(12) STANDARD PATENT (11) Application No. AU 2017349920 B2
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Ventricular assist device

(51) International Patent Classification(s)
A61M 60/00 (2021.01) ***A61M 60/139*** (2021.01)

(21) Application No: **2017349920** (22) Date of Filing: **2017.10.23**

(87) WIPO No: **WO18/078615**

(30) Priority Data

(31) Number	(32) Date	(33) Country
62/412,631	**2016.10.25**	**US**
62/543,540	**2017.08.10**	**US**

(43) Publication Date: **2018.05.03**
(44) Accepted Journal Date: **2023.03.23**

(71) Applicant(s)
Magenta Medical Ltd.

(72) Inventor(s)
Tuval, Yosi;Glozman, Daniel;Lubinsky, Gad

(74) Agent / Attorney
Spruson & Ferguson, GPO Box 3898, Sydney, NSW, 2001, AU

(56) Related Art
US 8690749 B1
US 6533716 B1
US 2012/0178986 A1

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) **World Intellectual Property Organization**
International Bureau

(43) **International Publication Date**
03 May 2018 (03.05.2018)

WIPO | PCT

(10) **International Publication Number**
WO 2018/078615 A1

(51) **International Patent Classification:**
A61M 1/10 (2006.01) *A61M 1/12* (2006.01)

(21) **International Application Number:**
PCT/IL2017/051158

(22) **International Filing Date:**
23 October 2017 (23.10.2017)

(25) **Filing Language:** English

(26) **Publication Language:** English

(30) **Priority Data:**
62/412,631 25 October 2016 (25.10.2016) US
62/543,540 10 August 2017 (10.08.2017) US

(71) **Applicant: MAGENTA MEDICAL LTD.** [IL/IL]; Haofeh 1, 60920 Kadima (IL).

(72) **Inventors: TUVAL, Yosi**; Hashalom 8, 40500 Even Yehuda (IL). **GLOZMAN, Daniel**; 37 Odem Street, 4034723 Kfar Yona (IL). **LUBINSKY, Gad**; 1 Tze'elon Street, 4069600 Ein Vered (IL).

(74) **Agent: COLB, Sanford T.** et al.; SANFORD T. COLB & CO., 4 Shaar Hagai Street, P.O. Box 2273, 7612201 Rehovot (IL).

(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,

(54) **Title:** VENTRICULAR ASSIST DEVICE

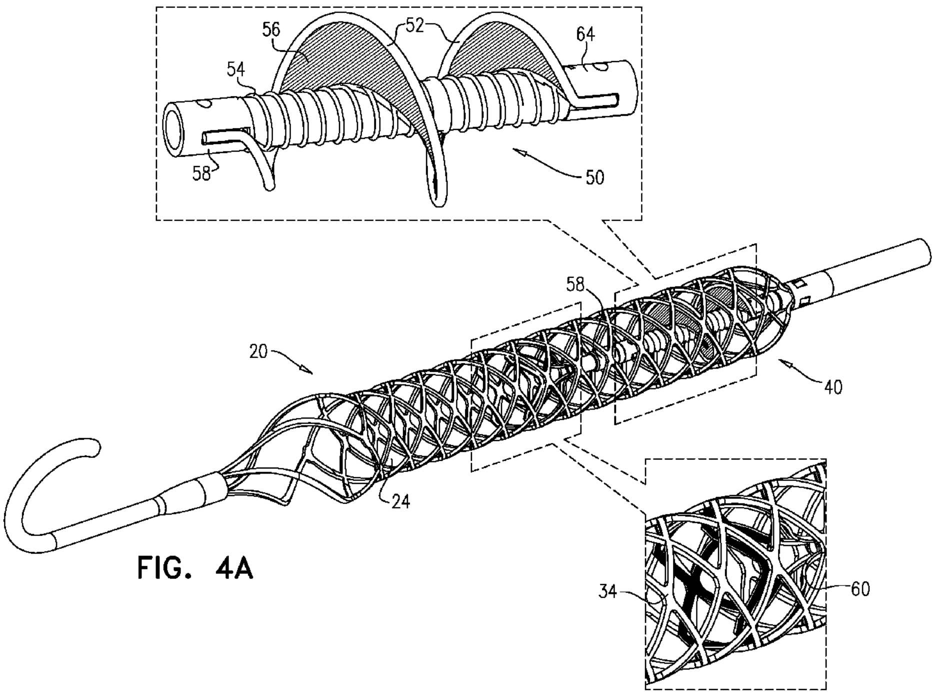

FIG. 4A

(57) **Abstract:** Apparatus and methods are described including placing within a blood vessel of a subject an impeller (50), the impeller including at least one helical elongate element (52), and a spring (54), the spring being disposed inside of, and coaxially with, the helical elongate element. A film of material (56) is supported between the helical elongate element and the spring. Blood is pumped through the subject's blood vessel, using the impeller. Other applications are also described.

WO 2018/078615 A1

[Continued on next page]

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

VENTRICULAR ASSIST DEVICE

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application claims priority from:

US Provisional Patent Application 62/412,631 to Tuval, entitled "Ventricular assist device," filed October 25, 2016; and

US Provisional Patent Application 62/543,540 to Tuval, entitled "Ventricular assist device," filed August 10, 2017.

Both of the above-referenced applications are incorporated herein by reference.

FIELD OF EMBODIMENTS OF THE INVENTION

Some applications of the present invention generally relate to medical apparatus. Specifically, some applications of the present invention relate to a ventricular assist device and methods of use thereof.

BACKGROUND

Ventricular assist devices are used to assist cardiac circulation, for patients suffering from a failing heart. Most commonly a left-ventricular assist device is applied to a defective heart, in order to assist left-ventricular functioning. In some cases, a right-ventricular assist device is used, in order to assist right-ventricular functioning.

SUMMARY OF EMBODIMENTS

In accordance with some applications of the present invention, an impeller includes a helical elongate element, a spring that is disposed inside of, and coaxially with, the helical elongate element, and a film of material supported between the helical elongate element and the spring. For some applications, the impeller comprises a portion of a ventricular assist device configured to assist ventricular functioning of a subject, e.g., a left-ventricular assist device is configured to assist left ventricular functioning of a subject. The ventricular assist device typically includes an elongate tube configured to traverse the subject's aortic valve, such that a proximal end of the tube is disposed within the subject's aorta and a distal end of the tube is disposed within the subject's left ventricle. The elongate tube includes a frame formed from a self-expandable shape-memory alloy, and a blood impermeable material that is disposed upon the frame. The ventricular assist device includes a pump, which typically includes the impeller and a cage disposed around the impeller. The impeller is typically configured to pump blood out of the subject's left ventricle and into the subject's aorta, by rotating. Typically, the impeller also impedes backflow of blood across the aortic valve, from the aorta into the left ventricle.

For some applications, the cage is integrally formed with the elongate tube such that the cage is disposed within the frame of the elongate tube at the proximal end of the elongate tube. The pump is thereby disposed within a proximal portion of the elongate tube, and a longitudinal axis of the pump is thereby aligned with a longitudinal axis of the elongate tube. Alternatively, the cage is not integrally formed with the elongate tube.

There is therefore provided, in accordance with some applications of the present invention, apparatus including:

an impeller including:

at least one helical elongate element;

a spring, the spring being disposed inside of, and coaxially with, the helical elongate element; and

a film of material supported between the helical elongate element and the spring.

In some applications, the impeller includes a plurality of helical elongate elements, and the film of material is supported between the plurality of helical elongate elements and the spring, such that the impeller defines a plurality of blades.

In some applications, when the impeller is disposed in a non-radially-constrained configuration, a pitch of the helical elongate element varies along a length of the helical elongate element.

In some applications, when the impeller is disposed in a non-radially-constrained configuration, a pitch of the helical elongate element is greater than 1 mm.

In some applications, when the impeller is disposed in a non-radially-constrained configuration, a pitch of the helical elongate element is less than 20 mm.

In some applications, the impeller is configured to be placed inside a blood vessel of a subject and to pump blood through the subject's blood vessel by the impeller rotating.

In some applications, the impeller is configured to be placed in an aorta of a subject and to pump blood from a left ventricle of the subject, by the impeller rotating.

In some applications, the impeller is configured to be placed in a ventricle of a subject and to pump blood from the ventricle, by the impeller rotating.

In some applications, the impeller is configured to be placed in an aorta of a subject and to impede backflow of blood from the aorta into a left ventricle of the subject.

In some applications, the impeller is configured to be radially constrained by the helical elongate element and the spring being axially elongated, and in response to the axial elongation of the helical elongate element and the spring, the film is configured to change shape without the film of material breaking.

In some applications, the apparatus further includes:

an elongate tube configured to traverse an aortic valve of a subject, such that a proximal end of the tube is disposed within an aorta of the subject and a distal end of the tube is disposed within a left ventricle of the subject, the elongate tube including:

a frame formed from a shape-memory alloy; and

a blood impermeable material that is disposed upon the frame; and

a cage disposed around the impeller,

the elongate tube being configured to be disposed around the cage and the impeller, and the impeller being configured to pump blood from the left ventricle to the aorta, by rotating.

In some applications, the spring, when disposed in a non-radially-constrained configuration thereof, is configured by virtue of its rigidity, to stabilize the impeller with respect to the elongate tube, during rotation of the impeller, such that a gap between an outer edge of the impeller and an inner surface of the elongate tube is maintained.

In some applications:

the spring defines a lumen therethrough, and

the impeller further includes:

proximal and distal bushings; and

a rigid shaft configured to extend from the proximal bushing to the distal bushing via the lumen defined by the spring, the rigid shaft being configured to stabilize the impeller with respect to the elongate tube, during rotation of the impeller, such that a gap between an outer edge of the impeller and an inner surface of the elongate tube is maintained.

In some applications, the cage is integrally formed with the frame of the elongate tube such that the cage is disposed within the frame of the elongate tube at the proximal end of the elongate tube, the impeller thereby being disposed within a proximal portion of the elongate tube, and a longitudinal axis of the impeller thereby being aligned with a longitudinal axis of the elongate tube.

In some applications, a gap between an outer edge of the impeller and an inner surface of the elongate tube is less than 1 mm.

In some applications, the gap between the outer edge of the impeller and the inner surface of the elongate tube is less than 0.4 mm.

In some applications, the impeller is configured to be stabilized with respect to the elongate tube, such that, during rotation of the impeller, the gap between the impeller and the elongate tube is maintained.

In some applications, the cage is not integrally formed with the frame of the elongate tube.

