

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
3 November 2005 (03.11.2005)

PCT

(10) International Publication Number
WO 2005/102414 A1

(51) International Patent Classification⁷: **A61M 1/10**

(21) International Application Number:
PCT/US2005/009061

(22) International Filing Date: 17 March 2005 (17.03.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/822,315 12 April 2004 (12.04.2004) US

(71) Applicant (for all designated States except US): **BOSTON SCIENTIFIC SCIMED, INC.** [US/US]; One Scimed Place, Maple Grove, MN 55311 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **LEASURE, Bryan** [US/US]; 10812 Culbertson, Austin, TX 78748 (US).

(74) Agent: **SEAGER, Glenn, M.**; Crompton Seager & Tufte LLC, 1221 Nicollet Avenue, Suite 800, MINNEAPOLIS, MN 55403 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

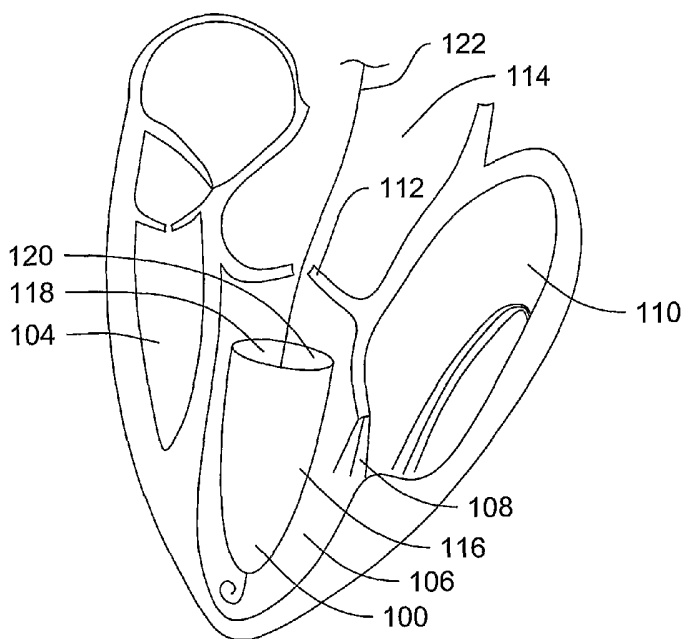
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

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(54) Title: CYCLICAL PRESSURE CORONARY ASSIST PUMP



(57) Abstract: An intravascular pump, which may be a left ventricle assist device, comprising a wall defining a pumping chamber, the wall support by struts, the struts attached to or part of an actuation system to move the wall from an expanded position to a contracted position and back to operated the pump, the actuation system may be electrically activated shape memory alloy struts, electroactive polymeric struts, or may be a balloon, struts attached to a slidable member or other suitable system.



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

CYCLICAL PRESSURE CORONARY ASSIST PUMP

Field

The present invention generally relates to coronary assist pumps. More specifically, the present invention relates to coronary assist pumps implantable within the heart.

Background

Millions of Americans are afflicted with heart failure, which is an inability of the heart to pump enough blood to sustain normal bodily functions. Every year, 15,000 to 20,000 of these patients require heart transplants but only a small fraction of these patients receive a transplant. Those patients who eventually receive a heart transplant wait about 200 days in the hospital. During this time in the hospital, the patient will need enhanced heart pumping function to keep them alive. Left ventricle assist devices (LVADs) have been helpful in this application, which is called "bridge to transplant". Moreover, some are developing LVADs that may be permanently installed and eliminate the need for a heart transplant.

One current LVAD is a pump that bypasses the left ventricle. The pump is installed in the upper abdomen and pumps blood from the left ventricle through a first tube and into the aorta through a second tube. This device requires major surgery to install and requires 24 hour monitoring once it is installed.

Another type of LVAD is a tiny turbine that is installed into the left ventricle chamber.

Some side effects of current LVADs include aortic valve stenosis, thrombosis formation, and right heart failure. The constant pumping pressure that some of the LVADs generate, rather than the systolic/ diastolic cycle associated with a healthy heart, may cause some of this valve and right heart damage. Also, the right heart may not have the strength to push the blood through the mitral valve into the left ventricle because of the high pressures some of the LVADs generate.

