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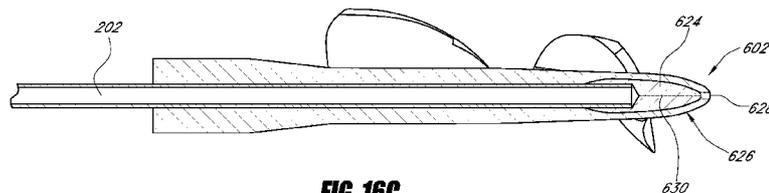


FIG. 16C

(57) Abstract: Disclosed herein are heart pumps that can include a catheter body and an impeller coupled with a distal end of the catheter body. The impeller can include a tip that is resealable or that includes a resealable member. The heart pump can also include a diffuser disposed between the distal end of the catheter body and the impeller, wherein the diffuser includes a flow directing surface.

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PERCUTANEOUS HEART PUMP

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Serial No. 61/43,0537 filed January 6, 2011 entitled *Percutaneous Heart Pump*, which is hereby incorporated by reference herein for all purposes.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] This application is directed to heart pumps that can be applied percutaneously.

Description of the Related Art

[0003] Heart disease is a major health problem that claims many lives per year. After a heart attack, only a small number of patients can be treated with medicines or other non-invasive treatment. However, a significant number of patients can recover from a heart attack or cardiogenic shock if provided with mechanical circulatory support.

[0004] In a conventional approach, a blood pump having a fixed cross-section is surgically inserted a heart chamber, such as into the left ventricle of the heart and the aortic arch to assist the pumping function of the heart. Other known applications involve providing for pumping venous blood from the right ventricle to the pulmonary artery for support of the right side of the heart. The object of the surgically inserted pump is to reduce the load on the heart muscle for a period of time, which may be as long as a week, allowing the affected heart muscle to recover and heal. Surgical insertion, however, can cause additional serious stresses in heart failure patients.

[0005] Percutaneous insertion of a left ventricular assist device ("LVAD"), a right ventricular assist device ("RVAD") or in some cases a system for both sides of the heart (sometimes called "biVAD") therefore is desired. Conventional fixed cross-section ventricular assist devices designed to provide near full heart flow rate are too large to be advanced percutaneously, e.g., through the femoral artery. There is an urgent need for a

pumping device that can be inserted percutaneous and also provide full cardiac rate flows of the left, right, or both the left and right sides of the heart when called for.

SUMMARY OF THE INVENTION

[0006] In one embodiment, a heart pump is provided that includes a catheter body, a housing, an impeller, and a diffuser. The catheter body includes a proximal end, a distal end, and an elongate body extending therebetween. The housing is coupled with the distal end of the catheter body and comprises a distal opening and a proximal opening. The impeller assembly is coupled with the distal end of the catheter body and positioned within the housing. The diffuser can include a flow directing surface. The diffuser is disposed between the distal end of the catheter body and the impeller. The diffuser is configured to be positioned within the housing and adjacent the proximal opening.

[0007] In another embodiment, a heart pump is provided that includes a catheter body comprising a proximal end, a distal end, and an elongate body extending therebetween. The pump also includes an impeller coupled with the distal end of the catheter body and comprising an axial lumen passing through a distal end of the impeller. The impeller comprises a tip positioned at the distal end of the impeller, the tip comprising a resealable member having a resealable path.

[0008] In another embodiment, a heart pump is provided that comprises a catheter body, an impeller, and a sheath. The catheter body has a proximal end, a distal end, and an elongate structure extending therebetween. The impeller is coupled with the distal end of the catheter body. The sheath is disposed over at least a portion of the distal end of the catheter body. The sheath also has an expandable distal end.

[0009] In another embodiment, a catheter assembly is provided that includes a catheter body, an impeller, and a deployment device. The catheter body comprises a proximal end, a distal end, and an elongate structure extending therebetween. The impeller is configured for relative motion in an axial direction, and is located at the distal end of the catheter body. The deployment device is located at the proximal end of the catheter assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] A more complete appreciation of the subject matter of the present inventions and the various advantages thereof can be realized by reference to the following detailed description, in which reference is made to the accompanying drawings in which:

[0011] Figure 1 illustrates one embodiment of a heart pump configured for percutaneous application and operation;

[0012] Figure 1A is a plan view of one embodiment of a catheter assembly adapted to be used with the heart pump of Figure 1;

[0013] Figure 2 is a detail view of a distal portion of the catheter assembly illustrated in Figure 1A;

[0014] Figure 3 is an exploded view of a portion of an impeller assembly of the catheter assembly of Figure 1A;

[0015] Figure 4A is a cross-sectional view of a distal portion of the catheter assembly, taken through the section plane 4A — 4A shown in Figure 2;

[0016] Figure 4B is a detail view of the distal portion of the catheter assembly, taken at 4B—4B shown in Figure 4A;

[0017] Figure 5 is a cross-sectional perspective view of a bearing assembly of the catheter assembly of Figure 1A;

[0018] Figure 6 is a cross-sectional view of a bearing housing of the bearing assembly of Figure 5;

[0019] Figure 7 is a perspective view of one embodiment of a catheter body that can be used to house a drive shaft and to convey an infusant to the bearing housing of Figure 5;

[0020] Figures 7A-7C show variations of the catheter body of Figure 7;

[0021] Figure 8 illustrates a surface configuration of one embodiment of a bearing adapted to enhance or control flow of an infusant in the bearing assembly of Figure 5;

[0022] Figure 9 illustrates one embodiment of an impeller assembly;

[0023] Figures 9A, 9B-1, 9B-2, 10 and 10A illustrate details of further embodiments of impeller blades;

[0024] Figure 11 is a cross-sectional view of a proximal portion of the catheter assembly, taken through the section plane 11—11 on Figure 1A;

[0025] Figures 12, 12A, and 12B are cross-section views similar to that of Figure 11, illustrating an infusant outflow path;

[0026] Figures 13A-B are cross-sectional views of two embodiments of a blood pump that includes a diffuser;

[0027] Figures 14A-B are partial cross-sectional views illustrating one embodiment of a blood pump including a retractable impeller assembly in deployed and retracted configurations, respectively;

[0028] Figures 15A-B illustrate a deployment device disposed at the proximal end of a catheter assembly illustrated in Figures 14A-B in deployed and retracted configurations, respectively;

[0029] Figure 15C is a cross-sectional view of a structure for actuating the deployment device illustrated in Figures 15A-B;

[0030] Figures 15D-F illustrate further embodiments of deployment devices that can actuate the catheter assembly between deployed and retracted configurations;

[0031] Figures 16A-C are cross-sectional views of three embodiments of a self-sealing impeller tip; and

[0032] Figures 17A-D are perspective views of variations of a sheath assembly having an expandable distal portion.

[0033] A more detailed description of various embodiments of components for heart pumps useful to treat patients experiencing cardiac stress, including acute heart failure, are set forth below.

DETAILED DESCRIPTION

[0034] Major components of heart pumps that can be applied percutaneously to a patient are described below in Section I. Section II describes various structures that facilitate the rotatable support of a cantilevered impeller. Section III describes various structures that facilitate deployment and/or retrieval of one or more components of the distal end 108 of the heart pump 10 within the cardiovascular system. Section IV describes various methods and techniques in connection with specific structures of heart pumps

I. OVERVIEW OF HEART PUMPS

[0035] Figure 1 illustrates one embodiment of a heart pump 10 that includes a catheter assembly 100 having a proximal end 104 adapted to connect to a motor 14 and a distal end 108 (see Figure 1A) adapted to be inserted percutaneously into a patient. The motor 14 is connected by a signal line 18 to a control module 22 that provides power and/or control signals to the motor 14. As discussed further below, the heart pump 10 in various embodiments has an infusion system 26 and a patient monitoring system 30.

[0036] The infusion system 26 can provide a number of benefits to the heart pump 10 which are discussed below. In one embodiment, the infusion system 26 includes a source of infusant 34, a fluid conduit 38 extending from the infusant source 34 to the proximal end 104 of the catheter assembly 100 and a fluid conduit 42 extending from the proximal end of the catheter assembly 100 to a waste container 46. The flow of infusant to and from the catheter assembly 100 can be by any means, including a gravity system or one or more pumps. In the illustrated embodiment, the infusant source 34 includes an elevated container 50, which may be saline or another infusant as discussed below. Flow from the elevated container 50 can be regulated by a pressure cuff 54 to elevate the pressure of the fluid in the container 50 to increase flow or by a pinch valve 58 or by other means.

[0037] The patient monitoring system 30 can be used to monitor the operation of the patient and/or the pump 10. For example, the patient monitoring system 30 can include a user interface 60 coupled with a source of data 64. The data source 64 can include one or more patient conditions sensors, such as pressure sensors 68 that are in pressure communication with the patient and/or operating components within the patient. In one embodiment, the pressure sensors 68 fluidly communicate by a conduit 72 that extends between the sensors and a proximal portion of the catheter assembly 100. The conduit 72 can

include a plurality of separable segments and can include a valve 76 to enable or disable the pressure communication to the sensors 68.

[0038] The heart pump 10 is adapted to provide an acute or other short-term treatment. A short-term treatment can be for less than a day or up to several days or weeks in some cases. With certain configurations the pump 10 can be used for a month or more.

[0039] The catheter assembly 100 extends between the proximal end 104 and the distal end 108. An impeller assembly 116 disposed at the distal end 108 is configured to pump blood to convey blood from one body cavity to another. In one arrangement, the impeller assembly 116 conveys blood proximally through or along a portion of the catheter assembly 100 to provide assistance to the left ventricle of the heart. In another embodiment, the impeller assembly 116 conveys blood distally through or along a portion of the catheter assembly 100 to provide assistance to the right ventricle of the heart. The heart pump 10 is useful as a heart assist device for treating patients with acute heart failure or other heart maladies. The heart pump 10 also can be used in connection with a surgical treatment to support the patient without providing full cardiovascular bypass. A patient could be supported on the device for longer term with proper controls and design.

[0040] The catheter assembly 100 is provided with a low profile configuration for percutaneous insertion. For example, the distal end 108 of the catheter assembly 100 can be configured to have about an 11 French (approximately 3.5 mm) size in a first configuration for insertion and an expanded configuration, such as up to about 21 French (approximately 7 mm), once positioned in the body. The larger size facilitates greater flow rates by the impeller assembly 116 as discussed below.

[0041] The catheter assembly 100 is configured to enable the distal end 108 to reach a heart chamber after being inserted initially into a peripheral vessel. For example, the catheter assembly 100 can have a suitable length to reach the left ventricle and sufficient pushability and torquability to traverse the intervening vasculature. The catheter assembly 100 may include a multilumen catheter body 120 that is arranged to facilitate delivery and operation of the impeller assembly 116. Further details concerning various embodiments of the catheter body 120 are discussed below in connection with Figures 7-7C.

[0042] A drive system is provided to drive an impeller within the impeller assembly 116. The drive system includes a motor 14 and a suitably configured drive controller (not shown) disposed within the control module 22. The motor 14 in various embodiments is configured to be disposed outside the patient, e.g., adjacent to the proximal end 104 of the catheter assembly 100. In one advantageous embodiment, the drive system employs a magnetic drive arrangement. The motor 14 is arranged to generate magnetic fields that will be sensed by permanent magnets disposed within the proximal end 104 of the catheter assembly 100. This arrangement facilitates very efficient generation of torque used to drive the impeller assembly 116, as discussed below.

[0043] Some embodiments described herein could be incorporated into a system in which a motor is miniaturized sufficiently to be inserted into the patient in use, including into the vasculature. Such an embodiment could be operated by disposing control signal lines within the proximal portion of the catheter body 120. Also, it may be useful to provide the capability to measure blood pressure at the distal end 108 using a device disposed at the proximal end 104. For example, a pressure sensor at the distal end can communicate with a device outside the patient through a lumen of the catheter body 120. Various details of these optional features are described in US Patent No. 7,070,555, which is incorporated by reference herein for all purposes and in its entirety.

[0044] In another embodiment, a mechanical interface can be provided between the motor and the proximal end 104 of the catheter assembly 100. The mechanical interface can be between the motor 14 and a drive shaft positioned at the proximal end of the catheter assembly 100.

[0045] A torque coupling system is provided for transferring torque generated by the drive system to the impeller assembly 116. The torque coupling system is discussed further in Section 11(C) - Torque Coupling System (as discussed below), but in general can include magnetic interface between the motor 14 and a drive assembly 146 disposed at the proximal end 104 of the catheter assembly 100. The drive assembly 146 is coupled with a proximal end of an elongate drive shaft 148 in one embodiment. The drive shaft 148 extends between the drive assembly 146 and the impeller assembly 116. A distal portion of the drive shaft 148 is coupled with the impeller assembly 116 as discussed below in connection with

one embodiment illustrated in Figures 4A and 4B. Figure 11 shows one manner of coupling the proximal end of the drive shaft 148 with the drive assembly 146.

[0046] As discussed above, the heart pump 10 may also include an infusion system 26. Figure 1A shows that the infusion system 26 can include an infusion inflow assembly 150 provided adjacent to the proximal end 104 in one embodiment. The infusion assembly 150 can be one component of an infusion system that is configured to convey one or more fluids within the catheter assembly 100. The fluids can be conveyed distally within the catheter assembly 100, *e.g.*, within the catheter body 120, to facilitate operation of the impeller assembly 116, some aspect of a treatment, or both. In one embodiment, the infusion system is configured to convey a lubricant, which can be saline, glucose, lactated Ringer's solution, acetated Ringer's solution, Hartmann's solution (*e.g.*, including compound sodium lactate), and D5W dextrose solution. In another embodiment, the infusion system is configured to convey a medication, or a substance that both acts as lubricant and medication. As sometimes used herein "infusant" is intended to be a broad term that includes any fluid or other matter that provides performance enhancement of a component of the heart pump 10 or therapeutic benefit, and can be wholly or partly extracted from the system during or after operation of the pump.

[0047] In one embodiment, the infusion inflow assembly 150 includes a catheter body 154 having a luer or other suitable connector 158 disposed at a proximal end thereof and an inflow port in fluid communication with one or more lumens within the catheter assembly 100. A lumen extending through the catheter body 154 is adapted to be fluidly coupled with a fluid source connected to the connector 158 to deliver the fluid into the catheter assembly 100 and through one or more flow paths as discussed below in connection with Figures 4A, 4B, and 7-7C.

[0048] Figures 1A and 12 show that the catheter assembly 100 in various embodiments also includes an outlet positioned at a location that is outside the patient when the heart pump 10 is in use to allow infusant to be removed from the pump and from the patient during or after the treatment. The outlet can be fluidly coupled with an infusant return flow path in the catheter body 120 through a fluid port 144 disposed at the proximal end 104.

[0049] The catheter assembly 100 can also include a sheath assembly 162 configured to constrain the impeller assembly 116 in a low profile configuration in a first state and to permit the impeller assembly 116 to expand to the enlarged configuration in a second state. The sheath assembly 162 has a proximal end 166, a distal end 170, and an elongate body 174 extending therebetween. In one embodiment, the elongate body 174 has a lumen extending between the proximal and distal ends 166, 170, the lumen being configured to be slidably disposed over the catheter body 120. The arrangement permits the sheath assembly 162 to be actuated between an advanced position and a retracted position. The retracted position is one example of a second state enabling the impeller assembly 116 to expand to an enlarged configuration. The advanced position is one example of a first state that enables the impeller assembly 116 to be collapsed to the low profile configuration. In some embodiments, a luer 102 or other suitable connector is in fluid communication with the proximal end 166 of the sheath assembly 162. The luer 102 can be configured to deliver fluids to the catheter assembly 100, such as priming fluid, infusant, or any other suitable fluid.

[0050] Figure 1A illustrates a retracted position, in which the distal end 170 of the elongate body 174 is at a position proximal of the impeller assembly 116. In an advanced position, the distal end 170 of the elongate body 174 is positioned distal of at least a portion of the impeller assembly 116. The sheath assembly 162 can be configured such that distal advancement of the distal end 170 over the impeller assembly 116 actuates the impeller assembly 116 from an enlarged state to a more compact state (or low profile configuration), *e.g.*, causing a change from the second state to the first state, as discussed above.

[0051] Figures 4A & 4B show the elongate body 174 as a single layer structure from the inner surface to the outer surface thereof. In another embodiment, the elongate body 174 has a multilayer construction. In one arrangement, the elongate body 174 has a first layer that is exposed to the catheter body 120 and a second layer exposed that corresponds to an outer surface of the catheter assembly 100. A third layer can be disposed between the first and second layers to reinforce the elongate body 174, particularly adjacent to the distal end thereof to facilitate collapse of the impeller assembly 116. In another construction, a reinforcing structure can be embedded in an otherwise continuous tubular structure forming

the elongate body 174. For example, in some embodiments, the elongate body 174 can be reinforced with a metallic coil.

[0052] Figure 2 show that an impeller housing 202 is disposed at the distal end 108. The impeller housing 202 can be considered part of the impeller assembly 116 in that it houses an impeller and provides clearance between the impeller and the anatomy to prevent any harmful interactions therebetween. The housing 202 and the impeller are also carefully integrated to maintain an appropriate flow regime, *e.g.*, from distal to proximal or from proximal to distal within the housing.

[0053] Figures 1A and 2 also show that the distal end 108 of the catheter assembly 100 includes an atraumatic tip 182 disposed distal of the impeller assembly 116 in one embodiment. Figure 1A shows that the atraumatic tip 182 can have an arcuate configuration such that interactions with the vasculature are minimally traumatic. The tip 182 can also be configured as a positioning member. In particular, the tip 182 can be rigid enough to help in positioning the impeller assembly 116 relative to the anatomy. In one embodiment, the tip 182 is rigid enough that when it is urged against a heart structure such as the ventricle wall, a tactile feedback is provided to the clinician indicating that the impeller assembly 182 is properly positioned against the heart structure.

II. IMPELLER ROTATION AND SUPPORT

[0054] The impeller assembly 116 can take any suitable form, but in various embodiments includes an impeller 200 adapted to move a fluid such as blood from an inlet to an outlet of the catheter assembly 100. In certain embodiments the impeller 200 can be cantilevered or otherwise supported for rotation primarily at one end.

[0055] Figure 3 shows that the impeller 200 includes a shaft 204, a central body or hub 208, and one or more blades 212.

[0056] The shaft 204 and hub 208 can be joined in any suitable fashion, such as by embedding a distal portion of the shaft within the hub 208. The blades 212 can be spaced out proximal to distal along the axis of the shaft. In some embodiments, the blades 212 are provided in blade rows. Figure 9 shows that the distal end of the shaft 204 can extend at least to an axial position corresponding to one of the blade rows. In some embodiments, the shaft 204 can be solid. In other embodiments, the shaft 204 has a lumen extending axially through the hub so that a guidewire can be passed through the catheter assembly 100. Details of

variations with a lumen are discussed further in U.S. Application No. 12/829359, filed July 1, 2010, titled *Blood Pump With Expandable Cannula*, which is hereby incorporated by reference herein in its entirety and for all purposes.

A. Infusant Delivery and Removal System

[0057] The operation and duty cycle of the impeller assembly 116 can be lengthened by providing a hydrodynamic bearing for supporting the shaft 204. A hydrodynamic bearing can be supported by a lubricant, such as isotonic saline, which can be delivered in a continuous flow. The lubricant can be delivered through the infusion system to an outside surface of the shaft 204. The infusant may be directed onto the shaft from a radially outward location. In some arrangements, the lubricant flow is controlled such that of a total lubricant volume introduced into the proximal end of the cannula, a first portion of the total volume of the lubricant flows proximally along the shaft 204. In some embodiments, a second portion of the total volume flows distally along the shaft, the first volume being different from the second volume. The second portion of the total volume can be substantially equal to the total volume introduced into the proximal end of the cannula less the first volume.

[0058] Figures 3 to 8 show various structures for providing rotational support of a proximal portion of the shaft 204 within the distal portion of the catheter assembly 100. For example, as shown in Figure 3, a bearing assembly 220 can be disposed at a distal end 224 of the multilumen catheter body 120. In one embodiment, the bearing assembly 224 includes a housing 228 (as shown in Figure 4B) and one or more bearings configured to support the proximal portion of the shaft 204. The bearing assembly 224, as illustrated in more detail in Figure 4B, includes a plurality of bearings 232a, 232b disposed within the bearing housing 228. Various materials that can be used for the bearings are discussed below.

[0059] Figure 6 shows that the bearing housing 228 has a lumen 234 extending therethrough with a proximal enlarged portion 236a and a distal enlarged portion 236b. The housing 228 comprises a shoulder defining a narrow portion 240 of the lumen 234 disposed between the enlarged portions 236a, 236b. The first and second bearings 232a, 232b can be disposed within the enlarged portions 236a, 236b of the bearing housing 228.

[0060] In one arrangement, the proximal end of the shaft 204 (*e.g.*, as shown in FIG. 4A) is received in and extends proximally of the second bearing 232b. In some embodiments there can be one bearing (*e.g.*, only bearing 232a), while in other embodiments both bearings 232a and 232b can be used. In some embodiments, the bearing(s), *e.g.*, bearings 232a and/or 232b, can be friction fit or interference fit onto the impeller shaft 204. Accordingly, the shaft 204 can be supported for rotation by the bearings 232a, 232b as well as in the narrow portion 240 of the housing 228. In embodiments where the bearing(s) 232a, 232b are friction or interference fit onto the shaft, the bearing(s) 232a, 232b can be configured to rotate with the shaft 204 relative to the bearing housing 228. Further, the bearing(s) 232a, 232b can have a relatively large clearance with the bearing housing 228. The clearance between the shaft 204 and the bearing housing 228, at regions that are not coupled with the bearing, can be in the range of about 0.0005 to about 0.001 inch. In certain embodiments, the clearance can be within a larger range, such as at least about 0.0005 inches, about 0.001 inches or up to about 0.005 inches. In embodiments with multiple bearing(s) 232a, 232b, the clearance can be different for the bearings 232a, 232b, such as providing a larger clearance at the proximal bearing 232a.