In some applications, the apparatus further includes one or more support arms that are configured to extend from the cage to the frame of the elongate tube, and that are configured, during rotation of the impeller, to stabilize a distal end of the impeller with respect to the frame of the elongate tube, such that a gap between an outer edge of the impeller and an inner surface of the elongate tube is maintained.

In some applications, the support arms are configured to be slidable with respect to the frame of the elongate tube.

In some applications, the support arms are configured to be coupled to the frame of the elongate tube.

In some applications, the apparatus further includes a plurality of winged projections that are coupled to the elongate tube such that planes defined by the winged projections are parallel with a longitudinal axis of the elongate tube, the winged projections being configured to stabilize turbulent blood flow that is generated by rotation of the impeller, by directing blood flow along a direction of the longitudinal axis of the elongate tube.

In some applications, the elongate tube is configured to be inserted into a body of the subject transcatheterally, while in a radially-constrained configuration, and the winged projections are configured to become folded, when the elongate tube 1s m its radially-constrained configuration.

In some applications, the spring defines a lumen therethrough, and the impeller further includes:

proximal and distal bushings; and

a rigid shaft configured to extend from the proximal bushing to the distal bushing via the lumen defined by the spring.

In some applications, the rigid shaft is configured to maintain the proximal bushing and the distal bushing aligned with each other.

In some applications, the impeller is configured to be placed into a body of a subject, and subsequent to placement of the spring inside the subject's body, the rigid shaft is configured to be placed within the lumen defined by the spring.

In some applications, the impeller is configured to be placed into a body of a subject, and the rigid shaft is configured to be disposed within the lumen defined by the spring, during placement of the impeller into the subject's body,

In some applications, the impeller further includes proximal and distal bushings, and the spring, when disposed in a non-radially-constrained configuration thereof, is configured, by virtue of its rigidity, to maintain the proximal bushing and the distal bushing aligned with each other.

In some applications, the spring, when disposed in the non-radially-constrained configuration thereof, is configured such that there are substantially no gaps between windings of the spring and adjacent windings thereto.

There is further provided, in accordance with some applications of the present invention, a method including:

placing within a blood vessel of a subject an impeller, the impeller including:

at least one helical elongate element;

a spring, the spring being disposed inside of, and coaxially with, the helical elongate element; and

a film of material supported between the helical elongate element and the spring;

pumping blood through the subject's blood vessel, using the impeller.

There is also provided, in accordance with some applications, an apparatus comprising:

an impeller comprising:

a proximal bushing and a distal bushing; and

at least one helical elongate element;

a coil spring, the coil spring being disposed inside of, and coaxially with, the helical elongate element, between the proximal and distal bushings, and the coil spring defining a lumen therethrough;

a film of material supported between the helical elongate element and the coil spring, wherein the impeller is structured such that the film of material extends from the helical elongate element to the coil spring to thereby define an impeller blade; and

a rigid shaft configured to extend from the proximal bushing to the distal bushing of the impeller via the lumen defined by the coil spring;

wherein the impeller is configured to be radially constrained by the helical elongate element and the coil spring being axially elongated, and wherein in response to the axial elongation of the helical elongate element and the coil spring, the film is configured to change shape without the film of material breaking.

There is also provided, in accordance with some applications, a method comprising:

placing within a blood vessel of a subject an impeller, the impeller including:

a proximal bushing and a distal bushing;

at least one helical elongate element;

a coil spring, the coil spring being disposed inside of, and coaxially with, the helical elongate element, between the proximal and distal bushing, and the spring defining a lumen therethrough;

a rigid shaft extending from the proximal bushing to the distal bushing via the lumen defined by the spring; and

a film of material supported between the helical elongate element and the coil spring, such that the film of material extends from the helical elongate element to the coil spring to thereby define an impeller blade; and

pumping blood through the subject's blood vessel, using the impeller

wherein placing the impeller within the blood vessel comprises inserting the impeller within the subject's blood vessel transcatheterally by axially elongating the helical elongate element and the coil spring, thereby causing the film of material to change shape without the film of material breaking.

The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1A and 1B are schematic illustrations of a ventricular assist device disposed in a subject's left ventricle, in accordance with some applications of the present invention;

Fig. 2 is a schematic illustration of a pump that includes an impeller and a cage, in accordance with some applications of the present invention;

Fig. 3 is a schematic illustration of a frame of an elongate tube of the ventricular assist device, and a cage of the impeller of the ventricular assist device, in accordance with some applications of the present invention;

Figs. 4A and 4B are schematic illustrations of a ventricular assist device, in accordance with some additional applications of the present invention;

Figs. 5A and 5B are schematic illustrations of respective cross-sectional views of an impeller of the ventricular assist device shown in Figs. 4A and 4B in accordance with some applications of the present invention;

Fig. 5C is a schematic illustration of a cross-sectional view of the ventricular assist device shown in Figs. 4A and 4B, in accordance with some applications of the present invention;

Fig. 5D is a schematic illustration of the impeller of the ventricular assist device shown in Figs. 4A and 4B in a radially-constrained configuration, in accordance with some applications of the present invention;

Figs. 6A and 6B are schematic illustrations of a stator of a ventricular assist device, in accordance with some applications of the present invention; and

Figs. 7A, 7B, and 7C are schematic illustrations of a ventricular assist device that includes a centrifugal pump, in accordance with some applications of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Figs. 1A and 1B, which are schematic illustrations of a ventricular assist device 20 disposed in a subject's left ventricle 22, in accordance with some applications of the present invention. The ventricular assist device includes an elongate tube

24, which traverses an aortic valve 26 of the subject, such that a proximal end 28 of the elongate tube is disposed in an aorta 30 of the subject and a distal end 32 of the tube is disposed within left ventricle 22. The elongate tube typically includes a radially-expandable frame 34 formed from a self-expandable shape-memory alloy, such as nitinol, and a blood impermeable material 36 that is disposed upon the frame. For example, the blood impermeable material may include polyurethane, polyester, and/or silicone. Typically, the frame provides the elongate tube with rigidity, and the blood impermeable material provides the elongate tube with blood impermeability. Further typically, the shape memory alloy of the frame is shape set such the frame assumes its tubular shape in the absence of any forces being applied to the tube. Typically, device 20 is inserted into the left ventricle transcatheterally (e.g., via the brachial artery), while the tube is in a radially constrained state. Upon being released from the catheter, the tube automatically assumes it tubular shape, due to the frame expanding. A pump 40 is disposed within the elongate tube (e.g., within a proximal portion of the elongate tube, as shown), and is configured to pump blood through the elongate tube from the left ventricle into the aorta, to thereby assist left ventricular functioning.

Fig. 2 is a schematic illustration of pump 40, in accordance with some applications of the present invention. Pump 40 typically includes a radially-expandable impeller 42 disposed inside a radially-expandable cage 44. Typically, pump 40 is inserted into the left ventricle transcatheterally, while the impeller and the cage are in radially constrained configurations. The impeller and the cage typically include a shape memory alloy (such as nitinol), which is shape set such that the impeller and the cage assume non-radially-constrained (i.e., radially-expanded) configurations thereof in the absence of any radially-constraining force acting upon the impeller and the cage. Thus, typically, the cage and the impeller radially expand upon being released from the distal end of the catheter via which they are inserted. For some applications, an engagement mechanism engages the impeller and the cage with respect to one another, such that in response to the cage becoming radially constrained the impeller becomes radially constrained, e.g., in accordance with apparatus and methods described in described in WO 14/141284 to Schwammenthal, which is incorporated herein by reference. In general, pump 40 is generally similar to the blood pumps described in WO 14/141284 to Schwammenthal, WO 15/177793 to Schwammenthal, and/or WO 16/185473 to Schwammenthal, all of which are incorporated herein by reference. Typically, pump 40 pumps blood through the elongate tube from the left ventricle into the aorta, by the impeller rotating.

For some applications, a rotating cable 46 (Fig. 1B) rotates the impeller. Typically, the rotating cable is rotated by a motor (not shown) which is disposed outside the subject's body, or inside the subject's body.

For some applications, pump 40 is disposed at a proximal end of the elongate tube, such that the pump is disposed within the aorta. For some applications, the pump is disposed at the distal end of the elongate tube, such that the pump is disposed within the subject's ventricle.

Reference is now made to Fig. 3, which is a schematic illustration of frame 34 of elongate tube 24 and cage 44 of pump 40 of ventricular assist device 20, in accordance with some applications of the present invention. As shown, for some applications, the cage is integrally formed with the frame of the elongate tube, such that the cage is disposed within the frame of the elongate tube at the proximal end of the elongate tube. Typically, by virtue of the cage being disposed within the frame of the elongate tube at the proximal end of the elongate tube, pump 40 is disposed within a proximal portion of the elongate tube, and the longitudinal axis of the pump is aligned with the longitudinal axis of the elongate tube. For some applications, frame 34 of elongate tube 24 and cage 44 are cut from a single piece (e.g., a single tube) of a shape memory material (e.g., a shape-memory alloy, such as nitinol). Typically, by virtue of being cut from the single piece of the shape-memory the region of the tube in which the cage is disposed is able to be radially compressed to a smaller diameter than would be possible if the cage were cut from a separate piece of the shape memory material and inserted inside the elongate tube or vice versa, *ceteris paribus*.

Reference is now made to Fig. 4A, which is a schematic illustration of a ventricular assist device 20, in accordance with some additional applications of the present invention. For some applications, pump 40 is generally as shown in Fig. 4A. Typically, the pump includes an impeller 50, which includes an outer helical elongate element 52, which winds around a central axial spring 54, such that the helix defined by the helical elongate element is coaxial with the central axial spring. For some applications, the helical elongate element and the central axial spring are made of a shape memory material, e.g., a shape memory alloy such as nitinol. Typically, the helical elongate element and the central axial spring support a film 56 of a material (e.g., a polymer, such as polyurethane, and/or silicone) therebetween. The helical elongate element, the axial spring and the film define the impeller blade, with the helical elongate element defining the outer edge of the impeller blade (and thereby defining the outer edge of the impeller), and the axial spring defining the axis of the impeller blade. For some applications, sutures (e.g., polyester sutures, not shown) are wound around the helical elongate element, e.g., as described in WO 14/141284, which is incorporated herein by reference. Typically, the sutures are configured to facilitate bonding between the film of material (which is typically a polymer, such as polyurethane, or silicone) and the helical elongate element (which is typically a shape memory alloy, such as nitinol). For some applications, sutures (e.g., polyester sutures, not shown) are wound around spring 54. Typically, the sutures are configured to facilitate bonding between the film of material (which is typically a polymer, such as polyurethane, or silicone) and the spring (which is typically a shape memory alloy, such as nitinol).

