration to create the lumen, while each also creates a working environment for an impeller, described below. Each of the expandable members, when in the deployed configuration, is maintained in a spaced relationship relative to a respective impeller, which allows the impeller to rotate within the expandable member without contacting the expandable member. Working portion 1104 includes first impeller 1116 and second impeller 1118, with first impeller 1116

disposed radially within first expandable member 1108 and second impeller 1118 disposed radially within second expandable member 1110. In this embodiment, the two impellers even though they are distinct and separate impellers, are in operable communication with a common drive mechanism (e.g., drive cable 1117), such that when the drive mechanism is activated the two impellers rotate together. In this deployed configuration, impellers 1116 and 1118 are axially spaced apart along longitudinal axis LA, just as are the expandable members 1108 and 1110 are axially spaced apart.

[0056] Impellers 1116 and 1118 are also axially within the ends of expandable members 1108 and 1110, respectively (in addition to being radially within expandable members 1108 and 1110). The impellers herein can be considered to be axially within an expandable member even if the expandable member includes struts extending from a central region of the expandable member towards a longitudinal axis of the working portion (e.g., tapering struts in a side view). In figure 2, second expandable member 1110 extends from first end 1124 (proximal end) to second end 1125 (distal end).

[0057] In figure 2, a distal portion of impeller 1118 extends distally beyond distal end 1126 of conduit 1112, and a proximal portion of impeller 1116 extends proximally beyond proximal end 1128 of conduit 1112. In this figure, portions of each impeller are axially within the conduit in this deployed configuration.

[0058] In the exemplary embodiment shown in figure 2, impellers 1116 and 1118 are in operable communication with a common drive mechanism 1117, and in this embodiment, the impellers are each coupled to drive mechanism 1117, which extends through shaft 1119 and working portion 1104. Drive mechanism 1117 can be, for example, an elongate drive cable, which when rotated causes the impellers to rotate. In this example, as shown, drive mechanism 1117 extends to and is axially fixed relative to distal tip 1114, although it is adapted to rotate relative to distal tip 1114 when actuated. Thus, in this embodiment, the impellers and drive mechanism 1117 rotate together when the drive mechanism is rotated. Any number of known mechanisms can be used to rotate drive mechanism, such as with a motor (e.g., an external motor).

[0059] The expandable members and the conduit are not in rotational operable communication with the impellers and the drive mechanism. In this embodiment, proximal end 1121 of proximal expandable member 1108 is coupled to shaft 1119, which may be a shaft of elongate portion 1106 (e.g., an outer catheter shaft). Distal end 1122 of proximal expandable member 1108 is coupled to central tubular member 1133, through which drive mechanism 1117 extends. Central tubular member 1133 extends distally from proximal expandable member 1108 within conduit 1112 and is also coupled to proximal end 1124 of distal expandable member 1110. Drive mechanism 1117 thus rotates within and relative to central tubular member 1133. Central

tubular member 1133 extends axially from proximal expandable member 1108 to distal expandable member 1110. Distal end 1125 of distal expandable member 1110 is coupled to distal tip 1114, as shown. Drive mechanism 1117 is adapted to rotate relative to tip 1114, but is axially fixed relative to tip 1114.

[0060] Working portion 1104 is adapted and configured to be collapsed to a smaller profile than its deployed configuration (which is shown in figure 2). This allows it to be delivered using a lower profile delivery device (smaller French size) than would be required if none of working portion 1104 was collapsible. Even if not specifically stated herein, any of the expandable members and impellers may be adapted and configured to be collapsible to some extent to a smaller delivery configuration.

[0061] The working portions herein can be collapsed to a collapsed delivery configuration using conventional techniques, such as with an outer sheath that is movable relative to the working portion (e.g., by axially moving one or both of the sheath and working portion). For example without limitation, any of the systems, devices, or methods shown in the following references may be used to facilitate the collapse of a working portions herein: U.S. Pat. No. 7841,976 or U.S. Pat. No. 8,052,749, the disclosures of which are incorporated by reference herein for all purposes.

[0062] Figures 3A-3E show an exemplary working portion that is similar in some ways to the working portion shown in figure 2. Working portion 340 is similar to working portion 1104 in that in includes two expandable members axially spaced from one another when the working portion is expanded, and a conduit extending between the two expandable members. Figure 3A is a perspective view, figure 3B is a side sectional view, and figures 3C and 3D are close-up side sectional views of sections of the view in figure 3B.

[0063] Working portion 340 includes proximal impeller 341 and distal impeller 342, which are coupled to and in operational communication with a drive cable, which defines therein a lumen. The lumen can be sized to accommodate a guidewire, which can be used for delivery of the working portion to the desired location. The drive cable, in this embodiment, includes first section 362 (e.g., wound material), second section 348 (e.g., tubular member) to which proximal impeller 341 is coupled, third section 360 (e.g., wound material), and fourth section 365 (e.g., tubular material) to which distal impeller 342 is coupled. The drive cable sections all have the same inner diameter, so that lumen has a constant inner diameter. The drive cable sections can be secured to each other using known attachment techniques. A distal end of fourth section 365 extends to a distal region of the working portion, allowing the working portion to be, for example, advanced over a guidewire for positioning the working portion. In this embodiment the second and fourth sections can be stiffer than first and third sections. For example, second

and fourth can be tubular and first and third sections can be wound material to impart less stiffness.

[0064] Working portion 340 includes proximal expandable member 343 and distal expandable member 344, each of which extends radially outside of one of the impellers. The expandable members have distal and proximal ends that also extend axially beyond distal and proximal ends of the impellers, which can be seen in figures 3B-3D. Coupled to the two expandable members is conduit 356, which has a proximal end 353 and a distal end 352. The two expandable members each include a plurality of proximal struts and a plurality of distal struts. The proximal struts in proximal expandable member 343 extend to and are secured to shaft section 345, which is coupled to bearing 361, through which the drive cable extends and is configured and sized to rotate. The distal struts of proximal expandable member 343 extend to and are secured to a proximal region (to a proximal end in this case) of central tubular member 346, which is disposed axially in between the expandable members. The proximal end of central tubular member 346 is coupled to bearing 349, as shown in figure 3C, through which the drive cable extends and rotates. The proximal struts of distal expandable member 344 extend to and secured to a distal region (to a distal end in this case) of central tubular member 346. Bearing 350 is also coupled to the distal region of central tubular member 346, as is shown in figure 3D. The drive cable extends through and rotates relative to bearing 350. Distal struts of distal expandable member extend to and are secured to shaft section 347 (see fig. 3A), which can be considered part of the distal tip. Shaft section 347 is coupled to bearing 351 (see fig. 3D), through which the drive cable extends and rotates relative to. The distal tip also includes bearing 366 (see figure 3D), which can be a thrust bearing. Working portion 340 can be similar to or the same in some aspects to working portion 1104, even if not explicitly included in the description. In this embodiment, conduit 356 extends at least as far as ends of the impeller, unlike in working portion 1104. Either embodiment can be modified so that the conduit extends to a position as set forth in the other embodiment. In some embodiments, section 360 can be a tubular section instead of wound.

[0065] In alternative embodiments, at least a portion of any of the impellers herein may extend outside of the fluid lumen. For example, only a portion of an impeller may extend beyond an end of the fluid lumen in either the proximal or distal direction. In some embodiments, a portion of an impeller that extends outside of the fluid lumen is a proximal portion of the impeller, and includes a proximal end (e.g., see the proximal impeller in figure 2). In some embodiments, the portion of the impeller that extends outside of the fluid lumen is a distal portion of the impeller, and includes a distal end (e.g., see the distal impeller in figure 2). When the disclosure herein refers to impellers that extend outside of the fluid lumen (or beyond an end), it is meant to refer

to relative axial positions of the components, which can be most easily seen in side views or top views, such as in figure 2.

[0066] A second impeller at another end of the fluid lumen may not, however, extend beyond the fluid lumen. For example, an illustrative alternative design can include a proximal impeller that extends proximally beyond a proximal end of the fluid lumen (like the proximal impeller in figure 2), and the fluid lumen does not extend distally beyond a distal end of a distal impeller (like in figure 3B). Alternatively, a distal end of a distal impeller can extend distally beyond a distal end of the fluid lumen, but a proximal end of a proximal impeller does not extend proximally beyond a proximal end of the fluid lumen. In any of the pump portions herein, none of the impellers may extend beyond ends of the fluid lumen.

[0067] While specific exemplary locations may be shown herein, the fluid pumps may be able to be used in a variety of locations within a body. Some exemplary locations for placement include placement in the vicinity of an aortic valve or pulmonary valve, such as spanning the valve and positioned on one or both sides of the valve, and in the case of an aortic valve, optionally including a portion positioned in the ascending aorta. In some other embodiments, for example, the pumps may be, in use, positioned further downstream, such as being disposed in a descending aorta.

[0068] Figure 4 illustrates an exemplary placement of working portion 1104 from system 1000 from figure 2. Once difference shown in figure 4 is that the conduit extends at least as far as the ends of the impellers, like in figures 3A-3D. Figure 4 shows working portion 1104 in a deployed configuration, positioned in place across an aortic valve. Working portion 1104 can be delivered as shown via, for example without limitation, femoral artery access (a known access procedure). While not shown for clarity, system 1000 can also include an outer sheath or shaft in which working portion 1104 is disposed during delivery to a location near an aortic valve. The sheath or shaft can be moved proximally (towards the ascending aorta "AA" and away from left ventricle "LV") to allow for deployment and expansion of working portion 1104. For example, the sheath can be withdrawn to allow for expansion of second expandable member 1110, with continued proximal movement allowing first expandable member 1108 to expand.