[0061] In other embodiments, such as in FIG. 5, the bearing(s) 232a, 232b may not be friction or interference fit onto the shaft 204. In these embodiments, the bearing(s) 232a, 232b may be disposed within the bearing housing 228, for example by an interference or press fit. The shaft 204 may then rotate with respect to the bearing(s) 232a, 232b, and there can be a clearance between the shaft 204 and the bearing(s) 232a, 232b. The clearance between the shaft 204 and the bearings 232a, 232b can be in the range of about 0.0005 to about 0.001 inch. In certain embodiments, the clearance can be within a larger range, such as at least about 0.0005 inches, about 0.001 inches or up to about 0.005 inches. The clearance can be different for the bearings 232a, 232b, such as providing a larger clearance at the proximal bearing 232a. In certain embodiments, the bearing housing 228 may provide a thrust surface for bearing axial loads. In other embodiments, there may be other bearings located either distally or proximally of the bearing housing 228 that are configured to bear axial loads. In other embodiments, the fit between the bearings 232a, 232b and the shaft 204 can be tight, which can also assist in bearing axial loads in some aspects.

[0062] At least the proximal portion of the shaft 204 can be made of a material that will not corrode or otherwise be made to be inert when immersed in the lubricant or other infusant. The material may be one that will not corrode in isotonic saline. Suitable materials may include a wide variety of metals, including alloys, and at least saline-resistant stainless steel and nickel-based alloys. Also, the shaft 204 could be made as a composite to include advantageous properties of a plurality of materials. In some cases the shaft 204 could be formed as a polymer. The class of polymers selected would include those that can form a shaft 204 of a certain stiffness suitable in this application. For example, polycarbonate or PEEK could be used. In certain configurations, the polycarbonate, PEEK, or other suitable polymer can provide enhanced performance by being combined with a second material or structure. A glass or carbon filled polycarbonate or other stiff polymer could also be used.

[0063] As discussed above, a hydrodynamic bearing between the shaft 204 and the bearings 232a, 232b may be utilized in various embodiments. In one such arrangement, a continuously replenished fluid film is provided at least between the inner wall of the bearing housing and an adjacent moving structure, such as the impeller shaft or an outer surface of a bearing. For example, the bearing housing 228 can be configured to permit a lubricant to be delivered therethrough into the lumen 234. The bearing housing 232 can include a plurality of channels 260 disposed therein extending proximally from a plurality of ports 264 located at the narrow portion 240 of the housing 228. Each port 264 can communicate with one of the channels 260 to provide fluid communication into the lumen 234.

[0064] As shown in Figure 5, the channels 260 can be formed in the wall of the housing 228. In one embodiment, the channels 260 are formed as open depressions, e.g., as flutes, extending along the housing 228. In this embodiment, the channels 260 can be enclosed by a separate structure, such as a separate outer sleeve, that is disposed around the housing 228. Figure 4B shows that a proximal portion 268 of the impeller housing 202 can be sized to tightly fit over the outer surface of the bearing housing 228, enclosing the radially outward portion of the channels 260. In this arrangement, at least a portion of a flow path is formed between an outer surface of the bearing housing 232 and a separate outer sleeve.

[0065] Fluid communication between the port 264 in the bearing housing 228 and the infusion inflow assembly 150 can be by any suitable combination of lumens within the

catheter assembly 100. For example, in one embodiment, each of the channels 260 has a proximal port 272 that communicates with an annular space 274 formed in the catheter assembly 100. The annular space 274 can be formed between a plurality of separate overlaid structures in the catheter assembly 100. Figure 4A and 4B show that the annular space 274 is formed between an outer surface 278 of the multilumen catheter body 120 and an inner surface of the proximal length 268 of the housing 202.

[0066] Fluid communication is provided in the catheter assembly 100 between the space 274 and the infusion inflow assembly 150. For example, a plurality of lumens 282 formed in the multi-lumen catheter body 120 can be dispersed circumferentially about the catheter body 120 at a peripheral circumferential region 284, as illustrated in Figures 7-7C. The peripheral position of the lumens 282 enables a central area of the catheter body 120 to be dedicated to a central lumen 286. By providing a plurality of smaller lumens 282 located at the periphery, a relatively large flow rate can be delivered through a relatively small circumferential band (when considered in cross-section) of the catheter body 120. Each of the lumen 282 has a distal port 290 that communicates with the space 274.

[0067] A proximal portion of the lumens 282 can take any suitable form. For example, the lumens 282 can communicate at their proximal end with a flow diverting structure (not shown) that is in fluid communication with the infusion inflow assembly 150. As described herein, in some embodiments the lumen 282 can be disposed circumferentially about the central lumen 286. The catheter assembly 100 can include a flow diverting structure or connector, e.g., disposed about the proximal end of the catheter body 120 that is configured to divert the infusant into the lumens 282 for distally directed flow therein. In other embodiments, the catheter assembly 120 can include a flow diverting structure disposed adjacent the distal end thereof that is configured to divert the infusant into the lumens 282 from the central lumen 286 for proximally directed flow in the lumens 282.

[0068] Figure 5 includes arrows that illustrate the flow of infusant into the bearing assembly 220. In one arrangement, the inflow of infusant is indicated by an arrow 300 which is shown pointing distally within one of the channels 260 of the bearing housing 228. The infusant flow enters the bearing housing through the ports 264. Although flow is shown in one channel 260, corresponding flow may be provided in each of a plurality of channels 260

disposed around the central lumen 234. An arrow 304 illustrates that at least a portion of the infusant delivered through the port 264 may flow generally proximally within the bearing housing 228. An arrow 308 illustrates that at least a portion of the infusant delivered through the port 264 may flow generally distally within the bearing housing 228.

[0069] Figure 5 illustrates the arrows 304, 308 as proximally and distally directed, respectively. However, the high speed rotation of the impeller shaft 204 within the housing 228 will create a thin film of lubricant spacing the impeller shaft 204 from the surfaces of the bearings 232a, 232b. This thin film will extend all the way around the shaft 204 and thus each portion of the flow will have a spiral or helical flow direction.

[0070] The bearings 232a, 232b can have different configurations to enhance the performance of the pump 10. For example, the proximal bearing 232a can be longer along the longitudinal axis of the bearing housing 228 than the distal bearing 232b. A longer proximal bearing 232a is believed to better control runout of the shaft 204. Better runout control on the shaft 204 is believed to enhance the control of the position of the blades 212 relative to the housing 202. Less runout reduces excessive variation in the gap between the blades 212 and the housing 202, providing biocompatibility benefits such as reduced hemolysis.

[0071] In some embodiments, such as those in FIG. 5 where the bearings 232a, 232b are not friction fit or interference fit onto the shaft 204, the distal bearing 232b has a smaller inner diameter than the proximal bearing 232a. If the shaft 204 has a constant diameter, the smaller inner diameter should provide greater control of angular deflection of the shaft. Controlling angular deflection can enhance relative position control of the blades 212 and housing 202, providing blood handling benefits such as reduced hemolysis. A smaller clearance could also be provided by enlarging the diameter of the shaft 204 at the axial position of the distal bearing. In some embodiments, the larger inner diameter of the bearing 232b enables a larger volume of lubricant to flow proximally and a lesser volume to flow distally in the lumen 234.

[0072] The continuous introduction of lubricant maintains a constant, predictable and durable rotational bearing state between stationary component, e.g., the bearing housing 282, and a moving component, e.g., the shaft 204, a component of the bearings 232a, 232b,

or both the shaft 204 and a component of the bearings 232a, 232b. Also, continuous lubricant inflow provides a means for removing heat generated by the relative motion between the shaft 204 and the bearings. Also, the infusant can create fluid pressure within the catheter assembly 100 that can push debris generated within or by the pump 10 out of the bearing housing 220. Enhancing the volume of infusant that flows along the path indicated by the arrow 304 enhances the likelihood that debris generated by or present in the pump will be removed from the proximal end rather than to be trapped inside the distal portion of the catheter assembly 100.

[0073] Another technique for controlling infusant flow in the lumen 234 is to locate the port 264 between the bearings 232a, 232b and closer to one of the bearing. For example, the ports 264 can be located adjacent to the proximal bearing 232a in one embodiment. This provides a shorter path of egress out of the narrow portion 240 of the bearing housing 228 in the proximal direction.

[0074] Other strategies for controlling the flow of infusant within the bearing housing 228 include modifying a surface within one or more of the bearings 232a, 232b. Figure 8 shows a surface modification 233 provided in a bearing 232a to enhance proximally directed flow. The surface modification 233 comprises a plurality of axially oriented grooves 235 in one embodiment. In another embodiment, the surface modification 233 includes one or more spiral grooves. The spiral grooves can be formed with a groove entrance that is substantially parallel with a flow direction of infusant between the bearings 232a, 232b such that a reduction of velocity of the flow is minimized. In one embodiment, each spiral groove includes at least about 3 turns disposed on the inner surface of the bearing between the proximal and distal ends of the bearing. In another embodiment, each spiral groove has adjacent turns that are spaced apart by a minimum pitch of 0.125 inches (3.2 mm). In another embodiment, each spiral groove has an axial density of about 32 turns per inch (about 1.3 turns per mm). The grooves are formed in the surface 237 of the bearing 232a upon which the impeller shaft 204 is supported. The grooves 235 locally enlarge the clearance between the shaft 204 and the surface 237 so that a greater volume of infusant can flow distal-to-proximal across the bearing 232a. The surface modification 233 reduces back-pressure limiting the distal-to-proximal flow across the bearing 232a.

[0075] In other embodiments, it may be desirable to enhance distally directed flow. For example, the infusant may be provided with a fluid intended to be delivered to the patient. In such embodiments, the surface modification 233 can be provided on the distal bearing 232b. In certain embodiments, both proximal and distal bearings 232a, 232b are provided with flow enhancing modifications to enhance heat transfer or purging of the bearing assembly 220. In such embodiments, one of the bearings may have a greater degree of flow enhancement provided on the bearing surface.

[0076] The arrangement of the bearing assembly 220 can be a factor in selecting an appropriate infusant. Saline is a preferred infusant, but other sufficiently biocompatible infusants could be used. Other embodiments are configured such that little or no infusant flows out of the pump into the patient. For such embodiments, other infusant fluids can be used, such as glucose.

[0077] Figure 7 illustrates further features of the catheter body 120. The catheter body 120 comprises an inner most portion 320 that defines the central lumen 286. The inner most portion 320 is disposed within, e.g., circumferentially surrounded by, the peripheral circumferential region 284. A continuous outer circumferential region 324 can be provided around the peripheral circumferential region 284 to fully enclose the lumens 282, discussed above. Figures 4A and 4B illustrate that a distal end of the inner most portion 320 is configured to be received and secured within a proximal portion of the lumen 234 within the bearing housing 228. Figure 4B illustrates that a region of overlap can be provided between a distal portion of the inner most portion 320 and a proximal portion of the bearing housing 228. This construction provides a continuous lumen defined in part by the central lumen 286 of the catheter body 120 and in part by the lumen 234 of the bearing housing. In another arrangement, the bearing housing 228 and the catheter body 120 are joined by a coupler that enhances the sealing between infusant inflow through the lumens 282 and the channels 260 and the infusant outflow through the central lumen 286. As discussed further below, this continuous lumen provides a space for the rotation of the shaft 204 of the impeller assembly 116 and the drive shaft 148 of the torque coupling system.

[0078] The physical connection between the bearing housing 228 and the catheter body 120 can be achieved in any suitable manner. Figure 3 illustrates that in one

arrangement, a slideable connection is provided. In this arrangement, a rod 332 is provided between the bearing housing 228 and the catheter body 120. The rod 332 can have any suitable configuration, but may have a proximal end configured to be received in a recess or lumen formed in the catheter body 120 and a distal end 340 configured to couple with the bearing housing 228. Figure 3 shows that the distal end 340 of the rod 332 can be configured to engage with a feature of the bearing housing 228 so that a limited range of sliding is permitted.

[0079] In one embodiment, the bearing housing 228 has an elongate channel 342 configured to receive a middle portion of the rod 332 and an enlarged depression 344 located at the distal end of the channel 342. The depression 344 has a width W that is sufficient to receive a wide distal end of the rod 332. The depression 344 can be configured to have an axial length along the housing 228 that can define a range of motion of the bearing housing 228 relative to the catheter body 120.

[0080] In one arrangement, the bearing housing 228 is positioned relative to the catheter body 120 and the rod 332 such that the distal portion of the rod 332 is located at the distal end of the depression 344. Thereafter, the catheter assembly 100 can be manipulated such that the bearing housing 228 moves distally relative to the catheter body 120 and the rod 332 such that the distal portion of the rod 332 is located at the proximal end of the depression 344. In the distal position, the impeller assembly 116 is located more distally than in the proximal position. As discussed further below, this enables a variety of techniques for unfurling the impeller blades 212 within the housing 202.

B. Bearing Configurations

[0081] Any suitable bearing can be used in the catheter assembly 100. The provision of an infusant for hydrodynamic support enables a wide range of bearing materials to be used. If saline or other more corrosive infusant is used, the bearing must be carefully configured to not degrade within the expected duty cycle of the pump 10. Some polymeric materials are advantageously not degraded by isotonic saline, and are acceptable materials from this perspective. Under the fluid-dynamic conditions, a hydrodynamic bearing that is supported by a biocompatible infusant such as isotonic saline is preferred. It is believed that certain polymer bearings in combination with isotonic saline can support such conditions as 35,000-50,000 psi-ft/min for an appropriate duty cycle. Other aspects that can guide the

choice of bearing configurations include minimizing thermal expansion, given the heat that could be generated in the heart pump 10, and minimizing moisture absorption.

[0082] Any suitable polymeric material may be used for the bearings 232a, 232b. The polymeric material can include a homopolymer, a copolymer, or a mixture of polymers. The polymeric material can include thermoplastic or thermoset polymers. Examples of polymers that can be used for bearings 232a, 232b include, but are not limited to, one or more of a polyketone, a polyether, a polyacetal, a polyamide-imide, a polyacetal, polyether ether ketone (PEEK), polytetrafluoroethylene (PTFE), and polyphenylene sulfide (PPS).

[0083] The polymeric material can also include (e.g., can be mixed, combined, and/or filled with) one or more additives such as a reinforcer and a lubricant. Specific additives include, but are not limited to, graphite, carbon fiber, glass fiber, and PTFE. Those of ordinary skill in the art may appreciate that the additives may be polymeric or non-polymeric. In some embodiments, the polymeric material used for bearings 232a and/or 232b can include PEEK, carbon fiber, PTFE, and graphite. In other embodiments, the polymeric material can include PPS and glass fiber. In yet other embodiments, the polymeric material can include a polyamide-imide polymer, carbon fiber, and graphite. The polymeric material can include any suitable amount of additive(s). For example, the polymeric material can include a total amount of additive(s) in the range of from about 1 wt% to about 50 wt%, based on the total weight of the polymeric material. In other embodiments, the polymeric material used for bearings 232a, 232b may not include any additives.

[0084] The polymeric material chosen for bearings 232a, 232b can have particular characteristics that advantageously affect the performance of the bearings. For example, in order to minimize thermal expansion caused by the heat generated in the heart pump 10, a preferred material would be subject to a minimum of dimensional change, and can have a coefficient of thermal expansion in the range of from about $1.2 \times 10^{-5} \text{ }^\circ\text{F}^{-1}$ to about $25.2 \times 10^{-5} \text{ }^\circ\text{F}^{-1}$. In other embodiments, the polymer used for bearings 232a, 232b has a coefficient of friction in the range of from about 0.15 to about 0.3. In another example, in order to minimize or prevent water absorption, the selected polymeric material can have a water adsorption in the range of from about 0.01% to about 0.4% over a 24 hour period. In yet another example, the polymeric material can be suitable for high pressure and velocity

performance, and can have a limiting pressure-velocity (PV) in the range of from about 20,000 psi-ft/min to about 50,000 psi-ft/min.

[0085] The polymeric material used for bearings 232a, 232b may be commercially available. Examples of suitable, commercially-available polymeric materials include, but are not limited to, Ketron PEEK-HPV, Turcite A, Turcite X, Turcite TX, Rulon LR, Rulon J, Rulon 641, Rulon AR, Techtron HPV PPS, Ryton PPS, Torlon 4301, and Torlon 4501. In some embodiments, the polymeric material used for bearings 232a, 232b is Ketron PEEK-HPV.

[0086] Of course, other bearing configurations and/or materials would be suitable under other conditions, e.g., with less corrosive infusants or if a hydrostatic or non-hydraulic bearing is used.

C. Torque Coupling Systems

[0087] A torque coupling system is provided to rotate the impeller 200 at a high rate to move blood from inside a heart chamber to a location within a patient's vasculature in amounts sufficient to sustain the patient or provide treatment to the patient. The torque coupling system couples the impeller 200 with the motor 136, which may be disposed outside the patient. It is expected that the impeller 200 and the drive shaft 148 are to be rotated at 25,000 - 30,000 revolutions per minute for a period of seven to ten days. To provide reliable performance under these conditions, isotonic saline or other lubricant is provided between the drive shaft 148 and stationary components therearound.

[0088] Figures 11 and 4B illustrate proximal and distal portions 400, 404 of the drive shaft 148. The proximal portion 400 is coupled with the drive assembly 146 such that rotation of the drive assembly 146 rotates the drive shaft 148. The distal portion 404 of drive shaft 148 is coupled with the impeller shaft 204 such that rotation of the drive shaft 148 causes rotation of the impeller shaft 204. The drive shaft 148 also includes an elongate body 408 that extends between the proximal and distal portions 400, 404. The elongate portion 408 comprises a lumen 412 extending therethrough.

[0089] The size of the elongate body 408 may be as small as possible to minimize the cross-sectional profile of the catheter assembly 100. The cross-sectional profile of the catheter assembly 100 corresponds to the crossing profile of the catheter assembly, which limits where the system can be inserted into the vasculature. The lumen 412 is sized to

permit a guidewire to be advanced therethrough in some embodiments. The use of a guidewire is optional, but may simplify insertion.

[0090] In one embodiment, the elongate body 408 comprises a multi-layer construction. In some embodiments, each layer can include at least one coil wire or a plurality of coil wires all wound in a same orientation. For example, a two-layer, counter-wound wire construction is particularly advantageous. A first layer (e.g., an inner layer) of the elongate body 408 is provided by a coiled wire of nickel-molybdenum-chromium alloy, such as 35NLT or MP35N. In other embodiments, the wire material can be MP35N LT. In one embodiment, the wire has a 0.008 inch diameter and the coil has a 5 filar right-hand wound construction. The outer diameter of the first layer may be about 0.071 inch. A second layer (e.g., an outer layer) of the elongate body 408 can include the same material as the first layer, disposed on the outside of the first layer. The first and second layers can be wound in the same direction, or in opposite directions. For example, in some embodiments the first layer (e.g., an inner layer) can be left-hand wound and the second layer (e.g., an outer layer) can be right-hand wound, or vice versa. In other embodiments, both the first and second layers can be left-hand wound. In yet other embodiments, both the first and second layers can be right-hand wound. The wound coil wire construction can advantageously facilitate proximal and/or distal flow of infusant along the outer layer of the elongate body 408. For example, the outer layer can be constructed such that the infusant travels along the coil and/or in the direction of the winding. Those skilled in the art may appreciate that, depending on the direction of rotation of the elongate body 408, the infusant flow can advantageously be directed either proximally or distally. The second layer may be a 5 filar left-hand wound construction. In one embodiment, each layer is formed using a 0.008 inch diameter wire, in the above-noted coiled configuration. In other embodiments, the elongate body 408 can include three or more coil wire layers, wherein the layers are wound in alternating directions. In some embodiments, the outer diameter of the second layer can be between about 0.072 inch and about 0.074 inch, while in other embodiments the diameter can be much larger or smaller. In some aspects, for example, the outer diameter of the second layer can be about 0.073 inch. The inner diameter of the elongate body 408 can be at least about 0.039 inch in some implementations. In some embodiments, one or more ends of the elongate body 408

can be welded and square cut, for example, with a 0.1 inch maximum weld length on each end. The length of the elongate body 408 can vary, but in some embodiments, the length can be between about 47 inches and 48 inches, for example, about 47.5 inches.

[0091] Other materials and other constructions are possible. The elongate body 408 can be made of other non-ferrous metals or other corrosion resistant material or constructions with appropriate modulus. Other materials that could meet the corrosion requirements include stainless steel (e.g., 302, 304, or 316). In certain embodiments, the elongate body 408 can have a structure that enables other materials to be used. For example varying at least one of coil layers, filars, wire diameter, and coil diameter may enable an otherwise less robust material to operate below the fatigue stress of that material.

[0092] In another embodiment, a four layer construction is provided. The four layers comprise three wire-wound layers, e.g., similar to the arrangement described above, but included a third wound layer on the outer surface of the second layer. A low friction layer can be disposed on the outside surface of the elongate body 408. One material that could be used as a low-friction layer is PTFE, known commercially as Teflon®. The low-friction layer should be configured to have sufficient wear resistance, such as by selection of the appropriate PTFE material, e.g. polyphenylene sulphone-filled PTFE, and/or by insuring appropriate infusant flow is maintained during the entire duration of use of the device in order to prevent undesirable local elevated temperature of the PTFE material.

