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Ventricular assist system and method of treatment of cardiovascular impairment

Abstract

A ventricular assist system including a cannula that defines a lumen and includes a first end and a second end. The second end of the cannula includes a tip that defines an opening, and a pump operably is coupled to the first end of the cannula. A pump anchor is operably coupled to the pump. The pump anchor has a retracted position and a deployed position. A tip anchor is operably coupled to the second end of the cannula proximate the tip. A sheath is selectively disposed around the cannula, and a guidewire disposed within the lumen of the cannula.

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Background/Summary

PRIORITY CLAIM (1) This application claims the benefit of PCT/US2023/080502 filed Nov. 20, 2023, which claims priority to U.S. Provisional Patent Application 63/426,957, filed Nov. 21, 2022, both of which are incorporated by reference herein in its entirety.

TECHNICAL FIELD

(1) This disclosure relates to a ventricular assist system and a method of treatment using the ventricular assist system.

SUMMARY

(2) One aspect of the disclosure provides a ventricular assist device that includes a cannula. The cannula defines a lumen and includes a first end and a second end. The second end of the cannula includes a tip that defines an opening. A pump is operably coupled to the first end of the cannula, and a pump anchor is operably coupled to the pump. The pump anchor has a retracted position and a deployed position. A tip anchor is operably coupled to the second end of the cannula proximate to the tip.

(3) Implementations of the disclosure may include one or more of the following optional features. In some implementations, the cannula may include a semi-rigid sigmoidal body that may be defined between the first end and the second end. Optionally, the tip may have a lower arcuate portion and an upper narrow portion that may collectively define the opening. In another example, the pump anchor and the tip anchor may each include an attachment portion and a plurality of extensions that extend from the attachment portion. In this example, the pump anchor and the tip anchor may be coupled to the pump and the second end of the cannula, respectively, at the respective attachment portions. Optionally, the plurality of extensions of the pump anchor may define an interconnected net disposed around the pump.

(4) In another implementation, the pump anchor may include a first pump anchor coupled to the pump and a second pump anchor coupled to the pump. In this implementation, each of the first and second pump anchors may include a plurality of extensions. Optionally, the plurality of extensions of the first pump anchor may extend toward the cannula, and the plurality of extensions of the second pump anchor may extend away from the cannula. According to another aspect of the disclosure, the tip anchor may have an inflatable body that has an expanded position and a contracted position. Optionally, the inflatable body defines a plurality of recesses, and at least one of the plurality of recesses may be aligned with the opening defined by the tip of the cannula. In another example, the pump anchor may have a spiral configuration.

(5) Another aspect of the disclosure provides a ventricular assist system that includes a cannula defining a lumen. The cannula includes a first end and a second end. The system includes a pump that is operably coupled to the first end of the cannula. A pump anchor is operably coupled to the pump, and the pump anchor has a retracted position and a deployed position. The system also includes a tip anchor that is operably coupled to the second end of the cannula proximate to the tip. A sheath is selectively disposed around the cannula, and a guidewire is disposed within the lumen of the cannula.

(6) This aspect may include one or more of the following optional features. In one example, the pump anchor may include a plurality of eyelets and a wire. In another aspect, the guidewire may include a cap removably coupled to the pump, and the guidewire may be aligned with the lumen of the cannula via the cap that may be coupled to the pump. Optionally, the sheath may define a linear body between the first end and the second end of the cannula when the sheath is disposed around the cannula. Optionally, the cannula has a sigmoidal body between the first end and the second end of the cannula when the sheath is removed from the cannula.

(7) Another aspect of the disclosure provides a method of treatment of a cardiovascular impairment

using a ventricular assist device across a right ventricular between an inferior vena cava and a pulmonary artery of a human. The method includes inserting the ventricular assist device in the inferior vena cava via a delivery device and a driveline at an access site. The ventricular assist device includes a pump including at least one anchor and a cannula operably coupled to the pump. The method also includes guiding the cannula inserted into the inferior vena cava through a right atrium of the human, into the right ventricle, and into the pulmonary artery. The at least one anchor of the ventricular assist device is then deployed in the inferior vena cava, and the delivery device is removed over the driveline. When the treatment is complete, the driveline is at least partially removed from the human. The method then includes inserting the delivery device over the driveline and into the inferior vena cava. The method also includes collapsing the at least one anchor of the ventricular assist device and removing the delivery device and the ventricular assist device from said human.

(8) This aspect may include one or more of the following optional steps and features. Optionally, the method may include inserting the driveline subcutaneously proximate to the access site and guiding, subcutaneously, the driveline toward a lower abdomen. In this example, the end of the driveline may be removed at an exit site that may be located at the lower abdomen. In another aspect, the access site may be proximate to a femoral vein. In an alternate aspect, the access site may be proximate to the inferior vena cava. In another implementation, the method may include partially removing the driveline at the access site, where the access site is proximate to a femoral vein, and bending the driveline extracorporeally. This example method may also include reinserting the driveline into a lower portion of the inferior vena cava from the access site, guiding an end of the driveline, subcutaneously, toward a lower abdomen from an exit site defined at the lower portion of the inferior vena cava, and removing the end of the driveline at a treatment site located at the lower abdomen. In another aspect, the method may include removing the driveline from the human by cutting the driveline.

(9) The details of one or more implementations of the disclosure are set forth in the accompanying drawings and the description below. Other aspects, features, and advantages will be apparent from the description and drawings, and from the claims.