Summary

One example embodiment pertains to an intravascular pump that may be installed into the left ventricle of the heart as a left ventricle assist device. The pump may include a flexible wall defining a pumping chamber and a pumping mechanism. The pumping mechanism may include a frame attached to the wall and an actuation mechanism attached to the frame. One possible actuation mechanism is an umbrella-like mechanism including a central shaft and struts slideably attached between the

shaft and the frame. The struts may be actuated by use of a shape memory alloy, balloon, electroactive polymer, or wire, as described in more detail below. The pump may include a power source, a controller, and sensors.

Another example embodiment is a method of installation. The pump is loaded into a percutaneous catheter such as a guide catheter. The catheter is then introduced into the vasculature of a patient and advanced to the left ventricle of the heart. The pump may then be advanced from the guide catheter or the catheter may be withdrawn from around the pump.

The above summary of some example embodiments is not intended to describe each disclosed embodiment or every implementation of the present invention. The figures and detailed description which follow more particularly exemplify these embodiments.

Brief Description of the Drawings

The invention may be more completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings in which:

Figure 1 depicts a cross-sectional view of a heart with a side diagrammatic view of a pump 100 disposed therein;

Figure 2 depicts a diagrammatic cross-sectional view of pump 100 in an expanded position;

Figure 3 depicts a diagrammatic cross-sectional view of pump 100 in a contracted position;

Figure 4 depicts a diagrammatic cross-sectional view of a pump 200 in an expanded position;

Figure 5A depicts a diagrammatic cross-sectional view of pump 200 in a first contracted position;

Figure 5B depicts a diagrammatic cross-sectional view of pump 200 in a second contracted position;

Figure 6 depicts a diagrammatic cross-sectional view of pump 300 in an expanded position;

Figure 7 depicts a diagrammatic cross-sectional view of pump 400 in an expanded position; and

Figure 8 depicts a diagrammatic cross-sectional view of pump 500 in an expanded position.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

Detailed Description of Example Embodiments

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” may include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Figure 1 is a diagrammatic side cross-sectional view of a heart 102 with a side view of a pump 100 disposed therein. Heart 102 includes right ventricle 104, left ventricle 106, mitral valve 108, left atrium 110, and aortic valve 112. The view also shows a portion of the aorta 114. Pump 100 is disposed in left ventricle 106. Blood is pumped by the left atrium 110 through mitral valve 108 and into left ventricle 106. The left ventricle then pumps the blood through the aortic valve into general circulation in the body. Pump 100 is positioned to aid the function of left ventricle 106 and consequently is positioned so that the outtake is facing aortic valve 112. Pump 100 has a wall 116 that defines a pumping chamber 118. Pumping chamber 118 has an opening 120, which may serve as both an intake and outtake for pump 100. Pump 100 has a generally conical shape to better fit in left ventricle 106. Pump 100 may have a round or a slightly oval cross-section, as desired for a particular application. Wall 116 may be made of any biocompatible flexible material. Wall 116 may be made from a non-elastic material, or from an elastic material. If wall 116 is made from an elastic material, the wall may be sized to be stretched when the pump is in an expanded position. Pump 100 may include elongate member 122. Elongate member 122 may include a shaped tip 123 such as a curl to position pump 100 in the

desired location and to prevent trauma to the ventricle wall. Pump 100 operates by moving wall 116 between an expanded state and a contracted state, preferably synchronous with the left ventricle's operation.

Figure 2 is a plan cross-sectional view of pump 100. Pump 100 includes wall 116 defining cavity 180. The cavity has an opening 120 at a first end. A pumping mechanism 124 includes frame 126 and actuating struts 128. Frame 126 includes support struts 130. Support struts 130 are attached to wall 116 and should be relatively rigid. Actuating struts 128 are made from a shape memory material. There may be any suitable number of support struts and actuating struts, and the number of support struts should generally correspond to the number of actuating struts. For example, there may be 3, 4, 5, 6, 7 or 8 of support struts and a corresponding number of actuating struts.