[0093] The drive shaft 148 operates within the multilumen catheter body 120. Because the drive shaft 148 is rotated at a very high rate when in use within the multilumen catheter body 120, the configuration of the surface forming the central lumen 286 is important. In some embodiments, this inner surface has high lubricity and high wear resistance. One material that can be used for the inner surface of the catheter body 120 is high density polyethylene (HDPE), which provides sufficient lubricity and wear resistance. In one embodiment, the entire multilumen catheter body 120 is formed of HDPE. PTFE provides good lubricity and could be used if made sufficiently wear resistant. One way to increase the wear resistance of PTFE is to impregnate it with polyphenylene sulphone (PPSO₂), another is to gamma irradiate the material. One way to increase the lubricity of

Polyimide materials is to impregnate it with Graphite, another is to impregnate it with Graphite and PTFE.

[0094] Figure 4B shows a clearance 412 between the elongate body 408 of the drive shaft 148 and the inner surface of the multilumen catheter body 120. The clearance 412 may be about 0.005 inch. Along a diameter between opposite sides of the inner surface of the central lumen 286 and outer surface of the elongate body 408 includes about 0.010 inch of space or diametric clearance. A larger minimum clearance may be desirable if the crossing profile can be enlarged or if other structures of the catheter assembly 100 can be made thinner or eliminated to allow more room between the elongate body 408 and the central lumen 286.

[0095] Figures 11 and 12 show further details of the drive assembly 146, which is disposed at the proximal end 104 of the catheter assembly 100. The drive assembly 146 includes a drive housing 450 having a recess or cavity 454 disposed therein. The cavity 454 is configured for mounting a rotor support shaft 458 for rotation therein. The support shaft 458 has a proximal end and a distal end and a plurality of components mounted thereon. The distal end of the support shaft 458 has a recess 462 formed therein to receive a proximal end of the drive shaft 148. The support shaft 458 may also have a lumen 466 disposed therein for slideably receiving a guidewire.

[0096] A rotor 470 is mounted on an outer surface of the support shaft 458 between sleeve bearings 474a, 474b, as shown in Figure 12. The rotor 470 can take any suitable form, but in one embodiment includes an elongate magnet 476 disposed between proximal and distal flywheels 478a, 478b.

[0097] The proximal end of the support shaft 458 has a tapered port 480 for receiving the guidewire. The proximal end can be configured for engaging the motor 136 in some embodiments. In other embodiments, a magnetic field is induced by the motor 136 in a manner that creates torque and rotation of the shaft 458.

[0098] An infusant outflow path 482 is provided within the drive assembly 146. The outflow path 482 is provided between an outer surface of the support shaft 458 and an inner surface 486 of the distal bearing. The flow path 482 continues from the distal bearing 474b radially outwardly along thrust surfaces 490a. The flow path continues proximally between the outer surface of the rotor 470 and the inner surface defining the cavity 454. The

flow path 482 continues radially inwardly along the thrust surface 490a toward the support shaft 458. The flow path 482 continues proximally between the support shaft 458 and the proximal bearing 474a. Proximal of the bearing 474a, the flow of infusant exits the catheter assembly 100 through an outflow port 144 through which it can be directed to the waste container 46 or discarded. The flow path is shown in more detail in Figures 1, 12, 12A, and 12B.

III. STRUCTURES THAT FACILITATE DEPLOYMENT AND RETREIVAL

[0099] The catheter assembly 100 can include one or more features that facilitate the deployment and/or retrieval of one or more components of the distal end 108 of the heart catheter assembly 100 (e.g., the impeller assembly 116 or a portion thereof).

A. Optionally-Expandable Diffuser

[0100] As shown in Figures 13A and 13B, the pump can include a diffuser 502a, 502b. As illustrated in Figure 13A, in some embodiments the diffuser 502a is connected to the impeller hub 208. For example, the diffuser 502a can be integral, or form a unitary structure, with the impeller hub 208. In another example, the proximal end of the impeller hub 208 can include the diffuser 502a. As illustrated in Figure 13B, in other embodiments, the diffuser 502b is separate from (e.g., not connected to) the impeller hub 208.

[0101] The diffuser 502a, 502b can be disposed between the distal end of the elongate body of the catheter body and the impeller. The diffuser 502a, 502b can be configured to be positioned within the housing 202 and adjacent to the proximal opening of the housing. In some embodiments, the diffuser 502a, 502b can be axially aligned with the proximal opening of the housing 202. Advantageously, this configuration can maximize the flow directing capabilities of the diffuser 502a, 502b, as discussed further herein. The diffuser 502a, 502b can be located adjacent the proximal end of the hub 208. The diffuser 502a, 502b can include a proximal end 504a, 504b and a distal end 505a, 505b. The proximal end 504a, 504b of the diffuser 502a, 502b can be positioned adjacent the distal end of the bearing housing 228 (e.g., over a bearing 516 and/or a front thrust washer 518). As shown in Figure 13A, the proximal end 504a can be separated from the bearing 516 by a gap 522. The gap 522 can have an axial length generally equal to the length of the bearing 516. The gap 522 can also be generally cylindrical with a longitudinal axis that is aligned with the longitudinal axis of the impeller shaft 204. The distal end 505a, 505b can be located adjacent

the proximal end of the impeller hub 208. The diffuser 502a, 502b can include a flow directing surface. For example, an outer surface 513 of the diffuser 502a, 502b can form a curved line from the proximal end 504a, 504b to the distal end 505a, 505b, as illustrated in Figures 13A-B. As viewed from the proximal or distal end, the diffuser 502a, 502b can have a generally circular cross sectional shape. As shown in Figures 13A and 13B, the diameter of the diffuser 502a, 502b can be greatest in the mid section and can taper to a smaller diameter in the distal and/or proximal directions. The diffuser 502a, 502b can have a maximum diameter that is generally greater than the diameter of the hub 208 and/or the bearing housing 228. The diameter of the proximal end 504a, 504b can be generally equal to the diameter of the bearing housing 228. The diameter of the distal end 505a, 505b can be generally equal to the diameter of the hub 208. The diffuser 502a, 502b may be referred to herein as a bulge, and in various embodiments can have a radially enlarged portion disposed downstream of the impeller.

[0102] Advantageously, the relatively large diameter and/or the curved outer surface can assist in directing (e.g., diffusing) fluid flow out of the housing 202. The geometry of the diffuser 502a, 502b (e.g., the radius of curvature of the outer surface) can be optimized to control desired fluid properties such as boundary layer flow, laminar flow, and pressure gradients and to reduce outlet flow losses.

[0103] The diffuser 502a, 502b can include a wall 511. The wall 511 can include an inner surface 512 and the outer surface 513, described above. The wall 511 can have a thickness extending from the inner surface 512 to the outer surface 513. In some embodiments, the wall 511 can have a generally uniform thickness along the axial length of the diffuser 502a, 502b. One advantage of a generally uniform wall thickness is that the diffuser 502b can be more easily expanded and/or collapsed, as described herein. In other embodiments, the wall 511 can have a variable thickness along the axial length of the diffuser 502a, 502b. For example, as illustrated in Figure 13A, the thickness of the wall 511 can increase in the distal direction. One advantage of a variable thickness wall is that it can have variable structural strength. For example, a wall having a thickness that increases distally can advantageously have greater strength in areas that are most exposed to oncoming blood flow.

[0104] The inner surface 512 can define a chamber 506 through which the impeller shaft 204 can pass. As shown in Figure 13A, the diffuser 502a can form part of the proximal end of the hub 208 of the impeller 200 (e.g., the hub 208 can be connected to the diffuser 502a). Thus, the diffuser 502a can rotate with the rotating hub 208. The diffuser 502a can also include a proximal cavity outlet 508. As shown in Figure 13B, the diffuser 502b can be a component separate from the impeller 200. In this embodiment, the diffuser 502b can be stationary when the hub 208 is rotating. The diffuser 502b can also include a distal cavity outlet 510.

[0105] There can be many advantages to including a diffuser 502a that is connected to the impeller hub 208. For example, the unitary construction can be easier to manufacture and/or assemble. As described herein, the distal end of the diffuser 502a can be relatively thick and strong (e.g., stiff). In addition, it can be advantageous for the infusant to exit the catheter assembly 100 at the proximal outlet 508, which is generally at the downstream end of the diffuser 502a.

[0106] There can also be advantages to including a diffuser 502b that is a structure separate from and not directly attached to the impeller hub 208. In some embodiments, the diffuser 502b can be made from a material that is different from the material used to make impeller hub 208. For example, the diffuser 502b can be made from a material that is relatively more flexible (softer) than the material of the impeller hub 208. In other embodiments, the wall 511 of diffuser 502b can have a generally uniform thickness. These features of diffuser 502b can facilitate the expansion and/or contraction of the diffuser 502b, described further herein.

[0107] As shown in Figures 13A and 13B, the diffuser 502a, 502b can be generally hollow, as defined by the chamber 506. The diffuser 502a, 502b can be sufficiently hollow and can be made of a relatively flexible material (e.g., a polymer or elastomer) to be expandable and/or collapsible. For example, the maximum diameter of the diffuser 502a, 502b can expand from a first diameter to a second diameter. Advantageously, the collapsible diffuser 502a, 502b can have a deployed, expanded configuration, and a retracted, collapsed configuration. In the deployed, expanded configuration, the diffuser 502a, 502b can have a maximum diameter (e.g., as measured at the mid-section or bulge) that is generally greater

than the diameter of the hub 208 and/or the bearing housing 228. In the retracted, collapsed configuration, the diffuser 502a, 502b can have a reduced diameter. For example, in the retracted, collapsed configuration, the diffuser 502a, 502b can have a maximum diameter that is generally less than or equal to the diameter of the hub 208 and/or the bearing housing 228. Although described as having a diameter, those skilled in the art may appreciate that while retracted and/or collapsed, the diffuser 502a, 502b may not have a generally circular cross section. A collapsible diffuser can be advantageous compared to a non-collapsible diffuser because a collapsible diffuser can allow the overall structure to maintain a low profile for the purpose of retracting back into a sheath and for insertion into and/or removal from a patient.

[0108] In some embodiments, the relatively flexible material itself may not be significantly expandable (e.g., stretchable and/or elastic). Rather, the terms "expandable" and "collapsible" can refer to the overall expansion and/or collapse of the chamber 506 of the diffuser 502a, 502b. In other embodiments, the relatively flexible material itself may be significantly expandable (e.g., balloon-like).

[0109] The chamber 506 can be configured (e.g., sized) to allow fluid (e.g., infusant) flow through the diffuser 502a, 502b. The diffuser 502a, 502b can be configured for fluid communication with a fluid, such as an infusant, that passes through the bearing assembly 220. The bearing assembly 220 illustrated in Figures 13A and 13B can have many, if not all, of the same features as described with respect to the bearing assembly 220 illustrated in Figure 5. As shown in Figures 13A and 13B, the infusant can follow an infusant path 514a, 514b out of the bearing assembly 220 and into the diffuser 502a, 502b via a passage or cavity 520 between the bearing 516 and the washer 518. For at least a portion of the infusant path 514a, 514b, the infusant can travel distally. In some embodiments, at least a portion of the infusant path 514a, 514b can be non-helical (e.g., generally linear). In other embodiments, at least a portion of the infusant path 514a, 514b can be generally helical. The helical shape of the infusant path 514a, 514b can be caused at least in part by rotation of one or more components of the impeller assembly 116 (e.g., the impeller shaft 204 and/or impeller hub 208).

[0110] As illustrated in Figure 13A, the infusant path 514a can extend from the proximal end 504a to the distal end 505a and can return back to the proximal end 504a to exit the proximal outlet 508 via the gap 522. The portion of the infusant path 514a that extends from the proximal end 504a to the distal end 505a is helical (e.g., can encircle the impeller shaft 204 one or more times along the axial length of the path). The return portion of the infusant path 514a can be non-helical (e.g., generally linear). The return portion of the infusant path 514a can be non-helical at least in part because the return portion can follow the curved interior surface 512 of the diffuser wall 511. In use, the infusant can exit the bearing assembly 220 at the cavity 520 to enter the chamber 506. At least a portion of the infusant can then follow infusant path 514a to travel helically around the impeller shaft 204 in the distal direction until the distal end 505a is reached. The infusant then changes direction and turn around to flow proximally along the non-helical return portion of the infusant path 514a and through the gap 522 to exit the pump via the proximal cavity outlet 508. Although shown as a single distal-to-proximal line, in some embodiments, exit flow can be induced along and generally following the shape of the inner surface 512 to the proximal cavity outlet 508. In use, as the infusant passes through the gap 522, the infusant can act as a hydrodynamic bearing (e.g., in addition to the hydrodynamic bearing that may be present between the impeller shaft and the bearing housing as described herein). This hydrodynamic bearing can generally be in the shape of a cylinder that extends axially, as defined by the gap 522. Advantageously, this hydrodynamic bearing can reduce friction between the diffuser 502a and the bearing housing 228.

[0111] As illustrated in Figure 13B, the infusant path 514b can extend from the proximal end 504b to the distal end 505b. As illustrated in Figure 13B, the infusant path 514b is helical (e.g., can encircle the impeller shaft 204 one or more times along the axial length of the path). In use, as shown in Figure 13B, generally all of the infusant flows proximally to distally within a distal portion of the bearing assembly 220 and exits the bearing assembly at the cavity 520 to enter the chamber 506. In various embodiments, a portion of the infusant flows proximally within a proximal portion of the bearing assembly 220 through a space between the drive shaft 148 and the catheter body 120. This return flow is discussed above, e.g., in connection with arrow 304 in Figure 8. At least a portion of the

infusant then follows the infusant path 514b to travel helically around the impeller shaft 204 in the distal direction and out through the distal cavity outlet 510. As illustrated in Figure 13B, the distal cavity outlet 510 defines a gap between the distal end 505b of diffuser 502b and the proximal end of impeller hub 208. In use, as the infusant passes through the distal cavity outlet 510, the infusant can act as a hydrodynamic bearing. This hydrodynamic bearing can generally be in the shape of a cylinder having a length extending axially along the length of the gap and a radius corresponding to the cross sectional radius of the gap. Advantageously, this layer of infusant between the diffuser and the impeller hub can reduce friction between the diffuser 502b and the impeller hub 208 when the pump is in operation.

[0112] As described herein, the diffuser 502a, 502b can be expandable. In some embodiments, one or more forces exerted by the infusant can be used to expand the diffuser 502a, 502b. The flow rate of the infusant can be sufficient to establish an area of positive pressure within the diffuser 502a, 502b, thereby allowing at least a portion of the infusant to exit adjacent to a distal end of the device. In some embodiments, the static pressure of the infusant entering the chamber 506 can cause the diffuser 502a, 502b to expand. In any of these embodiments, an inflated diffuser 502a, 502b can be deflated by interrupting and/or discontinuing the flow of infusant into the diffuser 502a, 502b and by allowing the infusant to exit the diffuser via the proximal outlet 508 or the distal outlet 510. In some embodiments, the wall is elastic but the pliability is relatively low such that upon removal of the infusant flow a transition from expanded to low profile is rapid. The diffuser 502a, 502b self-collapses displacing the infusant out of the chamber 506 through one or more small apertures. In addition to promoting quick deflation, the relatively low pliability will provide a uniform diffuser profile, e.g., will not be deformed or deflected by any varying pressure or flow rate of the blood from the impeller 200. A lower infusant pressure configuration can also be provided by increasing the pliability of the structure forming the diffuser 502a, 502b. The structure can be of enhanced pliability by material selection or constructions (e.g., by being thinner or adopting other balloon-like features).

[0113] In other embodiments, the centrifugal force exerted by the infusant as it travels along the helical path 514a, 514b can be used to expand the diffuser 502a, 502b. As illustrated in Figure 13A, the diffuser 502a can be connected to the impeller assembly 116.

In these embodiments, the diffuser 502a and the impeller assembly 116 can be rotated. In use, when the impeller assembly 116 and the diffuser 502a are rotated, the infusant can also rotate due to, e.g., shear forces generated from the fluid contact with the rotating diffuser 502a and/or the rotating impeller shaft 204. The rotating infusant can exert a pressure on the inner surface 512 to thereby expand the diffuser 502a from the collapsed configuration to the expanded configuration. Thus, in some embodiments, the diffuser 502a can be centrifugally expanded. In yet other embodiments, the diffuser 502a can be expanded using a combination of static and centrifugal forces.

[0114] As illustrated in Figure 13B, the diffuser 502b may not be rotatable. In these embodiments, when the impeller shaft 204 is rotated, the infusant can also rotate due to, e.g., shear forces generated from the fluid contact with the rotating impeller shaft 204. As described herein, the rotating infusant can exert a pressure on the inner surface 512 to thereby expand the diffuser 502b from the collapsed configuration to the expanded configuration. Thus, in some embodiments, the diffuser 502b can be centrifugally expanded. In yet other embodiments, the diffuser 502b can be expanded using a combination of static and centrifugal forces.

[0115] Infusant exiting the diffuser 502a, 502b can be continuously replenished with additional infusant via the flow path 514. If the impeller shaft 204 stops rotating, the pressure generated from rotation can decrease to match the pressure acting on the outside of the diffuser 502a, 502b, thereby allowing the diffuser 502a, 502b to collapse.

[0116] In yet other embodiments, the diffuser 502a, 502b can be expanded and/or inflated by a combination of static and centrifugal forces. For example, the diffuser 502a, 502b can be expanded and/or inflated by a combination of the static force of the infusant as it enters the chamber 506 and the centrifugal force of the infusant as it travels along the helical path 514.

B. Relatively Axially-Moveable Impeller Housing

[0117] As illustrated in Figure 14B, when the impeller and the diffuser 502 are in the proximal position, at least a portion of the impeller (e.g., the blades 212 and/or the hub) and/or the diffuser 502 may be relatively positioned in a portion of the housing 202 having minimal or no coating, such as an outlet 802 of the housing 202 (e.g., the outlet through

which blood is pumped). In some embodiments, the housing 202 can be moved axially relative to the impeller and/or the diffuser 502. In some embodiments, the housing 202 is moved axially over the impeller and the impeller is stationary. Those skilled in the art may appreciate that in some embodiments, the housing 202 may not be configured to move axially relative to the impeller and/or the diffuser 502 (e.g., housing 202 is fixed or stationary relative to impeller and/or the diffuser 502). For example, the housing 202 and the diffuser 502 can be spaced apart by a relatively constant axial distance in all operational states, or at least in a collapsed and an expanded state.

[0118] As illustrated in Figures 14A and 14B and as described herein, the rod 332 provided between the catheter body 120 and the bearing housing 228 enables a slideable engagement between the catheter body 120 and the bearing housing 228. The distal end of the catheter body 120 can be connected to the proximal portion 268 of the impeller housing 202. The catheter body 120 can translate distally from a proximal position to a distal position, and vice versa, by the application of an axial force described further herein. As described herein, for example with respect to Figures 4A-4B, the catheter body 120 can be coupled to the proximal portion 268 of the impeller housing 202. For example, the proximal portion 268 of the impeller housing 202 can be fitted over the distal end of the catheter body 120.

[0119] In the proximal position, illustrated in Figure 14A, the axial position of the outlet 802 can be proximal of the axial position of the proximal-most blade 212. In the distal position, illustrated in Figure 14B, the axial position of the outlet 802 can generally correspond to the axial position of the proximal-most blade 212. Advantageously, the rod 332 and the enlarged depression 344 can control the axial distance over which the impeller housing 202 is capable of sliding. The rod 332 can also advantageously prevent the bearing housing 228 from rotating with the impeller shaft 204.

[0120] Those skilled in the art may appreciate that the axial movement of the catheter body 120 and the impeller housing 202 relative to the impeller and/or the diffuser 502 can have the same relative effect as axially moving the impeller and/or the diffuser 502 relative to the catheter body 120 or the impeller housing 202, even if the impeller and/or the diffuser are not actually moved axially. Accordingly, in some embodiments the catheter body

120 in the proximal position can be referred to as the deployed position of the impeller and/or the diffuser 502. The catheter body 120 in the distal position can be referred to as the retracted position of the impeller and/or the diffuser 502.

[0121] The ability of the impeller and/or the diffuser 502 to be retracted and deployed relative to the impeller housing can have many advantages. For example, axial movement of the impeller housing relative to the impeller and/or the diffuser can reduce the profile of the pump to ease insertion and retrieval. In some embodiments, in the retracted position, the impeller hub 208, blades 212, and/or diffuser 502 can be positioned at the same axial location as a portion of the housing 202 that does not have a covering (e.g., the outlet 802). Accordingly, the cross-sectional area of the catheter assembly 100 measured at the axial position of the diffuser 502 in the retracted position, for example, is comparatively smaller than when it is in the deployed position. The smaller cross sectional area can be advantageous for minimizing trauma to a user during insertion into and/or retrieval from the body.

[0122] In other embodiments, the retracted position of the impeller and/or the diffuser can be distal of the deployed position of the impeller and/or the diffuser. In some embodiments, the impeller housing can have a rigidity that varies axially. For example, the impeller housing can have a proximal portion that is more rigid (e.g., less flexible) than a distal portion. In these embodiments, the impeller and/or the diffuser can reside in the proximal, rigid portion while in the deployed position. The impeller and/or the diffuser can reside in the distal, flexible portion while in the retracted position. Advantageously, when the impeller and/or the diffuser reside in the flexible portion of the impeller housing, this portion of the pump may be collapsed to a lower profile than would otherwise be achievable if the impeller and/or the diffuser remained in the rigid portion of the impeller housing.