Typically, proximal ends of both spring 54 and helical elongate element 52 are coupled to a proximal bushing (i.e., sleeve bearing) 64 of the impeller, such that the proximal ends of both spring 54 and helical elongate element 52 are disposed at a similar radial distance from the longitudinal axis of the impeller, as each other. Similarly, typically, distal ends of both spring 54 and helical elongate element 52 are coupled to a distal bushing 58 of the impeller, such that the distal ends of both spring 54 and helical elongate element 52 are disposed at a similar radial distance from the longitudinal axis of the impeller, as each other.

For some such applications, frame 34 of elongate tube 24 does not include a cage integrally formed therewith, as described hereinabove with reference to Fig. 3. Rather, for some such applications, a distal bushing 58 of the impeller is stabilized with respect to the elongate tube, by means of one or more support arms 60 that extend radially outwardly from the distal bushing of the impeller to frame 34 of elongate tube 24. As shown in Fig. 4A, for some applications, the support arms are not coupled to frame 34 of the elongate tube, but are configured to engage an inner surface of the elongate tube, to thereby stabilize the distal bushing of the impeller with respect to the elongate tube. For such applications, the support arms are typically configured to be moveable with respect to the elongate tube, by the support arms sliding along the inner surface of the elongate tube. Alternatively, even if the support arms are not integrally formed with frame 34 of the elongate tube, the support arms are coupled to frame 34 of the elongate tube (e.g., via welding, suturing, and/or an adhesive), such that, at least at the locations at which the support arms are coupled to the frame of the elongate tube, the support arms cannot undergo motion relative to the elongate tube. Further alternatively, the device includes support arms that are integrally formed with frame 34 of the elongate tube, as shown in Fig. 4B.

Reference is now made to Fig. 4B, which is a schematic illustration of device 20, the device including support arms 59, which are integrally formed with frame 34 of the elongate tube 24, the support arms being coupled to frame 34 at coupling points 61, in accordance with some applications of the present invention. Typically, the support arms are configured to extend from the distal bushing of the impeller to the coupling points, and are configured to thereby stabilize the distal bushing of the impeller with respect to the elongate tube.

With respect to device 20 as shown in Figs. 4A-B, it is noted that for some applications, impeller 50 is disposed at a proximal end of the elongate tube, as shown, such that, during use of device 20, the impeller is disposed within the aorta, and pumps blood from the left ventricle into the aorta by rotating within the aorta. For some applications (not shown), the impeller is disposed at the distal end of the elongate tube, such that, during use of device 20, the impeller is disposed within the ventricle, and pumps blood out of the ventricle, by rotating within the ventricle. In general, in the context of the present application, the term "blood vessel" should be interpreted as including a ventricle. Similarly, an impeller that is described as being placed within a blood vessel, should be interpreted as including an impeller that is placed within a ventricle.

Reference is now made to Figs. 5A and 5B, which are schematic illustrations of cross-sectional views of impeller 50, respectively perpendicularly to the longitudinal axis of the impeller, and along the longitudinal axis of the impeller, in accordance with some applications of the present invention. Reference is also made to Fig. 5C, which is a schematic illustration of a cross-sectional view of ventricular assist device 20 along the longitudinal axis of the device, in accordance with some applications of the present invention. As shown in Fig. 5B for example, spring 54 defines a lumen 62 therethrough. For some applications, a rigid shaft 63 is disposed along the lumen at least from proximal bushing 64 of the impeller to distal bushing 58. The rigid shaft is configured to impart rotational motion from the proximal bushing to the distal bushing, and/or to maintain the distal bushing and the proximal bushing aligned with each other and aligned with the longitudinal axis of the elongate tube. Alternatively or additionally, spring 54 itself acts as a shaft. Thus, for some applications, the spring imparts rotational motion from the proximal bushing to the distal bushing, and/or maintains the distal bushing and the proximal bushing aligned with each other and aligned with the longitudinal axis of the elongate tube. For some such applications, the spring is configured such that, when the spring is disposed in a non-radially-constrained configuration, there are substantially no gaps between windings of the spring and adjacent windings thereto.

Reference is now made to Fig. 5D, which is a schematic illustration of impeller 50 in a radially constrained (i.e., axially-elongated) configuration, in accordance with some applications of the present invention. Typically, pump 40 is inserted into the left ventricle transcatheterally, while impeller 50 is in its radially constrained configuration. As shown, in the radially constrained configuration, both helical elongate element 52 and central axial spring 54 become axially elongated, and radially constrained. Typically film 56 of the material (e.g., silicone) changes shape to conform to the shape changes of the helical elongate element and the axial support spring, both of which support the film of material. Typically, using a spring to support the inner edge of the film allows the film to change shape without the film becoming broken or collapsing inwardly onto a shaft disposed within lumen 62, due to the spring providing a large surface area to which the inner edge of the film bonds. For some applications, using a spring to support the inner edge of the film reduces a diameter to which the impeller can be radially constrained, relative to if, for example, a rigid shaft was to be used to support the inner edge of the film, since the diameter of the spring itself can be reduced by axially elongating the spring. As described hereinabove and as shown in Fig. 5C, for some applications, rigid shaft 63 is disposed along lumen 62 (defined by spring 54) at least from proximal bushing 64 of the impeller to distal bushing 58. For some applications, the rigid shaft is disposed inside the lumen even during the transcatheteral insertion of the impeller into the subject's left ventricle. Alternatively, the rigid shaft is advanced into lumen 62 once the impeller has already been released from the insertion catheter, and is disposed inside with subject's ventricle.

Referring again to Fig. 5A, typically there is a gap G, between the outer edge of the impeller and the inner surface of elongate tube 24, even at a location at which the span of the impeller is at its maximum. For some applications, it is desirable that the gap between the outer edge of the blade of the impeller and elongate tube 24 be relatively small, in order for the impeller to efficiently pump blood from the subject's left ventricle into the subject's aorta. However, it is also desirable that a gap between the outer edge of the blade of the impeller and elongate tube 24 be maintained, for example, in order to reduce a risk of hemolysis. For some applications, the gap G between the outer edge of the impeller and the inner surface of elongate tube 24, at the location at which the span of the impeller is at its maximum, is greater than 0.05

mm (e.g., greater than 0.1 mm), and/or less than 1 mm (e.g., less than 0.4 mm), e.g., 0.05 mm-1 mm, or 0.1 mm-0.4 mm). As described hereinabove, for some applications, distal bushing 58 of the impeller is stabilized with respect to the elongate tube, by means of one or more support arms 60, or support arms 59. For some applications, by stabilizing distal bushing 58 of the impeller with respect to the elongate tube, even a relatively small gap between the outer edge of the blade of the impeller and elongate tube 24 (e.g., a gap that is as described above) is maintained, during rotation of the impeller. Alternatively or additionally, a rigid shaft is inserted along the axis of the impeller via lumen 62 defined by spring 54, and the rigid shaft stabilizes distal bushing 58 of the impeller with respect to the elongate tube, such that even a relatively small gap between the outer edge of the blade of the impeller and elongate tube 24 (e.g., a gap that is as described above) is maintained, during rotation of the impeller. Further alternatively or additionally, spring 54 is sufficiently rigid as to stabilize distal bushing 58 of the impeller with respect to the elongate tube, such that even a relatively small gap between the outer edge of the blade of the impeller and elongate tube 24 (e.g., a gap that is as described above) is maintained, during rotation of the impeller.

Typically, the pitch of helical elongate element 52, when impeller 50 is in a non-radially-constrained configuration (e.g., inside the subject's ventricle), is greater than 1 mm (e.g., greater than 6 mm), and/or less than 20 mm (e.g., less than 10 mm). Typically, *ceteris paribus*, the greater the pitch of the helical elongate element (and therefore the impeller blade), the greater the blood flow that is generated by the impeller. Therefore, as described, the pitch of the helical elongate element 52, when impeller 50 is in the non-radially-constrained configuration, is typically greater than 1 mm (e.g., greater than 6 mm). On the other hand, it is typically desirable that the impeller occludes backflow from the subject's aorta into the subject's left ventricle during diastole. *Ceteris paribus*, it is typically the case that the smaller the pitch of the helical elongate element (and therefore the impeller blade), the greater the occlusion that is provided by the impeller. Therefore, as described, the pitch of the helical elongate element 52, when impeller 50 is in the non-radially-constrained configuration, is typically less than 20 mm (e.g., less than 10 mm).

For some applications, the pitch of the helical elongate element (and therefore the impeller blade) varies along the length of the helical elongate element, at least when the impeller is in a non-radially-constrained configuration. Typically, for such applications, the pitch increases from the distal end of the impeller (i.e., the end that is inserted further into the subject's body, and that is placed upstream with respect to the direction of antegrade blood flow) to the proximal end of the impeller (i.e., the end that is placed downstream with respect to the direction of antegrade blood flow), such that the pitch increases in the direction of the blood flow. Typically, the blood flow velocity increases along the impeller, along the direction of blood flow. Therefore, the pitch is increased along the direction of the blood flow, such as to further accelerate the blood.

For some applications (not shown), impeller 50 is generally as shown in Figs. 4A-5D, but the impeller includes a plurality of helical elongate elements. For example, the impeller may include two or three helical elongate elements. Typically, the film of material is supported between the plurality of helical elongate elements and the spring, such that the impeller defines a plurality of blades. Typically, the number of impeller blades corresponds to the number of helical elongate elements that are disposed upon the impeller, e.g., as is generally described in WO 14/141284 to Schwammenthal, which is incorporated herein by reference.

Reference is now made to Figs. 6A and 6B, which are schematic illustrations of a stator 65 of ventricular assist device 20, in accordance with some applications of the present invention. Fig. 6B shows the stator in the absence of some other elements of the ventricular assist device, for illustrative purposes. For some applications, as shown, stator 65 is disposed within a proximal portion of frame 34 of elongate tube 24. Typically, the stator includes a plurality of (e.g., more than 2, and/or less than 8) winged projections 66 that, when device 20 is in a non-radially constrained configuration, extend from frame 34, and that are made of a flexible material, e.g., a polymer, such as polyurethane, and/or silicone. The winged projections are typically configured to define planes that are parallel to the longitudinal axis of the elongate tube, and are thereby configured to stabilize turbulent blood flow that is generated by the impeller, by directing blood flow along the direction of the longitudinal axis of the elongate tube.

It is noted that, as shown in Fig. 6A, typically elongate tube 24 includes blood impermeable material 36 that is disposed upon frame 34 of the tube. For example, the blood impermeable material may include polyurethane, polyester, or silicone, as described hereinabove. It is noted that, typically, the elongate tube includes the blood impermeable material, even though, for illustrative purposes, the blood impermeable material of the tube is not shown in all of the figures of the present application.