Description

DESCRIPTION OF DRAWINGS

- (1) FIGS. 1A and 1B are schematics of a cross-sectional heart with a ventricular assist device of the present disclosure;
- (2) FIG. 2A is a perspective view of a ventricular assist device of the present disclosure;
- (3) FIG. 2B is a perspective view of a connector of a driveline of a ventricular assist device of the present disclosure;
- (4) FIG. 3A is a perspective view of a mold and a body of a cannula of the present disclosure;
- (5) FIG. 3B is a perspective view of a cannula of a ventricular assist device of the present disclosure;
- (6) FIG. 4A is a plan view of a cannula within a sheath of the present disclosure with the cannula in a linear configuration;
- (7) FIG. 4B is a plan view of the cannula of FIG. 4 with the sheath partially withdrawn and the cannula in a sigmoidal configuration;
- (8) FIG. 5 is a plan view of the cannula of FIGS. 4A and 4B with the sheath withdrawn and the cannula in a sigmoidal configuration;
- (9) FIG. 6A is an enlarged partial perspective view of a cannula of the present disclosure with a guidewire partially inserted into a lumen of the cannula;
- (10) FIG. 6B is a cross-sectional view of a lumen of the cannula of FIG. 6A with a secondary

lumen for receiving the guidewire;

(11) FIG. 7A is a perspective view of a ventricular assist device of the present disclosure with a guidewire inserted in a lumen of a cannula;

(12) FIG. 7B is an enlarged partial perspective view of a tip of the cannula of FIG. 7 with the guidewire partially inserted into the lumen;

(13) FIG. 8 is a perspective view of a driveline of the present disclosure attached to a pump and with a connector;

(14) FIG. 9 is an enlarged partial perspective view of an alignment feature coupled to a ventricular assist device of the present disclosure via a cap;

(15) FIG. 10 is an enlarged partial perspective view of the alignment feature and cap of FIG. 9 removed from the ventricular assist device;

(16) FIG. 11A is a partial side cross-sectional view of a ventricular assist device of the present disclosure with a pump and an alignment feature disposed over a driveline;

(17) FIG. 11B is an enlarged partial perspective view of an alignment feature coupled to a driveline and proximate a ventricular assist device of the present disclosure

(18) FIGS. 11C and 11D are enlarged partial perspective views of an alignment feature with a catheter tip and pins;

(19) FIG. 11E is an enlarged perspective view of a pump tip of the present disclosure with indentations;

(20) FIG. 12A is a partial perspective view of a pump of a ventricular assist device of the present disclosure;

(21) FIG. 12B is a schematic of a pump of a ventricular assist device of the present disclosure indicating potential placements of a pump anchor;

(22) FIGS. 13A and 13B are perspective views of a pump with first and second pump anchors of the present disclosure;

(23) FIG. 13C is a partial perspective view of a pump with a single pump anchor of the present disclosure;

(24) FIGS. 14A and 14B are perspective views of a pump anchor of the present disclosure;

(25) FIG. 14C is a partial perspective view of a pump anchor of the present disclosure attached to a driveline;

(26) FIG. 15A is an enlarged partial perspective view of a pump anchor of the present disclosure having a net configuration;

(27) FIG. 15B is an enlarged partial perspective view of a pump anchor of the present disclosure with eyelets and a wire;

(28) FIG. 15C is a perspective view of a pump anchor of the present disclosure disposed over a pump and including a net configuration and eyelets;

(29) FIGS. 16A and 16B are perspective views of a pump anchor of the present disclosure;

(30) FIG. 17 is a perspective view of a tip of a ventricular assist device of the present disclosure;

(31) FIGS. 18A and 18B are perspective views of a tip anchor of the present disclosure;

(32) FIGS. 19A and 19B are perspective views of a tip anchor of the present disclosure;

(33) FIGS. 20A-20C are plan views of a ventricular assist system of the present disclosure with a delivery device retracting a sheath from a ventricular assist device of the present disclosure;

(34) FIG. 20D is a plan view of a ventricular assist system of the present disclosure with stages of retraction of a sheath by a delivery device of the present disclosure;

(35) FIG. 20E is a partial elevational view of a sheath being removed from a ventricular assist device of the present disclosure;

(36) FIGS. 21A-21C are schematics of a ventricular assist system of the present disclosure being removed from a heart;

(37) FIG. 22 is a schematic of a circulatory system of a human;

(38) FIGS. 23A and 23B are schematics of the circulatory system of FIG. 22 illustrating an access

site and insertion of a ventricular assist system of the present disclosure;

(39) FIGS. 24A and 24B are schematics of the ventricular assist system of FIGS. 23A and 23B and depict subcutaneous repositioning of a driveline of the present disclosure at a treatment site;

(40) FIGS. 24C-24E are schematics of the ventricular assist system of FIGS. 24A and 24B and depict removal of the ventricular assist system of the present disclosure;

(41) FIGS. 25A and 25B are schematics of the ventricular assist system of FIGS. 23A and 23B and depict repositioning of a driveline of the present disclosure toward a treatment site from an access site;

(42) FIGS. 25C-25F are schematics of the ventricular assist system of FIGS. 25A and 25B and depict removal of the ventricular assist system of the present disclosure;

(43) FIG. 26A is a schematic of the circulatory system of FIG. 22 illustrating an access site and insertion of a ventricular assist system of the present disclosure;

(44) FIGS. 26B and 26C are schematics of the ventricular assist system of FIG. 26A and depict repositioning of a driveline of the present disclosure toward a treatment site from an access site;

(45) FIGS. 26D-26F are schematics of the ventricular assist system of FIGS. 26A-26C and depict removal of the ventricular assist system of the present disclosure; and

(46) FIG. 27 is a flow diagram of a method of treatment using the ventricular assist system of the present disclosure.

(47) Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

(48) Example configurations will now be described more fully with reference to the accompanying drawings. Example configurations are provided so that this disclosure will be thorough, and will fully convey the scope of the disclosure to those of ordinary skill in the art. Specific details are set forth such as examples of specific components, devices, and methods, to provide a thorough understanding of configurations of the present disclosure. It will be apparent to those of ordinary skill in the art that specific details need not be employed, that example configurations may be embodied in many different forms, and that the specific details and the example configurations should not be construed to limit the scope of the disclosure.

(49) The terminology used herein is for the purpose of describing particular exemplary configurations only and is not intended to be limiting. As used herein, the singular articles “a,” “an,” and “the” may be intended to include the plural forms as well, unless the context clearly indicates otherwise. The terms “comprises,” “comprising,” “including,” and “having,” are inclusive and therefore specify the presence of features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. The method steps, processes, and operations described herein are not to be construed as necessarily requiring their performance in the particular order discussed or illustrated, unless specifically identified as an order of performance. Additional or alternative steps may be employed.