[0123] As described herein, the catheter body can be coupled to the impeller housing. The retraction and deployment (e.g., movement between proximal and distal positions) of the impeller housing can be controlled by manipulation of a proximal end of the catheter assembly that results in an application of axial force to the catheter body. For example, the impeller housing can be moved axially by the rotational force applied by a nut

disposed at the proximal end of the catheter assembly. A section of the proximal end of the catheter assembly is illustrated in Figures 15A and 15B.

[0124] In some embodiments, axial force is applied to the catheter body via an impeller deployment assembly 800. The impeller deployment assembly includes a nut 804 that is engaged with a portion of the catheter assembly, such as a flow diverter 806. As described herein, the flow diverter 806 can be a part of the infusion inflow assembly 150, illustrated in Figure 1. The distal end of the flow diverter 806 can be connected to a proximal portion of the catheter body. In some embodiments, the nut 804 can be engaged with a pin 808. The pin 808 can penetrate through the wall of the drive housing 450 and can be coupled with or fixedly attached to the flow diverter 806. The nut 804 can be disposed over at least a portion of the drive housing 450 and/or the flow diverter 806. The nut 804 can include an internal engagement structure that is configured to engage the flow diverter 806 (e.g., via the pin 808). In some embodiments, the internal engagement structure can include internal threading. In other embodiments, the internal engagement structure can include a cam track 812 having first and second ends (e.g., a proximal end and a distal end), as illustrated in Figure 15C. In these embodiments, the pin 808 can be configured to travel along the cam track 812. The internal engagement structure can be generally helical. The drive housing 450 can also include a longitudinal channel 810 along which the pin 808 can travel.

[0125] As illustrated in Figures 15A and 15B, the drive housing 450 can contain the support shaft 458 and the drive shaft 148. The drive housing 450 can also capture the nut 804. For example, a retention structure can be formed in the outside surface of the housing 450 to prevent the nut 804 from slipping proximally or distally relative to the housing 450. One embodiment of a retention structure is illustrated below in connection with the deployment device of Figures 15D-F but can be included with the deployment device 800 as well. The pin 808 can penetrate the wall of the drive housing 450 and permit axial translation of the flow diverter 806 by acting as a cam. In some embodiments, the support shaft 458 and the thread advance nut 804 may be rotatable but not translatable relative to the drive housing 450.

[0126] In use, a rotational force can be applied to the nut 804. This application of rotational force can be converted into an axial force that is applied to the flow diverter 806

and the catheter body. As described herein, the pin 808 can be fixedly attached to the flow diverter 806 at one end and have a second end disposed within the inner surface of the nut 804 along the cam track thereof. The rotation of the nut 804 in a first direction (e.g., clockwise or counter-clockwise) can cause the pin 808 to translate from a proximal position (e.g., proximal end) to a distal position (e.g., distal end) in the longitudinal channel 810. Accordingly, the flow diverter 806, the catheter body, and the impeller housing can also translate from a proximal position to a distal position. As described herein, the distal translation of the catheter body and the impeller housing can improve the ease of the retraction of the impeller hub and the blades into the impeller housing. In embodiments where the outlet 802 is generally free of a polymeric coating, relative movement of at least a portion of the impeller and/or the diffuser proximally into the outlet 802 or distally into a more flexible region of the impeller housing (i.e., mid section of the housing where there is less strut material) can advantageously reduce the profile of the pump upon collapsing into the sheath. In addition, axial adjustment of the impeller housing relative to the impeller can advantageously promote more efficient flow dynamics. In some embodiments, the impeller is positioned closer to the outlet 802 than the middle portion of the housing in order to improve flow dynamics.

[0127] A rotational force applied to the nut 804 in a second direction (e.g., counter-clockwise or clockwise) can cause the pin 808 to translate from the distal position to the proximal position. Accordingly, the flow diverter 806, the catheter body 120, and the impeller housing 202 can also translate from a distal position to a proximal position. As described herein, the proximal translation of the catheter body 120 and the impeller housing 202 can effectively result in the deployment of the impeller hub 208 and the blades 212.

[0128] Figures 15D-F illustrate another embodiment of a deployment device 850 that can be used to manipulate or deploy a distal structure of the catheter assembly and/or the impeller housing. As with the deployment device 800, the deployment device 850 can be used to actuate the impeller 200 between retracted and deployed configurations.

[0129] As discussed above, the catheter assembly can include a flow diverter 852 that is part of the infusion system. The flow diverter 852 may be coupled with a proximal portion 122 of the catheter body 120. In one embodiment, the proximal end of the proximal

portion 122 is inserted into a recess 854 formed at a distal 852a end of the flow diverter 852. The connection between the proximal portion 122 of the catheter body 120 the flow diverter 852 can be further made secure by a strain relief 856 disposed at the junction and extending distally thereof. The strain relief 856 overlaps a proximal length of the proximal portion 122 and absorbs movements of the portions of the catheter assembly to isolate the connection between the flow diverter 852 and the catheter body. A cap 860 can be used to securely couple strain relief 856 to the flow diverter 852. A proximal portion 862 of the flow diverter 852 is received within a recess 864 of the housing 450. A seal device 866, such as an O-ring, may be provided between the proximal portion 862 of the flow diverter 852 and inside surface of the recess 864 to prevent infusion from exiting the housing 450 in an undesirable manner.

[0130] The flow diverter 852 also includes a lumen 868 that extends from a proximal end 852b to the distal end 852a thereof. The lumen 868 is configured to permit a proximal portion of the drive shaft 148 to reside therein. In some embodiments, flow diverter 852 is configured to cause some infusant to flow proximally in the lumen 868 between the drive shaft 148 and the inner surface of the flow diverter 852 that forms the lumen 868 to lubricate and cool the drive shaft. The flow diverter 852 can be configured to cause most or substantially all of the infusant entering the diverter through the lumen in the catheter body 154 to flow distally between the catheter body 120 and the drive shaft 148. In one arrangement, the lumen 868 is enlarged from a location proximal of where the catheter body 154 couples with the flow diverter 852 toward the distal end 852a of the flow diverter. This enlargement creates a path of least resistance toward the distal direction to divert the flow distally. In one embodiment, the lumen 868 is further enlarged at a location between where the catheter body 154 couples with the flow diverter 852 and the recess 854 such that a substantially continuous lumen can be formed to keep flow resistance at the junction between the flow diverter 852 and the proximal portion 122 of the catheter body 120 to a minimum.

[0131] The deployment device 850 includes a guide track 872 on a proximal portion 862 of the flow diverter 852, a guide member 874, and an actuator 876. The guide track 872 can comprise an axially oriented slot or recess formed in the outside surface of the proximal portion 862. The guide track 872 may be configured to slidably receive a guide

member 874 such that relative movement can be provided between the guide track 872 and a guide member 874. A portion of the guide member 874 may extend through sidewall of the drive housing 450 such that the axial position of the guide member 874 can be fixed and relative movement is provided by movement of the flow diverter 852 relative to the guide member. In one embodiment the guide member 874 is a pin that has one end received in a small hole in the drive housing 450 and the other end disposed in the guide track 872.

[0132] The actuator 876 is configured to translate rotational motion thereof into axial motion of the flow diverter 852. For example, the actuator 876 can comprise a nut that includes internal threads that are engaged with external threads on the outside surface of the flow diverter 852. In various embodiments, a proximal portion of the actuator 876 is anchored to the drive housing 450 to prevent the actuator 876 from moving axially along the drive housing. In one embodiment a retention structure 882 is provided between the actuator 876 and the drive housing 450. One embodiment of the retention structure 882 is illustrated in detail B of Figure 15D. In particular, the retention structure 882 includes an inwardly protruding member 884 that is received in an annular recess formed in the outside surface of the drive housing 450. The protruding member 890 can include an inwardly protruding ring having a diameter that is less than the diameter of the actuator 876 distally and proximally of the protruding member 884.

[0133] Figures 15E-F illustrate operation of the deployment device. Figure 15E corresponds to an expanded configuration of the catheter assembly 100. In this position, the pin 874 is positioned at the distal end of the guide track 872 and the flow diverter 852 is in a proximal position. Because the flow diverter 852, the catheter body 120, and the impeller housing are coupled together so that they move in unison, the catheter body 120 and the impeller housing are also positioned in a relatively proximal position. Relative axial movement is permitted between the impeller and the catheter body, as well as between the diffuser and the catheter body. Also, because the catheter body 120, the flow diverter 852, and the impeller housing move in unison, relative axial movement is permitted between the impeller (and/or diffuser) and the impeller housing. As a result, the impeller will be in a more distal position relative to the impeller housing when the catheter assembly 100 is in the

configuration of Figure 15E. The more distal position moves the impeller into the largest volume portion of the impeller housing enabling the impeller to expand.

[0134] Figure 15F corresponds to a collapsed configuration of the catheter assembly 100. In this position, the pin 874 is positioned at the proximal end of the guide track 872 and the flow diverter 852 is in a distal position. This causes the impeller to be in a more proximal position relative to the housing when the catheter assembly is in the configuration of Figure 15F. This more proximal position moves the impeller into engagement with the inside surface of the housing tending to collapse the impeller.

[0135] To move from the expanded configuration of Figure 15E to the collapsed configuration of Figure 15F, the actuator 876 is rotated in a manner that causes the threads to act upon each other which creates axial movement of the catheter body 120 and the impeller housing 202.

C. **Impellers Having Self-Sealing Impeller Tips and Lumens With Valves**

[0136] In some embodiments, the tip 602 of impeller hub 208 can be self-sealable or resealable (e.g., configured to automatically effectively form a seal to substantially stop the flow of a fluid in the absence of direct action by a user or operator to form the seal), as illustrated in Figures 16A-C. As illustrated in Figures 16B-C, the tip 602 of impeller hub 208 can include a resealable member having a resealable path therethrough.

[0137] As shown in Figure 16A, the impeller tip 602 can be made of an elastomeric material (e.g., a silicone or polyisoprene polymer). As shown in Figure 16A, the tip 602 can include a resealable path 604 that extends along the length of the tip. The resealable path 604 can extend from the outer surface at the distal end of tip 602 to the impeller shaft, which can be hollow. The hollow shaft extension 606 is shown in Figures 16A and 16B connected by the resealable path 604 to the tip 602 and is connected at its proximal end to the impeller shaft 204. Thus, the resealable path 604 can extend from the impeller shaft 204 to the outer surface of the tip 602. The resealable path 604 can be configured for guidewire passage. The resealable path 604 can generally pass through the center of rotation of the impeller tip 602.

[0138] The resealable path 604 can be created using a very small diameter, e.g., a 32 gauge (0.00925 inch or 0.235 mm) wire or pin. In some embodiments, the resealable path 604 can be created without coring the impeller tip 602 (e.g., without punching out or

otherwise removing a cylinder of material). The resealable path 604 can be self-sealable. For example, the resealable path 604 can close or seal automatically, without the use of additional tools or implements. The resealable path 604 can be self-sealable due to the elastomeric properties of the material used for impeller tip 602 (e.g., a silicone or polyisoprene polymer) and/or the diameter of the resealable path 604. In some embodiments, circumferential and radial forces of the tip material and/or external pressure forces (illustrated with arrows at 612) exerted while the catheter assembly 100 is implanted can also contribute to sealing the resealable path 604.

[0139] In some embodiments, the tip 602 or resealable member 622, 624 can be made of the same material as the rest of the impeller system (e.g., hub, blades, shaft, and/or shaft extension). In other embodiments, the tip 602 or resealable member 622, 624 can be made from a different material than the rest of the impeller system (e.g., hub, blades, shaft, and/or shaft extension). For example, the tip 602 or resealable member 622, 624 can be made of a material that is more elastomeric (e.g., has greater elasticity) than the material from which the impeller shaft 204 and/or shaft extension 606 are formed. In another example, the tip 602 or resealable member 622, 624 can be made from a polyisoprene polymer and at least a portion of the impeller shaft 204 (e.g., the distal end) and/or shaft extension 606 are formed from an acrylonitrile butadiene styrene (ABS) polymer or a polycarbonate polymer.

[0140] In some embodiments where the impeller tip 602 comprises a resealable member 622 that is made separately from the rest of the impeller system, the resealable member 622 can include one or more proximally-extending tabs 616. The one or more tabs 616 can be disposed about the proximal end of resealable member 622. In some embodiments, the resealable member 622 can include one generally cylindrical tab 616 that is disposed about the proximal end of the resealable member 622. The one or more tabs 616 can be configured to mate with (e.g., can engage and/or be disposed within) one or more of the corresponding recesses 618 disposed on the distal end of a portion of the impeller assembly 116 (e.g., the hub 208, shaft 204, and/or shaft extension 606). As illustrated in Figure 16B, the recess 618 can be bounded by the surfaces of the hub 208 and the shaft extension 606. The one or more recesses 618 can be disposed about the distal end of impeller assembly 116. In some embodiments, the distal end of the impeller assembly 116 can include

one recess 618. For example, the recess 618 can be a generally cylindrical channel surrounding at least a portion of the shaft extension 606.

[0141] Engagement of the resealable member 622 with the distal end of the impeller assembly 116 as illustrated in Figure 16B can have many advantages. For example, an interface 620 between the resealable member 622 and the distal end of the impeller assembly 116 can be non-planar. Accordingly, a non-planar interface 620 can have a greater surface area than an otherwise similar interface that is planar. The increased surface area can advantageously increase the connection strength between the resealable member 622 and the distal end of the impeller assembly 116. In one embodiment, the interface 620 can be much longer than the radial distance from the lumen 610 to the outer surface of the hub 208. For example, the interface 620 can be at least about twice as long as this radial distance.

[0142] As illustrated in Figure 16B, resealable member 622 can include a valve 608 that extends proximally into an axial lumen 610. One valve structure that can be used is a duck bill valve. The lumen 610 can pass through one or more components of the distal end of the impeller assembly 116, such as the impeller shaft 204, the impeller shaft extension 606, and/or the hub 208. The lumen 610 can have a diameter that is greater than the diameter of the resealable path 604. The lumen 610 may also not be self-sealing. The valve 608 can be tapered or otherwise have a reduced cross section compared to the lumen 610. As a result, the impeller tip can also include one or more corners 614 where the lumen 610 extends distally to overlap with the valve 608. The outer surface of valve 608 can be separated by a distance from the inner surface of the resealable member 622. Advantageously, where the pressure within the lumen 610 is greater than the pressure outside the catheter assembly 100, the internal pressure can be exerted on valve 608 to close resealable path 604. The proximal extension of the valve 608 into the lumen 610 can also promote easier entry of a guidewire into the lumen 610 when the guidewire is introduced from the distal end of the pump. Other valves structures that may be used in place of the valve 608 are discussed in US Application No. 12/829,359 and in US Patent No. 7,022,100, which are incorporated by reference herein for all purposes and in its entirety.

[0143] Another embodiment of an impeller tip 602 that includes a resealable member 624 is illustrated in Figure 16C. The resealable member 624 can have a resealable

path 630 therethrough. The resealable member 624 can optionally include a distal tapered portion. As described herein, the impeller can be coupled with the catheter body through a drive shaft 148, which can be disposed or received within the axial lumen of the impeller or within the impeller shaft 204. As illustrated in Figure 16C, a distal portion of a shaft, e.g., the drive shaft 148 or the impeller shaft 204, can be disposed or received within the resealable member 624. The impeller tip 602 can further include a non-resealable portion 626 having a non-resealable path 628 extending therethrough (e.g., a path that generally does not seal or close once it has been opened or created, and/or remains permanently open allowing fluid to pass therethrough). The resealable path 630 and the non-resealable path 628 can be co-linear (e.g., coaxial). As illustrated in Figure 16C, the non-resealable portion 626 can extend distally of the resealable member 624. In some embodiments, the non-resealable portion 626 can partially or fully surround an outer surface of the resealable member 624. For example, the resealable member 624 can be partially or entirely contained within the non-resealable portion 626. As illustrated in Figure 16C, the non-resealable portion 626 can include the distal-most portion of the impeller tip 602. In some embodiments, the non-resealable portion 626 can be a unitary structure that includes the hub and one or more blades of the impeller. In one embodiment, the non-resealable portion 626 can include the entire impeller body except for the resealable member 624. For example, as discussed above, the impeller can include a hub disposed between the impeller blades and the impeller shaft 204. The impeller hub can surround the resealable member 624.

[0144] Advantageously, the impeller tip 602 can be configured to receive a guidewire through both the resealable path and the non-resealable path 628. In some embodiments, the resealable path (when open) and/or the non-resealable path can have a diameter that is no more than one-half the diameter of the guidewire. Where the impeller tip 602 includes a resealable member 624 disposed therein, the resealable member can be advantageously protected from the trauma to which the outer surface of the impeller tip 602 may be exposed. In addition, the distally-extending non-resealable path can act as a guide or channel that directs the guidewire through the impeller. Furthermore, as discussed herein, the tapered shape of the distal portion of the resealable member 624 can help to reseal the resealable member 624, as radial forces extending inwards can surround the tapered portion

and help to close the resealable path. Note in this case that the non-resealable member, also made of an elastomeric material (but different actual material), retains a level of elasticity that can stretch to a lesser degree than the resealable material to accommodate passage of the guidewire.

[0145] The impeller tip 602 illustrated in Figure 16C can be manufactured by first molding a soft and/or elastomeric material over at least a portion of the drive shaft 148 of the impeller shaft 204 to form the resealable member 624. Some suitable materials for forming the member 624 include polyurethane and silicone. Some materials having low durometer, e.g., below 60A, can be used for the resealable member 624. In some embodiments, the material can have a durometer in the range of from about 25A to about 55A. For example, the material can be a polyurethane or a silicone polymer having a durometer below 60A (e.g., in the range of from about 25A to about 55A). In some embodiments with a polyurethane material, the hardness can be for example, about 25A, about 35A, about 45A, or about 55A. In other embodiments, a silicone material can be used for the tip 602 and/or the resealable member 622, 624. The silicone material can have a hardness ranging from about 20A to about 60A. In some embodiments, the hardness can be about 38A. As described above, the resealable member 624 can optionally be formed to include a distal tapered portion. The rest of the impeller, or a portion thereof, can then be molded over the resealable member 624 and the drive shaft 148. The remainder of the impeller tip 602 can be formed from a second material (e.g., a second polymer) that is different from the material used to form the resealable member 624. The non-resealable path 628 and the resealable path 630 can be created after the impeller is molded over the drive shaft 148 or the impeller shaft 204. A variety of methods and/or tools can be used to create these paths, including but not limited to a drill, a needle, or a small gauge screw. In some embodiments, the paths 628, 630 can be formed from a proximal end to a distal end of a wall of the impeller hub, e.g., distal of the distal most blade. In other embodiments, the paths 628 can be formed from a distal end of the impeller toward a proximal end of the impeller.

[0146] In use, those skilled in the art may appreciate that non-sealable (e.g., non-resealable or non-self-sealing) devices may require a constant flow of infusant in the distal direction to prevent the proximal flow of fluid or blood into the device. Advantageously, a

resealable tip can allow for guidewire passage through the center of the catheter assembly 100 to ease insertion without requiring a constant flush of infusant. The tip in various embodiments the resealable tip self-seals when the guidewire is removed. Valves discussed herein provide the advantage of preventing blood from entering other portions of the catheter assembly 100, such as the impeller shaft 204 or the lumen 234 or the bearing housing 228. In various embodiments, valves are configured to be actuated from an at least partially open configuration to a closed configuration, such as by application of a force or pressure on one side thereof.

D. Sheath Having Expandable Distal End

[0147] As described herein, the pump can include a sheath assembly. The sheath assembly can control the collapse and expansion of the impeller and/or the impeller housing. In some embodiments, the distal end of the sheath assembly can optionally include one or more structures that aid in the deployment and/or retrieval of the impeller assembly.

[0148] In some embodiments, as shown in Figures 17A to 17D, the sheath assembly can include an expandable distal end 170a, 170b, 170c. For example, the distal end can expand when a radial force is applied, and can contract when the radial force is removed. The distal end may also be able to expand and/or contract repeatedly. When expanded, the distal end 170a, 170b, 170c can have a conical and/or funnel-like configuration. When not expanded, the distal end 170a, 170b, 170c can have a generally cylindrical (e.g., generally constant diameter) configuration, for example as illustrated in Figure 17A. To assist with expansion and/or contraction, the distal end 170a, 170b, 170c or portions thereof may be made from materials having a different flexibility and/or elasticity (e.g., more or less flexible and/or elastic) than the material(s) used for all or a portion of the remainder of the sheath assembly. In some embodiments, the sheath assembly 162 can have at least one configuration where it is at least partially disposed over the impeller housing, catheter assembly, and/or impeller assembly. Advantageously, the conical and/or funnel-like configuration can aid the deployment and/or retraction of the impeller assembly and/or impeller housing as described herein.

[0149] As illustrated in Figure 17A, the distal end 170a can include one or more axial slits 702 (e.g., 2, 3, or 4 slits). Slit 702 can extend proximally from the distal end 170a at least partially along the length of the elongate body 174. The distal end 170a can also

include a plurality of elongate members 704 (e.g., 2, 3, or 4 elongate members). Each elongate member 704 can be joined at one end (e.g., proximal end) to the sheath assembly. Each elongate member 704 can also have a distal end 705 that is outwardly deflectable away from axis 708. The elongate members 704 can be separated from each other by the slits 702. Each elongate member 704 can have a width that is defined by the distance between slits 702 and a length defined by the length of each adjacent slit 702. In some embodiments, the elongate members 704 and slits 702 can be generally equally spaced circumferentially about the elongate body 174. In some embodiments, the elongate members 704 can each have a length that is generally equal to or greater than the axial length of the outlet portion of the impeller housing. For example, in some embodiments, the elongate members 704 can each have a length in the range of from about 0.25 in. up to about 2.0 in. In other embodiments, the elongate members 704 can each have a length in the range of from about 0.5 in to about 0.75 in. The elongate members 704 and/or at least a portion of the sheath assembly 162 (e.g., the portion of the sheath assembly 162 that connects to elongate members 704) can be made from a relatively elastic material (e.g., any of the elastomeric polymers described herein).