As shown in Fig. 6B, for some applications, sutures 68 are wound around portions of frame 34, in order to facilitate coupling between the winged projections and frame 34, in accordance with the techniques described hereinabove. For some applications, the winged projections extend from frame 34 to an axial support element 69. Typically, the axial support element is a tubular element formed of metal, plastic, and/or a polymer (such as polyurethane and/or silicone). For some applications, stator 65 is integrally formed with frame 34 of elongate tube 24. Alternatively or additionally, the stator is formed separately from the elongate tube.

As described hereinabove, typically, device 20 is inserted into the subject's ventricle transcatheterally, while elongate tube 24 is in a radially constrained state. Upon being released from the catheter, the tube automatically assumes it tubular shape, due to frame 34 of elongate tube 24 self-expanding. Typically, the stator is inserted into subject's left ventricle inside the elongate tube. During the insertion, the winged projections of the stator are in folded states, and do not substantially increase the minimal diameter to which the elongate tube can be radially-constrained, relative to if the tube did not contain the winged projections. Upon frame 34 of the elongate tube expanding, the winged projections are configured to automatically assume their winged configurations, due to the winged projections being coupled to frame 34.

It is noted that, although Figs. 1A and 1B show ventricular assist device 20 in the subject's left ventricle, for some applications, device 20 is placed inside the subject's right ventricle, such that the device traverses the subject's pulmonary valve, and techniques described herein are applied, *mutatis mutandis*. Alternatively or additionally, device 20 and/or a portion thereof (e.g., impeller 50, even in the absence of elongate tube 24) is placed inside a different portion of the subject's body, in order to assist with the pumping of blood from that portion. For example, device 20 and/or a portion thereof (e.g., impeller 50, even in the absence of elongate tube 24) may be placed in a blood vessel and may be used to pump blood through the blood vessel. For some applications, device 20 and/or a portion thereof (e.g., impeller 50, even in the absence of elongate tube 24) is configured to be placed within the subclavian vein or jugular vein, at junctions of the vein with a lymph duct, and is used to increase flow of lymphatic fluid from the lymph duct into the vein, *mutatis mutandis*.

Reference is now made to Fig. 7A, which is a schematic illustration of a ventricular assist device 70 that includes a centrifugal pump 72, in accordance with some applications of the present invention. Reference is also made to Figs. 7B and 7C, which show, respectively, three-dimensional and two-dimensional cross-sectional views of the centrifugal pump, in accordance with some applications of the present invention.

For some applications, ventricular assist device assists pumping of a ventricle (e.g., left ventricle 22) by using centrifugal pump to pump blood from the subject's left ventricle, out of the subject body, and into the subject's aorta 30. For some applications, a catheter 74 is inserted into the subject's vasculature that extends from centrifugal pump 72 to the subject's ventricle. As shown in Figs. 7B and 7C, typically, catheter 74 defines concentric tubes 76 and 78. Blood is pumped out of the subject's left ventricle via a first one of concentric tubes (e.g., inner tube 76, as indicated by the dashed arrows indicating the direction of blood flow in Fig. 7C), and blood is pumped into the subject's aorta via a second one of the concentric tubes (e.g., outer tube 78, as shown in Fig. 7C). Typically, the first and second tubes are inserted into the subject's body via a single insertion point, e.g., femoral artery 80, as shown in Fig. 7A, or via a different insertion point, such as the subclavian artery. For some applications, centrifugal pump 72 defines an additional tube 82, via which blood pressure is measured.

The scope of the present invention includes combining any of the apparatus and methods described herein with any of the apparatus and methods described in one or more of the following applications, all of which are incorporated herein by reference:

International Patent Application PCT/IL2017/051092 to Tuval, filed Sep. 28, 2017, entitled "Blood vessel tube," which US Provisional Patent Application 62/401,403 to Tuval, filed Sep. 29, 2016;

International Patent Application PCT/IL2016/050525 to Schwammenthal (published as WO 16/185473), filed May 18, 2016, entitled "Blood pump," which claims priority from US Provisional Patent Application 62/162,881 to Schwammenthal, filed May 18, 2015, entitled "Blood pump;"

International Patent Application PCT/IL2015/050532 to Schwammenthal (published as WO 15/177793), filed May 19, 2015, entitled "Blood pump," which claims priority from US Provisional Patent Application 62/000,192 to Schwammenthal, filed May 19, 2014, entitled "Blood pump;"

International Patent Application PCT/IL2014/050289 to Schwammenthal (published as WO 14/141284), filed March 13, 2014, entitled "Renal pump," which claims priority from (a) US Provisional Patent Application 61/779,803 to Schwammenthal, filed March 13, 2013, entitled "Renal pump," and (b) US Provisional Patent Application 61/914,475 to Schwammenthal, filed December 11, 2013, entitled "Renal pump;"

US Patent Application 14/567,439 to Tuval (published as US 2015/0157777), filed Dec. 11, 2014, entitled "Curved catheter," which claims priority from US Provisional Patent Application 61/914,470 to Tuval, filed Dec. 11, 2013, entitled "Curved catheter;" and

International Patent Application PCT/IL2013/050495 to Tuval (published as WO 13/183060), filed June 06, 2013, entitled "Prosthetic renal valve," which claims priority from US Provisional Patent Application 61/656,244 to Tuval, filed June 06, 2012, entitled "Prosthetic renal valve."

There is therefore provided, in accordance with some applications of the present invention, the following inventive concepts:

Inventive concept 1. Apparatus comprising:

a left ventricular assist device configured to assist left ventricular functioning of a subject, the left ventricular assist device comprising:

an elongate tube configured to traverse an aortic valve of the subject, such that a proximal end of the tube is disposed within an aorta of the subject and a distal end of the tube is disposed within a left ventricle of the subject, the elongate tube comprising:

a frame formed from a shape-memory alloy; and

a blood impermeable material that is disposed upon the frame;

a rotatable impeller configured to pump blood from the subject's left ventricle to the subject's aorta by rotating; and

a plurality of winged projections that are coupled to the elongate tube such that planes defined by the winged projections are parallel with a longitudinal axis of the elongate tube, the winged projections being configured to stabilize turbulent blood flow that is generated by rotation of the impeller, by directing blood flow along a direction of the longitudinal axis of the elongate tube.

Inventive concept 2. The apparatus according to inventive concept 1, wherein the elongate tube is configured to be inserted into a body of the subject transcatheterally, while in a radially-constrained configuration, and wherein the winged projections are configured to become folded, when the elongate tube is in its radially-constrained configuration.

Inventive concept 3. A method comprising:

placing an elongate tube into a body of a subject, such that the elongate tube traverses an aortic valve of the subject, such that a proximal end of the tube is disposed within an aorta of the subject and a distal end of the tube is disposed within a left ventricle of the subject, the elongate tube including:

a frame formed from a shape-memory alloy, and

a blood impermeable material that is disposed upon the frame; and

pumping blood from the subject's left ventricle to the subject's aorta by rotating an impeller that is disposed within the elongate tube,

a plurality of winged projections being coupled to the elongate tube such that planes defined by the winged projections are parallel with a longitudinal axis of the elongate tube, the winged projections being configured to stabilize turbulent blood flow that is generated by rotation of the impeller, by directing blood flow along a direction of the longitudinal axis of the elongate tube.

Inventive concept 4. The method according to claim inventive concept 3, wherein placing the elongate tube into the subject's body comprises placing the elongate tube into the subject's body transcatheterally while the elongate tube is in a radially-constrained configuration, the winged projections being configured to become folded, when the elongate tube is in its radially-constrained configuration.

Inventive concept 5. Apparatus comprising:

a left ventricular assist device configured to assist left ventricular functioning of a subject, the left ventricular assist device comprising:

an elongate tube configured to traverse an aortic valve of the subject, such that a proximal end of the tube is disposed within an aorta of the subject and a distal end of the tube is disposed within a left ventricle of the subject, the elongate tube comprising:

a frame formed from a shape-memory alloy; and

a blood impermeable material that is disposed upon the frame; and

a pump comprising a rotatable impeller and a cage disposed around the rotatable impeller,

the cage being integrally formed with the elongate tube such that the cage is disposed within the frame of the elongate tube at the proximal end of the elongate tube, the pump thereby being disposed within a proximal portion of the elongate tube, and a longitudinal axis of the pump thereby being aligned with a longitudinal axis of the elongate tube.

Inventive concept 6. A method comprising:

placing, into a subject's body, a left ventricular assist device configured to assist left ventricular functioning of a subject, the left ventricular assist device including:

an elongate tube configured to traverse an aortic valve of the subject, such that a proximal end of the tube is disposed within an aorta of the subject and a distal end of the tube is disposed within a left ventricle of the subject, the elongate tube including:

a frame formed from a shape-memory alloy, and

a blood impermeable material that is disposed upon the frame, and

a pump comprising a rotatable impeller and a cage disposed around the rotatable impeller,

the cage being integrally formed with the elongate tube such that the cage is disposed within the frame of the elongate tube at the proximal end of the elongate tube, the pump thereby being disposed within a proximal portion of the elongate tube, and a longitudinal axis of the pump thereby being aligned with a longitudinal axis of the elongate tube; and

pumping blood from the subject's left ventricle to the subject's aorta by rotating the impeller,

Inventive concept 7. A blood pump for pumping blood from a first location in a body of a subject to a second location in the subject's body, the blood pump comprising:

a first tube for pumping the blood away from the first location;

a second tube for pumping the blood toward to second location, the first and second tubes being coaxial with respect to each other; and

a centrifugal pump configured to pump the blood through the first and second tubes.

Inventive concept 8. A method comprising:

pumping blood from a first location in a body of a subject to a second location in the subject's body, by:

pumping the blood away from the first location via a first tube;

pumping the blood toward to second location via a second tube, the first and second tubes being coaxial with respect to each other; and using a centrifugal pump to pump the blood through the first and second tubes.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

CLAIMS:

1. Apparatus comprising:

an impeller comprising:

a proximal bushing and a distal bushing; and

at least one helical elongate element;

a coil spring, the coil spring being disposed inside of, and coaxially with, the helical elongate element, between the proximal and distal bushings, and the coil spring defining a lumen therethrough;

a film of material supported between the helical elongate element and the coil spring, wherein the impeller is structured such that the film of material extends from the helical elongate element to the coil spring to thereby define an impeller blade; and

a rigid shaft configured to extend from the proximal bushing to the distal bushing of the impeller via the lumen defined by the coil spring;

wherein the impeller is configured to be radially constrained by the helical elongate element and the coil spring being axially elongated, and wherein in response to the axial elongation of the helical elongate element and the coil spring, the film is configured to change shape without the film of material breaking.