Shape memory materials include NiTi alloys such as Nitinol™ and other alloys such as CuAlNi. Shape memory materials may be plastically deformed in their martensitic phase to a first shape and then when heated to their austenitic phase may assume another shape. When cooled down back to the martensitic phase, they may return to the first shape. Many shape memory alloys, including Nitinol™, may be heated to their austenitic phase by passing a current through them.

In this embodiment, actuating struts 128 are made from a suitable shape memory alloy. Each strut may have two electrically separated branches connected at the end to form an electrical path out and back. Each strut may also electrically connected to a voltage source through elongate member 122 or through another suitable source. Each strut may be formed so that the pump is in its contracted position when the shape memory material is in the austenitic phase and in its expanded position when the shape memory alloy is in its martensitic phase. Alternatively, the struts could be formed so that each strut is in the austenitic phase when the pump is in its expanded position and in the martensitic phase when the pump is in its contracted position. In another alternative, the actuating struts could be divided into two equal or roughly equal groups, each group electrically connected to a separate voltage source, or to a voltage source that could apply voltage to each group selectively. The first group is formed as the struts in the first embodiment described above, and the second group is formed as the struts in the second embodiment describe above. In this manner, some of the actuating struts could be working during both the expansion and contraction of the pump. Each of the struts would have a

suitable polymeric coating to both thermally and electrically isolate the struts from the body fluid and to prevent electrical shorts, and the electrical conduits in elongate member 122 would be suitably insulated.

In an alternative configuration, each strut may include only a single electrical path. The voltage may flow through elongate member 122, through each actuating strut 128, through each connecting support strut 126, and back to a separate electrical conduit in elongate member 122. Of course, in this configuration, struts 126 would be suitably insulated as well.

Figure 3 is a diagrammatic cross-sectional view of pump 100 in the contracted position. In operation, intermittent voltage from the voltage source moves actuating struts 128 into the martensitic phase by heating the struts up. When the voltage ceases, actuating struts 128 cool down to their austenitic phase. Pump 100 therefore may be moved between an expanded state and a contract state, as illustrated by Figures 1 and 2 respectively. When the pump moves to the expanded state, blood fills cavity 118. When the pump moves to the contracted state, blood rushes out in the direction of the aortic valve (see Figure 1), and thus enhances the operation of the left ventricle.

Figure 4 is a diagrammatic cross-sectional view of a pump 200. Pump 200 includes wall 216, which forms pumping cavity 218 having opening 220. An elongate member 222 passes through the center of pumping cavity 218 and may include atraumatic end 223, which may be a flexible coil or other suitable configuration. The actuation mechanism consists of actuating struts 228. Actuating struts 228 are attached to wall 216 generally along the length of the wall and are attached to sliding collar 232 at a first end and to elongate member 222 at a second end. Actuating struts 228 are made from a shape memory alloy such as Nitinol™ as described above. Each strut has two separate sections electrically connected at sliding collar 232. Each section of each strut is also electrically connected to a voltage source at elongate member 222 at the second end. Thus voltage may travel down elongate member, up through each strut, back down each strut and back up the elongate member. Each strut also has a polymeric layer surrounding the shape memory material to provide electrical and thermal insulation. There may be any suitable number of actuating struts. For example, there may be 3, 4, 5, 6, 7, or 8 actuating struts.

Figure 5A is a diagrammatic cross-sectional view of pump 200 according to a first embodiment. In this embodiment, when the pump moves between the expanded and the contracted position, actuation struts 228 move between the elongated position shown in this Figure and the expanded position shown in Fig. 4. The struts may be in their martensitic phase when elongated and in their austenitic phase when expanded. Alternatively, the struts may be in their austenitic phase when elongated and in their martensitic phase when expanded. A third alternative may be a configuration similar to the third alternative described above with respect to Fig. 2, where there are two sets of struts.

Figure 5B is a diagrammatic cross-sectional view of pump 200 according to a second embodiment. The embodiment of Figure 5B is similar to that of Figure 5A, except that the struts are folding inwards when the pump is in the contracted position. This may be advantageous to get the mouth of the pump closer to the aortic valve. Other configurations besides those shown are possible.