[0150] In use, an outwardly-acting radial force resulting from the radial stiffness of the impeller housing can be applied to the elongate members 704 which causes the elongate members 704 to deflect outwards, as illustrated in Figure 17B. For example, the axial movement of the impeller housing in the proximal direction into the sheath assembly (or distal movement of the sheath over the expanded impeller housing) can cause the elongate members 704 to deflect outwards. The outward deflection of the elongate members 704 can result in the conical or funnel-like configuration of the distal end 170a when sheathed over an expanded section of the impeller housing. When the elongate members 704 are deflected outwards, the width of each slit 702 can increase at the distal end to define a gap 709. In some embodiments, the elongate members 704 can be self-collapsing. For example, the elongate members 704 can be configured to return to their original configuration when the internal outward-acting radial forces are released (e.g., where the elongate members 704 are made of a relatively elastic material).

[0151] As illustrated in Figure 17C, the distal end 170b of the sheath assembly can include an deformable structure 706 (e.g., a webbing) that at least partially covers one or

more slits 702. In some embodiments, the deformable (e.g., stretchable, expandable, flexible, and/or elastic) structure 706 can surround, coat, and/or cover at least a portion of the distal end 170b (e.g., the elongate members 704). As illustrated in Figure 17C, the deformable structure 706 can be an elastomeric coating (e.g., incorporating those elastomeric materials described herein). In other embodiments, the deformable structure 706 can include a spring, such as a semi-circular spring member having a straight or oscillatory pattern. In use, the deformable structure 706 can be configured to return the elongate members 704 to their original, non-conical configuration and/or prevent over-deflection of the elongate members 704 beyond their elastic limit.

[0152] In some embodiments, the elongate members 704 can be stiffer (in the circumferential and/or axial direction(s)) than the proximally-adjacent portion of the sheath assembly. Advantageously, the stiffer material can prevent or inhibit the distal-most end of the sheath assembly from folding over itself when it encounters resistance (e.g., advancing the sheath over an expanded cannula housing). In one embodiment, one or more elongate members 704 can be reinforced with a plurality of wires that extend to the distal-most tip of the elongate member 704. In another embodiment, one or more elongate members 704 can be made from a polymer that is stiffer than the material (e.g., a second polymer) of the proximally-adjacent portion of the sheath assembly.

[0153] As illustrated in Figure 17D, in some embodiments the distal end 170c of sheath assembly 162 can include an integral funnel 710 having a distal, conically-shaped portion 711. As described further herein, the integral funnel 710 can be expandable and/or collapsible. Advantageously, the integral funnel 710 can assist in deployment and retraction of the housing while minimally increasing the profile of the pump. The integral funnel 710 can be connected to a non-expandable portion 712 of the sheath, for example, at a distal-most tip 714. The integral funnel 710 can include an outer layer 713 and an inner layer 715 that converge at an interface 717. The integral funnel 710 can be layered over an outer surface 716 and over an inner surface 718 of the non-expandable portion 712. Accordingly, as illustrated in Figure 17D, at least a portion of the inner layer 715 can reside, at least temporarily, within the lumen of the sheath assembly 162. The integral funnel 708 can be connected to either the outer surface 716 or the inner surface 718 of the sheath. In some

embodiments, the funnel 710 can be a distal extension of distal end 170 that is folded over the non-expandable portion 712.

[0154] The integral funnel 710 can be slideable over the outer surface 716 and/or the inner surface 718 of the non-expandable portion 712. The contact surfaces between the non-expandable portion 712 and the integral funnel 710 and/or between the outer layer 713 and the inner layer 715 can be lubricated, e.g., using a silicone lubricant, to establish and/or maintain slideability and/or low friction. The integral funnel 710 can be made from a thin, flexible material, such as a polyurethane polymer. In some embodiments, the integral funnel 710 can be made from a material that is more flexible and/or elastic than the material that is used for all or a portion of the remainder of the sheath assembly. In some embodiments, the material used for the integral funnel 710 can have one or more membrane-like qualities. In use, the axial movement of the housing 202 (not shown) can frictionally engage the integral funnel 710, causing the integral funnel 710 to deploy or retract. For example, in embodiments where the outer layer 713 is affixed to the non-expandable portion 712 of the sheath, axial movement of the housing 202 in a distal direction can cause the inner layer 715 to translate distally (e.g., slide distally along the inner surface 718 of the sheath), thus deploying the conical portion 711 (e.g., pulling the conical portion 711 out of the sheath). Axial movement of the housing in a proximal direction can cause the inner layer 715 to translate proximally (e.g., slide proximally along the inner surface 718 of the sheath), thus retracting the conical portion 711 into the sheath (e.g., pulling the conical portion 711 into the sheath). The thin, flexible material of the conical portion 711 can advantageously allow the conical portion 711 to deform upon retraction into the sheath.

[0155] In embodiments where the inner layer 715 is affixed to the non-expandable portion of the sheath, axial movement of the housing 202 can cause the outer layer 713 to translate. For example, distal movement of the housing can cause the outer layer 713 to slide distally along the outer surface 716 of the sheath. Proximal movement of the housing can cause the outer layer 713 to slide proximally along the outer surface 716 of the sheath.

[0156] In some embodiments where the funnel 710 is a distal extension of the non-expandable portion 712 that is folded over the non-expandable portion 712, the funnel 710 can slide distally as the non-expandable portion 712 is moved proximally. In use, as the

non-expandable portion 712 is moved proximally, the funnel 710 can slide distally to unfold and surround the impeller assembly 116.

IV. METHODS

[0157] Various methods and techniques are discussed above in connection with specific structures of heart pumps. The following elaborates on some aspects of these techniques and methods. The following discussion is to be read in light of and freely combined with the foregoing discussion.

A. Retracting and Deploying the Impeller Housing By Way of the Impeller Deployment Assembly at the Proximal End of the Catheter Body

[0158] As discussed above, in various embodiments the heart pump 10 is inserted in a less invasive manner, *e.g.*, using techniques that can be employed in a catheter lab. Various general techniques pertinent to the heart pump 10 are described in U.S. Patent Application No. 12/829,359, filed on July 1, 2010, and entitled *Blood Pump With Expandable Cannula*, which is incorporated by reference herein in its entirety and for all purposes.

[0159] Because the catheter assembly 100 is to be delivered through a small access site, it can be important to ensure that the impeller housing is reliably deployed and retracted, as described above. A clinician may begin a heart pumping procedure by introducing the catheter assembly 100 into the patient percutaneously, *e.g.*, by urging the catheter assembly through the femoral artery and into a heart chamber. Because the impeller and impeller housing are advanced through a narrow artery in some embodiments, the impeller and impeller housing can initially be inserted into the patient in a retracted, or collapsed (or low profile), state, as described above. Once the distal end of the catheter assembly 100 (including the impeller housing) has reached the desired operating location (*e.g.*, a heart chamber), the clinician can deploy the impeller housing into an advanced or expanded configuration.

[0160] One method of deploying the impeller and/or diffuser is by using the impeller deployment assembly 800, which can be located near the proximal end of the catheter assembly. As shown in Figures 15A and 15B, the clinician can rotate the nut 804 (clockwise or counter-clockwise depending on the threading) such that the nut 804 translates from a distal position to a proximal position. In turn, the flow diverter 806, the catheter

body, and the impeller housing can also translate from a distal position to a proximal position and thereby advance the impeller distally into a wider portion of the impeller housing to allow for deployment of the impeller hub 208 and blades 212. Thus, in some embodiments, the clinician can deploy the impeller, located at a distal end of the catheter assembly, by rotating a nut disposed near the proximal end of the catheter assembly.

[0161] In some embodiments, the impeller 200 and housing 202 can be axially displaced relative to their operational positions during delivery of the distal end to the heart (e.g., the impeller and housing can be delivered to the vasculature in an axially separated configuration). As used in this context, "axially displaced" includes configurations where there is axial movement of the impeller 200 relative to any portion of the housing 202 prior to or during the process of delivery. For example, axial displacement includes conditions in which the impeller 200 is moved from a first position near a proximal end port (outlet for left side support or inlet for right side support) of the housing 202 to a second position distal the first position. The second position can be one that is still between the proximal end port and a distal end port (inlet for left side support or outlet for right side support) of the housing 202. The first position may be the operational position of the impeller 200 relative to the housing 202. Axial displacement also includes conditions in which the impeller is located proximal of an operational position, e.g., at a location proximal of a proximal end port of the housing 202, including being disposed within a non-expandable portion of the heart pump. When the clinician delivers the distal end of the heart pump to the heart chamber, rather than delivering the distal end with the impeller housing disposed over the impeller blades, the impeller housing can be in a proximally displaced position or retracted configuration (or distally displaced position or advanced configuration in other embodiments) with respect to the impeller, such that it is axially moved from the operational position, as discussed above.

[0162] In some embodiments, the impeller and the housing can be delivered in series (with the impeller being delivered before the housing, or vice versa). For example, in one embodiment, the impeller housing 202 is first advanced into position, e.g., in the heart. The housing 202 may then be expanded if the housing has expanded and compressed configurations. Thereafter the impeller 200 may be positioned, e.g., advanced through a catheter body similar to the catheter body 120 to be positioned within the impeller housing

202. Thereafter the impeller 200 can be rotated by a source of rotational energy. In various embodiments, the source of rotational energy can comprise a motor positioned outside of the patient to drive a shaft similar to the shaft 148. In other embodiment, the source of rotational energy can comprise a motor that is miniaturized to be positionable within the patient, as discussed in US Patent No. 7,070,555, which is incorporated by reference herein for all purposes and in its entirety. In another embodiment, the distal end of the impeller 200 can be configured to be advanced into position in the patient and, at a later stage of a procedure, the impeller housing 202 can be positioned thereover. In one technique, the impeller 200 is positioned in the heart chamber (or wherever the procedure is to occur), the clinician can then advance the impeller housing over the impeller blades and begin operating the heart pump. For removal of the catheter assembly from the patient after the procedure, the clinician can retract or displace the impeller housing proximally to axially displace and/or separate the impeller from the impeller housing.

[0163] The configurations enabling displaced or serial delivery also can decouple the design of the impeller housing 202 from the complexities of the design of the impeller 200. For example, the impeller housing 202 can have a greater range of expansion from a collapsed state to an expanded state. If no structures are disposed inside the housing 202 in the collapsed state, greater compression and a lower crossing profile can be achieved compared to where the housing 202 must be sized in the collapsed state to accommodate the impeller 200 in its collapsed state. This provides one or more of the benefits of access through smaller vessels, in smaller patients, or a larger expanded size in standard patients through typical access (e.g., femoral vessel). Similarly, greater compression of the impeller 200 may be possible if the impeller 200 is delivered using a dedicated compression sheath or device that is not required to expand and/or to be present around the impeller during operation. As a result, larger blades may be delivered from the same collapsed profile, providing the advantages of higher flow discussed above. More details of serial delivery of blood pumps are discussed in US 7,022,100, which is incorporated by reference herein for all purposes and in its entirety.

[0164] Once the impeller is deployed, the clinician can conduct the procedure, e.g., by running the heart pump within a heart chamber. Once the procedure is finished, the

clinician can remove the catheter assembly from the patient by retracting the impeller. The clinician can simply rotate the nut 804 in a direction opposite to that rotated for deploying the impeller. The nut can then translate from the proximal position to the distal position, which in turn can cause the flow diverter 806, the catheter body, and the impeller housing to also translate from the proximal position to the distal position. The impeller can thereby be retracted proximally into an area near the outlet 802 to reduce the profile of the pump upon collapsing into the sheath. Thus, the clinician can both deploy and retract the impeller by rotating a nut located near the proximal end of the catheter assembly.

B. Controlling the Collapse and Deployment of the Impeller Housing with the Sheath Assembly

[0165] As mentioned above in Section IV(A), it can be advantageous in certain embodiments to enable a clinician to deploy and retract the impeller assembly prior to and after a heart procedure. One method of collapsing the impeller housing can be performed by advancing the sheath assembly 162 distally over the impeller housing to collapse the impeller assembly, *e.g.*, for removal of the catheter assembly from the patient after a heart procedure. As mentioned above, elongate body 174 of the catheter assembly 162 can be slidably disposed over the catheter body 120. The clinician can distally advance the elongate body 174 over the impeller housing, or alternatively proximally retract the catheter body 120 such that the impeller housing collapses into the elongate body 174 of the sheath assembly 162.

[0166] As Figures 17A-D illustrate, the sheath assembly can have expandable distal ends 170a, 170b, 170c, that expand when a radial force is applied. Thus, when the clinician advances the elongate body 174 of the sheath over the impeller housing, the impeller housing can contact the distal end 170 and can induce a radial force that causes the distal ends 170a, 170b, 170c, to expand in order to aid in retraction of the impeller assembly. Similarly, when the clinician slides the elongate body 174 in a proximal direction, the impeller assembly can deploy through the distal end 170 of the catheter assembly 162, because the distal ends 170a, 170b, 170c, can contract when a radial force is removed (or not applied). Thus, the clinician can reliably deploy and retract the impeller assembly by sliding the elongate body 174 of the sheath relative to the catheter body 120. In other embodiments, the sheath assembly need not have expandable distal ends as described above. The clinician

can therefore simply deploy the impeller assembly 116 by providing relative motion between the elongate body 174 of the sheath and the impeller assembly, e.g., by retracting the elongate body 174 from the impeller assembly, and can collapse the impeller assembly by providing relative motion between the elongate body 174 of the sheath and the impeller assembly 116, e.g., by advancing the elongate body over the impeller assembly. The distal end of the elongate body 174 can therefore effectuate collapse of the impeller assembly 116 without using the expandable distal ends described above. In embodiments where the impeller assembly is self-expanding, the retraction of the elongate body 174 from the impeller assembly 116 or extension of the impeller assembly 116 out of the elongate body 174 can release the impeller assembly to self-expand.

[0167] It will be apparent to those skilled in the art that various modifications and variations can be made in the present embodiments without departing from the scope or spirit of the advantages of the present application. Thus, it is intended that the present application cover the modifications and variations of these embodiments and their equivalents.

WHAT IS CLAIMED IS:

1. A heart pump comprising
a catheter body comprising a proximal end, a distal end, and an elongate body extending therebetween; and
an impeller coupled with the distal end of the catheter body and comprising an axial lumen passing through a distal end of the impeller;
wherein the impeller comprises a tip positioned at the distal end of the impeller, the tip comprising a resealable member having a resealable path therethrough.
2. The heart pump of Claim 1, wherein the resealable member comprises a distal tapered portion.
3. The heart pump of Claim 1, wherein the resealable member comprises a first elastomeric material and the tip comprises a second material that is different from the first elastomeric material.
4. The heart pump of Claim 1, wherein the impeller is coupled with the catheter body through a drive shaft.
5. The heart pump of Claim 4, wherein the resealable member is coupled to the drive shaft of the impeller.
6. The heart pump of Claim 5, wherein a distal portion of the drive shaft is disposed within the resealable member.
7. The heart pump of Claim 5, wherein the drive shaft is disposed within the axial lumen of the impeller.
8. The heart pump of Claim 1, wherein the impeller tip further comprises a non-resealable portion having a non-resealable path therethrough that extends distally of the resealable member, the resealable and non-resealable paths being co-linear.
9. The heart pump of Claim 8, wherein the non-resealable portion surrounds an outer surface of the resealable member.
10. The heart pump of Claim 8, wherein the non-resealable portion comprises a distal-most portion of the impeller tip.

11. The heart pump of Claim 8, wherein the non-resealable portion is a unitary structure comprising a hub and one or more blades of the impeller.
12. The heart pump of Claim 8, wherein the impeller tip is configured to receive a guidewire through the resealable path and the non-resealable path.
13. The heart pump of Claim 1, wherein the impeller tip comprises a valve that extends proximally into the axial lumen of the impeller.
14. The heart pump of Claim 13, wherein the valve is a duck bill valve that tapers proximally into the axial lumen of the impeller.
15. The heart pump of Claim 1, wherein the impeller comprises an impeller body, the impeller body and the resealable member having a monolithic configuration.
16. The heart pump of Claim 1, further comprising a sheath disposed over at least a portion of the distal end of the catheter body and having an expandable distal end.
17. A heart pump comprising:
 - a catheter body comprising a proximal end, a distal end, and an elongate body extending therebetween;
 - a housing coupled with the distal end of the catheter body and comprising a distal opening and a proximal opening;
 - an impeller coupled with the distal end of the catheter body and positioned within the housing; and
 - a diffuser comprising a flow directing surface and disposed between the distal end of the catheter body and the impeller, the diffuser configured to be positioned within the housing and adjacent the proximal opening.
18. The heart pump of Claim 17, wherein the diffuser has a first diameter in an expanded configuration that is greater than a second diameter in a collapsed configuration.
19. The heart pump of Claim 18, further comprising a bearing assembly disposed between the distal end of the catheter body and the diffuser, wherein the bearing assembly includes a cavity that is configured to direct infusant through the bearing assembly and into the diffuser.
20. The heart pump of Claim 19, wherein the diffuser further comprises an outlet that is configured to direct infusant out of the heart pump.

21. The heart pump of Claim 19, wherein the diffuser is capable of expanding via flow of infusant into the diffuser.
22. The heart pump of Claim 17, wherein the diffuser is connected to the impeller.
23. A catheter assembly comprising
 - a catheter body comprising a proximal end, a distal end, and an elongate structure extending therebetween;
 - an impeller configured for relative motion in an axial direction, and located at the distal end of the catheter body; and
 - a deployment device located at the proximal end of the catheter assembly.