(50) When an element or layer is referred to as being “on,” “engaged to,” “connected to,” “attached to,” or “coupled to” another element or layer, it may be directly on, engaged, connected, attached, or coupled to the other element or layer, or intervening elements or layers may be present. In contrast, when an element is referred to as being “directly on,” “directly engaged to,” “directly connected to,” “directly attached to,” or “directly coupled to” another element or layer, there may be no intervening elements or layers present. Other words used to describe the relationship between elements should be interpreted in a like fashion (e.g., “between” versus “directly between,” “adjacent” versus “directly adjacent,” etc.). As used herein, the term “and/or” includes any and all combinations of one or more of the associated listed items.

(51) The terms first, second, third, etc. may be used herein to describe various elements, components, regions, layers and/or sections. These elements, components, regions, layers and/or sections should not be limited by these terms. These terms may be only used to distinguish one

element, component, region, layer or section from another region, layer or section. Terms such as “first,” “second,” and other numerical terms do not imply a sequence or order unless clearly indicated by the context. Thus, a first element, component, region, layer or section discussed below could be termed a second element, component, region, layer or section without departing from the teachings of the example configurations.

(52) Referring to FIGS. 1A-27, reference numeral **10** generally designates a ventricular assist device for a ventricular assist system **100**. The ventricular assist device **10** includes a cannula **12** that defines a lumen **14**. The cannula **12** includes a first end **16** and a second end **18**. The second end **18** of the cannula **12** includes a tip **20** that defines an opening **22**. A pump **24** is operably coupled to the first end **16** of the cannula **12**, and a pump anchor **26** is operably coupled to the pump **24**. The pump anchor **26** has a retracted position and a deployed position. A tip anchor **28** may be operably coupled to the second end **18** of the cannula **12** proximate to the tip **20**.

(53) Referring now to FIGS. 1A-6B, the ventricular assist device **10** is illustrated as inserted into a heart **200** of a human. The ventricular assist device **10** is positioned inside an inferior vena cava **202** with the cannula **12** ultimately exiting the heart **200** through a pulmonary artery **204**. The cannula **12** extends from a right atrium **206** and across a right ventricle **208** of the heart to enter the pulmonary artery **204**. The ventricular assist system **100** is configured to insert and deploy the ventricular assist device **10** within the heart **200** to assist in a treatment of a cardiovascular impairment, as described below. The ventricular assist system **100** includes, in addition to the ventricular assist device **10**, a sheath **102** and a guidewire **104**. The sheath **102** is selectively disposed around the cannula **12**, and the guidewire **104** is disposed within the lumen **14** of the cannula **12**. As illustrated in FIG. 2, the sheath **102** may be selectively removed from the cannula **12** to deploy the pump anchor **26** within the inferior vena cava **202**. The sheath **102** may be utilized to collapse and cover the pump anchor **26**, such that the sheath **102** may remain over the pump anchor **26** during placement of the ventricular assist device **10**. Once the ventricular assist device **10** is in place, the sheath **102** may be removed to deploy the pump anchor **26**.

(54) The cannula **12** may have a semi-rigid body **40** having a sigmoidal shape that, as illustrated in FIG. 3, is defined between the first end **16** and the second end **18**. The body **40** may include an internal spiral structure **42** positioned within the lumen **14** of the cannula **12** and may provide general flexibility for the body **40** during positioning of the ventricular assist device **10** within the heart **200**. For example, the lumen **14** may be formed from a polymer conduit and the spiral structure **42** may be formed from a metal structure that is positioned within the polymer conduit. The spiral structure **42** may have a range of dimension between each coil, such that the shape of the body **40** may be altered based on the coil spacing of the spiral structure **42**.

(55) With further reference to FIGS. 1-6, the body **40** may be pre-shaped with the spiral structure within the lumen **14** to define the sigmoidal configuration, such that the pre-shaped nature of the body **40** retains the shape of the cannula **12**, while the spiral structure **42** provides general flexibility to the otherwise semi-rigid body **40**. The cannula **12** may be formed from a plurality of laminated polymer tubes with a metal coil reinforcement between layers. The polymer tubes may be formed from any practicable material including, but not limited to, polypropylene, polyvinyl chloride (PVC), thermoplastic polyurethane (TPU), and/or polytetrafluoroethylene (PFTE). The metal coil may be formed using any practicable material including, but not limited to, metal or metal alloys such as stainless steel or titanium, shape memory alloy (e.g., nickel titanium (NiTi)), or a polymer (e.g., polyether ether ketone (PEEK)). It is generally contemplated that the body **40** of the cannula **12** may be formed using a heat set process using a mold **106** to set the shape of the body **40**. The shape formed by the mold **106** is configured to mimic the path from the inferior vena cava, where the cannula **12** starts, to the pulmonary artery, where the cannula **12** ends at the tip **20**. As illustrated in FIGS. 4 and 5, the sheath **102** may be disposed over the body **40** to define a generally linear configuration, and when the sheath **102** is removed (FIG. 5), the body **40** returns to the pre-formed sigmoidal configuration. Stated differently, the sheath **102** defines a linear body **40**

between the first end **16** and the second end **18** of the cannula **12** when the sheath **102** is disposed around the cannula **12**, and the cannula **12** has a sigmoidal body **40** between the first end **16** and the second end **18** when the sheath **102** is removed from the cannula **12**. The utilization of the sheath **102** to straighten the body **40** is described in more detail below with reference to FIGS. **22-26F**. (56) With reference to FIGS. **2** and **6A-11**, the guidewire **104** is operably coupled to the cannula **12** to assist in placement of the ventricular assist device **10** within the inferior vena cava **202**. In one implementation illustrated in FIGS. **6A-8**, the guidewire **104** is positioned within the lumen **14** proximate the spiral structure **42**. The guidewire **104** may be inserted through and/or extend from the tip **20** to assist in the placement and alignment of the ventricular assist device **10** within the heart **200**. For example, the lumen **14** may define a channel **44** through which the guidewire **104** may extend. The channel **44** may extend through a length **L** of the lumen **14**, such that the guidewire **104** may extend from both the first end **16** and the second end **18** of the cannula **12**. It is contemplated that the channel **44** may be formed as a secondary lumen **44** in which the guidewire **104** may be disposed. For example, the secondary lumen **44** may be formed on a radius of the lumen **14**. FIG. **6B** illustrates the secondary lumen **44** formed along the radius of the lumen **14** in which the guidewire **104** may be positioned. While it is contemplated that the guidewire **104** may be generally rigid and may promote a more planar configuration of the cannula **12**, it is contemplated that the guidewire **104** may be sufficiently flexible so as to guide and manipulate the cannula **12** during placement of the ventricular assist device **10**.