[0069] In this embodiment, second expandable member 1110 has been expanded and positioned in a deployed configuration such that distal end 1125 is in the left ventricle "LV," and distal to aortic valve leaflets "VL," as well as distal to the annulus. Proximal end 1124 has also been positioned distal to leaflets VL, but in some methods proximal end 1124 may extend slightly axially within the leaflets VL. This embodiment is an example of a method in which at least half of the second expandable member 1110 is within the left ventricle, as measured along its length (measured along the longitudinal axis). And as shown, this is also an example of a method in

which the entire second expandable member 1110 is within the left ventricle. This is also an example of a method in which at least half of second impeller 1118 is positioned within the left ventricle, and also an embodiment in which the entire second impeller 1118 is positioned within the left ventricle.

[0070] Continued retraction of an outer shaft or sheath (and/or distal movement of working end 1104 relative to an outer sheath or shaft) continues to release conduit 1112, until central region 1113 is released and deployed. The expansion of expandable members 1108 and 1110 causes conduit 1112 to assume a more open configuration, as shown in figure 4. Thus, while in this embodiment conduit 1112 does not have the same self-expanding properties as the expandable members, the conduit will assume a deployed, more open configuration when the working end is deployed. At least a portion of central region 1113 of conduit 1112 is positioned at an aortic valve coaptation region. In figures 3, there is a short length of central region 1113 that extends distally beyond the leaflets VL, but at least some portion of central region 1113 is axially within the leaflets.

[0071] Continued retraction of an outer shaft or sheath (and/or distal movement of working end 1104 relative to an outer sheath or shaft) deploys first expandable member 1108. In this embodiment, first expandable member 1108 has been expanded and positioned (as shown) in a deployed configuration such that proximal end 1121 is in the ascending aorta AA, and proximal to leaflets "VL." Distal end 1122 has also been positioned proximal to leaflets VL, but in some methods distal end 1122 may extend slightly axially within the leaflets VL. This embodiment is an example of a method in which at least half of first expandable member 1110 is within the ascending aorta, as measured along its length (measured along the longitudinal axis). And as shown, this is also an example of a method in which the entire first expandable member 1110 is within the AA. This is also an example of a method in which at least half of first impeller 1116 is positioned within the AA, and also an embodiment in which the entire first impeller 1116 is positioned within the AA.

[0072] At any time during or after deployment of working portion 1104, the position of the working portion can be assessed in any way, such as under fluoroscopy. The position of the working portion can be adjusted at any time during or after deployment. For example, after second expandable member 1110 is released but before first expandable member 1108 is released, working portion 1104 can be moved axially (distally or proximally) to reposition the working portion. Additionally, for example, the working portion can be repositioned after the entire working portion has been released from a sheath to a desired final position.

[0073] It is understood that the positions of the components (relative to the anatomy) shown in figure 4 are considered exemplary final positions for the different components of working portion 1104, even if there was repositioning that occurred after initial deployment.

[0074] The one or more expandable members herein can be configured to be, and can be expanded in a variety of ways, such as via self-expansion, mechanical actuation (e.g., one or more axially directed forces on the expandable member, expanded with a separate balloon positioned radially within the expandable member and inflated to push radially outward on the expandable member), or a combination thereof.

[0075] Expansion as used herein refers generally to reconfiguration to a larger profile with a larger radially outermost dimension (relative to the longitudinal axis), regardless of the specific manner in which the one or more components are expanded. For example, a stent that self-expands and/or is subject to a radially outward force can "expand" as that term is used herein. A device that unfurls or unrolls can also assume a larger profile, and can be considered to expand as that term is used herein.

[0076] The impellers can similarly be adapted and configured to be, and can be expanded in a variety of ways depending on their construction. For examples, one or more impellers can, upon release from a sheath, automatically revert to or towards a different larger profile configuration due to the material(s) and/or construction of the impeller design (see, for example, U.S. Pat. No. 6,533,716, or U.S. Pat. No. 7,393,181, both of which are incorporated by reference herein for all purposes). Retraction of an outer restraint can thus, in some embodiments, allow both the expandable member and the impeller to revert naturally to a larger profile, deployed configuration without any further actuation.

[0077] As shown in the example in figure 4, the working portion includes first and second impellers that are spaced on either side of an aortic valve, each disposed within a separate expandable member. This is in contrast to some designs in which a working portion includes a single elongate expandable member. Rather than a single generally tubular expandable member extending all the way across the valve, working end 1104 includes a conduit 1112 extending between expandable members 1108 and 1110. The conduit is more flexible and deformable than the expandable baskets, which can allow for more deformation of the working portion at the location of the leaflets than would occur if an expandable member spanned the aortic valve leaflets. This can cause less damage to the leaflets after the working portion has been deployed in the subject.

[0078] Additionally, forces on a central region of a single expandable member from the leaflets might translate axially to other regions of the expandable member, perhaps causing undesired deformation of the expandable member at the locations of the one or more impellers. This may

cause the outer expandable member to contact the impeller, undesirably interfering with the rotation of the impeller. Designs that include separate expandable members around each impeller, particularly where each expandable member and each impeller are supported at both ends (i.e., distal and proximal), result in a high level of precision in locating the impeller relative to the expandable member. Two separate expandable members may be able to more reliably retain their deployed configurations compared with a single expandable member.

[0079] As described herein above, it may be desirable to be able to reconfigure the working portion so that it can be delivered within a 9F sheath and still obtain high enough flow rates when in use, which is not possible with some products currently in development and/or testing. For example, some products are too large to be able to reconfigured to a small enough delivery profile, while some smaller designs may not be able to achieve the desired high flow rates. An exemplary advantage of the examples in figures 1, 2, 3A-3D and 4 is that, for example, the first and second impellers can work together to achieve the desired flow rates, and by having two axially spaced impellers, the overall working portion can be reconfigured to a smaller delivery profile than designs in which a single impeller is used to achieved the desired flow rates. These embodiments thus use a plurality of smaller, reconfigurable impellers that are axially spaced to achieve both the desired smaller delivery profile as well as to achieve the desired high flow rates.

[0080] The embodiment herein can thus achieve a smaller delivery profile while maintaining sufficiently high flow rates, while creating a more deformable and flexible central region of the working portion, the exemplary benefits of which are described above (e.g., interfacing with delicate valve leaflets).

[0081] Figure 5 illustrates a working portion that is similar to the working portion shown in figure 1. Working portion 265 includes proximal impeller 266, distal impeller 267, both of which are coupled to drive shaft 278, which extends into distal bearing housing 272. There is a similar proximal bearing housing at the proximal end of the working portion. Working portion also includes expandable member, referred to 270 generally, and conduit 268 that is secured to the expandable member and extends almost the entire length of expandable member. Expandable member 270 includes distal struts 271 that extend to and are secured to strut support 273, which is secured to distal tip 273. Expandable member 270 also includes proximal struts there are secured to a proximal strut support. All features similar to that shown in figure 1 are incorporated by reference for all purposes into this embodiment even if not explicitly stated. Expandable member 265 also includes helical tension member 269 that is disposed along the periphery of the expandable member, and has a helical configuration when the expandable member is in the expanded configuration as shown. The helical tension member 269 is disposed and adapted to induce rotation wrap upon collapse. Working portion 265 can be collapsed from the shown

expanded configuration while simultaneously rotating one or both impellers at a relatively slow speed to facilitate curled collapse of the impellers due to interaction with the expandable member. Helical tension member 269 (or a helical arrangement of expandable member cells) will act as a collective tension member and is configured so that when the expandable basket is pulled in tension along its length to collapse (such as by stretching to a much greater length, such as approximately doubling in length) tension member 269 is pulled into a straighter alignment, which causes rotation/twisting of the desired segment(s) of the expandable member during collapse, which causes the impeller blades to wrap radially inward as the expandable member and blades collapse. An exemplary configuration of such a tension member would have a curvilinear configuration when in helical form that is approximately equal to the maximum length of the expandable member when collapsed. In alternative embodiments, only the portion(s) of the expandable member that encloses a collapsible impeller is caused to rotate upon collapse.

[0082] There are alternative ways to construct the working portion to cause rotation of the expandable member upon collapse by elongation (and thus cause wrapping and collapse of the impeller blades). Any expandable member can be constructed with this feature, even in dual-impeller designs. For example, with an expandable member that includes a plurality of "cells," as that term is commonly known (e.g., a laser cut elongate member), the expandable member may have a plurality of particular cells that together define a particular configuration such as a helical configuration, wherein the cells that define the configuration have different physical characteristics than other cells in the expandable member. In some embodiments the expandable member can have a braided construction, and the twist region may constitute the entire group of wires, or a significant portion (e.g., more than half), of the braided wires. Such a twisted braid construction may be accomplished, for example, during the braiding process, such as by twisting the mandrel that the wires are braided onto as the mandrel is pulled along, especially along the length of the largest-diameter portion of the braided structure. The construction could also be accomplished during a second operation of the construction process, such as mechanically twisting a braided structure prior to heat-setting the wound profile over a shaped mandrel.