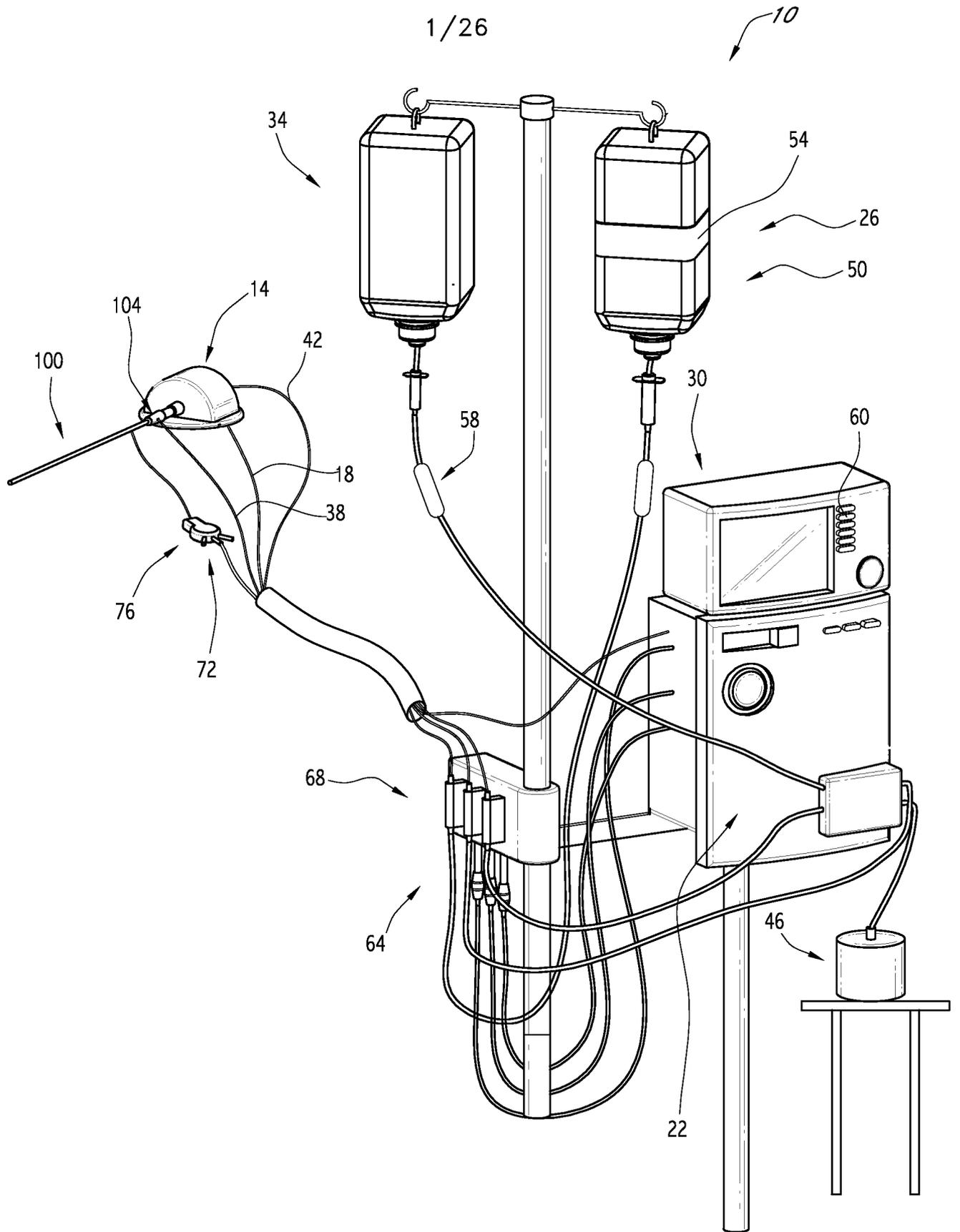


FIG. 1

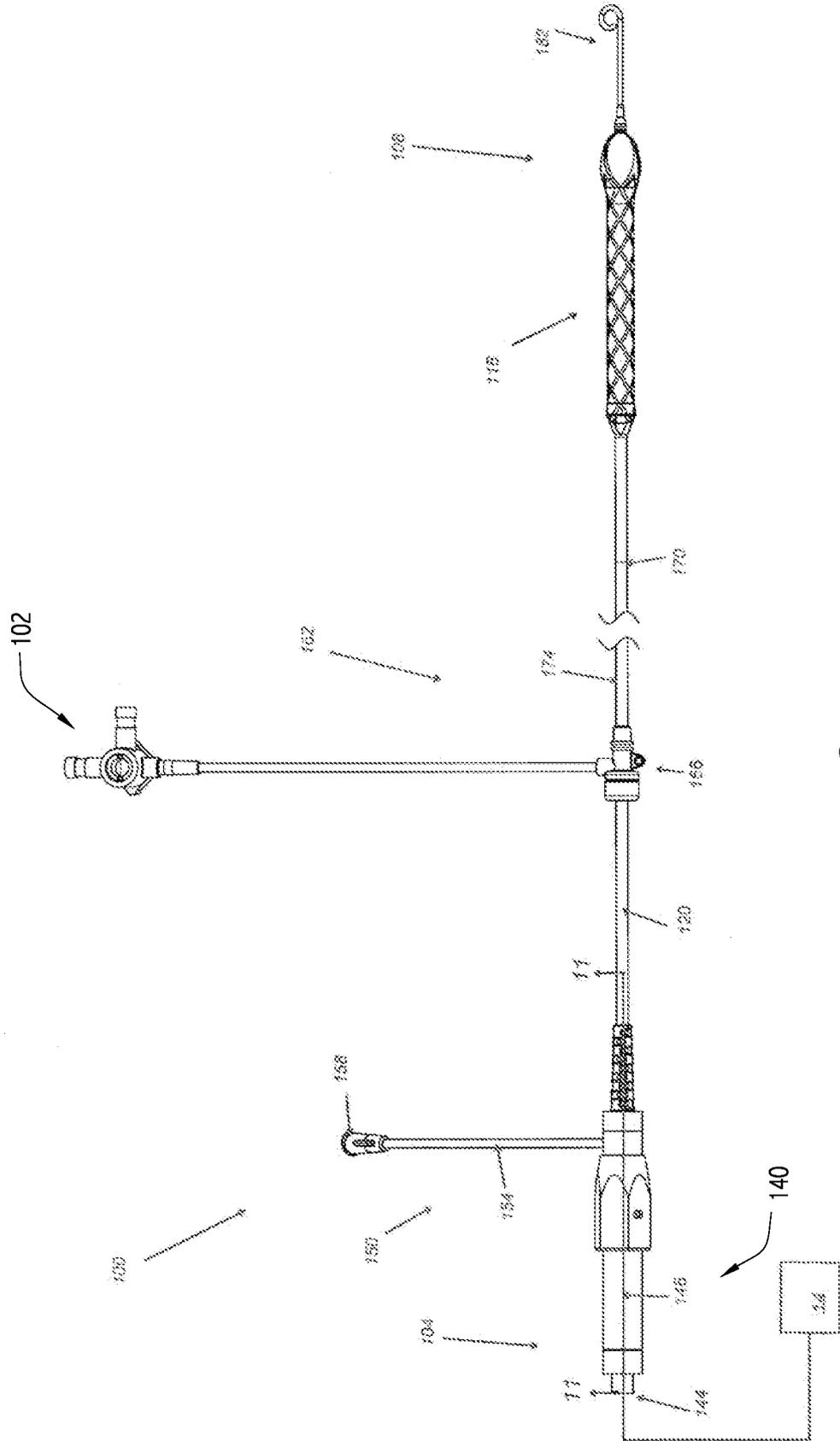


FIG. 1A

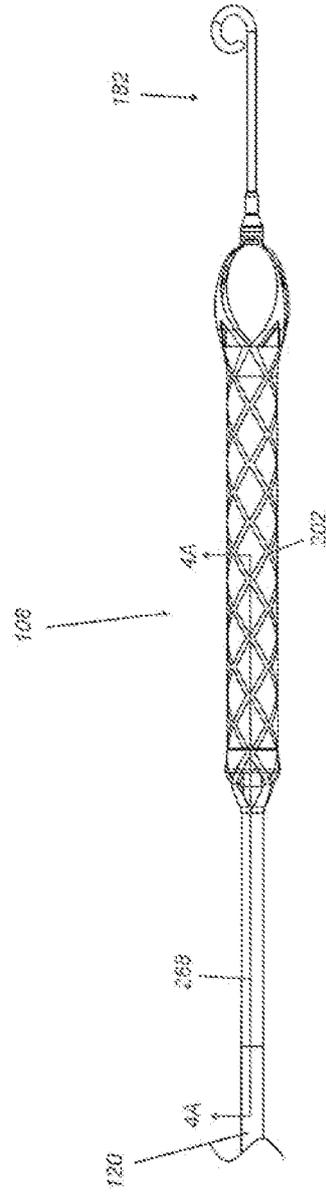


FIG. 2

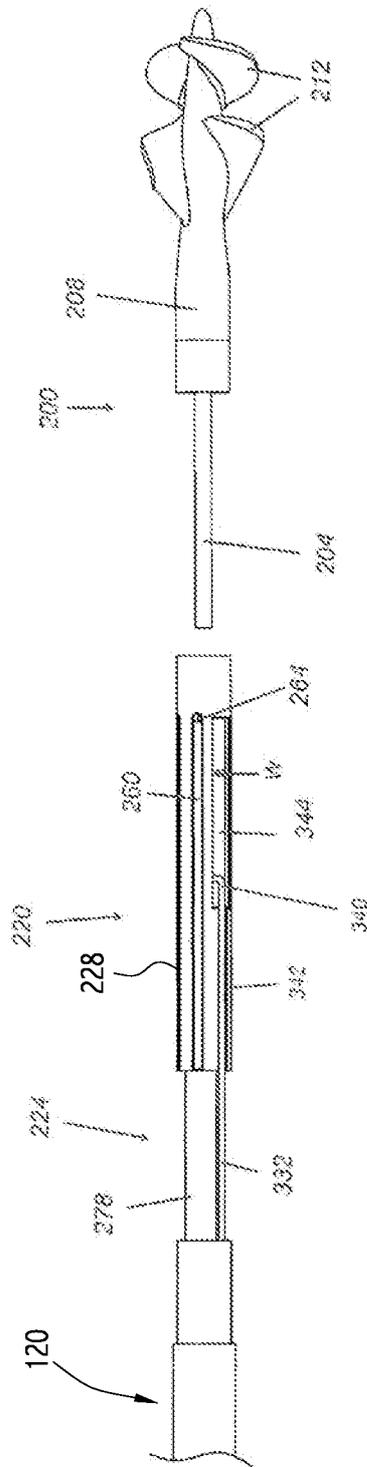


FIG. 3

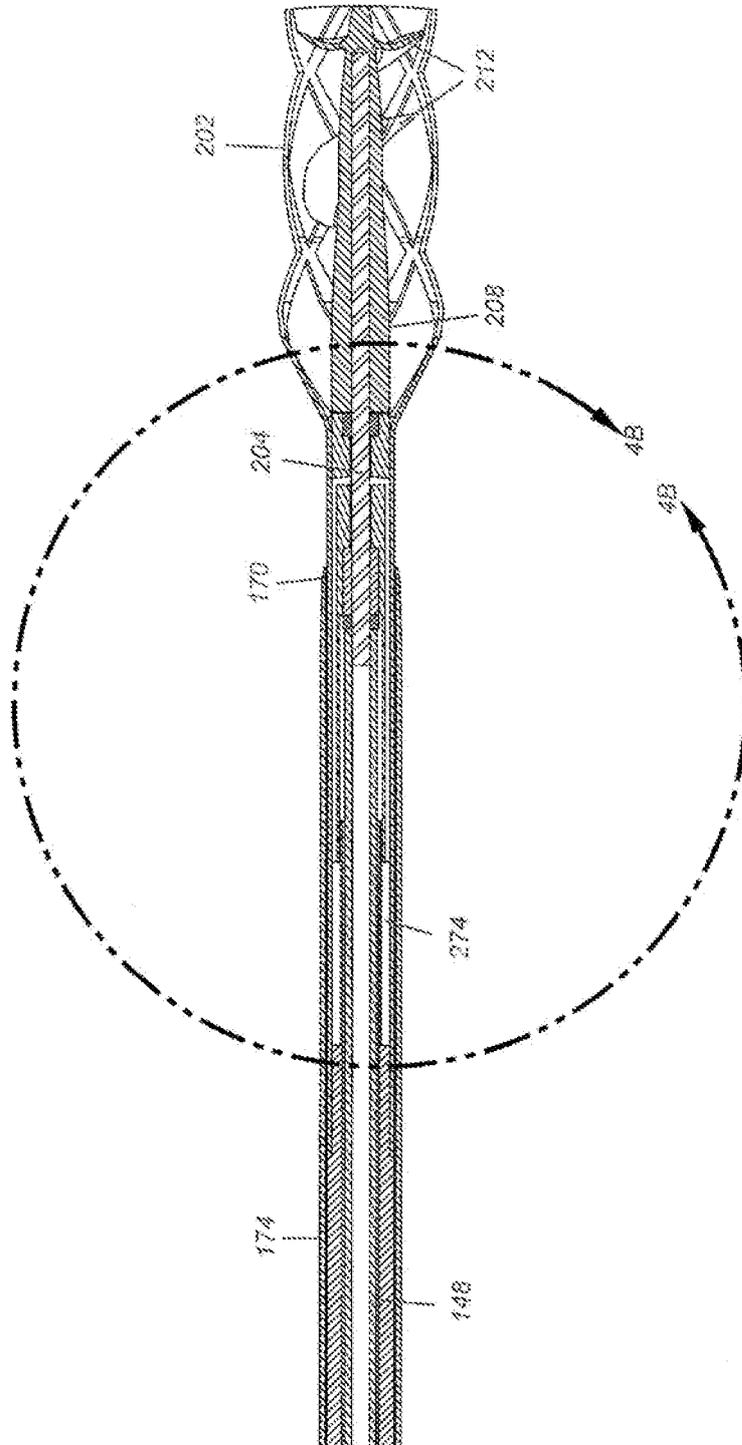


FIG. 4A

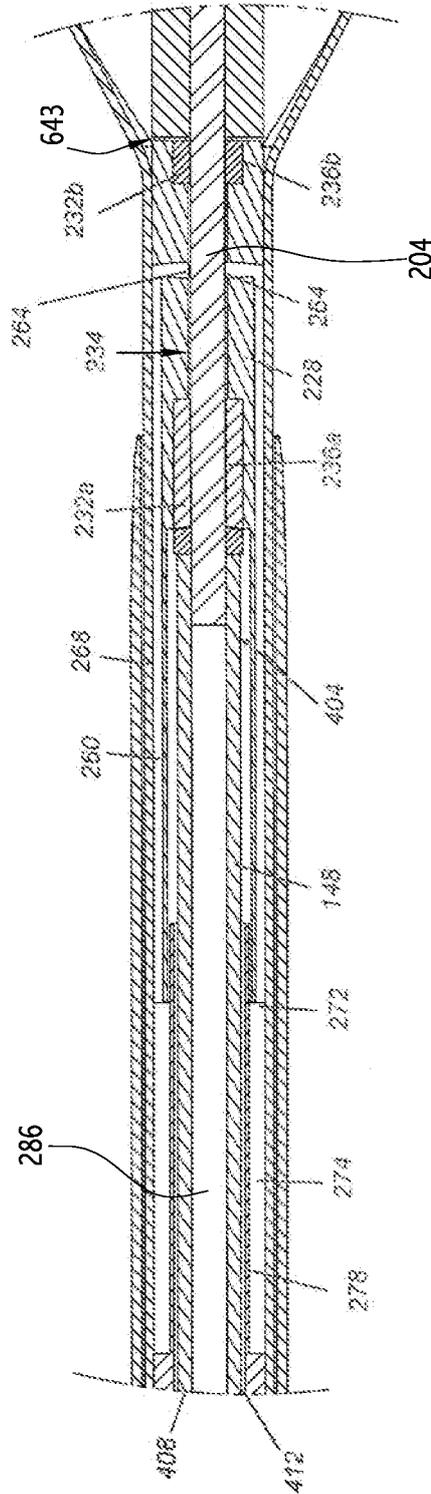


FIG. 4B

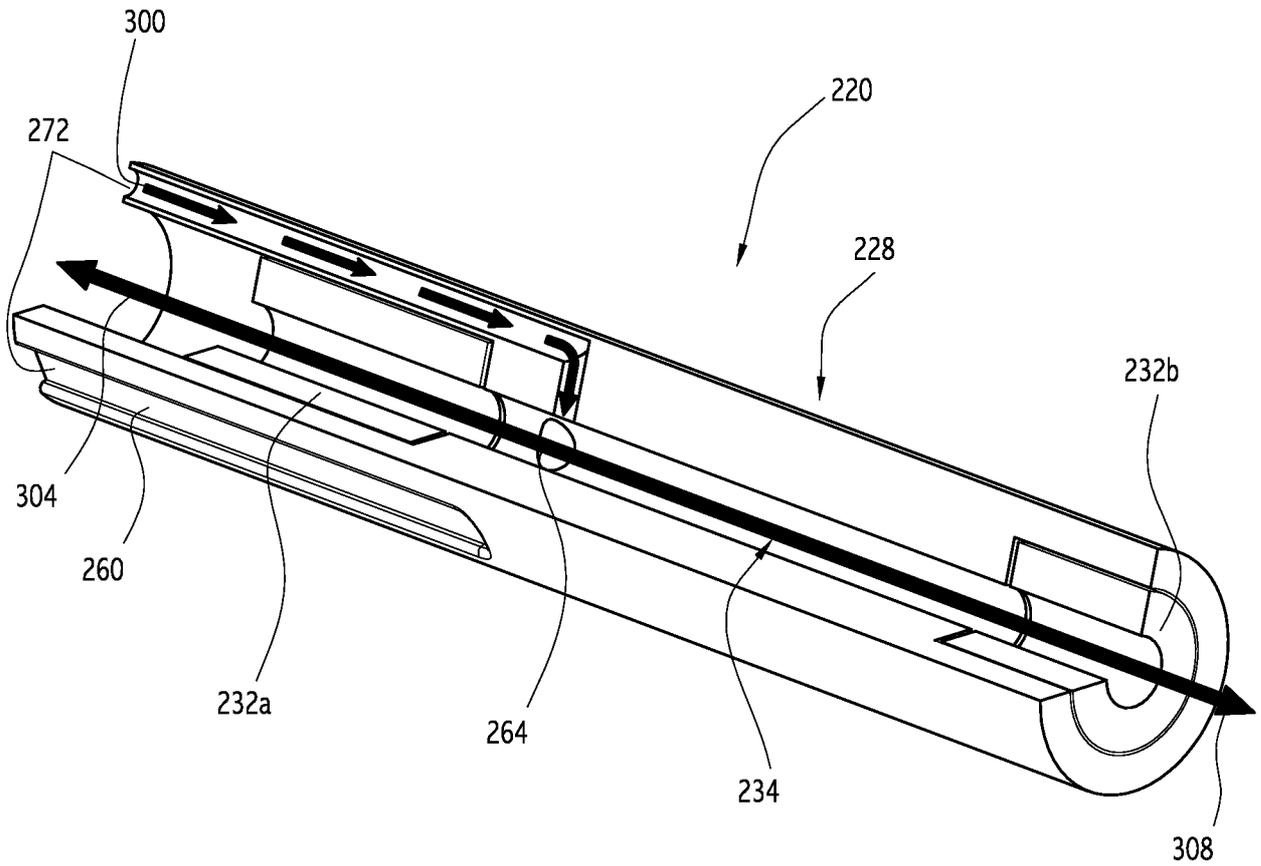


FIG. 5

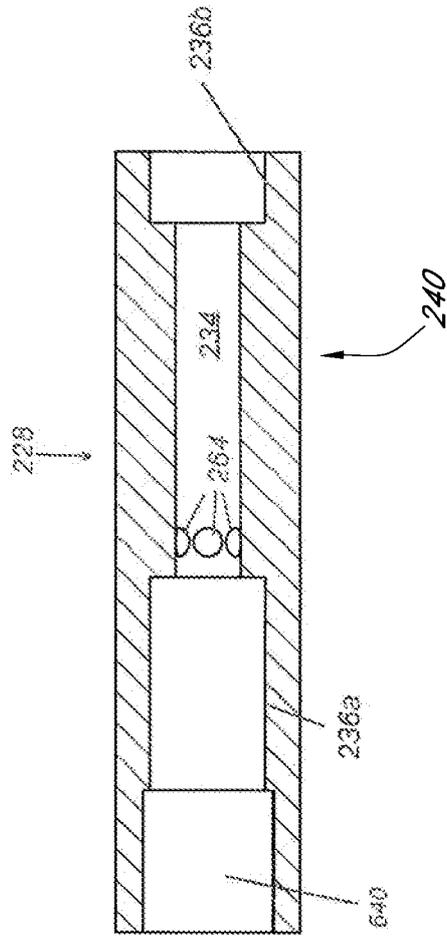


FIG. 6

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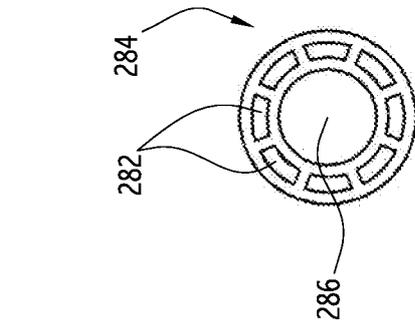