(57) With reference now to FIGS. **8-11B**, a cap **108** may be configured to have a snap-fit arrangement with the pump **24** proximate a driveline **110** of the ventricular assist system **100**. The driveline **110** may be configured as a polymer extrusion and may include a plurality of wires. The driveline **110** is configured to transmit power and information between the pump **24** and an external controller of the ventricular assist system **100**. The driveline **110** may also include a connector **110a** (FIG. **2**) at a distal end of the driveline **110** to connect the ventricular assist device **10** with the external controller. The connector **110a** is an electrical connector at the distal end of the driveline **110** and is configured to interface with the external controller. In one configuration the connector **110a** may have a diameter between approximately 5 millimeters and 10 millimeters. Alternatively, the driveline **110** may be free from a connector, such that the driveline **110** may be capped during implantation of the ventricular assist device **10** and separately coupled to an external connector once the driveline **110** is externalized from the body. For example, the driveline **110** may have circumferential contacts on the distal end configured to mate with the external connector. The cap **108** couples an alignment feature **112** with the pump **24**, such that the alignment feature **112** and the cap **108** may be removed from the pump **24**. Stated differently, the cap **108** is removably coupled to the pump **24**, such that the alignment feature **112** is aligned with the lumen **14** of the cannula **12** via the cap **108** coupled to the pump **24**. In this configuration, it is contemplated that the alignment feature **112** may be a stiff or generally rigid wire to assist in manipulation about the driveline **110**. The cap **108** and the alignment feature **112** may be removed once the ventricular assist device **10** is positioned within the pulmonary artery **204**. In a further alternate configuration, the alignment feature **112** may be configured as a tube, as illustrated in FIG. **11A**. In this configuration, the alignment feature **112** extends over the driveline **110** and may be connected to the cannula **12** via the cap **108** along the driveline **110**. It is contemplated that during removal, the alignment feature **112** illustrated in FIG. **11A** may be separated into two pieces or otherwise peeled back. As described in more detail below, the alignment feature **112** may be removed after positioning of the ventricular assist device **10** and deployment of the pump and tip anchors **26, 28**. In either configuration of the alignment feature **112**, the alignment feature **112** is generally utilized to assist the alignment of the pump **24** during deployment of the ventricular assist system **100**.

(58) With reference to FIG. **11B-11E**, the alignment feature **112** may be disposed over the driveline **110** and is configured to push against the pump **24** during positioning of the ventricular device system **100**. The alignment feature **112** in guiding the system during placement of the ventricular

assist device **10** (FIG. **11A**). For example, the alignment feature **112** may assist in guiding the ventricular assist device **10** as the sheath **102** (FIG. **11A**) is retracted. As illustrated in FIGS. **11C** and **11D**, the alignment feature **112** may include a catheter tip **114**, which may be divided into two halves each including a pin **116**, as illustrated in FIG. **11C**. It is contemplated that the catheter tip **114** may be formed from a polymer or metal. The pins **116** of the catheter tip **114** may couple to indentations **118** formed in the pump **24**, as illustrated in FIG. **11E**, to assist in rotating and directing the placement of the system **100**. To remove the alignment feature **112**, the catheter tip **114** may be split to peel the alignment feature **112** away from the driveline **110**.

(59) Referring now to FIGS. **12A-13B**, the pump **24** is configured as a percutaneous ventricular assist device to provide endovascular mechanical circulatory support of either the right or left portions of the heart for up to approximately 30 days. As described herein, the pump **24** assists the right portion of the heart, but it is contemplated that a similar execution may be performed for the left portion. The pump **24** is configured to pump a blood volume from the inferior vena cava, where the pump **24** is anchored, through the cannula **12** into the pulmonary artery. The ventricular assist device **10** is configured to bypass the right ventricle by being disposed into the pulmonary artery. The pump **24**, as mentioned above, is anchored in the inferior vena cava via the pump anchor **26**, variations of which are described below.

(60) The pump anchor **26** may be positioned at various locations along the pump **24**. For example, FIG. **12B** illustrates four potential locations along the pump **24** at which the pump anchor **26** may be positioned. Alternate positions along the ventricular assist device **10** may also be contemplated, such that the positions illustrated in FIG. **12B** are by example only and not to be limiting examples. The pump anchor **26** may advantageously minimize frictional movement relative to the inferior vena cava vessel walls, minimize potential thrombus formation, and stabilize radial and axial movement of the pump **24** within the inferior vena cava. It is contemplated that the pump anchor **26** may be positioned proximate the driveline **110** and/or the cannula **12**. By way of example, not limitation, the pump anchor **26** may include a first pump anchor **26a** and a second pump anchor **26b**, such that the first pump anchor **26a** may be coupled to the pump **24** proximate the cannula **12** and the second pump anchor **26b** may be coupled to the pump **24** proximate the driveline **110**. As illustrated in FIG. **13A**, the first and second pump anchors **26a**, **26b** extend in opposing directions. Stated differently, FIG. **13A** illustrates the first pump anchor **26a** extending toward the cannula **12**, and the second pump anchor **26b** extending toward the driveline **110**. In an alternate implementation, the first and second pump anchors **26a**, **26b** may extend in the same direction. For example, FIG. **13B** illustrates the first and second pump anchors **26a**, **26b** extending toward the cannula **12**. It is also contemplated that both the first and second pump anchors **26a**, **26b** may extend toward the driveline **110**.

(61) The pump anchor **26** may include a plurality of extensions **50** that extend from an attachment portion **52**. For example, each of the first and second pump anchors **26a**, **26b** may include both the attachment portion **52** and the plurality of extensions **50**, as illustrated in FIGS. **13A** and **13B**. As generally mentioned above, the plurality of extensions **50** of the first pump anchor **26a** may extend toward the cannula **12**, and the plurality of extensions **50** of the second pump anchor may extend away from the cannula **12**. It is also contemplated that alternate configurations of the pump anchor **26** may include an extension body **50a** and/or a single extension **50b**, as illustrated in FIGS. **14A** and **16A**, respectively. The pump anchor **26** is formed from a generally flexible material, such that the pump anchor **26** may be collapsed by the sheath **102** during placement and installation of the ventricular assist device **10**. The pump anchor **26** is operable between the retracted position and the deployed position. For example, when the sheath **102** is disposed around the pump anchor **26**, the pump anchor **26** is in the retracted position, and the pump anchor **26** is in the deployed position when the sheath **102** is removed from the ventricular assist device **10**. It is also contemplated that the pump anchor **26** may translate between the retracted and deployed positions while being free from engagement with the sheath **102**, as described below.