Figure 6 is a diagrammatic cross-sectional view of a pump 300 shown in the expanded position. Pump 300 includes support struts 326, which may be biased to be in the contracted position. Elongate member 322 includes a first portion 334 that is fluidly connected to balloons 336, and may optionally include a second portion 338 extending to an atraumatic tail 323. Wall 316 forms pumping chamber 318, which has an opening 320, and are attached to support struts 326. When inflated, balloons 336 extend outward generally radially from the centerline of the pump and push supporting struts 326 to the expanded position. There may be any suitable number of balloon 336. Other configurations are contemplated. For example, first portion 334 could be connected to an inflatable toroidal balloon, which would function much as balloons 336 do. In operation, inflation of balloons 336 moves the pump to an expanded position. Deflation of balloons 336, which may be biased to move inwardly to the centerline, moves the pump to a contracted position, expelling the blood towards the aortic valve.

Figure 7 is a diagrammatic cross-sectional view of a pump 400, which is depicted in its expanded position. Pump 400 includes a wall 416, which defines pumping chamber 418 having opening 420. Wall 416 is attached to support struts 426. Support struts 426 are attached to elongate member 422 and are generally rigid. Elongate member 422 may include atraumatic end 423, which serves to position the pump in the left ventricle. Electroactive polymer actuators 440 are attached between

elongate member 422 and support struts 426. When exposed to a voltage source, actuators 440 will decrease in length; and when the exposure ceases, actuators 440 will return to their original length. The voltage path may be through elongate member 422, up electroactive polymer actuators 440, through struts 426, and back to a second electrical conduit in elongate member 422. Thus, this pump may be operated by exposing actuators 440 intermittently to a voltage source. Elongate member 422, actuators 440, and struts 426 may be electrically insulated using a suitable polymer or combination of polymers.

Electroactive polymers (EAPs) are polymers that respond to electrical stimulation by displaying size or shape displacement. For example, some electroactive polymers contract when electrically stimulated. Suitable EAPs may include ferroelectric polymers such as poly(vinylidene fluoride) and its copolymers, acrylic elastomer tape such as VHBTM sold by 3MTM, electrostrictive graft elastomers such as an elastomer grafted to a piezoelectric poly(vinylidene fluoride-trifluoroethylene) copolymer, and liquid crystal elastomer materials such as monodomain nematic liquid crystal elastomers with conductive polymers distributed within their network structure. Other EAPs that may be suitable in this application include ionic EAPs such as ionic polymer gels such as polyacrylonitrile materials, ionomeric polymer-metal composites, conductive polymers such as those fabricated from polypyrrole, polyaniline, PAN doped with HCl, polyethylenedioxythiophene, poly(p-phenylene vinylene)s, or polythiophenes, and carbon nanotubes.

Figure 8 is a diagrammatic cross-sectional view of a pump 500. Pump 500 includes wall 516, which forms pumping cavity 518 having opening 520. An elongate member 522 passes through the center of pumping cavity 518 and may include atraumatic end 523, which may be a flexible coil or other suitable configuration. Wall 516 is attached to support struts 526, which are attached at one end to elongate member 522. The actuation mechanism consists of actuating struts 228. Actuating struts 228 are attached at one end to support struts 526 and at the other end are attached to sliding member 542. Sliding member 542 is disposed over elongate member 522 and is configured to easily slide proximally and distally with respect to elongate member 522. A sheath 544 may be disposed over sliding member 542. Struts 528 may be made from a relatively rigid material. There may be any suitable number of actuating and support struts. For example, there may be 3, 4, 5, 6, 7, or 8 actuating struts. In use, movement of sliding member 542 proximally and

distally moves actuating struts 528 inward and outward, which in turn moves support struts 526 inward and outward. This movement expands and contracts the pump wall, thereby pumping the fluid.

Each of these pumps would be attached to a power source, which would provide electrical power or pressurized fluid. The power source may include a control mechanism to control the rate of operation of the pump. The control mechanism may be configured to receive data from a heart monitoring device or a pacemaker to synchronize the operation of the pump with the operation of the left ventricle. Each pump may also be coated with an anti-clotting agent or other suitable therapeutic agent.