FIG. 7A

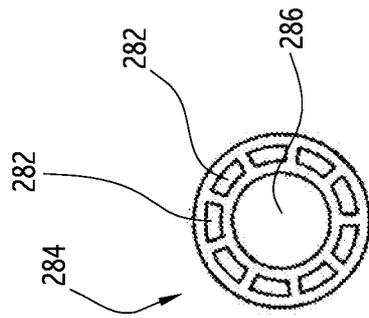


FIG. 7B

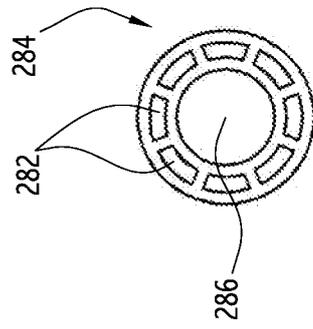


FIG. 7C

11/26

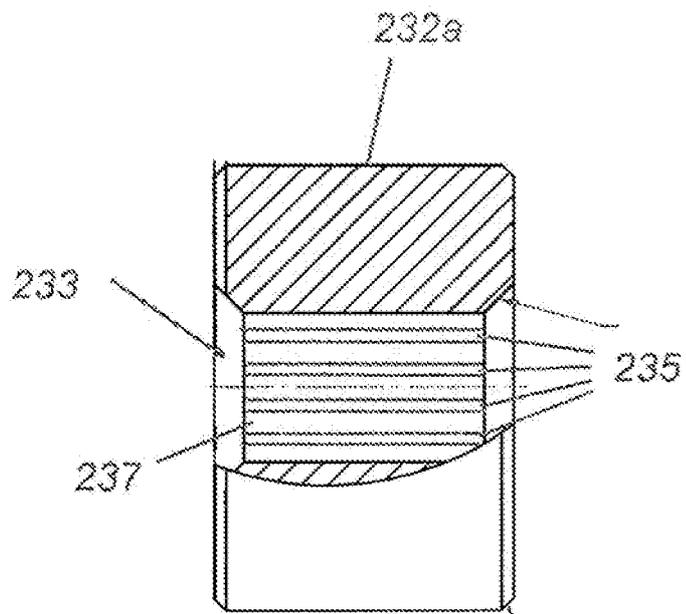


FIG. 8

12/26

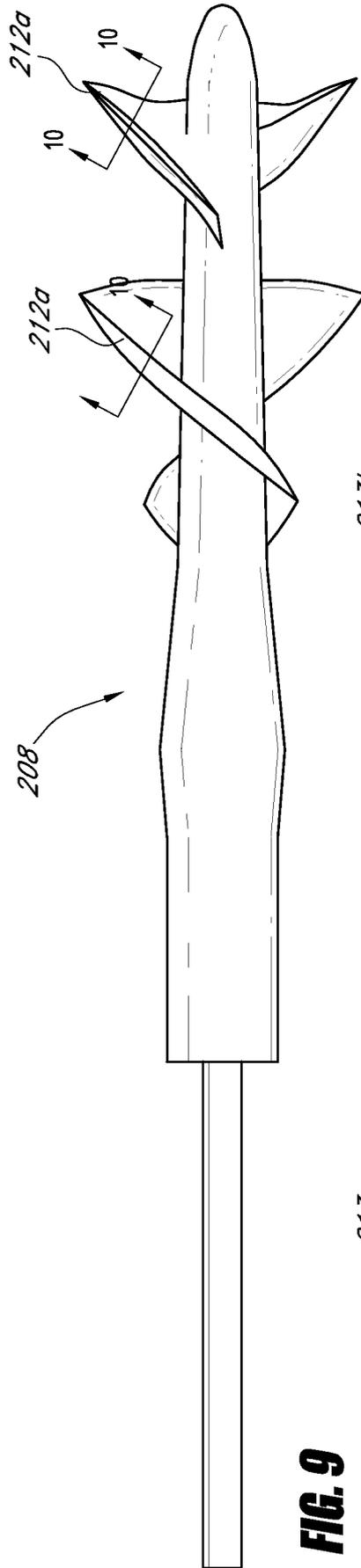


FIG. 9

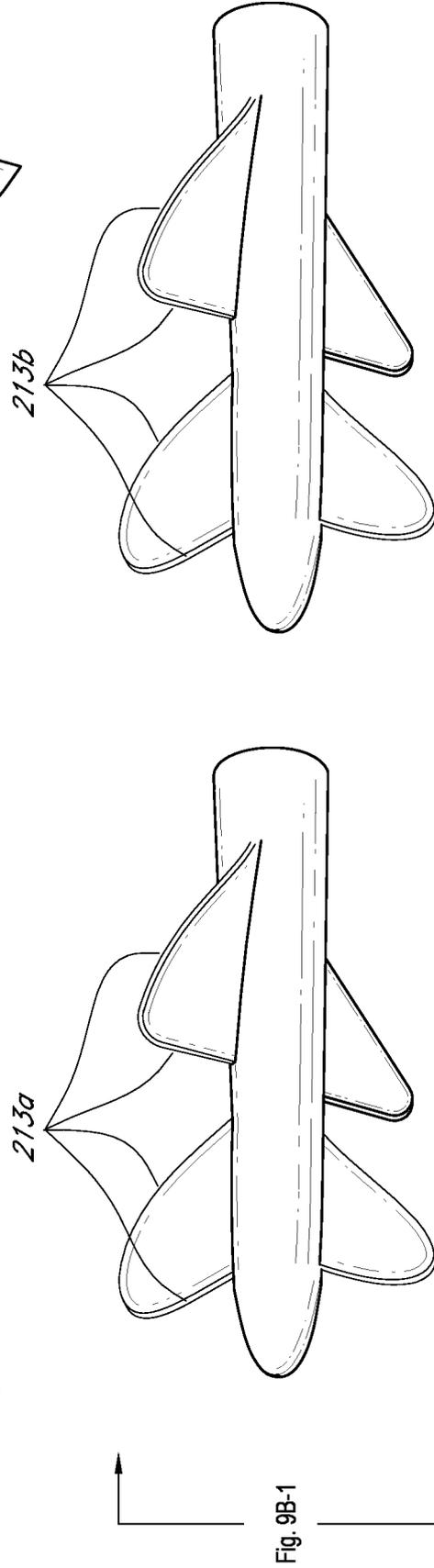


FIG. 9A

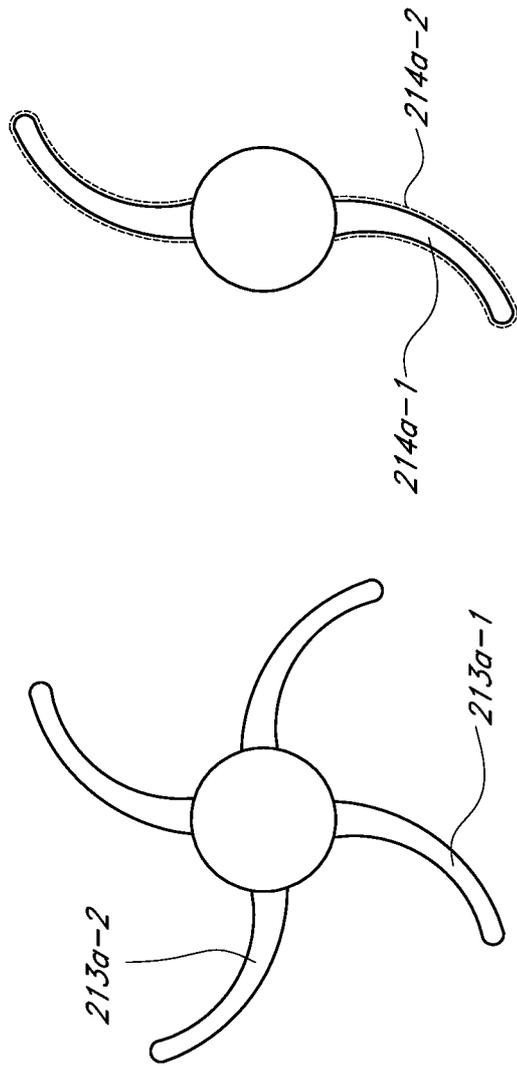


FIG. 9B-1

FIG. 9B-2

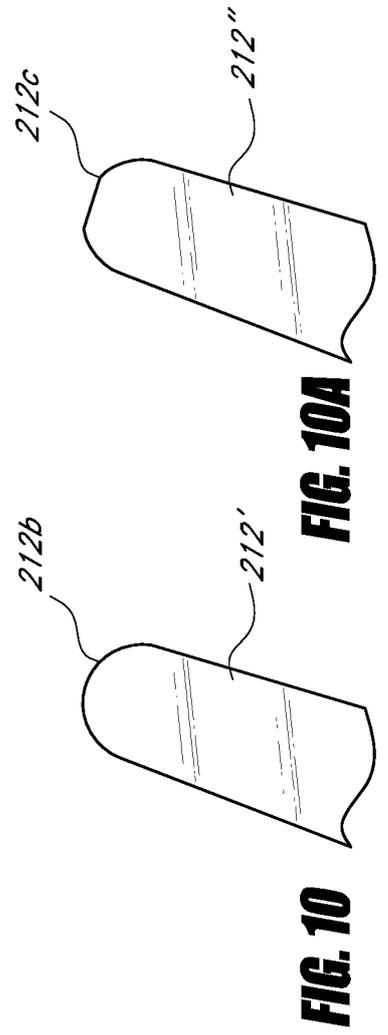


FIG. 10

FIG. 10A

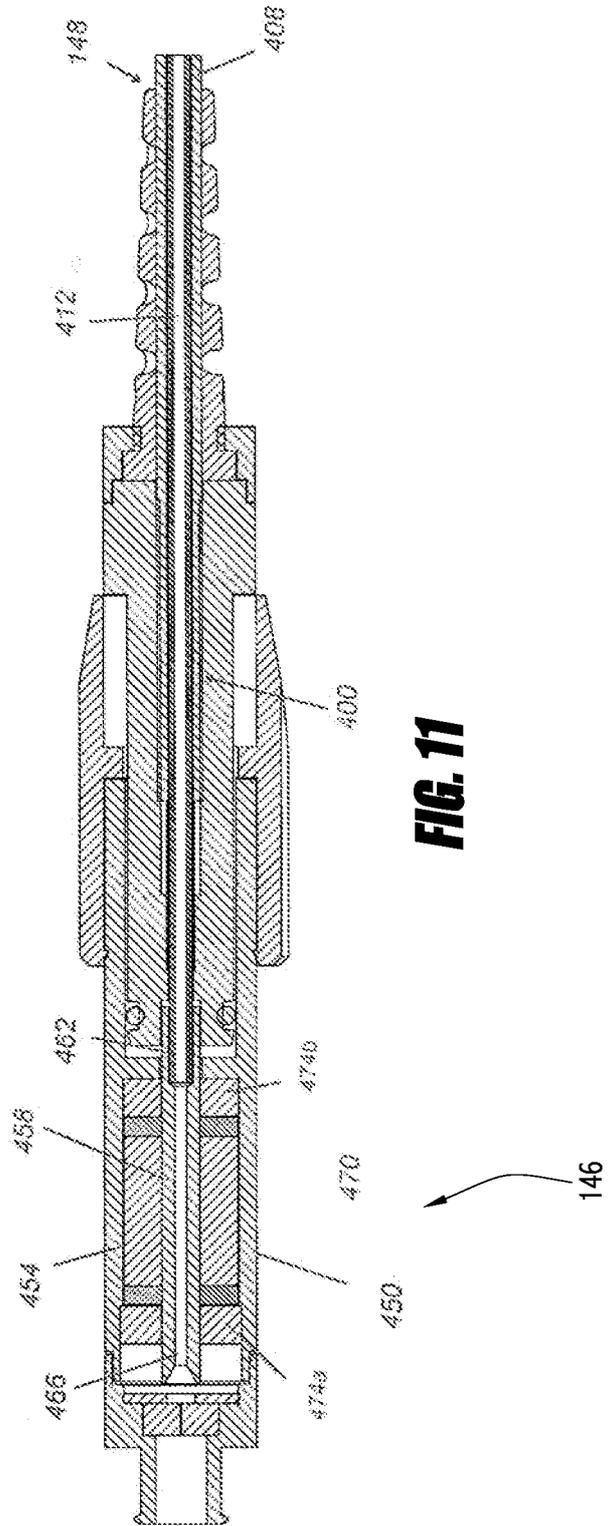


FIG. 11

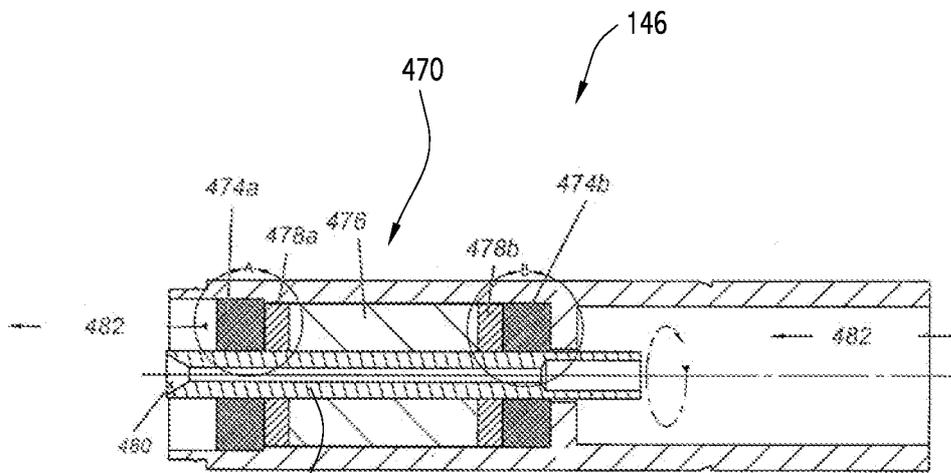


FIG. 12

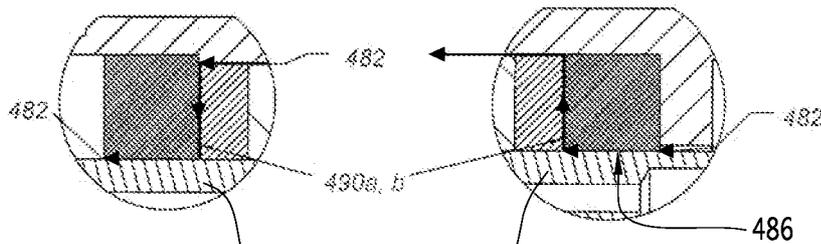


FIG. 12A

FIG. 12B

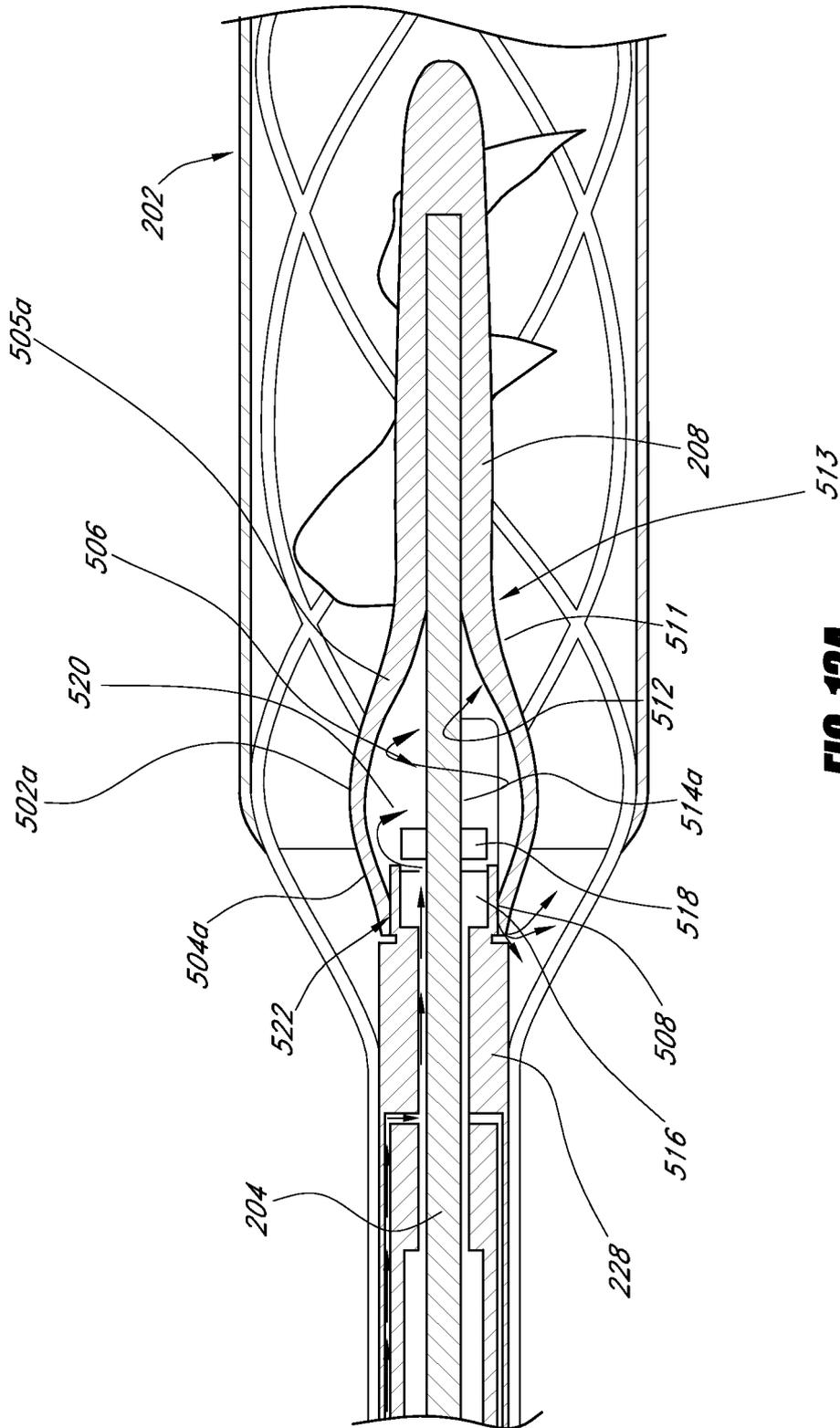


FIG. 13A

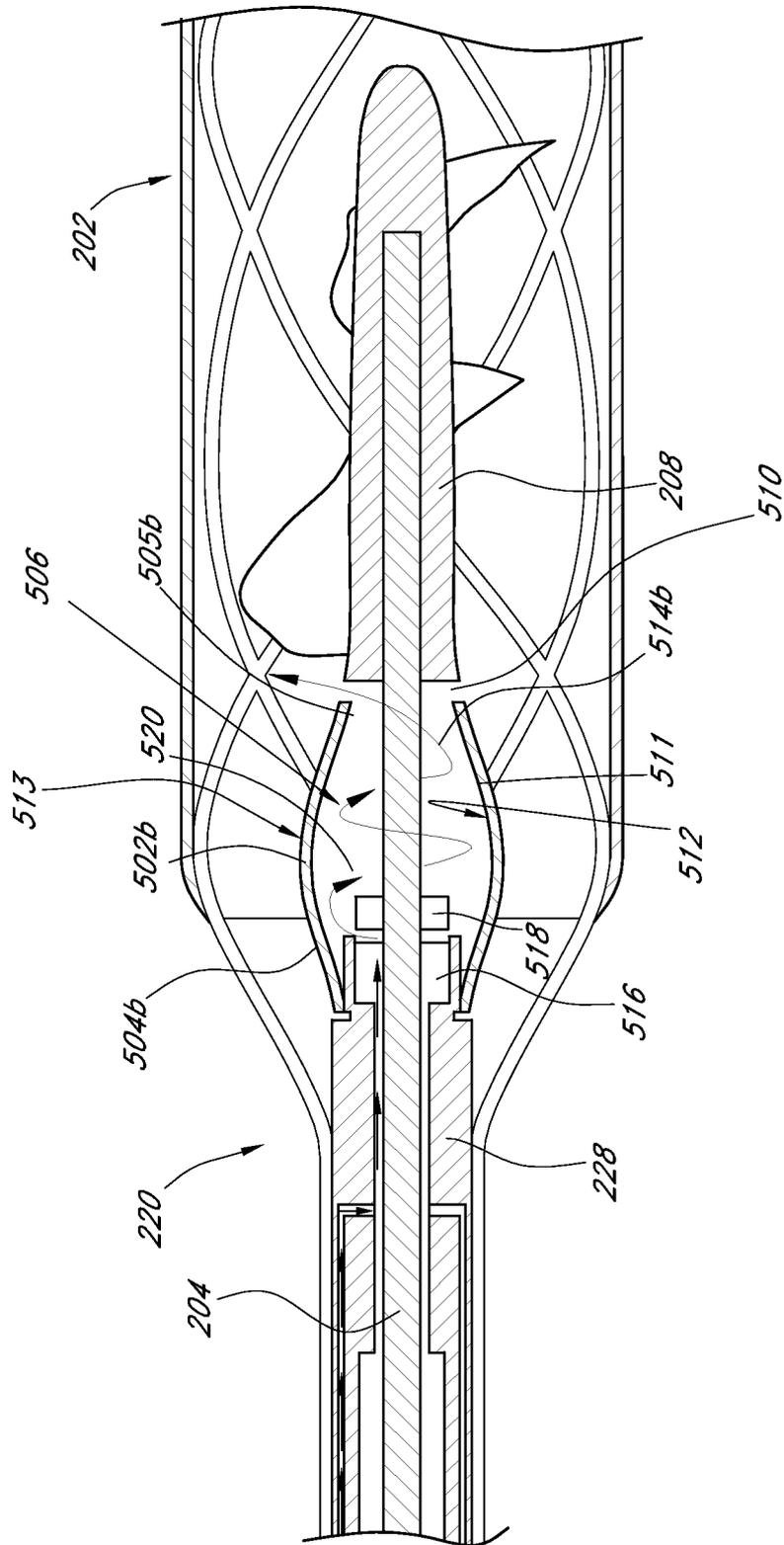


FIG. 13B

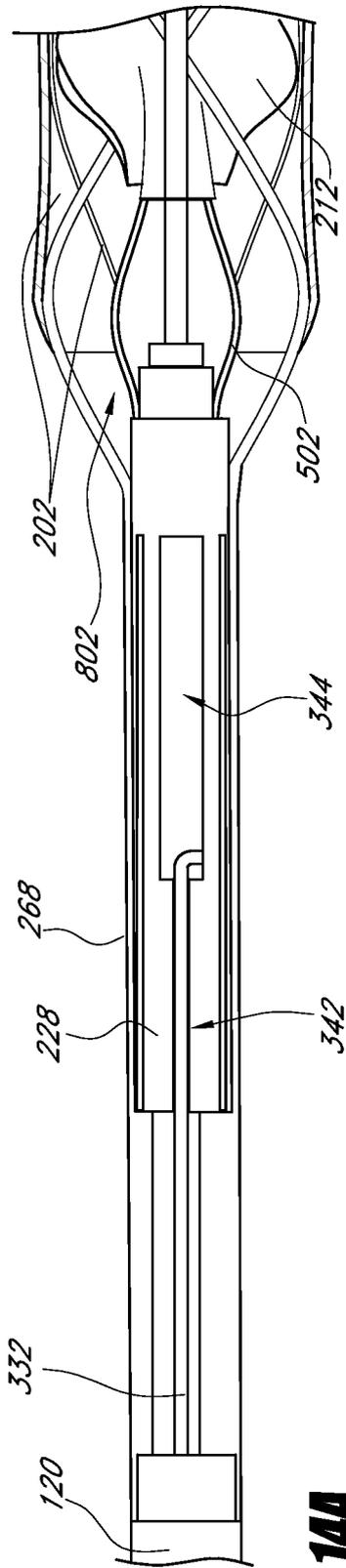