(62) With reference now to FIGS. 14A-15B, the pump anchor 26 is illustrated with the extension body 50a extending from the attachment portion 52. Stated differently, the plurality of extensions 50 may define an interconnected net 50a disposed around the pump 24. In this configuration, the extension body 50a is depicted as having a net configuration, such that a plurality of apertures 54 are defined within the extension body 50a. The pump anchor 26 may be formed from a nickel-titanium (e.g., Nitinol) tube and is attached at an exterior surface of the pump 24. The pump anchor 26 is configured to expand and subsequently radially collapse around the pump 24 when the sheath 102 is deployed. When the sheath 102 is removed, the pump anchor 26 returns to the expanded state. The plurality of apertures 54 of the pump anchor 26 may assist in maintaining fluid communication within the inferior vena cava (FIG. 1A) while anchoring the ventricular assist device 10 within the inferior vena cava (FIG. 1A). The pump anchor 26 may have greater or fewer apertures 54 than those illustrated. For example, an increased number of apertures 54 may assist as a thrombus filter while also providing additional radial force. As mentioned above, the extension body 50a of the pump anchor 26 may extend toward (FIG. 14A) or away from (FIG. 14B) the driveline 110. The pump anchor 26 may also be coupled to the driveline 110, such that the pump anchor 26 may extend over the driveline 110, as depicted in FIG. 14C. The positioning of the pump anchor 26 along the driveline 110 may minimize the overall diameter of the system 100, which may be advantageous during implantation of the ventricular assist device 10.

(63) As illustrated in FIG. 15A, the extension body 50a may include a plurality of eyelets 56 and a wire 58 at an opposing end from the attachment portion 52. The plurality of eyelets 56 may provide an alternate method of retracting and deploying the pump anchor 26, such that the eyelets 56 may be proximate one another in the retracted position of the pump anchor 26. For example, the wire 58 may be drawn to draw the eyelets 56 close to one another and retracting the pump anchor 26 away from the walls of the inferior vena cava 202. It is further contemplated that the eyelets 56 may be offset at varying lengths to assist in recapture of the pump anchor 26 by the sheath 102. Alternatively, the pump anchor 26 may have a uniform edge, as depicted in FIGS. 14A and 14B. Although illustrated with respect to the extension body 50a, it is contemplated that the eyelets 56 and wire 58 may be incorporated and utilized in any of the pump anchor 26 configurations described herein.

(64) Referring to FIGS. 16A and 16B, the pump anchor 26 is illustrated with the single extension 50b. In this configuration, the single extension 50b of the pump anchor 26 has a spiral configuration. The spiral configuration may assist in providing flexibility in multiple directions for the ventricular assist device 10, such that the pump anchor 26 may be generally compressed along the pump 24 while retaining a general circumference. It is also contemplated that the single extension 50b may be wound around the pump 24 to expand and retract about the pump during positioning and install of the ventricular assist device 10. In any of the configurations of the pump anchor 26 illustrated in FIGS. 13A-16B, it is contemplated that the pump anchor 26 is deployed within the inferior vena cava 202 to retain the ventricular assist device 10 in the desired position during a treatment period, described in more detail below.

(65) With reference now to FIGS. 17-19A, the tip 20 of the cannula 12 may have a single opening 22 on each side 70 of the tip 20, as mentioned above, and/or may have multiple openings 22, as illustrated in FIG. 17, around a circumference of the tip 20. It is generally contemplated that the tip 20 may have a lantern or lighthouse configuration. In one implementation, the lantern configuration is defined by the openings 22 being staggered around the tip 20. For example, a first row 22a of the openings 22 may be offset relative to a second row 22b of the openings 22. The lantern configuration and alignment of the openings 22 may assist in preventing clot formation within the ventricular assist device 10, the tip 20, and the pulmonary artery 204 (FIG. 1B) where the tip 20 is ultimately positioned. Stated differently, the openings 22 assist in providing uniform flow distribution and minimal pressure drop. Additionally, a top opening 22c cooperates with the guidewire 104 (FIG. 8), such that the tip 20 may track over the guidewire 104. In either

configuration, the tip **20** has a lower arcuate portion **72** and an upper narrow portion **74**. As illustrated in FIGS. **18A-19B**, the lower arcuate portion **72** and the upper narrow portion **74** may define a droplet shape of the opening **22**. This shape may assist in the transport of fluid exiting the cannula **12** into the pulmonary artery **204** (FIG. **1B**). The tip **20** may also include the tip anchor **28**, mentioned above, to align and retain the tip **20** in the desired position within the pulmonary artery **204** (FIG. **1B**).

(66) For example, the tip anchor **28** illustrated in FIGS. **18A** and **18B** has a net configuration similar to the pump anchor **26** illustrated in FIGS. **14A** and **14B**. The tip anchor **28** of this configuration may be deployed and retracted in a similar manner as described with respect to the pump anchor **26**, such that the tip anchor **28** may also include the attachment portion **52** and plurality of extensions **50** extending from the attachment portion and the eyelets **56** and wire **58** at an opposing end from the attachment portion **52**. The eyelets **56** and the wire **58** may retract the tip anchor **28** around the tip **20** and/or cannula **12**. In one implementation, the pump anchor **26** (FIG. **13A**) and the tip anchor **28** may be coupled to the pump **24** (FIG. **13A**) and the second end **18** of the cannula **12**, respectively, at the respective attachment portions **52**. It is generally contemplated that the tip anchor **28** may extend toward either the tip **20** or the cannula **12**, and in either configuration, the tip **20** retains the tip **20** in the installed position.