It should be understood that this disclosure is, in many respects, only illustrative. Numerous advantages of the invention covered by this document have been set forth in the foregoing description. Changes may be made in details, particularly in matters of shape, size and arrangement of parts without exceeding the scope of the invention. Those of skill in the art will readily appreciate that other embodiments may be made and used which fall within the scope of the claims attached hereto. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A medical device, comprising
a blood-impermeable wall defining a cavity having a lumen through the wall
at a first end opposite a second end, the wall including a flexible section;
a frame attached to the wall; and
an actuation system attached to the frame for moving the frame between an
expanded position and a contracted position.
2. The medical device of claim 1, wherein the actuation system comprises
a shape memory material having a transformation temperature and means for moving
the shape memory material through its transformation temperature.
3. The medical device of claim 2, wherein the actuations system
comprises struts formed of the shape memory material, and wherein the struts are
electrically connected to a voltage source.
4. The medical device of claim 1, wherein the actuation system comprises
a balloon and an inflation lumen fluidly attached to the balloon.
5. The medical device of claim 1, wherein the actuation system comprises
an electroactive polymer.
6. The medical device of claim 1, wherein the cavity has a volume of
between 40 cc and 100 cc.
7. The medical device of claim 6, wherein the cavity has a volume of
between 60 cc and 85 cc.
8. The medical device of claim 1, wherein a cross-section of the cavity at
the first end is larger than a cross-section of the cavity at the second end when the
frame is in the expanded position.
9. The medical device of claim 8, wherein the cavity has a generally
conical shape when the frame is in the expanded position.

10. The medical device of claim 8, wherein the cavity has a slightly flattened conical shape when the frame is in the expanded position.

11. The medical device of claim 1, wherein the frame comprises a first set of struts extending out from a position proximate the second end of the wall.

12. The medical device of claim 11, further comprising a central shaft extending longitudinally from the second end, and wherein the actuation system comprises a second set of struts attached to the central shaft.

13. The medical device of claim 12, where the second set of struts is slideably attached to the first set of struts.

14. The medical device of claim 12, wherein the second set of struts is slideably attached to the central shaft.

15. The medical device of claim 12, wherein the central shaft comprises a sliding member having a proximal end, a distal end and a lumen therebetween and a core member at least partially disposed in the lumen of the sliding member, wherein the second set of struts is attached to the sliding member of the central shaft.

16. The medical device of claim 15, further comprising a sheath disposed over a portion of the central shaft proximal the actuation system.

17. The medical device of claim 1, further comprising an anti-clotting agent.

18. An intravascular pump, comprising:
a flexible wall defining a pumping chamber; and
a pumping mechanism including a frame attached to the wall.

19. The pump of claim 18, wherein the pumping mechanism includes a central shaft and moveable struts extending between the central shaft and the frame.

20. The pump of claim 19, wherein the pumping mechanism includes a balloon.

21. The pump of claim 19, wherein the pumping mechanism further includes a member made from a shape memory alloy having a transformation temperature and means to move the shape memory alloy through the transformation temperature.