2. The apparatus according to claim 1, wherein the impeller comprises a plurality of helical elongate elements, and the film of material is supported between the plurality of helical elongate elements and the coil spring, such that the impeller defines a plurality of blades.

3. The apparatus according to claim 1, wherein, when the impeller is disposed in a non-radially-constrained configuration, a pitch of the helical elongate element varies along a length of the helical elongate element.

4. The apparatus according to claim 1, wherein, when the impeller is disposed in a non-radially-constrained configuration, a pitch of the helical elongate element is greater than 1 mm.

5. The apparatus according to claim 1, wherein, when the impeller is disposed in a non-radially-constrained configuration, a pitch of the helical elongate element is less than 20 mm.

6. The apparatus according to claim 1, wherein the impeller is configured to be placed inside a blood vessel of a subject and to pump blood through the subject's blood vessel by the impeller rotating.

7. The apparatus according to claim 1, wherein the impeller is configured to be placed in an aorta of a subject and to pump blood from a left ventricle of the subject, by the impeller rotating.

8. The apparatus according to claim 1, wherein the impeller is configured to be placed in a ventricle of a subject and to pump blood from the ventricle, by the impeller rotating.

9. The apparatus according to claim 1, wherein the impeller is configured to be placed in an aorta of a subject and to impede backflow of blood from the aorta into a left ventricle of the subject.

10. The apparatus according to any one of claims 1-9, further comprising:

an elongate tube configured to traverse an aortic valve of a subject, such that a proximal end of the tube is disposed within an aorta of the subject and a distal end of the tube is disposed within a left ventricle of the subject, the elongate tube comprising:

a frame formed from a shape-memory alloy; and

a blood impermeable material that is disposed upon the frame; and

a cage disposed around the impeller,

the elongate tube being configured to be disposed around the cage and the impeller, and the impeller being configured to pump blood from the left ventricle to the aorta, by rotating.

11. The apparatus according to claim 10, wherein the spring, when disposed in a non-radially-constrained configuration thereof, is configured by virtue of its rigidity, to stabilize the impeller with respect to the elongate tube, during rotation of the impeller, such that a gap between an outer edge of the impeller and an inner surface of the elongate tube is maintained.

12. The apparatus according to claim 10, wherein the rigid shaft is configured to stabilize the impeller with respect to the elongate tube, during rotation of the impeller, such that a gap between an outer edge of the impeller and an inner surface of the elongate tube is maintained.

13. The apparatus according to claim 10, wherein the cage is integrally formed with the frame of the elongate tube such that the cage is disposed within the frame of the elongate tube at the

proximal end of the elongate tube, the impeller thereby being disposed within a proximal portion of the elongate tube, and a longitudinal axis of the impeller thereby being aligned with a longitudinal axis of the elongate tube.

14. The apparatus according to claim 10, wherein a gap between an outer edge of the impeller and an inner surface of the elongate tube is less than 1 mm.

15. The apparatus according to claim 14, wherein the gap between the outer edge of the impeller and the inner surface of the elongate tube is less than 0.4 mm.

16. The apparatus according to claim 14, wherein the impeller is configured to be stabilized with respect to the elongate tube, such that, during rotation of the impeller, the gap between the impeller and the elongate tube is maintained.

17. The apparatus according to claim 10, wherein the cage is not integrally formed with the frame of the elongate tube.

18. The apparatus according to claim 17, further comprising one or more support arms that are configured to extend from the cage to the frame of the elongate tube, and that are configured, during rotation of the impeller, to stabilize a distal end of the impeller with respect to the frame of the elongate tube, such that a gap between an outer edge of the impeller and an inner surface of the elongate tube is maintained.

19. The apparatus according to claim 18, wherein the support arms are configured to be slidable with respect to the frame of the elongate tube.

20. The apparatus according to claim 18, wherein the support arms are configured to be coupled to the frame of the elongate tube.

21. The apparatus according to claim 10, further comprising a plurality of winged projections that are coupled to the elongate tube such that planes defined by the winged projections are parallel with a longitudinal axis of the elongate tube, the winged projections being configured to stabilize turbulent blood flow that is generated by rotation of the impeller, by directing blood flow along a direction of the longitudinal axis of the elongate tube.

22. The apparatus according to claim 21, wherein the elongate tube is configured to be inserted into a body of the subject transcatheterally, while in a radially-constrained configuration, and wherein the winged projections are configured to become folded, when the elongate tube is in its radially-constrained configuration.

23. The apparatus according to claim 1, wherein the rigid shaft is configured to maintain the proximal bushing and the distal bushing aligned with each other.

24. The apparatus according to claim 1, wherein the impeller is configured to be placed into a body of a subject, and wherein subsequent to placement of the coil spring inside the subject's body, the rigid shaft is configured to be placed within the lumen defined by the coil spring.

25. The apparatus according to claim 1, wherein the impeller is configured to be placed into a body of a subject, and wherein the rigid shaft is configured to be disposed within the lumen defined by the coil spring, during placement of the impeller into the subject's body,

26. The apparatus according to any one of claims 1-9, wherein the coil spring, when disposed in a non-radially-constrained configuration thereof, is configured, by virtue of its rigidity, to maintain the proximal bushing and the distal bushing aligned with each other.

27. The apparatus according to claim 26, wherein the coil spring, when disposed in the non-radially-constrained configuration thereof, is configured such that there are substantially no gaps between windings of the coil spring and adjacent windings thereto.

28. A method comprising:

placing within a blood vessel of a subject an impeller, the impeller including:

a proximal bushing and a distal bushing;

at least one helical elongate element;

a coil spring, the coil spring being disposed inside of, and coaxially with, the helical elongate element, between the proximal and distal bushing, and the spring defining a lumen therethrough;

a rigid shaft extending from the proximal bushing to the distal bushing via the lumen defined by the spring; and a film of material supported between the helical elongate element and the coil spring, such that the film of material extends from the helical elongate element to the coil spring to thereby define an impeller blade; and

pumping blood through the subject's blood vessel, using the impeller

wherein placing the impeller within the blood vessel comprises inserting the impeller within the subject's blood vessel transcatheterally by axially elongating the helical elongate element and the coil spring, thereby causing the film of material to change shape without the film of material breaking.

29. The method according to claim 28, wherein placing the impeller within the subject's blood vessel comprises placing the impeller within the subject's blood vessel, the impeller including a plurality of helical elongate elements, and the film of material being supported between the plurality of helical elongate elements and the coil spring, such that the impeller defines a plurality of blades.

Magenta Medical Ltd.
Patent Attorneys for the Applicant/Nominated Person
SPRUSON & FERGUSON