(67) As illustrated in FIGS. **19A** and **19B**, the tip anchor **28** is illustrated as having a balloon configuration. In this example, the tip anchor **28** may be deployed by inflation of an inflatable body **76** about the cannula **12** at the base of the tip **20**. The inflatable body **76** has an expanded position and a contracted position, such that the inflatable body **76** is in the contracted position as the ventricular assist device **10** is being installed and translates to the expanded position to at least partially secure the ventricular assist device **10** within the pulmonary artery **204** (FIG. **1B**). The inflated tube **76** has a circumference that assists in aligning the ventricular assist device **10** within the pulmonary artery **204** and heart **200** more generally. For example, it is contemplated that the inflation of the inflatable body **76** may center the tip **20** within the pulmonary artery **204**. FIG. **19B** illustrates another configuration of the inflatable body **76**. In this alternate configuration, the inflatable body **76** defines a plurality of recesses **78**. As illustrated in FIG. **19B**, the recesses **78** align with the opening **22** defined by the tip **20**, which promotes ease of fluid flow around the ventricular assist device **10** and, specifically, the tip **20**. While fluid may pass through the ventricular assist device **10**, it is also contemplated that the ventricular assist device **10** may promote fluid flow between the inferior vena cava **202** (FIG. **1B**) and the pulmonary artery **204** (FIG. **1B**) to assist in performance of the heart **200** (FIG. **1B**).

(68) Referring now to FIGS. **20A-21C**, a delivery device **120** is illustrated as coupled to the ventricular assist device **10** for installation in the heart **200**. The delivery device **120** may be part of the ventricular assist system **100** or may be separate from the system **100**. The delivery device **120** is configured to deliver and remove the ventricular assist device **10**. It is contemplated that the delivery device **120** is configured to extend and retract both the alignment feature **112** and the sheath **102**, described above. The delivery device **120** includes an actuator **122** coupled to a handle **124** within a guide channel **126** defined by the handle **124**. The guide channel **126** may have a defined pattern that may assist in the operation of the delivery device **120** where visibility of the handle **124** may be impaired. The handle **124** may also include a locking feature **128** configured to prevent movement of the actuator **122** within the guide channel **126**. The locking feature **128** is operable between a first, locked position and a second, unlocked position. As illustrated in FIG. **20D**, the locking feature **128** extends proximate to the actuator **122** in the first position and extends away from the actuator **122** in the unlocked position. It is further contemplated that the locking feature **128** may be identified with a color to indicate the locked or unlocked state of the locking feature **128**. By way of example, not limitation, the portion of the locking feature **128** proximate to the actuator **122** in the first, locked position may be red and the portion extending away from the actuator **122** in the second, unlocked position may be green. It is contemplated that other color

combinations may also be utilized to visually depict the locked and unlocked positions of the locking feature **128**.

(69) In addition, the locking feature **128** includes a cutout **130** that corresponds to the guide channel **126** when the locking feature **128** is in the unlocked position. When the locking feature **128** is in the locked position, the locking feature **128** may block a portion of the guide channel **126** and may otherwise prevent movement of the actuator **122** within the guide channel **126**. FIG. 20D illustrates the transition of the locking feature **128** and the actuator **122** relative to the guide channel **126**. As the locking feature **128** is transitioned from the locked position to the unlocked position, the cutout **130** of the locking feature **128** is aligned with the guide channel **126**, and the actuator **122** may transition within the guide channel **126** along an x-axis and a y-axis. Stated differently, the actuator **122** is positioned in a first channel **126a** of the guide channel **126** when the locking feature is in the locked position, and the actuator **122** is translated within the first channel **126a** toward the cannula **12** when the locking feature **128** is in the unlocked position. The actuator **122** may then be drawn into a second channel **126** to deploy the sheath **102**.

(70) For example, the delivery device **120** is operably coupled to the sheath **102** to extend and retract the sheath **102** about the ventricular assist device **10**. It is contemplated that the handle **124** may be generally and/or partially hollow, such that the sheath **102** may be housed within the handle **124** and deployed for installation of the ventricular assist device **10**. The delivery device **120** may also deploy the guidewire **104** within the lumen **14** (FIG. 6) of the cannula **12**. The delivery device **120** may also retract and/or advance the alignment feature **112**, such that the alignment feature **112** may be coupled to the actuator **122** of the handle **124**. It is contemplated that the alignment feature **112** may be fixed to the handle **124**, such that the handle **124** is configured to push and position the ventricular assist device **10** within the vasculature. The sheath **102** may be coupled to the actuator **122**, such that the sheath **102** is configured to slide axially to uncover and cover the device **10** while the delivery device **120** remains stationary. The actuator **122** may be utilized to maneuver the alignment feature **112** during insertion and deployment of the system **100**. In one configuration, the sheath **102** may be uncoupled from the delivery device **120** to assist in axial translation of the sheath **102** relative to the guidewire **104**. Additionally or alternatively, the delivery device **120** may be free from the alignment feature **112**, such that the device **10** may be positioned into place via the driveline **110** connected to the device **10**.

(71) FIGS. 20A-20D illustrate a partial view of how the delivery device **120** retracts the sheath **102** from the ventricular assist device **10** once the ventricular assist device is installed. The sheath **102** may form the outermost portion of the delivery device **120**. The sheath **102** is configured to collapse and cover the pump anchor **26** and may remain over the pump anchor **26** as the system **100** is advanced into the inferior vena cava **202** (FIG. 21A). Once the system **100** is in place, the sheath **102** may be retracted via the delivery device **120**, and the pump anchor **26** is deployed. The removal of the sheath **102**, as illustrated in FIGS. 20B and 20C, releases the extensions **50** of the pump anchor **26** to secure the ventricular assist device **10** within the inferior vena cava **202** (FIG. 21A) of the heart **200** (FIG. 21A). FIGS. 21A-21C illustrate, in part, the process in which the delivery device **120** is utilized to reposition the sheath **102** over the ventricular assist device **10**, such that the pump anchor **26** is translated from the deployed position to the retracted position. The cannula **12** may be retracted into the sheath **102** and removed from the heart **200** once treatment is complete.