[0083] Any of the conduits herein act to, are configured to, and are made of material(s) that create a fluid lumen therein between an first end (e.g., distal end) and a second end (e.g., proximal end). Fluid flows into the inflow region, through the fluid lumen, and then out of an outflow region. Flow into the inflow region may be labeled herein as "I," and flow out at the outflow region may be labeled "O." Any of the conduits herein can be impermeable. Any of the conduits herein can alternatively be semipermeable. Any of the conduits herein may also be porous, but will still define a fluid lumen therethrough. In some embodiments the conduit is a

membrane, or other relatively thin layered member. Any of the conduits herein, unless indicated to the contrary, can be secured to an expandable member such that the conduit, where is it secured, can be radially inside and/or outside of the expandable member. For example, a conduit can extend radially within the expandable member so that inner surface of the conduit is radially within the expandable member where it is secured to the expandable member.

[0084] Any of the expandable member(s) herein can be constructed of a variety of materials and in a variety of ways. For example, the expandable member may have a braided construction, or it can be formed by laser machining. The material can be deformable, such as nitinol. The expandable member can be self-expanding or can be adapted to be at least partially actively expanded.

[0085] In some embodiments, the expandable member is adapted to self-expand when released from within a containing tubular member such as a delivery catheter, a guide catheter or an access sheath. In some alternative embodiments, the expandable member is adapted to expand by active expansion, such as action of a pull-rod that moves at least one of the distal end and the proximal end of the expandable member toward each other. In alternative embodiments, the deployed configuration can be influenced by the configuration of one or more expandable structures. In some embodiments, the one or more expandable members can deployed, at least in part, through the influence of blood flowing through the conduit. Any combination of the above mechanisms of expansion may be used.

[0086] The blood pumps and fluid movement devices, system and methods herein can be used and positioned in a variety of locations within a body. While specific examples may be provided herein, it is understood that that the working portions can be positioned in different regions of a body than those specifically described herein.

[0087] In any of the embodiments herein in which the medical device includes a plurality of impellers, the device can be adapted such that the impellers rotate at different speeds. Figure 6A illustrates a medical device that includes gearset 1340 coupled to both inner drive member 1338 and outer drive member 1336, which are in operable communication with distal impeller 1334 and proximal impeller 1332, respectively. The device also includes motor 1342, which drives the rotation of inner drive member 1338. Inner drive member 1338 extends through outer drive member 1336. Activation of the motor 1332 causes the two impellers to rotate at different speeds due to an underdrive or overdrive ratio. Gearset 1340 can be adapted to drive either the proximal or distal impeller faster than the other. Any of the devices herein can include any of the gearsets herein to drive the impellers at different speeds.

[0088] Figure 6B illustrates a portion of an alternative embodiment of a dual impeller device (1350) that is also adapted such that the different impellers rotate at different speeds. Gearset

1356 is coupled to both inner drive member 1351 and outer drive member 1353, which are coupled to distal impeller 1352 and proximal impeller 1354, respectively. The device also includes a motor like in figure 6A. Figure 6A and 6B illustrate how a gearset can be adapted to drive the proximal impeller slower or faster than the distal impeller.

[0089] Figure 7 shows an exemplary alternative embodiment of fluid pump 1370 that can rotate first and second impellers at different speeds. First motor 1382 drives cable 1376, which is coupled to distal impeller 1372, while second motor 1384 drives outer drive member 1378 (via gearset 1380), which is coupled to proximal impeller 1374. Drive cable 1376 extends through outer drive member 1378. The motors can be individually controlled and operated, and thus the speeds of the two impellers can be controlled separately. This system setup can be used with any system herein that includes a plurality of impellers.

[0090] In some embodiments, a common drive cable or shaft can drive the rotation of two (or more) impellers, but the blade pitch of the two impellers (angle of rotational curvature) can be different, with the distal or proximal impeller having a steeper or more gradual angle than the other impeller. This can produce a similar effect to having a gearset. Figure 6C shows a portion of a medical device (1360) that includes common drive cable 1366 coupled to proximal impeller 1364 and distal impeller 1362, and to a motor not shown. The proximal impellers herein can have a greater or less pitch than the distal impellers herein. Any of the working portions (or distal portions) herein with a plurality of impellers can be modified to include first and second impellers with different pitches.

[0091] In any of the embodiments herein, the pump portion can have a compliant or semi-compliant (referred to generally together as "compliant") exterior structure. In various embodiments, the compliant portion is pliable. In various embodiments, the compliant portion deforms only partially under pressure. For example, the central portion of the pump may be formed of a compliant exterior structure such that it deforms in response to forces of the valve. In this manner the exterior forces of the pump on the valve leaflets are reduced. This can help prevent damage to the valve at the location where it spans the valve.

[0092] Figure 8 illustrates an exemplary embodiment of a pump portion that includes first, second and third axially spaced impellers 152, each of which is disposed within an expandable member 154. Conduit 155 can extend along the length of the pump portion, as in described in various embodiments herein, which can help create and define the fluid lumen. In alternative embodiments, however, the first, second, and third impellers may be disposed within a single expandable member, similar to that shown in figure 1. In figure 8, a fluid lumen extends from a distal end to a proximal end, features of which are described elsewhere herein. The embodiment in figure 8 can include any other suitable feature, including methods of use, described herein.

[0093] The embodiment in figure 8 is also an example of an outer housing having at least one bend formed therein between a proximal impeller distal end and a distal impeller proximal end, such that a distal region of the housing distal to the bend is not axially aligned with a proximal region of the housing proximal to the bend along an axis. In this embodiment there are two bends 150 and 151 formed in the housing, each one between two adjacent impellers.

[0094] In a method of use, a bend formed in a housing can be positioned to span a valve, such as the aortic valve shown in figure 8. In this method of placement, a central impeller and distal-most impeller are positioned in the left ventricle, and a proximal-most impeller is positioned in the ascending aorta. Bend 151 is positioned just downstream to the aortic valve.

[0095] A bend such as bend 151 or 152 can be incorporated into any of the embodiments or designs herein. The bend may be a preformed angle or may be adjustable in situ.

[0096] In any of the embodiments herein, unless indicated to the contrary, the outer housing can have a substantially uniform diameter along its length.

[0097] In figure 8, the pump is positioned via the axillary artery, which is an exemplary method of accessing the aortic valve, and which allows the patient to walk and be active with less interruption. Any of the devices herein can be positioned via the axillary artery. One will appreciate from the description herein, however, that the pump may be introduced and tracked into position in various manner including a femoral approach over the aortic arch.

[0098] One aspect of the disclosure is an intravascular blood pump that includes a distal impeller axially spaced from a proximal impeller. In one embodiment, the distal and proximal impellers are separated from each other. For example, the distal and proximal impellers may be connected solely by their individual attachment to a common driveshaft. This is distinct from an impeller having multiple blade rows. A distal impeller as that phrase is used herein does not necessarily mean a distal-most impeller of the pump, but can refer generally to an impeller that is positioned further distally than a proximal impeller, even if there is an additional impeller than is disposed further distally than the distal impeller. Similarly, a proximal impeller as that phrase is used herein does not necessarily mean a proximal-most impeller of the pump, but can refer generally to an impeller that is positioned further proximally than a proximal impeller, even if there is an additional impeller than is disposed further proximally than the proximal impeller. Axial spacing (or some derivative thereof) refers to spacing along the length of a pump portion, such as along a longitudinal axis of the pump portion, even if there is a bend in the pump portion. In various embodiments, each of the proximal and distal impellers are positioned within respective housings and configured to maintain a precise, consistent tip gap, and the span between the impellers has a relatively more flexible (or completely flexible) fluid lumen. For example, each of the impellers may be positioned within a respective housing having relatively rigid outer wall

to resist radial collapse. The sections between the impellers may be relatively rigid, in some embodiments the section is held open primarily by the fluid pressure within.

[0099] Although not required for the embodiments therein, there may be advantages to having a minimum axial spacing between a proximal impeller and a distal impeller. For example, a pump portion may be delivered to a target location through parts of the anatomy that have relatively tight bends, such as, for example, an aorta, and down into the aortic valve. For example, a pump portion may be delivered through a femoral artery access and to an aortic valve. It can be advantageous to have a system that is easier to bend so that it is easier to deliver the system through the bend(s) in the anatomy. Some designs where multiple impellers are quite close to each other may make the system, along the length that spans the multiple impellers, relatively stiff along that entire length that spans the multiple impellers. Spacing the impellers apart axially, and optionally providing a relatively flexible region in between the impellers, can create a part of the system that is more flexible, is easier to bend, and can be advanced through the bends more easily and more safely. An additional exemplary advantage is that the axial spacing can allow for a relatively more compliant region between the impellers, which can be positioned at, for example, the location of a valve (e.g., an aortic valve). Furthermore, there are other potential advantages and functional differences between the various embodiments herein and typical multistage pumps. A typical multistage pump includes rows of blades (sometimes referred to as impellers) in close functional spacing such that the rows of blades act together as a synchronized stage. One will appreciate that the flow may separate as it passes through the distal impeller. In various embodiments as described herein, distal and proximal impellers can be spaced sufficiently apart such that the flow separation from the distal impeller is substantially reduced (i.e., increased flow reattachment) and the localized turbulent flow is dissipated before the flow enters the proximal impeller.