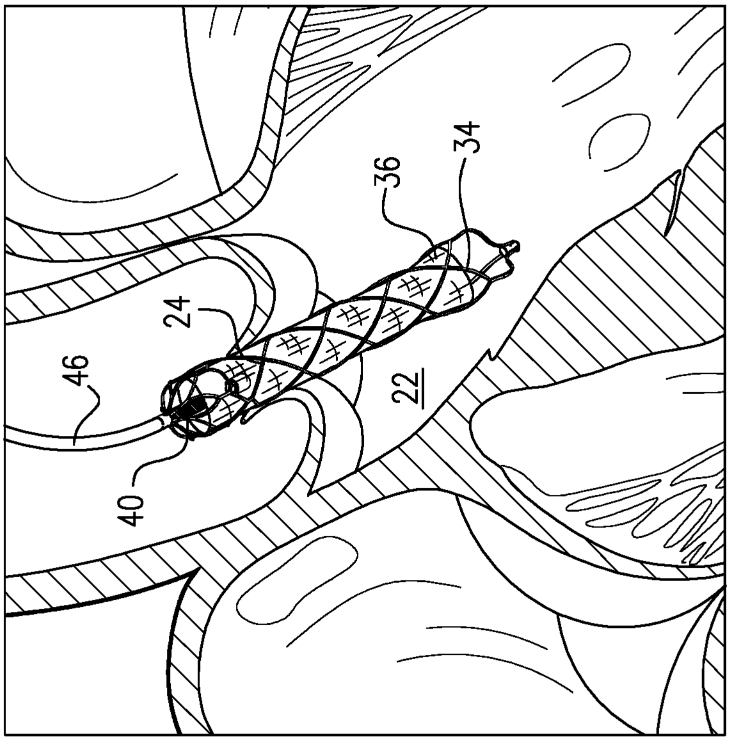

FIG. 1B

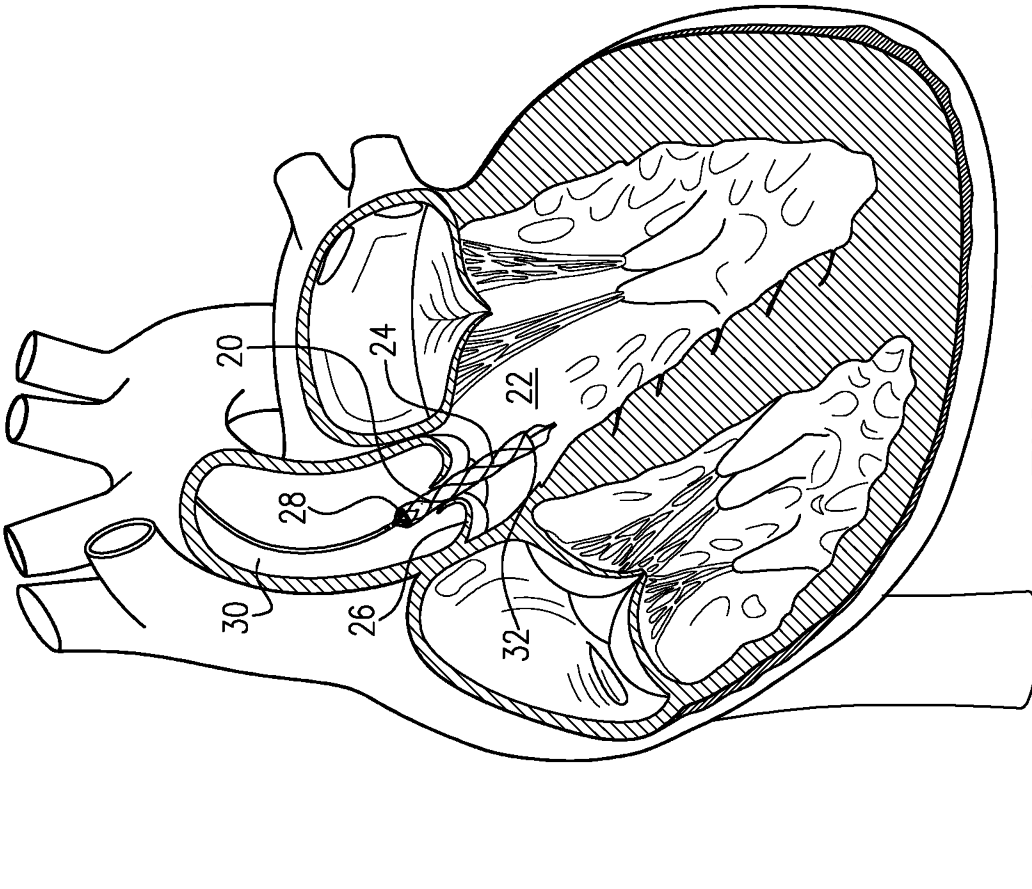

FIG. 1A

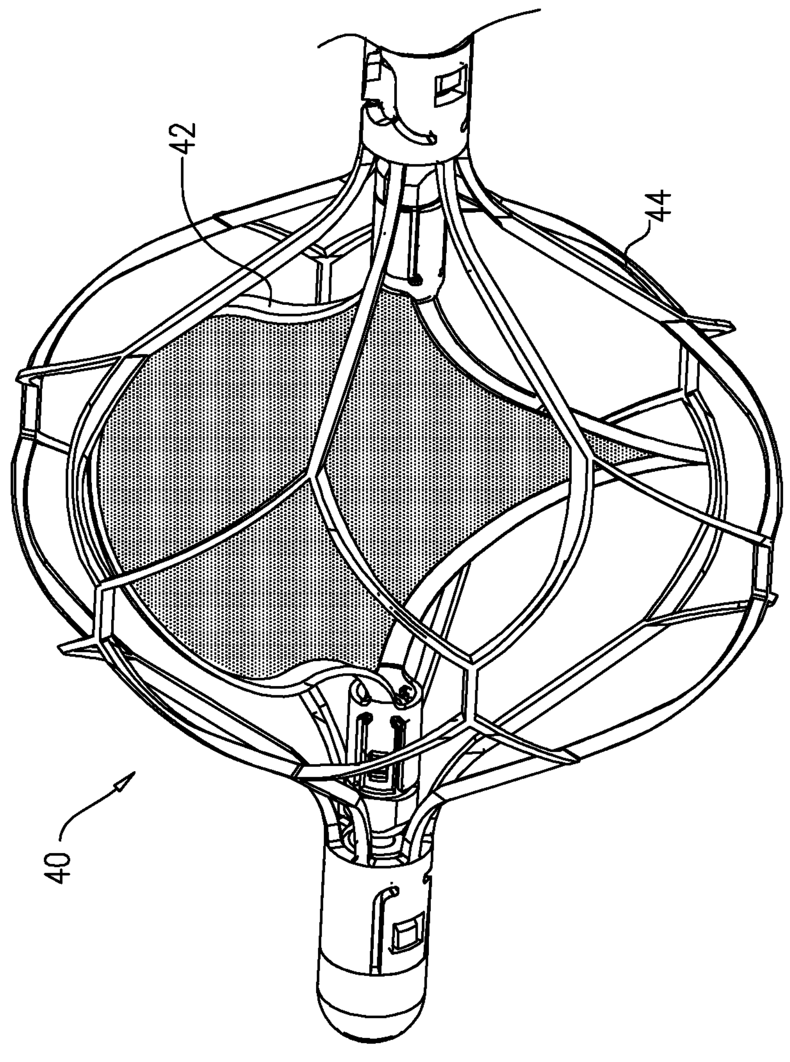

FIG. 2

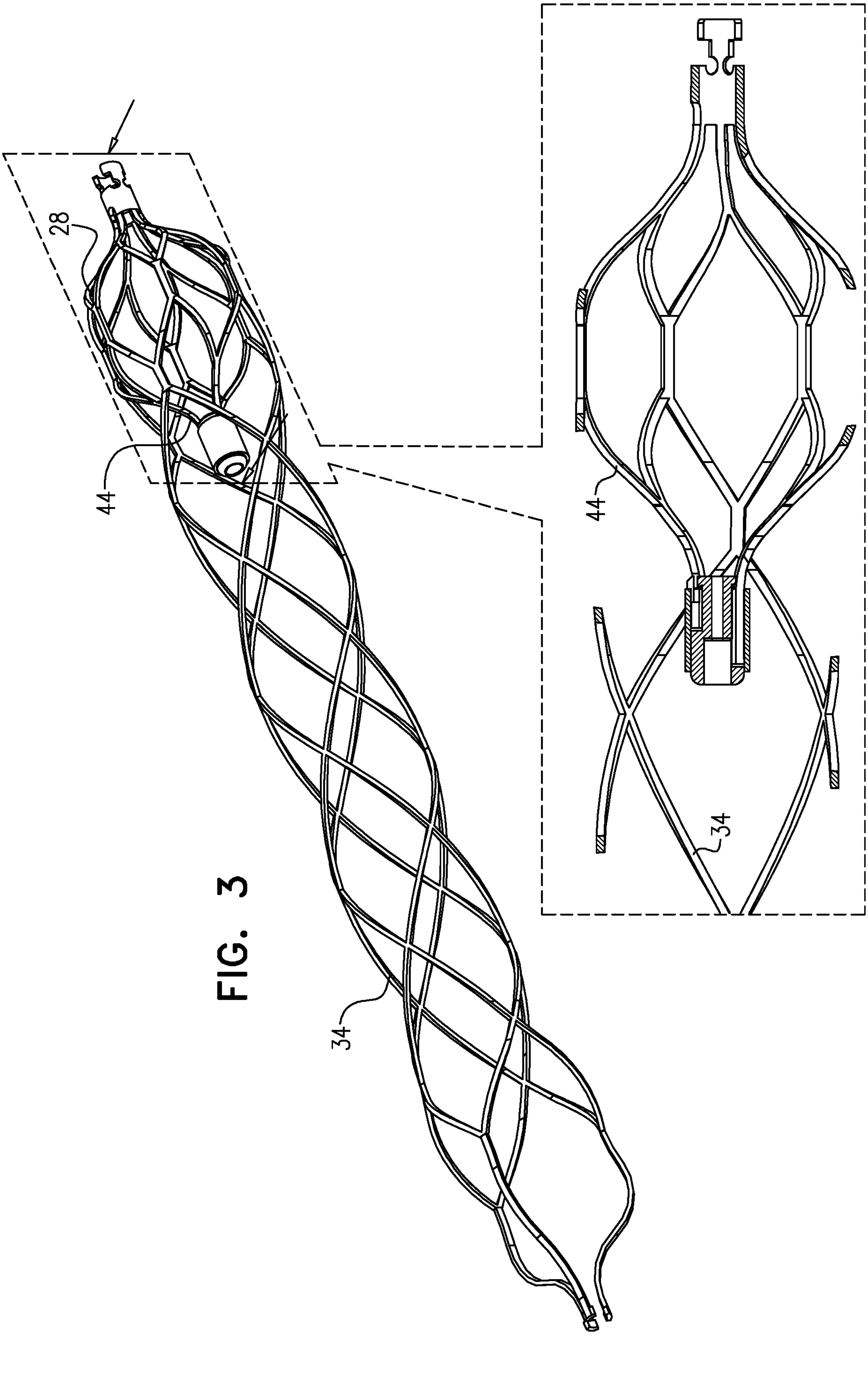

FIG. 3

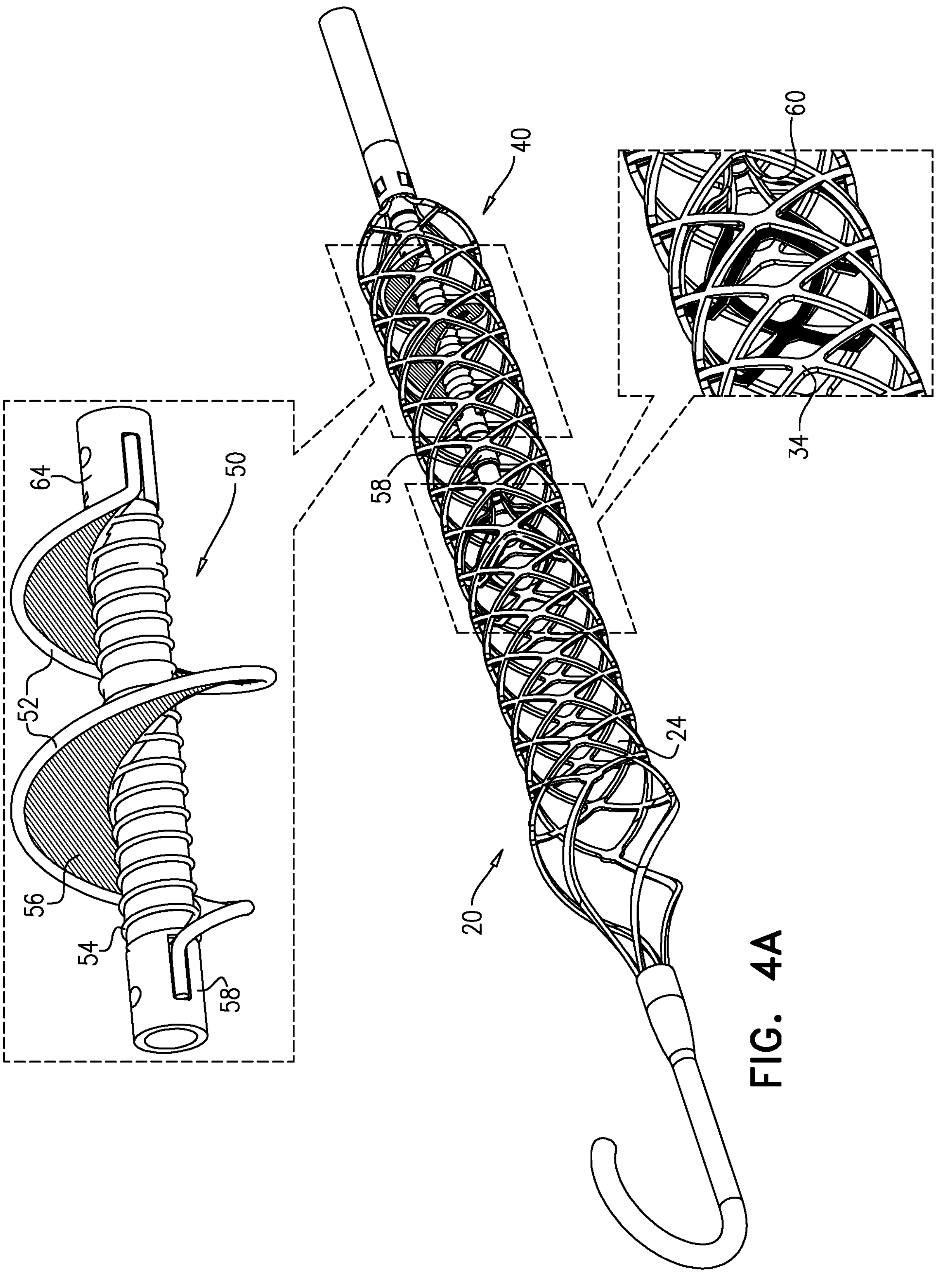

FIG. 4A