(72) Referring now to FIGS. 22-27, a method **400** of treatment of a cardiovascular impairment is described using the ventricular assist device **10** across the right ventricle **208** between the inferior vena cava **202** and the pulmonary artery **204** of a body **230**, for example a human body. FIG. 22 illustrates a schematic figure of a human and a lower portion of a circulatory system **220**. The circulatory system **220** includes femoral veins **222**, which for purposes of this disclosure is discussed in relation to a single femoral vein **222**, the inferior vena cava **202**, the heart **200**, and the pulmonary artery **204**, among other arteries and veins. The inferior vena cava **202** extends between

the femoral vein **222** and the heart **200** within an abdomen **232** of the body **230**. The femoral vein **222** may be accessed via a thigh **234** of the human proximate a groin region **236**.

(73) The method **400** generally sets forth, at step **402**, that the ventricular assist device **10** is inserted in the inferior vena cava **202** via the delivery device **120** and the driveline **110** at an access site **240**, such as a femoral vein. For example, the cannula **12** of the ventricular assist device is inserted in the inferior vena cava **202**. The cannula **12** of the ventricular assist device **10** is guided, at step **404**, through the inferior vena cava **202** and the right atrium **206** and into the right ventricle **208**. It is contemplated that the ventricular assist device **10**, including the pump **24** and the cannula **12**, may be rotated during implantation, which may optimize the anatomic positioning of the device **10**. The cannula **12** is ultimately guided into the pulmonary artery **204**. The pump anchor **26** is deployed, at step **406**, in the inferior vena cava **202**. Stated differently, at least one anchor **26a**, **26b** of the ventricular assist device is deployed in the inferior vena cava **202**. The delivery device **120** is then removed, at step **408**, over the driveline **110**. When treatment is complete, the driveline **110** is at least partially removed, at step **410**, from the body **230**. The access site **240** is closed around the driveline **110**, such that the driveline **110** is directed to a treatment site **242**, such as at the abdomen, where the driveline **110** exits the body to interface with an external controller. Stated differently, the driveline **110** is subcutaneously tunneled from the access site **240** to the treatment site **242**. It is contemplated that the driveline **110** remains external to the body **230** for the duration of treatment at the treatment site **242**. The delivery device **120** is inserted, at step **412**, over the partially removed driveline **110** and into the inferior vena cava **202**. The pump anchor **26** of the ventricular assist device **10** is collapsed, at step **414**, and the delivery device **120** and the ventricular assist device **10** are removed, at step **416**, from the body **230**. Each of these steps is described in more detail below.

(74) With reference to FIGS. **22-24E**, one implementation of the method **400** of treatment is illustrated. The ventricular assist system **100**, which includes the ventricular assist device **10** and the delivery device **120**, may be inserted into the body **230** at the access site **240**. In this implementation, the access site **240** is proximate the femoral vein **222** along the thigh **234**. The ventricular assist system **100** may be advanced through the vasculature toward the inferior vena cava **202** up to an inferior cavoatrial junction proximate the heart **200**. As mentioned above, the cannula **12** is advanced through the right atrium **206** and right ventricle **208** and into the pulmonary artery **204**. It is contemplated that the shape of the cannula **12** may be configured to minimize interference with the pulmonary valve. Additionally or alternatively, the tip anchor **26** illustrated in FIGS. **18A** and **18B** may be utilized to minimize interference with the pulmonary valve. It is further contemplated that the cannula **12** is disposed within the center of the pulmonary valve while valve leaflets will coapt around the cannula **12**. The tip anchor **26** may assist in centering the cannula **12** within the valve to assist in improving coaptation of the valve leaflets against the cannula **12**. For example, the cannula **12** may press against one of the valve leaflets if the cannula **12** is off-center. As discussed above, the pump anchor **26** is deployed and the delivery device **120** is removed over the driveline **110**. It is contemplated that the driveline **110** may exit the body **230** at the access site **240**. For example, the driveline **110** may be partially removed at the access site **240**. It is contemplated that the access site **240** may provide access both to the femoral vein **222** as well as subcutaneous access within the body **230**.

(75) The driveline **110** may be fed into the access site **240** at an approximately 180-degree turn and directed subcutaneously from the access site **240** into the abdomen **232** in a superior direction. The driveline **110** may exit the abdomen **232** at a treatment site **242** where a treatment may be executed using the driveline **110** and the ventricular assist device **10**. It is contemplated that the treatment site **242** may be, for example, at a subcostal or lower abdomen location. In this implementation, the access site **240** may be closed during treatment. Once treatment has concluded, the access site **240** may be reopened and the driveline **110** may be severed from the ventricular assist device **10**. The severed driveline **110** may then be pulled retrograde back to the access site **240**, and the delivery

device **120** may be reinserted over the driveline **110** at the access site **240** to remove the ventricular assist device **10**. The delivery device **120** deploys the sheath **102** to collapse the anchor **26**, and the delivery device **120** and the ventricular assist device **10** may then be removed from the body **230** via the access site **240**. It is also contemplated that a separate removal device, similar to the delivery device **120**, may be utilized during removal of the device **10**. In one example, the delivery device **120** may include a snare or other collapsing device that may be utilized to collapse the tip anchor **26** and covered by the sheath **102**.

(76) With reference now to FIGS. **22-23B** and **25A-25F**, an alternate implementation of the method **400** of treatment is illustrated. As discussed above, the ventricular assist system **100** may be inserted into the body **230** at the access site **240**. In this implementation, the access site **240** is still proximate the femoral vein **222** along the thigh **234**. The ventricular assist system **100** may be advanced through the inferior vena cava **202** up to an inferior cavoatrial junction proximate the heart **200**. As mentioned above, the cannula **12** is advanced through the right atrium **206** and right ventricle **208** and into the pulmonary artery **204**. As discussed above, the pump anchor **26** is deployed and the delivery device **120** is removed over the driveline **110**. It is contemplated that the driveline **110** may exit the body **230** at the access site **240**. For example, the driveline **110** may be partially removed at the access site **240**. It is contemplated that the access site **240** may provide access both to the femoral vein **222** as well as subcutaneous access within the body **230**.