[0100] In any of the embodiments or in any part of the description herein that include a distal impeller and a proximal impeller, the axial spacing between a distal end of the proximal impeller and a proximal end of the distal impeller can be from 1.5 cm to 25 cm (inclusive) along a longitudinal axis of the pump portion, or along a longitudinal axis of a housing portion that includes a fluid lumen. The distance may be measured when the pump portion, including any impellers, is in an expanded configuration. This exemplary range can provide the exemplary flexibility benefits described herein as the pump portion is delivered through curved portions of the anatomy, such as, for example, an aortic valve via an aorta. Figure 9 (shown outside a patient in an expanded configuration) illustrates length Lc, which illustrates an axial spacing between impellers, and in some embodiments may be from 1.5 cm to 25 cm as set forth herein. In embodiments in which there may be more than two impellers, any two adjacent impellers (i.e.,

impellers that do not have any other rotating impeller in between them) may be spaced axially by any of the axial spacing distances described herein.

[0101] While some embodiments include a proximal impeller distal end that is axially spaced 1.5 cm to 25 cm from a distal impeller proximal end along an axis, the disclosure herein also includes any axial spacings that are subranges within that general range of 1.5 cm to 25 cm. That is, the disclosure includes all ranges that have any lower limit from 1.5 and above in that range, and all subranges that have any upper limit from 25 cm and below. The examples below provide exemplary subranges. In some embodiments, a proximal impeller distal end is axially spaced 1.5 cm to 20 cm from a distal impeller proximal end along an axis, 1.5 cm to 15 cm, 1.5 cm to 10 cm, 1.5 cm to 7.5 cm, 1.5 cm to 6 cm, 1.5 cm to 4.5 cm, 1.5 cm to 3 cm. In some embodiments the axial spacing is 2 cm to 20 cm, 2 cm to 15 cm, 2 cm to 12 cm, 2 cm to 10 cm, 2 cm to 7.5 cm, 2 cm to 6 cm, 2 cm to 4.5 cm, 2 cm to 3 cm. In some embodiments the axial spacing is 2.5 cm to 15 cm, 2.5 cm to 12.5 cm, 2.5 cm to 10 cm, 2.5 cm to 7.5 cm, or 2.5 cm to 5 cm (e.g., 3 cm). In some embodiments the axial spacing is 3 cm to 20 cm, 3 cm to 15 cm, 3 cm to 10 cm, 3 cm to 7.5 cm, 3 cm to 6 cm, or 3 cm to 4.5 cm. In some embodiments the axial spacing is 4 cm to 20 cm, 4 cm to 15 cm, 4 cm to 10 cm, 4 cm to 7.5 cm, 4 cm to 6 cm, or 4 cm to 4.5 cm. In some embodiments the axial spacing is 5 cm to 20 cm, 5 cm to 15 cm, 5 cm to 10 cm, 5 cm to 7.5 cm, or 5 cm to 6 cm. In some embodiments the axial spacing is 6 cm to 20 cm, 6 cm to 15 cm, 6 cm to 10 cm, or 6 cm to 7.5 cm. In some embodiments the axial spacing is 7 cm to 20 cm, 7 cm to 15 cm, or 7 cm to 10 cm. In some embodiments the axial spacing is 8 cm to 20 cm, 8 cm to 15 cm, or 8 cm to 10 cm. In some embodiments the axial spacing is 9 cm to 20 cm, 9 cm to 15 cm, or 9 cm to 10 cm. In various embodiments, the fluid lumen between the impellers is relatively unsupported.

[0102] In any of the embodiments herein the one or more impellers may have a length, as measured axially between an impeller distal end and an impeller proximal end (shown as "L_{SD}" and "L_{SP}", respectively, in figure 9), from .5 cm to 10 cm, or any subrange thereof. The examples below provides exemplary subranges. In some embodiments the impeller axial length is from .5 cm to 7.5 cm, from .5 cm to 5 cm, from .5 cm to 4 cm, from .5 cm to 3 cm, from .5 cm to 2, or from .5 cm to 1.5 cm. In some embodiments the impeller axial length is from .8 cm to 7.5 cm, from .8 cm to 5 cm, from .8 cm to 4 cm, from .8 cm to 3 cm, from .8 cm to 2 cm, or from .8 cm to 1.5 cm. In some embodiments the impeller axial length is from 1 cm to 7.5 cm, from 1 cm to 5 cm, from 1 cm to 4 cm, from 1 cm to 3 cm, from 1 cm to 2 cm, or from 1 cm to 1.5 cm. In some embodiments the impeller axial length is from 1.2 cm to 7.5 cm, from 1.2 cm to 5 cm, from 1.2 cm to 4 cm, from 1.2 cm to 3 cm, from 1.2 to 2 cm, or from 1.2 cm to 1.5 cm. In some embodiments the impeller axial length is from 1.5 cm to 7.5 cm, from 1.5 cm to 5 cm, from 1.5

cm to 4 cm, from 1.5 cm to 3 cm, or from 1.5 cm to 2 cm. In some embodiments the impeller axial length is from 2 cm to 7.5 cm, from 2 cm to 5 cm, from 2 cm to 4 cm, or from 2 cm to 3cm. In some embodiments the impeller axial length is from 3 cm to 7.5 cm, from 3 cm to 5 cm, or from 3 cm to 4 cm. In some embodiments the impeller axial length is from 4 cm to 7.5 cm, or from 4 cm to 5 cm.

[0103] In any of the embodiments herein the fluid lumen can have a length from a distal end to a proximal end, shown as length Lp in figure 9. In some embodiments the fluid lumen length Lp is from 4 cm to 40 cm, or any subrange therein. For example, in some embodiments the length Lp can be from 4 cm to 30 cm, from 4 cm to 20 cm, from 4 cm to 18 cm, from 4 cm to 16 cm, from 4 cm to 14 cm, from 4 cm to 12 cm, from 4 cm to 10 cm, from 4 cm to 8 cm, from 4 cm to 6 cm.

[0104] In any of the embodiments herein the housing can have a deployed diameter, at least the location of an impeller (and optionally at a location between impellers), shown as dimension Dp in figure 9. In some embodiments Dp can be from .3 cm to 1.5 cm, or any subrange therein. For example, Dp may be from .4 cm to 1.4 cm, from .4 cm to 1.2 cm, from .4 cm to 1.0 cm, from .4 cm to .8 cm, or from .4 cm to .6 cm. In some embodiments, Dp may be from .5 cm to 1.4 cm, from .5 cm to 1.2 cm, from .5 cm to 1.0 cm, from .5 cm to .8 cm, or from .5 cm to .6 cm. In some embodiments Dp may be from .6 cm to 1.4 cm, from .6 cm to 1.2 cm, from .6 cm to 1.0 cm, or from .6 cm to .8 cm. In some embodiments Dp may be from .7 cm to 1.4 cm, from .7 cm to 1.2 cm, from .7 cm to 1.0 cm, or from .7 cm to .8 cm.

[0105] In any of the embodiments herein an impeller can have a deployed diameter, shown as dimension Di in figure 9. In some embodiments Di can be from 1 mm – 30 mm, or any subrange therein. For example, in some embodiments Di may be from 1 mm – 15 mm, from 2 mm – 12 mm, from 2.5 mm – 10 mm, or 3 mm – 8mm.

[0106] In any of the embodiments herein, a tip gap exists between an impeller outer diameter and a fluid lumen inner diameter. In some embodiments the tip gap can be from 0.01 mm – 1mm, such as .05 mm to .8 mm, or such as 0.1 mm – 0.5 mm.

[0107] In any of the embodiments herein, at least one of a flow diffuser or diffusers and a stator or stators is/are located between two or more impellers along the catheter shaft. Such a flow diffuser may help to reduce swirl of the fluid and overall increase the efficiency of the multiple impellers as a group.

[0108] In any of the embodiments herein, features at the fluid exit of an expandable shroud basket or expandable member are shaped to act as a flow diffuser, such as stent-like struts at the attachments between the catheter shaft outer dimension and the expandable member outer dimension, which can be blade-shaped with a twist directed to change the flow direction of blood. In any of the embodiments herein, one or more portions of the catheter shaft downstream

of an impeller may flare to a larger diameter to change the angle of blood flow and cause deceleration of the blood flow to a speed closer to native aortic blood flow. Exemplary locations for a larger diameter downstream of an impeller would be at or near the area where an expandable shroud basket attaches to the catheter shaft, and/or at a bearing housing adjacent the impeller, or on or adjacent an internal motor.

Claims

1. An intravascular blood pump, comprising:

a collapsible housing comprising a fluid lumen, the fluid lumen having a distal end and a proximal end;

a collapsible distal impeller axially spaced from a collapsible proximal impeller, at least a portion of the distal impeller and the proximal impeller disposed axially between the distal end and the proximal end of the fluid lumen,

wherein the distal impeller has an expanded configuration in an expanded state, and the proximal impeller has an expanded configuration in an expanded state, and

wherein the expanded configuration of the distal impeller is different than the expanded configuration of the proximal impeller.

2. A blood pump of claim 1, wherein the collapsible distal impeller has a distal blade and the proximal impeller has a proximal blade, wherein the distal blade has a different pitch than the proximal blade.

3. A blood pump of claim 2, wherein the distal blade is one of a plurality of distal blades, and wherein the proximal blade is one of a plurality of proximal blades, wherein the plurality of distal blades have a different pitch than each of the plurality of proximal blades.