FIG. 14A

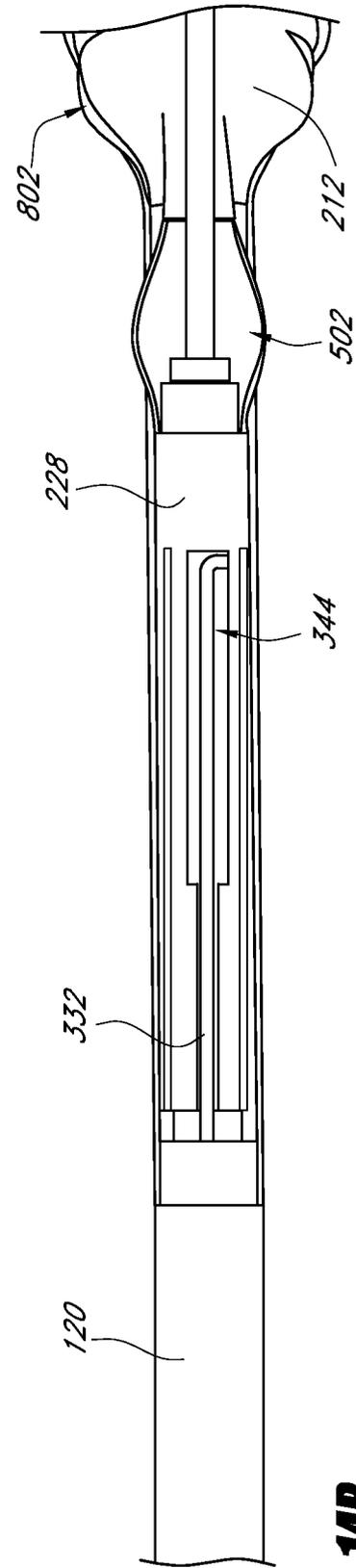
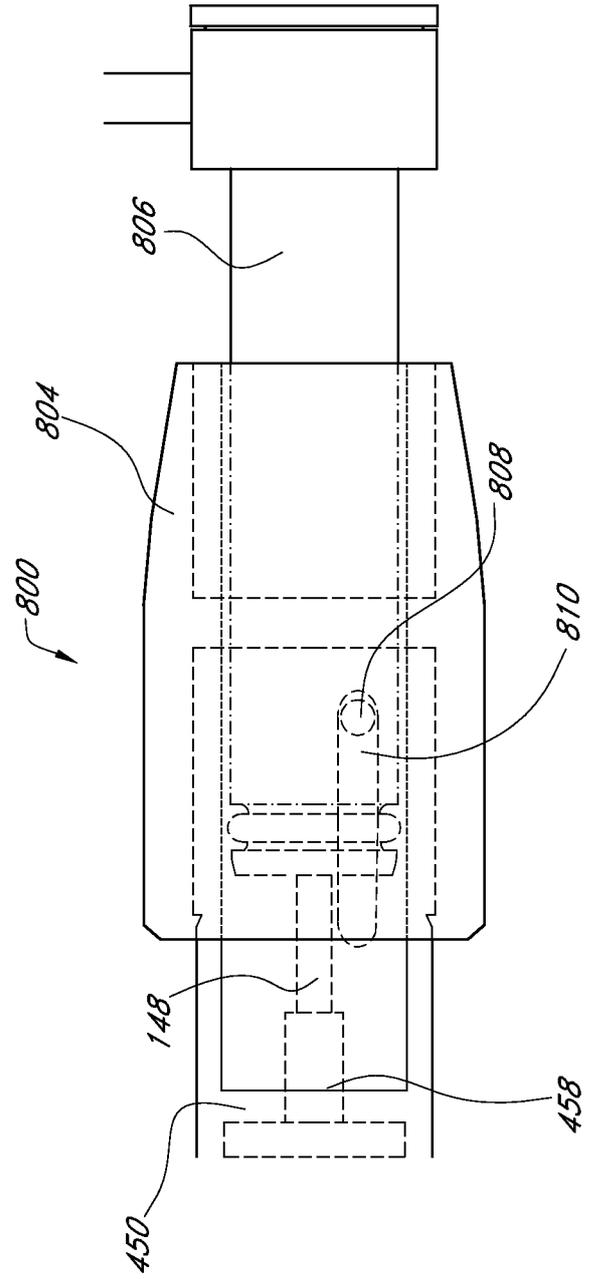
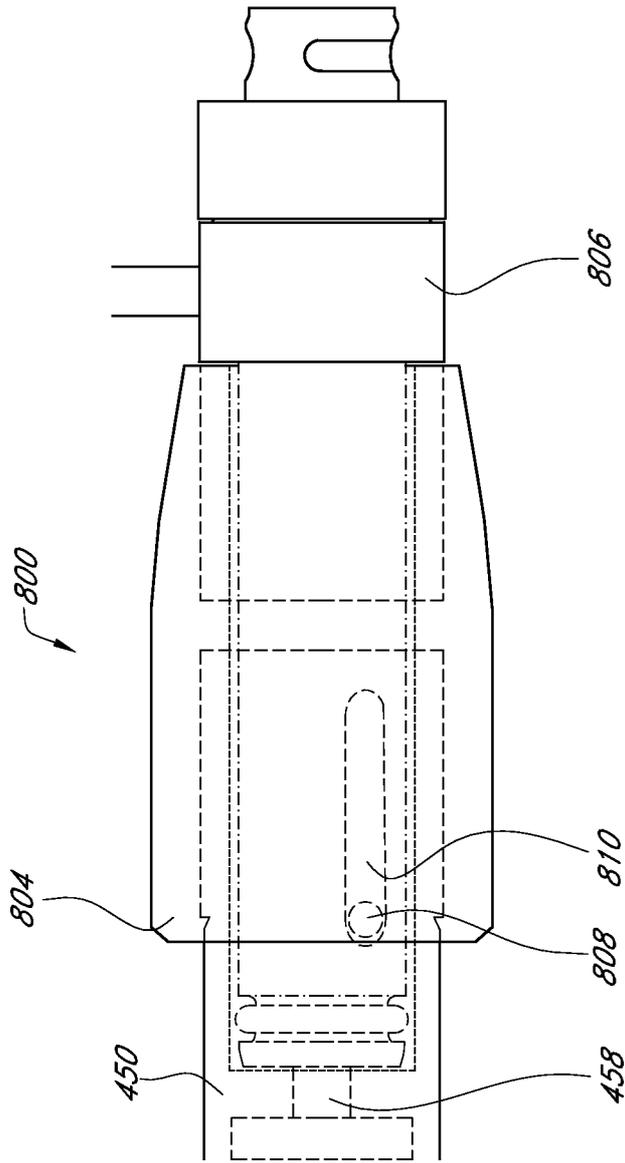


FIG. 14B



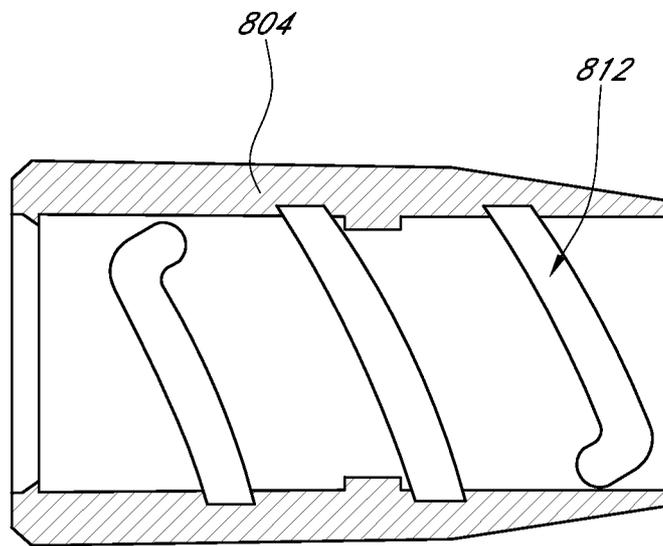


FIG. 15C

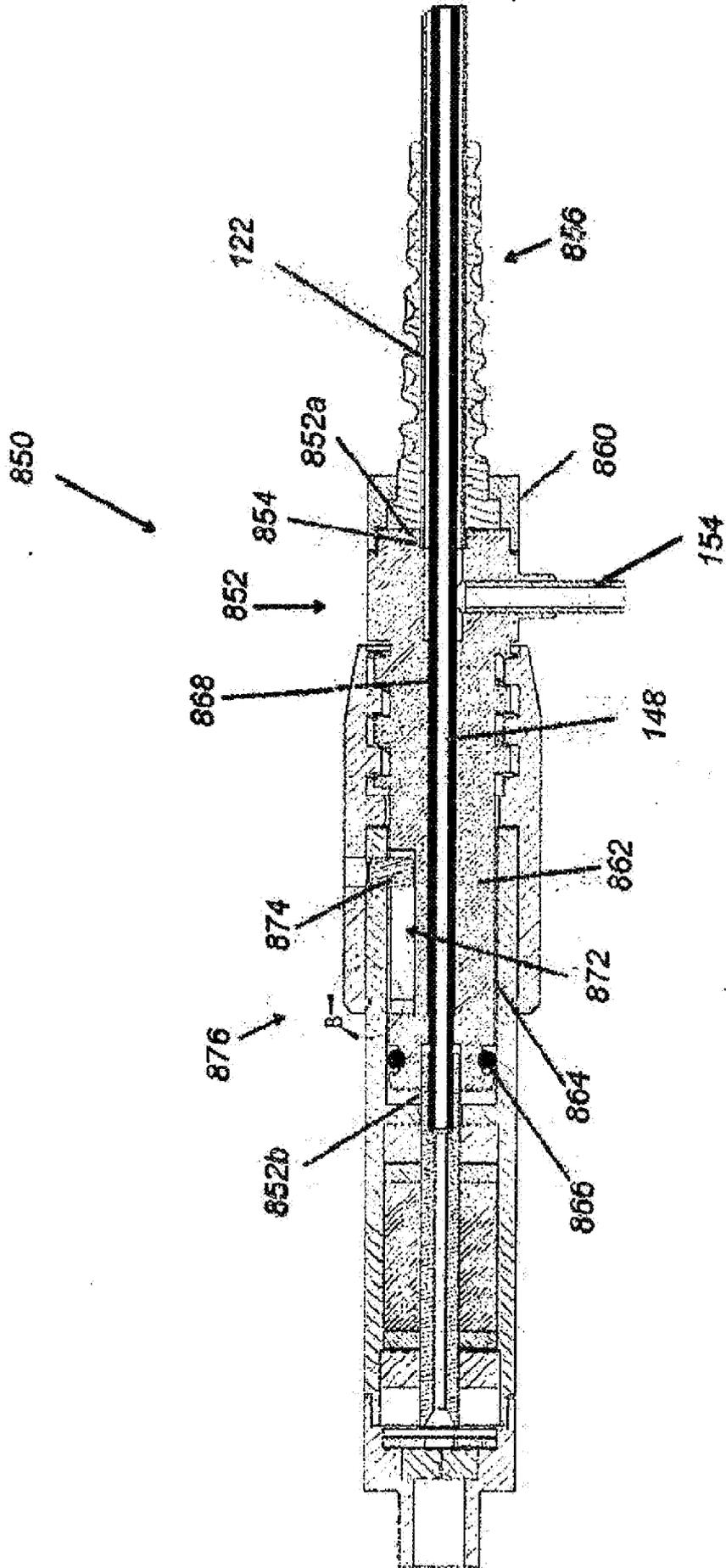
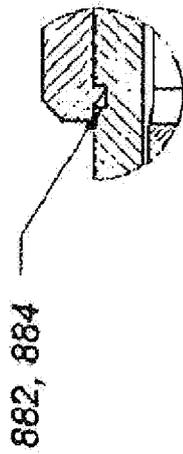


FIG. 15D



DETAIL B

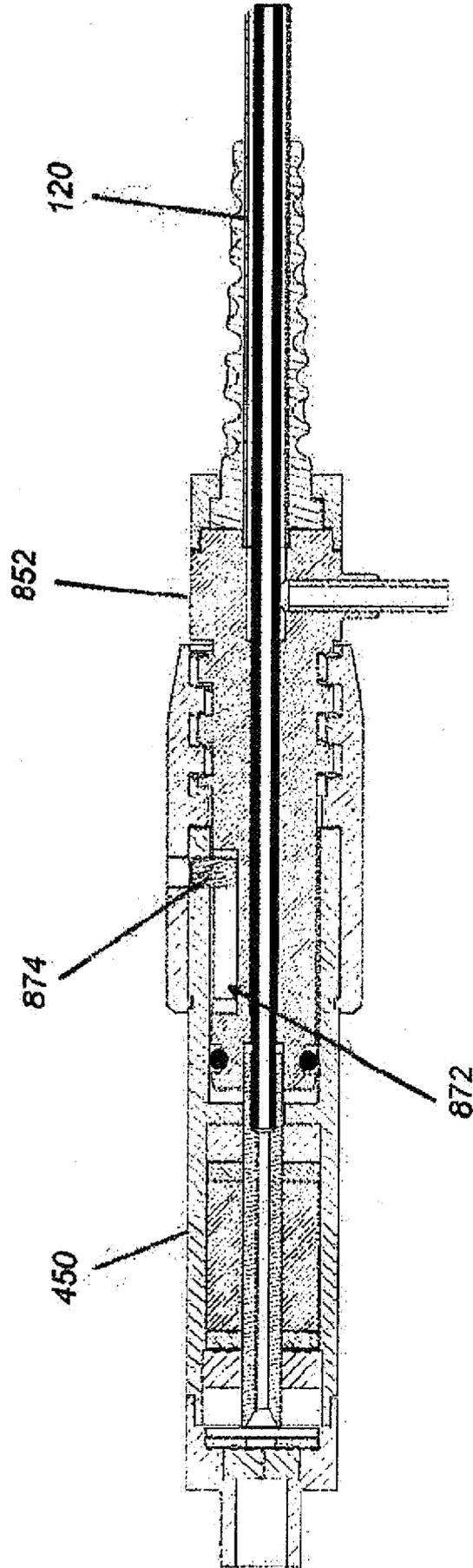


FIG. 15E

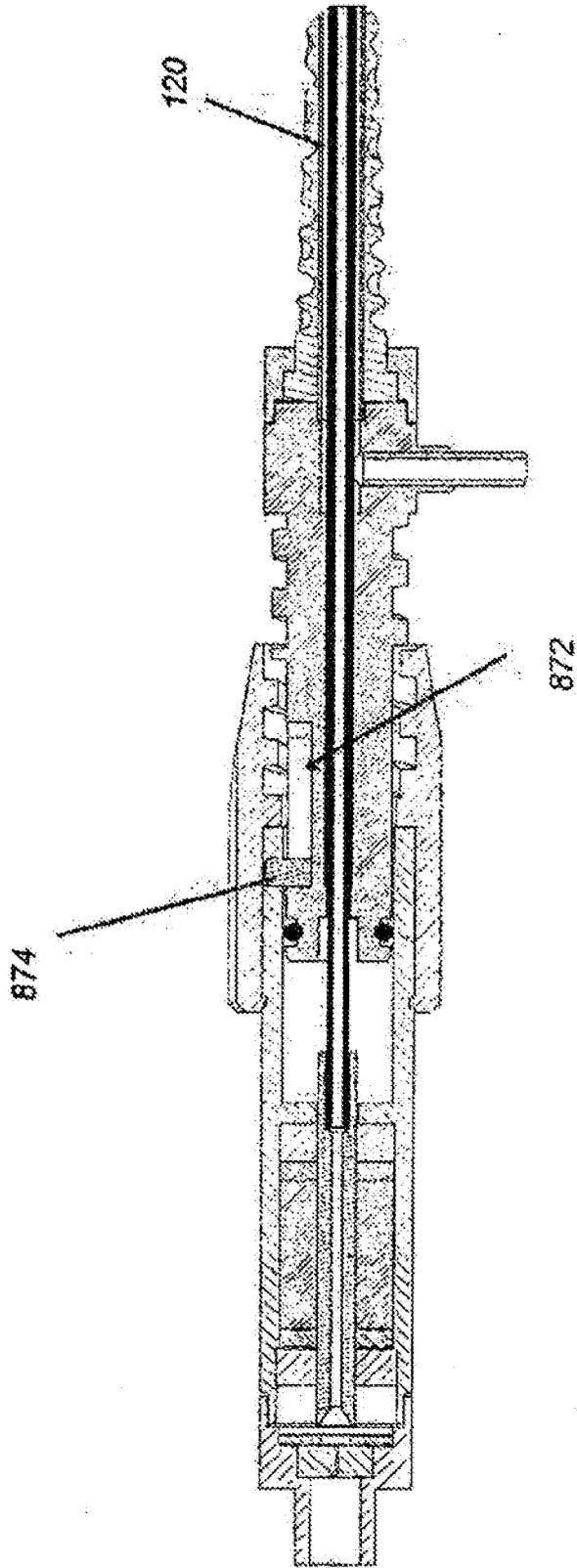


FIG. 15F

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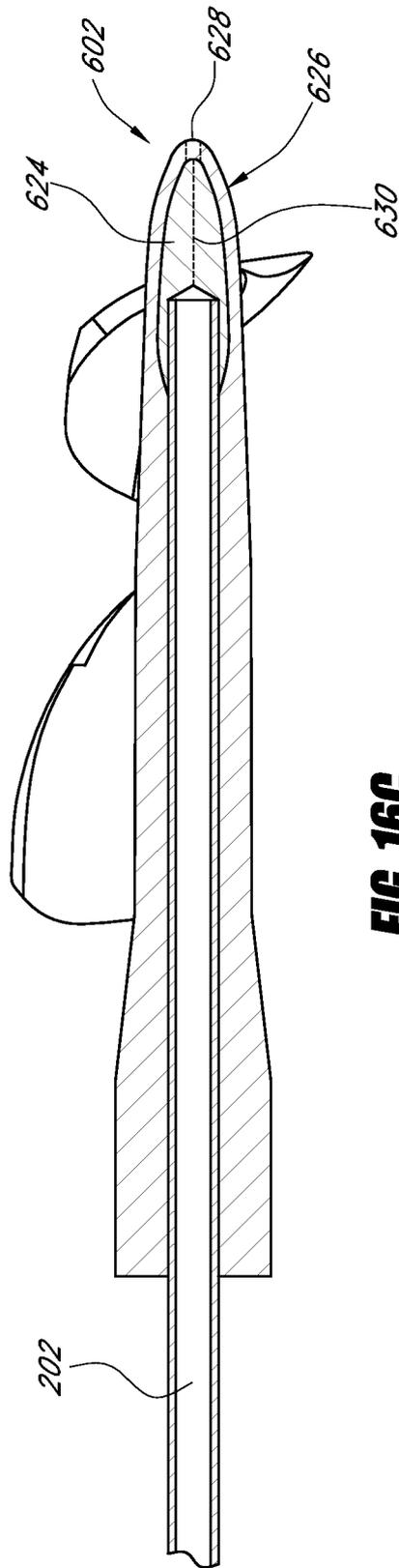


FIG. 16C

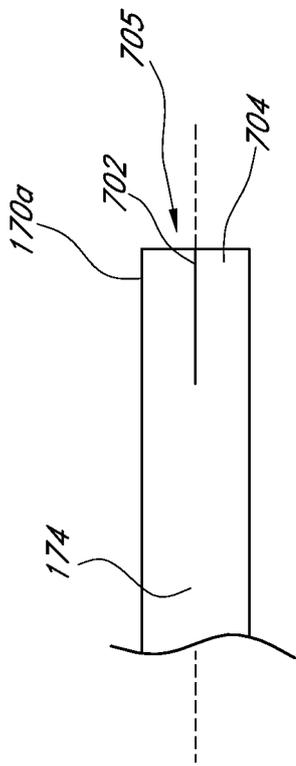


FIG. 17A

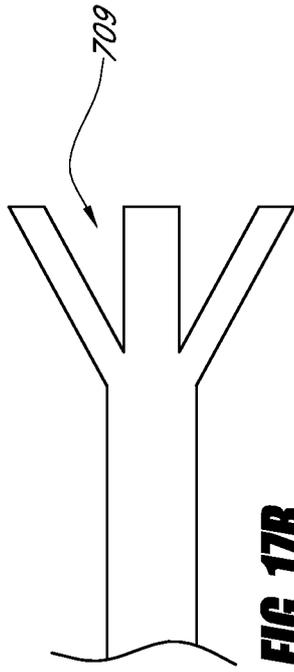


FIG. 17B

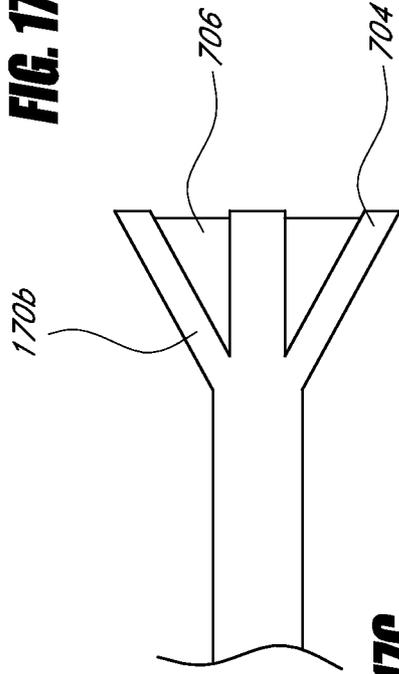


FIG. 17C

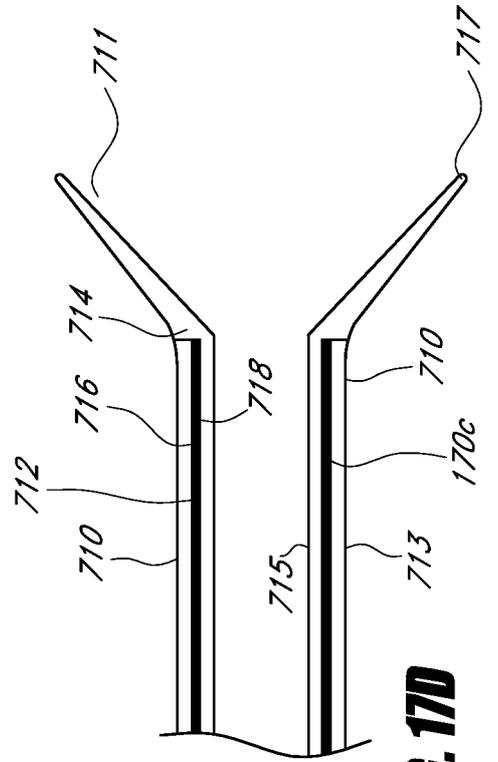


FIG. 17D