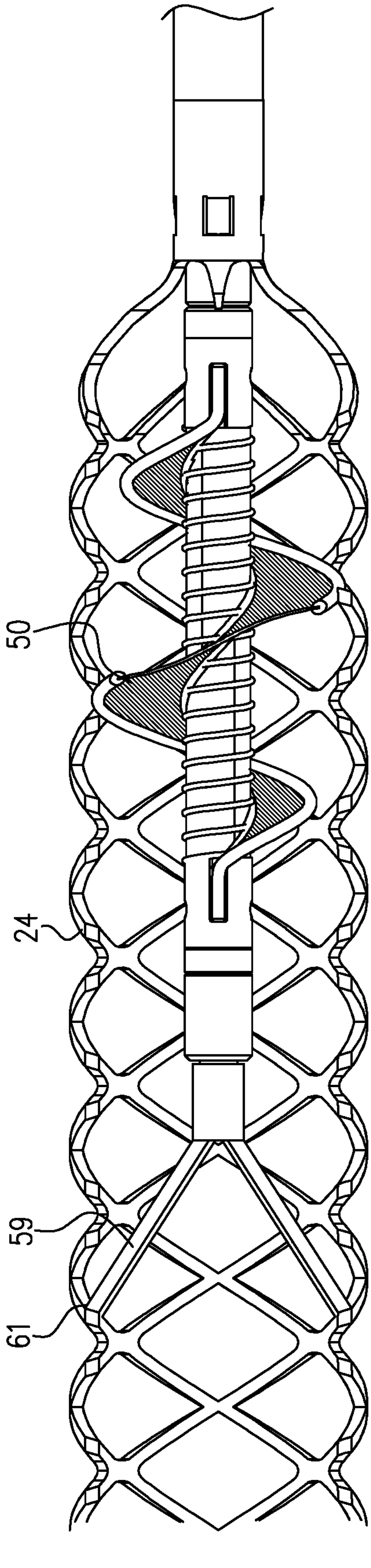

FIG. 4B

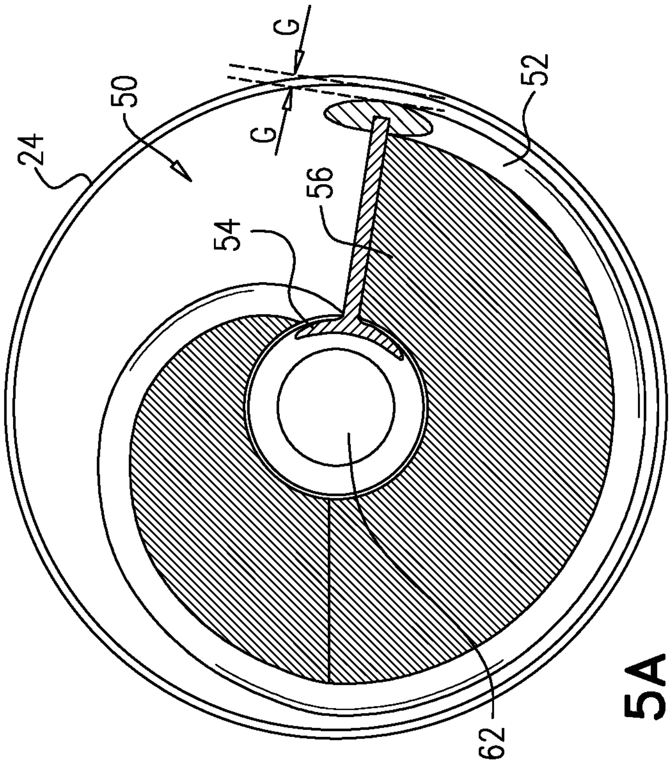

FIG. 5A

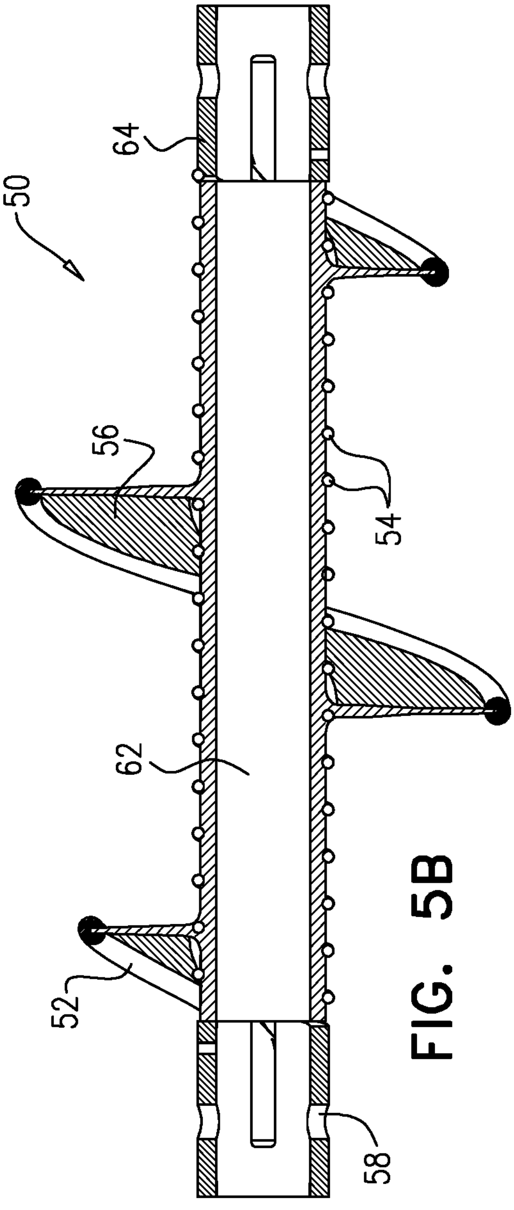

FIG. 5B

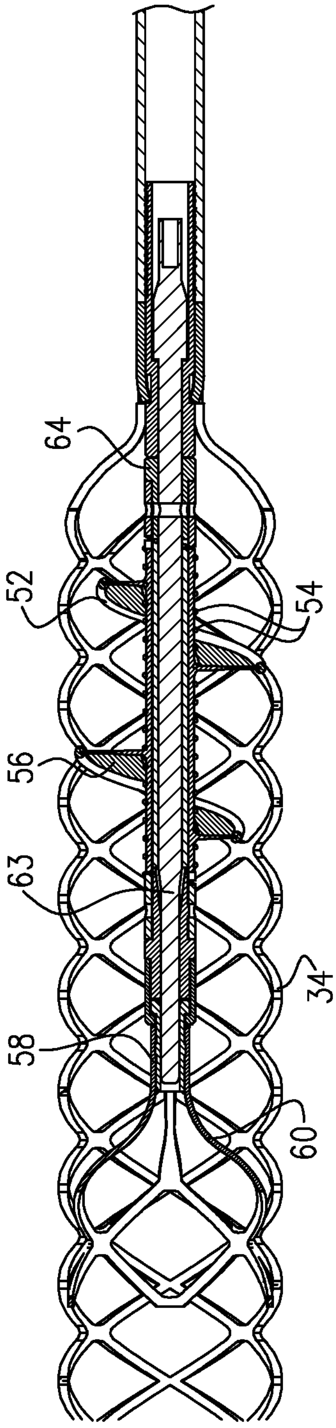

FIG. 5C

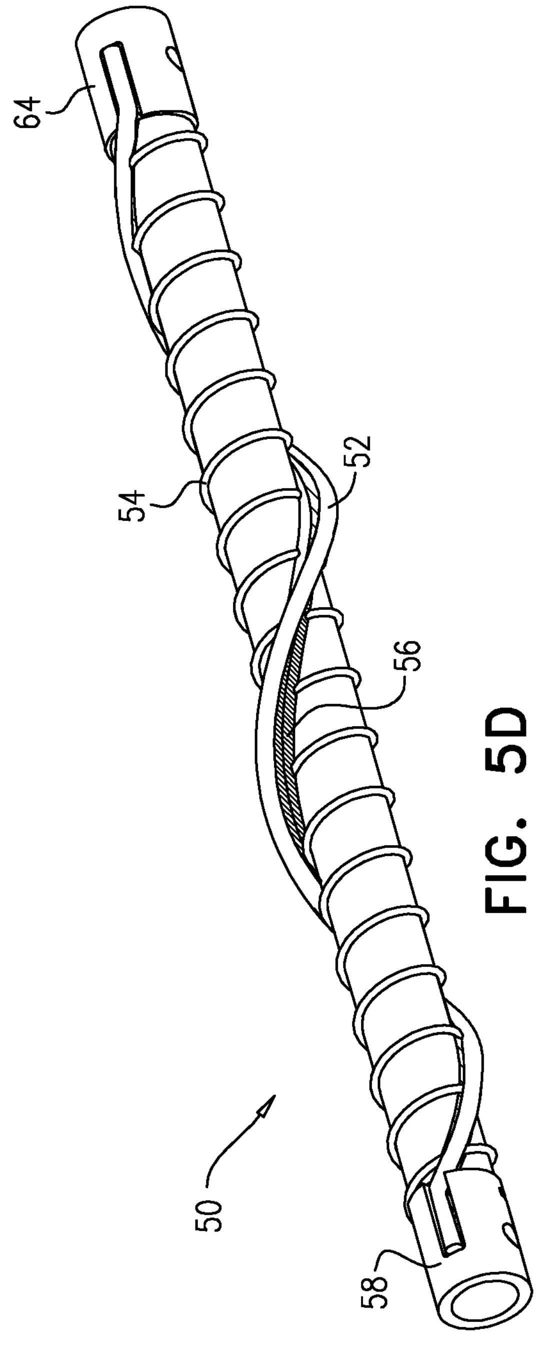

FIG. 5D