4. A blood pump of claim 2, wherein the proximal impeller is shaped, dimensioned and positioned to provide predominantly centrifugal flow and the distal impeller is shaped and dimensioned to provide predominantly axial flow.

5. A blood pump of claim 1, wherein distal impeller and proximal impeller are adapted and configured to move fluid in the same direction.

6. An intravascular blood pump, comprising:

a collapsible housing comprising a fluid lumen, the fluid lumen having a distal end and a proximal end;

a collapsible distal impeller axially spaced from a collapsible proximal impeller, at least a portion of the distal impeller disposed axially between the distal end and the proximal end of the fluid lumen,

wherein a proximal end of the proximal impeller is, when the collapsible housing is in an expanded configuration and when the collapsible proximal impeller is in an expanded configuration, disposed proximal to the proximal end of the fluid lumen.

7. The blood pump of claim 6, wherein a distal end of the distal impeller is, when the collapsible housing is in the expanded configuration and when the collapsible distal impeller is in an expanded configuration, disposed no further distally than the distal end of the fluid lumen.

8. A method of positioning an intravascular blood pump in a subject, comprising:

positioning a pump housing fluid lumen first end in a left ventricle;

positioning a distal impeller of the blood pump in the left ventricle;

positioning a proximal impeller of the blood pump in an ascending aorta;

positioning a pump housing fluid lumen second end in the ascending aorta;

positioning at least a portion of a central region of the fluid lumen across an aortic valve, the central region extending between a distal end of the proximal impeller and a proximal end of the distal impeller,

creating a flow path between the fluid lumen first end positioned in the left ventricle and the fluid lumen second end positioned in the ascending aorta such that the distal impeller and the proximal impeller can pump blood through the fluid lumen.

9. The method of claim 8, further comprising creating axial flow at the distal impeller by activating the distal impeller, and creating outflow of the blood pump that has a centrifugal component and an axial component by activating the proximal impeller.