(77) Once partially removed, the driveline **110** may be bent extracorporeally and reinserted into the access site **240** toward a lower portion **210** of the inferior vena cava **202**. The driveline **110** may be fed into the access site **240** at an approximately 180-degree turn and directed through the femoral vein **222** into the lower portion **210** of the inferior vena cava **202**. An exit site **246** is defined at the lower portion **210** of the inferior vena cava **202**, and an end of the driveline **110** may be guided subcutaneously toward the treatment site **242** in the lower abdomen **232** from the exit site **246** defined at the lower portion **210** of the inferior vena cava **202**. The driveline **110** may be positioned subcutaneously from the inferior vena cava **202** toward the treatment site **242** at the abdomen **232**. The treatment site **242** is defined, and the driveline **110** is removed at the treatment site **242**. As mentioned above, the driveline **110** remains positioned at the treatment site **242** in the abdomen **232** for the duration of the treatment. Once treatment is complete, an abdominal access site **244** is opened, and the driveline **110** is severed. The severed driveline **110** may be removed via the abdominal access site **244**, and the delivery device **120** may be inserted and positioned over the ventricular assist device **10** within the inferior vena cava **202**. The delivery device **120** deploys the sheath **102** to collapse the anchor **26**, and the delivery device **120** and the ventricular assist device **10** may then be removed from the body **230** via the abdominal access site **244**.

(78) With reference now to FIGS. **22** and **26A-26F**, a third implementation of the method **400** of treatment is illustrated. The ventricular assist system **100** may be inserted into the body **230** at the access site **240**. In this implementation, the access site **240** is positioned at the abdomen, such that the ventricular assist system **100** is inserted via the abdominal access site **244**, and the abdominal access site **244** is proximate to the inferior vena cava **202**. While discussed above as separate access points, it is contemplated that terminology of the access site **240** may be interchangeable with the abdominal access site **244** in the third implementation discussed herein.

(79) The ventricular assist system **100** may be inserted through the lower portion **210** of the inferior vena cava **202** and advanced upward within the inferior vena cava **202** to an inferior cavoatrial junction proximate the heart **200**. As mentioned above, the cannula **12** is advanced through the right atrium **206** and right ventricle **208** and into the pulmonary artery **204**. As discussed above, the pump anchor **26** is deployed and the delivery device **120** is removed over the driveline **110**. It is contemplated that the driveline **110** may exit the lower portion **210** of the inferior vena cava **202** and at least partially exit the abdominal access site **244**.

(80) The driveline **110** may be fed into the abdominal access site **244** at an approximately 180-degree turn and directed subcutaneously from the abdominal access site **244** into the abdomen **232**

toward the treatment site **242**. The treatment site **242** is defined in the abdomen **232** above the abdominal access site **244**. Additionally or alternatively, the treatment site **242** may be defined below, adjacent, or otherwise proximal to the abdominal access site **244**. As discussed above, the driveline **110** may exit the treatment site **242** during the duration of the treatment. In this implementation, the abdominal access site **244** may be closed during treatment. Once treatment has concluded, the abdominal access site **244** may be reopened and the driveline **110** may be severed from the ventricular assist device **10**. The severed driveline **110** may then be removed from the treatment site **242**, and the delivery device **120** may be reinserted at the abdominal access site **244** to remove the ventricular assist device **10** at the lower portion **210** of the inferior vena cava **202**. The delivery device **120** deploys the sheath **102** to collapse the anchor **26**, and the delivery device **120** and the ventricular assist device **10** may then be removed from the body **230** via the abdominal access site **244**.

(81) It is contemplated that the ventricular assist device **10** may cooperate with a pressure sensor during use. For example, a desired central venous pressure may fall within a range of approximately 0 mmHg to 10 mmHg and typical physiological limits are approximately 5 mmHg to 25 mmHg. The ventricular assist device **10** may function independent of the pressure sensor to maintain the pressure within the central venous pressure or may cooperate with the pressure sensor to maintain the central venous pressure within the desired range. The ventricular assist device **10** is also configured to meet hemodynamic requirements. In either configuration, the ventricular assist device **10** is configured to assist a failing ventricle of the heart. By way of example, not limitation, the ventricular assist device **10** may assist a failing right ventricle, such that the ventricular assist device **10** may be configured as a right ventricular assist device **10**.

(82) Each of these implementations provide various improvements to current treatment. For example, the first and second implementations provide a single vascular access point while avoiding direct contact with the inferior vena cava. In particular, the second implementation maximizes the ease of delivery of the ventricular assist device into the final functional position. The third implementation also provides a single vascular access site and minimizes the number of incisions of the body. In addition, the third implementation may provide for a shorter delivery device and a shorter driveline connection.

(83) A number of implementations have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the disclosure. Accordingly, other implementations are within the scope of the following claims.

Claims

1. A ventricular assist device, comprising: a cannula defining a lumen and including a first end and a second end, the second end of the cannula including a tip that defines an opening for outflow of blood; a pump operably coupled to the first end of the cannula and having an inlet in fluid communication with the opening; a pump anchor operably coupled to the pump, the pump anchor having a retracted position and a deployed position; and a tip anchor operably coupled to the second end of the cannula proximate the tip; wherein the pump anchor and the tip anchor each include an attachment portion and a plurality of extensions extending from the attachment portion, and wherein the pump anchor and the tip anchor are coupled to the pump and the second end of the cannula, respectively, at the respective attachment portions; wherein the plurality of extensions of the pump anchor define an interconnected net disposed around the pump such that the inlet of the pump in use intakes the blood in circulation upstream ahead of the blood passing through apertures of the interconnected net; and wherein the pump anchor includes a plurality of eyelets and a wire disposed through the plurality of eyelets and configured to be drawn to draw the plurality of eyelets closer to one another.

2. The ventricular assist device of claim 1, wherein the cannula includes a semi-rigid sigmoidal

body defined between the first end and the second end.

3. The ventricular assist device of claim 1, wherein the tip has a lower arcuate portion and an upper narrow portion that collectively define the opening.

4. The ventricular assist device of claim 1, wherein the pump anchor includes a first pump anchor coupled to the pump and a second pump anchor coupled to the pump, and wherein each of the first and second pump anchors include a plurality of extensions.

5. The ventricular assist device of claim 4, wherein the plurality of extensions of the first pump anchor extend toward the cannula and the plurality of extensions of the second pump anchor extend away from the cannula.

6. The ventricular assist device of claim 1, wherein the plurality of eyelets are proximate one another in the retracted position of the pump anchor.

7. The ventricular assist device of claim 1, wherein the pump anchor includes the plurality of eyelets at an opposing end from the attachment portion of the pump anchor.