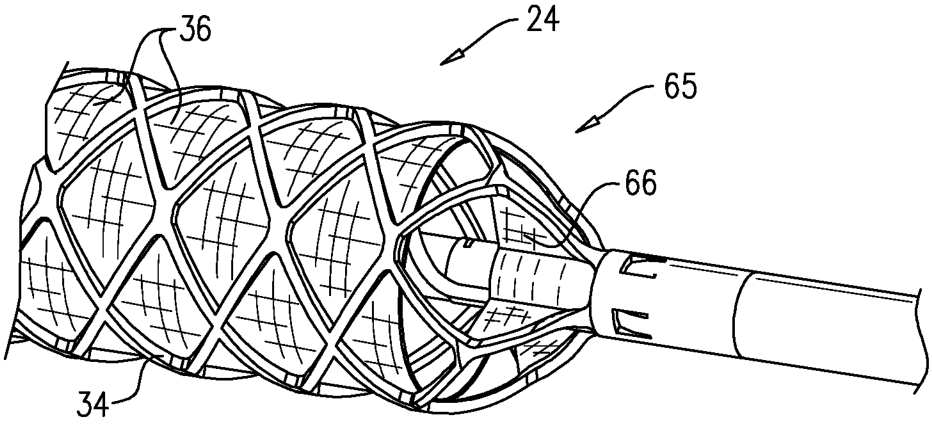

FIG. 6A

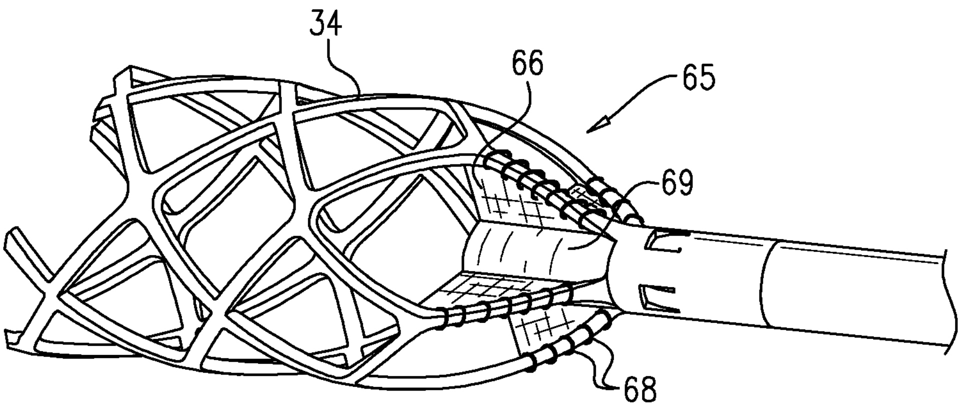

FIG. 6B

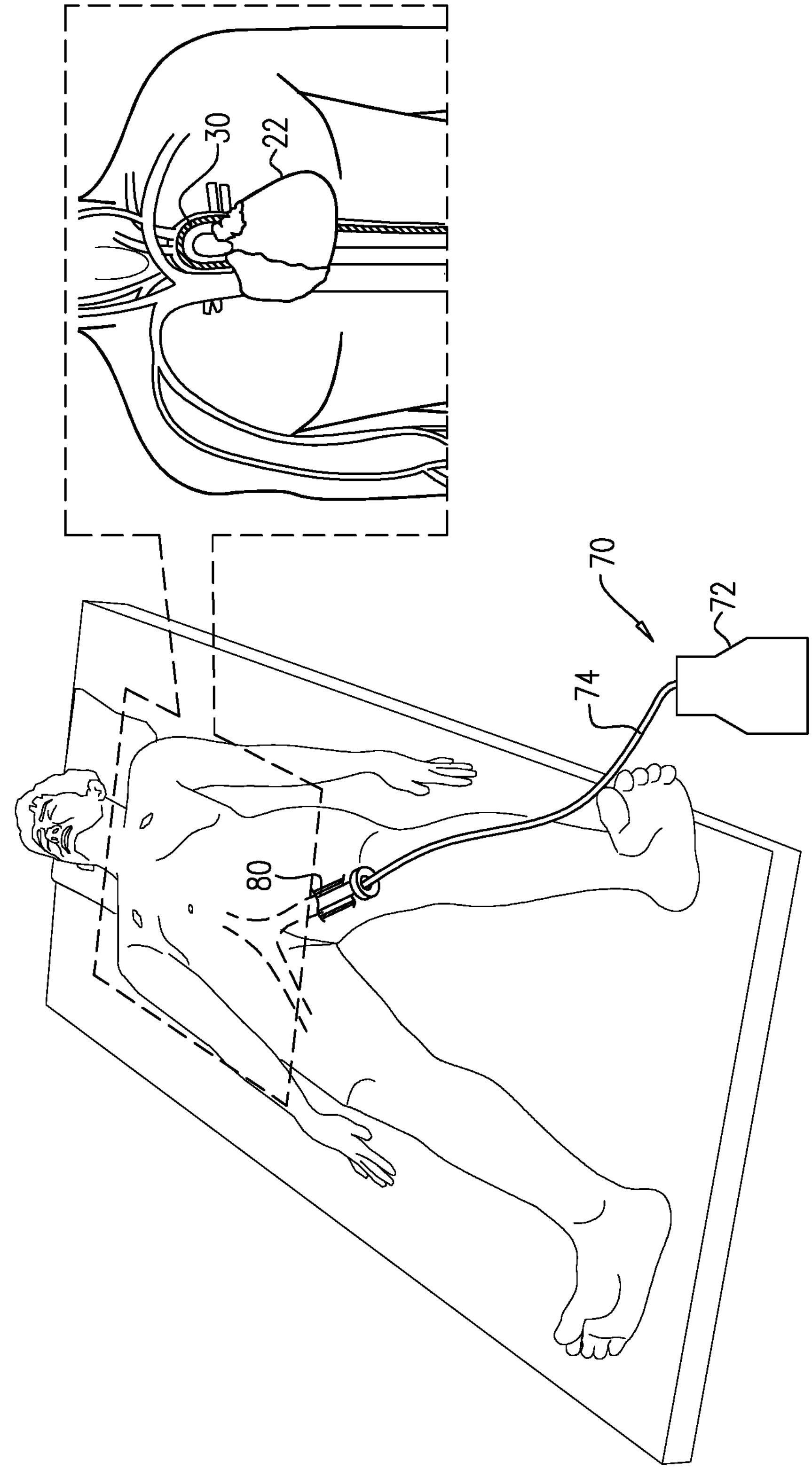

FIG. 7A

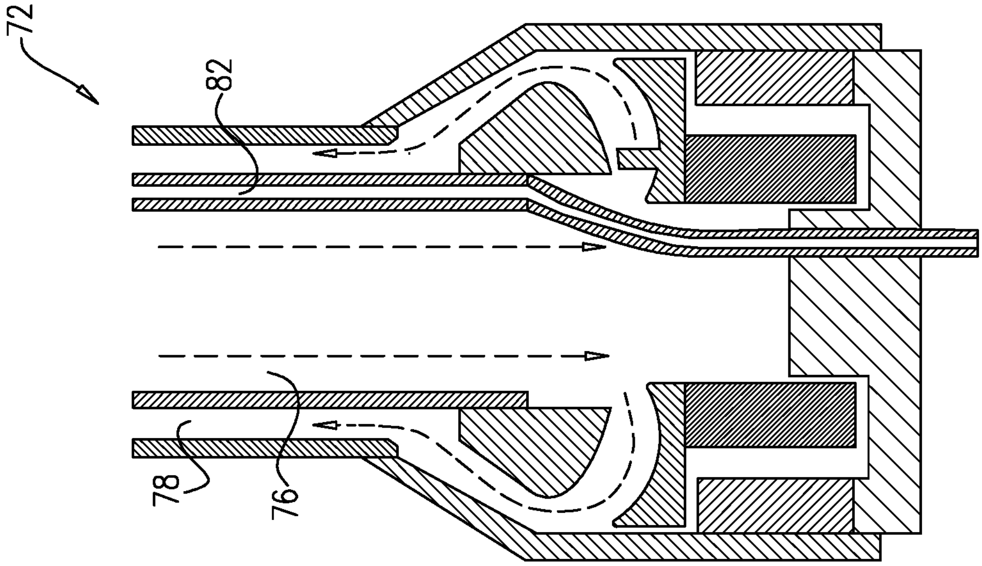

FIG. 7C

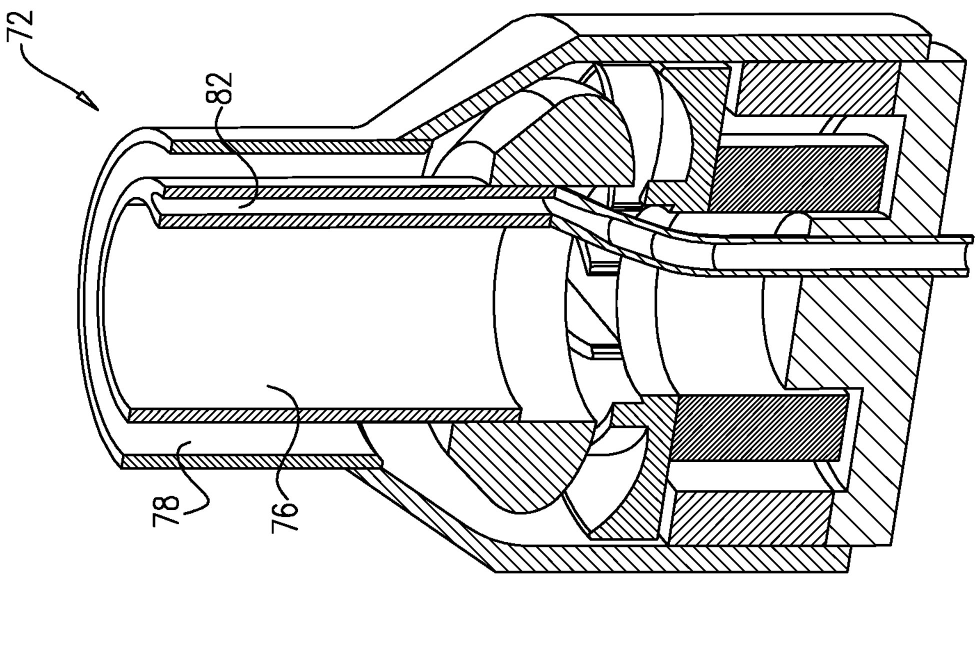

FIG. 7B