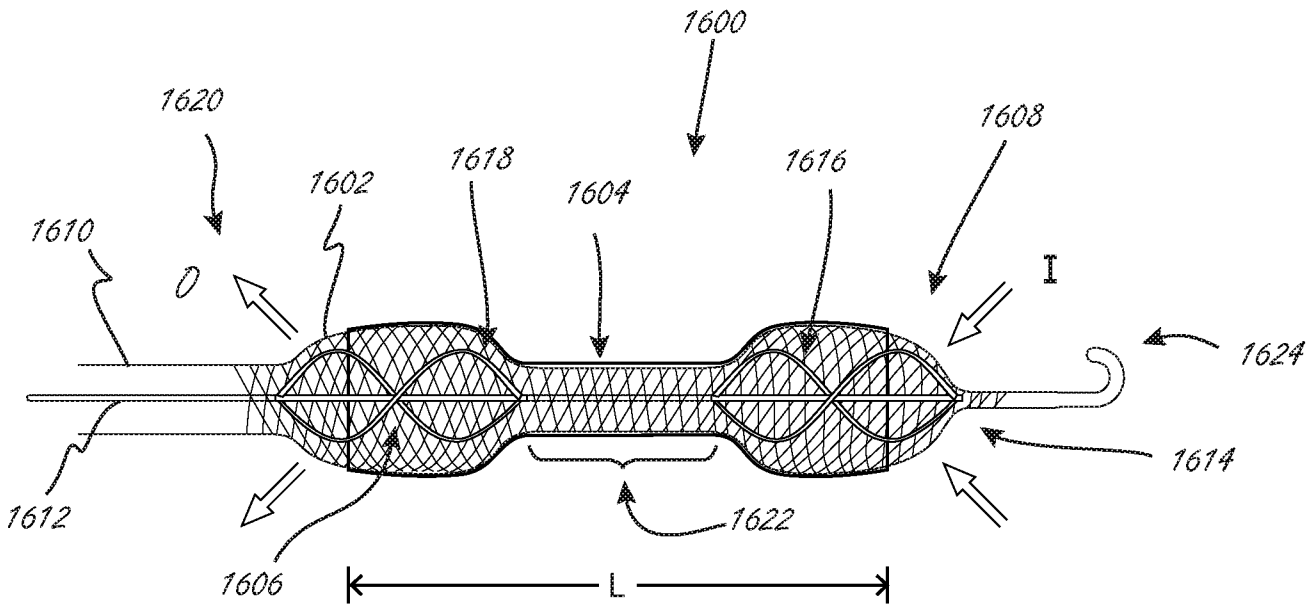

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Fig. 1

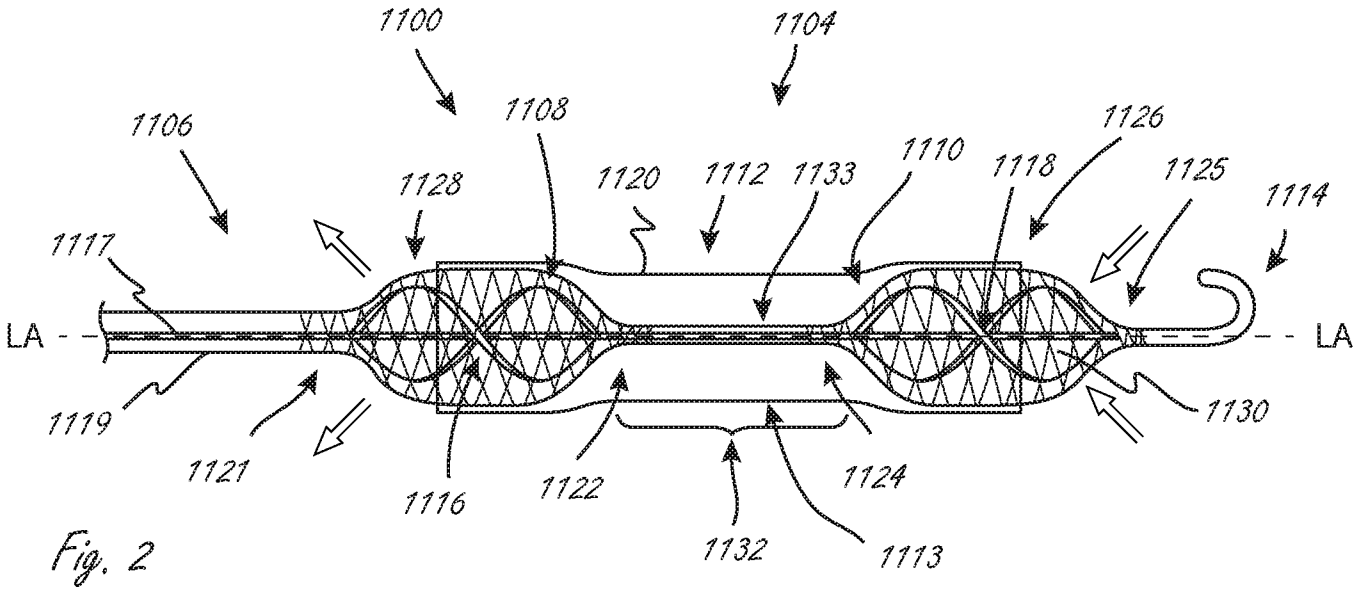

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Fig. 2

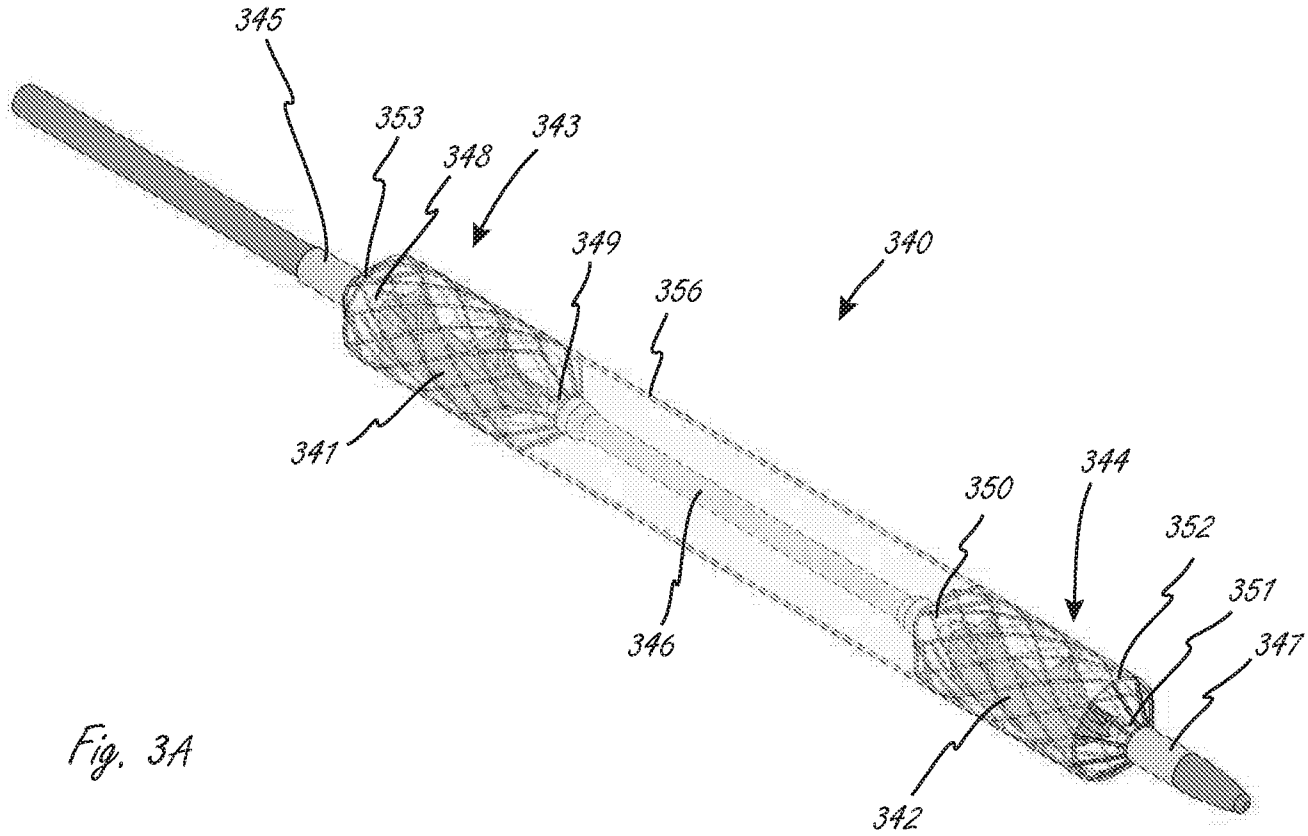

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Fig. 3A

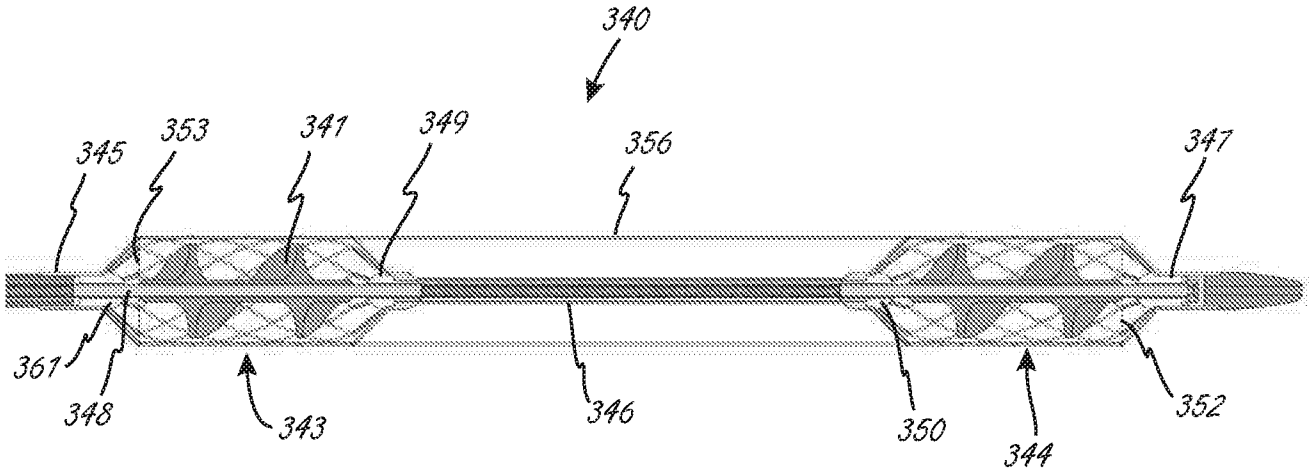

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Fig. 3B

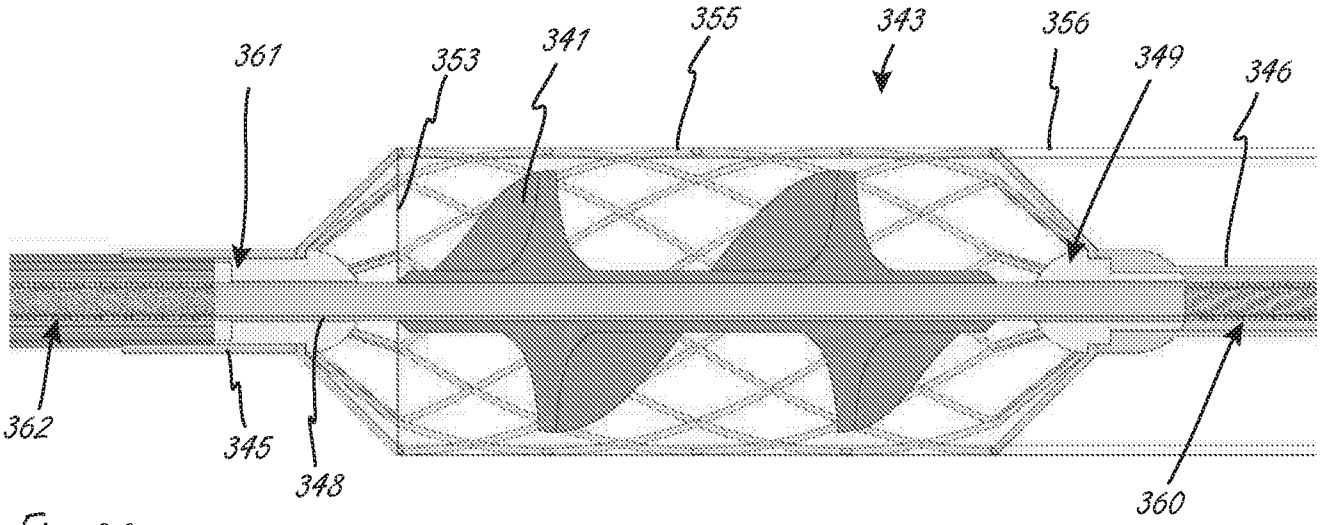

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Fig. 3C

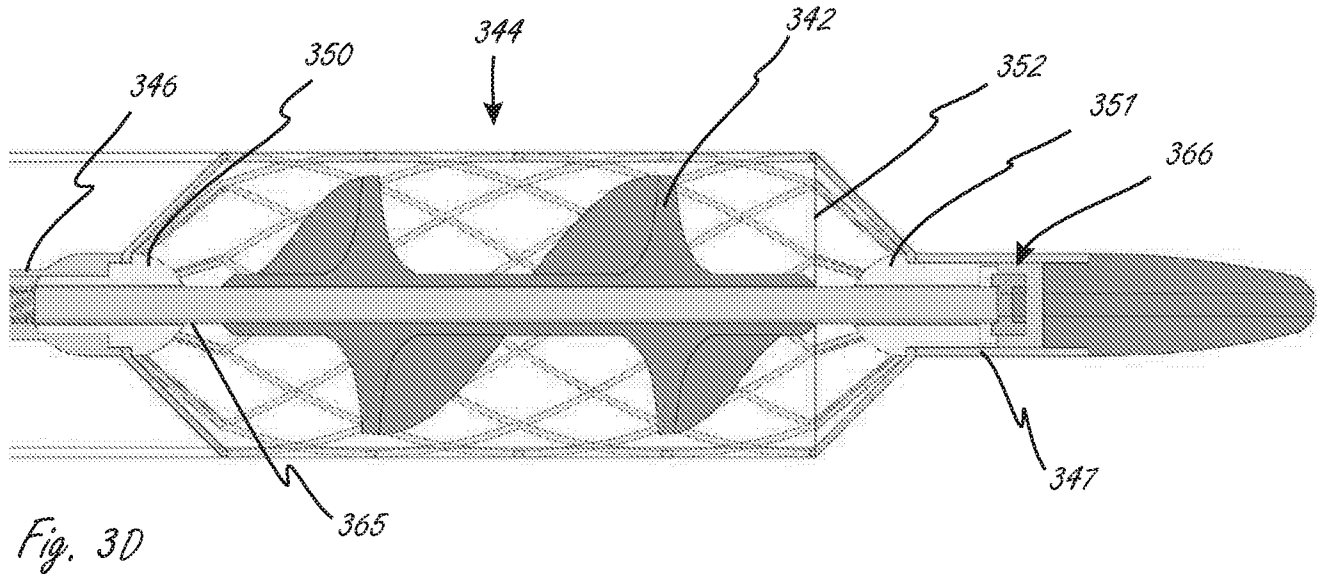

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Fig. 3D

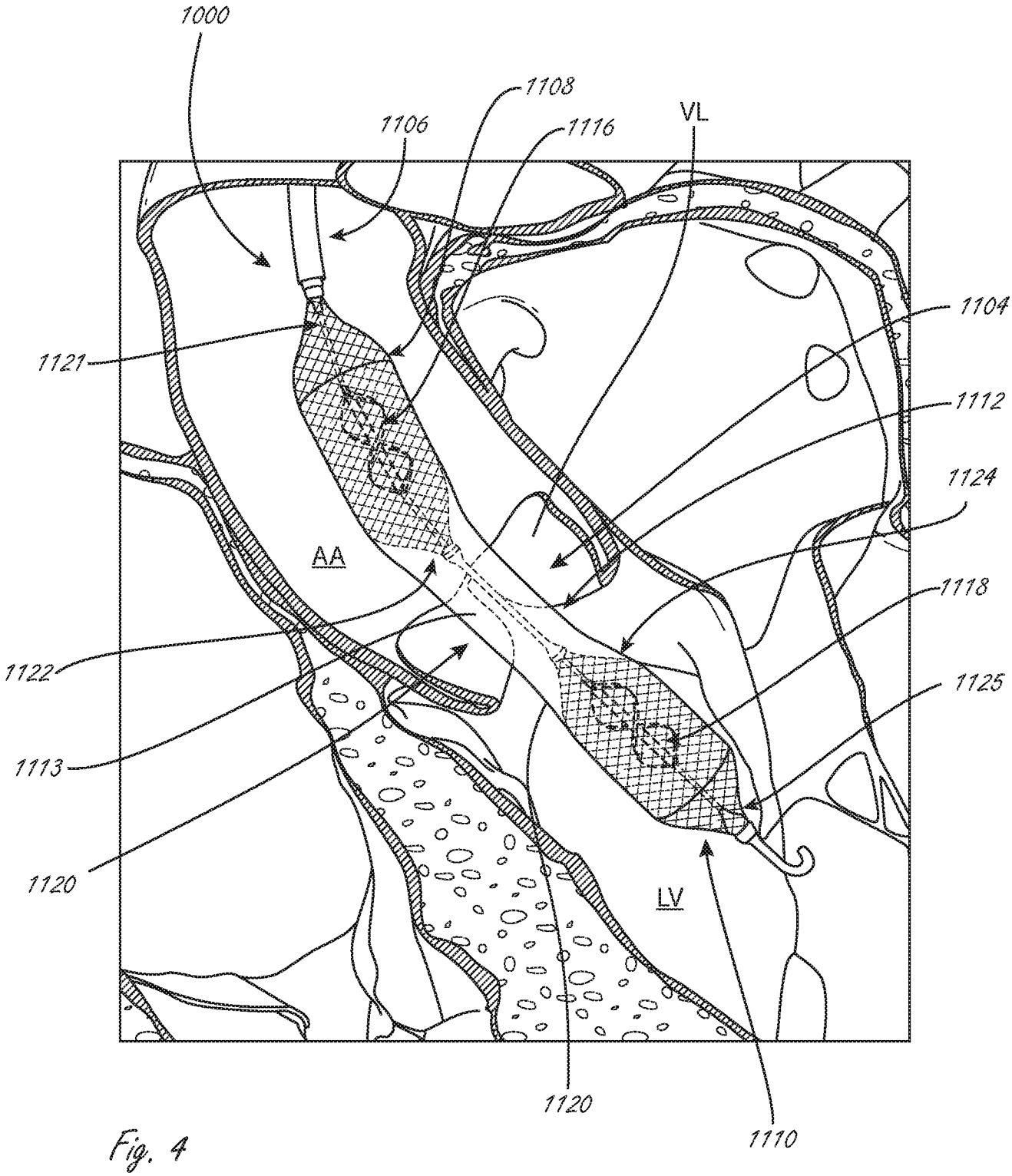

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Fig. 4

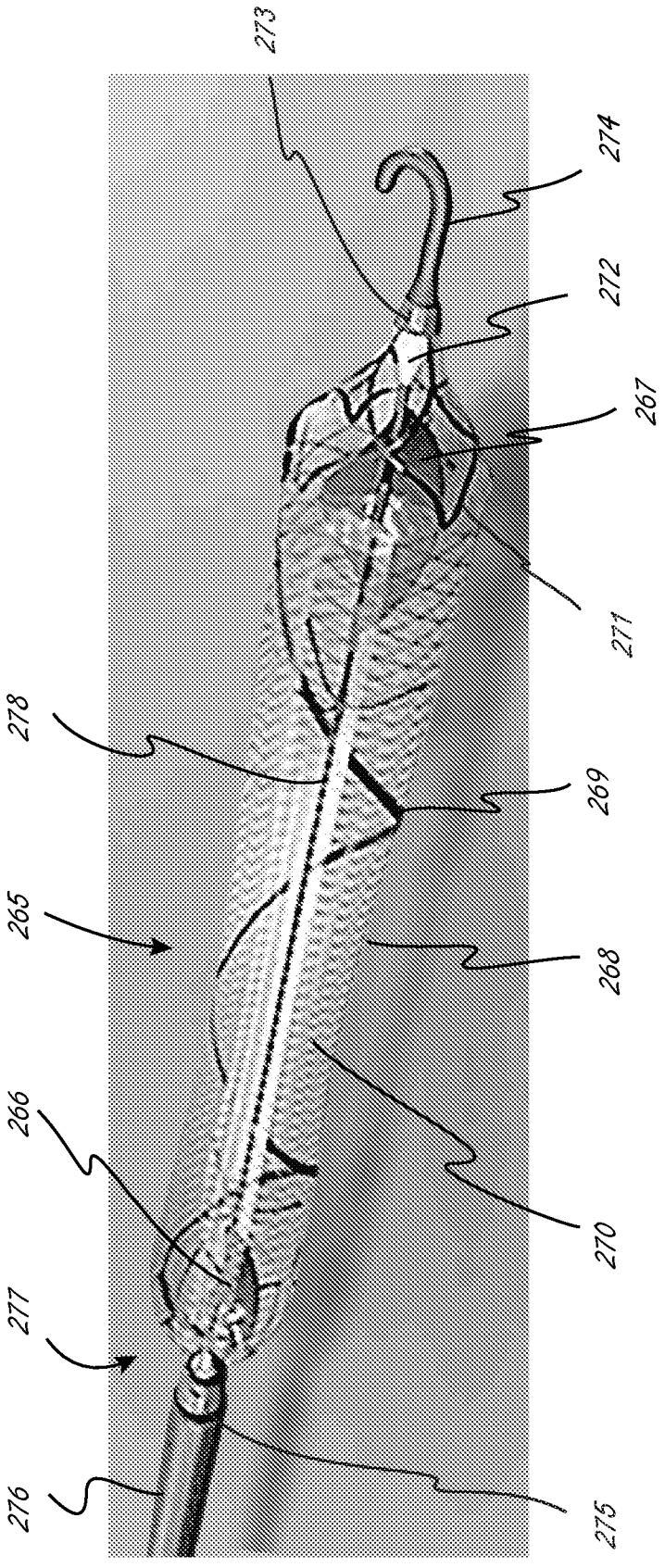


Fig. 5

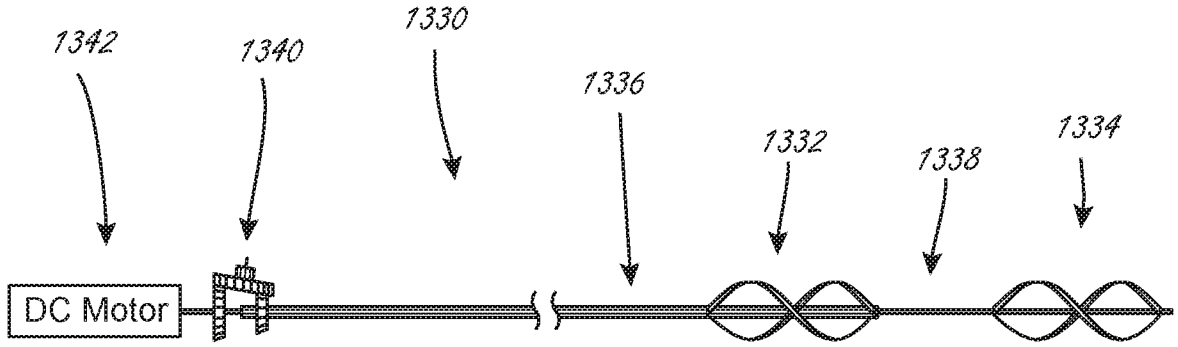


Fig. 6A

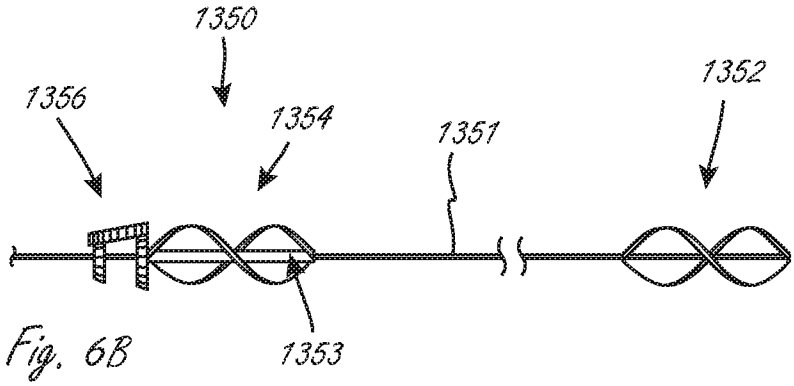


Fig. 6B

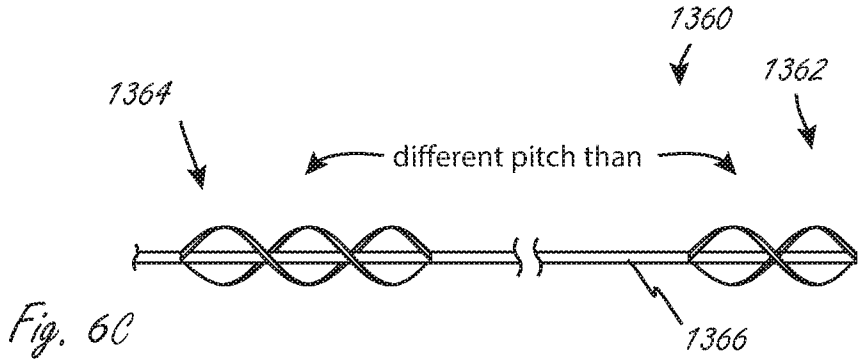


Fig. 6C

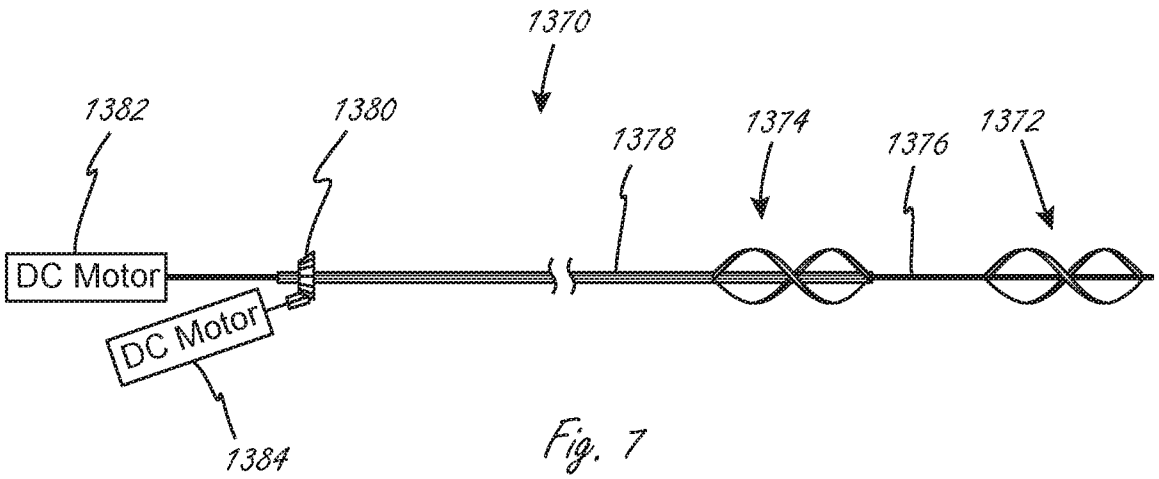


Fig. 7

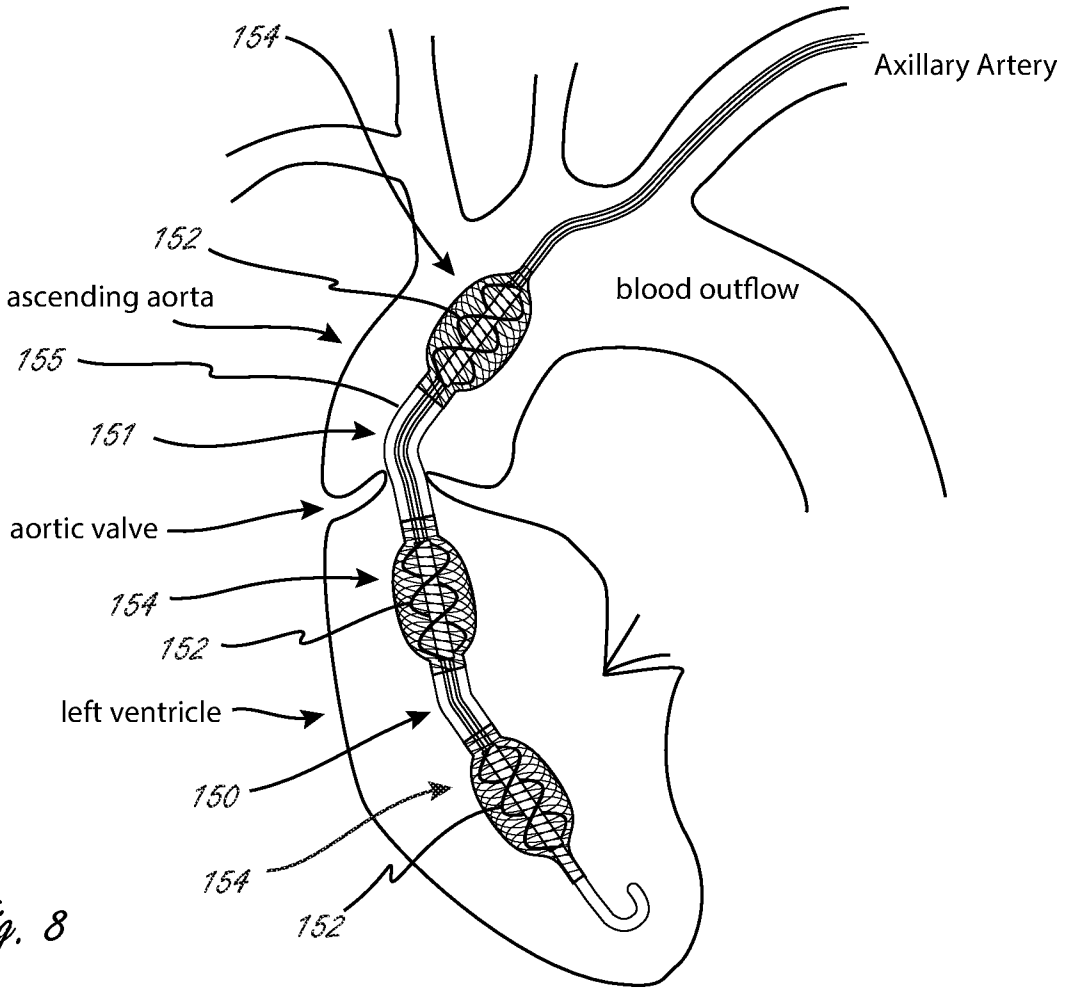

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Axillary Artery
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Fig. 8

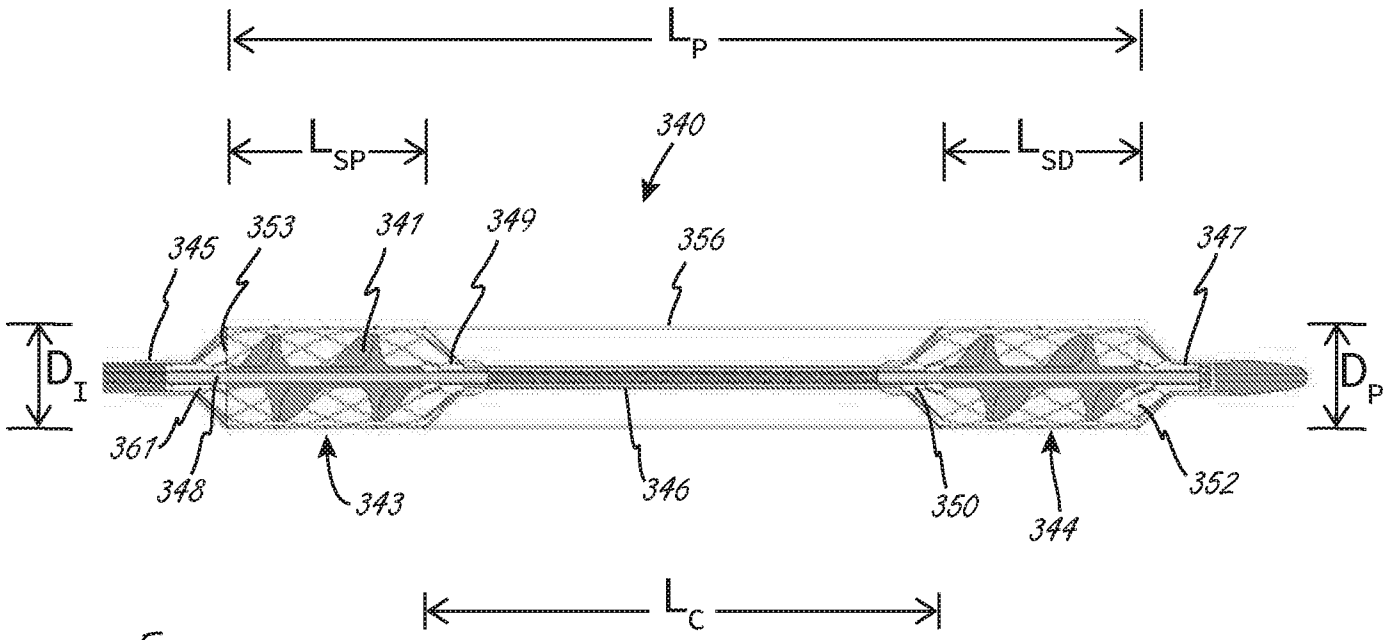

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Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US18/60815

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 1/10, 1/12 (2018.01)
CPC - A61M 1/101, 1/1024, 1/122, 1/125

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2013/0303831 A1 (MINNETRONIX, INC.) 14 November 2013; figures 30-32; paragraphs [0192], [0195]; claims 13, 19	1-3, 5-7 -------- 4
X -- Y	US 2011/0152999 A1 (HASTINGS, RN et al.) 23 June 2011; figure 12; paragraphs [0081]-[0083]	8 -------- 9
Y	US 2016/0030649 A1 (THORATEC CORPORATION) 04 February 2016; figure 20D; paragraphs [0129]-[0131], [0134]	4
Y	US 2012/0095281 A1 (REICHENBACH, SH et al.) 19 April 2012; paragraphs [0085]-[0086]	9
A	US 2017/0100527 A1 (MAGENTA MEDICAL LTD.) 13 April 2017; entire document	1-9
A	US 2006/0036127 A1 (DELGADO, III, RM) 16 February 2006; entire document	1-9

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

* Special categories of cited documents:
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"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 December 2018 (20.12.2018)	16 JAN 2019
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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