22. The pump of claim 21, wherein the shape memory alloy comprises Nitinol.

23. The pump of claim 19, wherein the pumping mechanism further includes an electroactive polymer.

24. The pump of claim 19, further comprising a control system for controlling the pump.

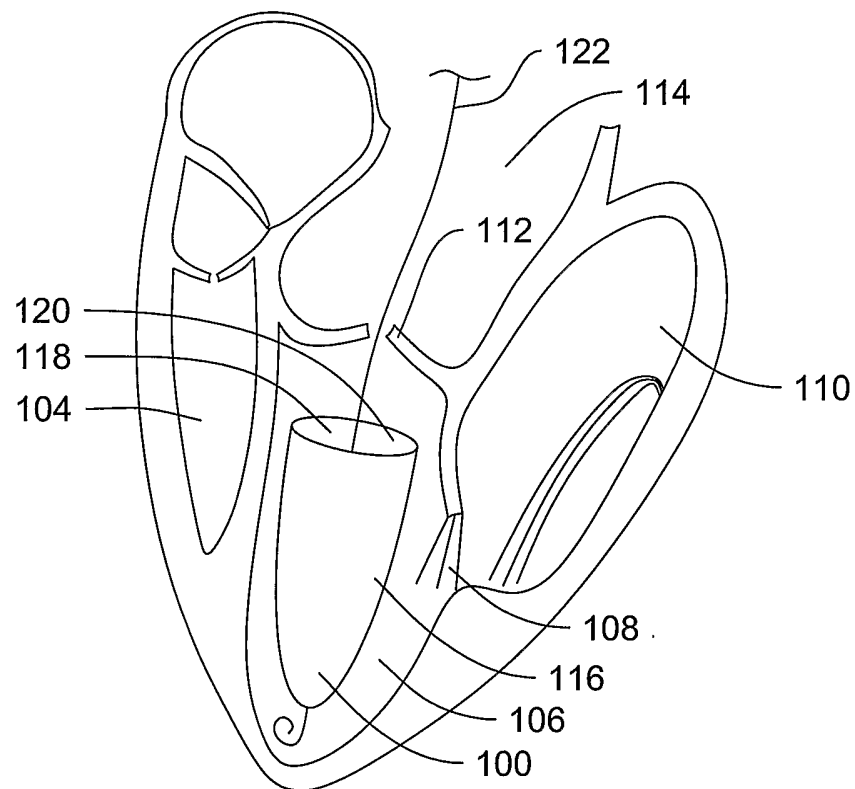
25. The pump of claim 24, wherein the control system comprises a sensor for measuring heart activity.

26. The pump of claim 24, wherein the control system includes an interface for use with a pacemaker.

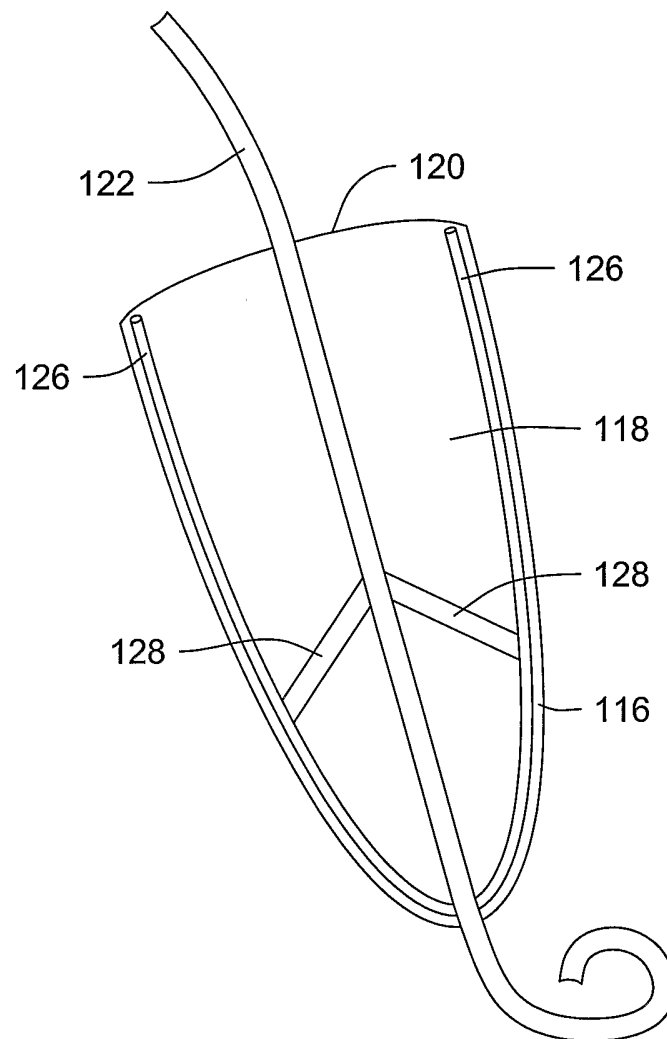
27. A method for installing a pump intravascularly, comprising the steps of:

- providing a percutaneous catheter;
- providing a pump;
- disposing the pump in the percutaneous catheter;
- moving the percutaneous catheter proximate a desired position in the intravascular system;
- withdrawing the percutaneous catheter; and
- leaving the pump.

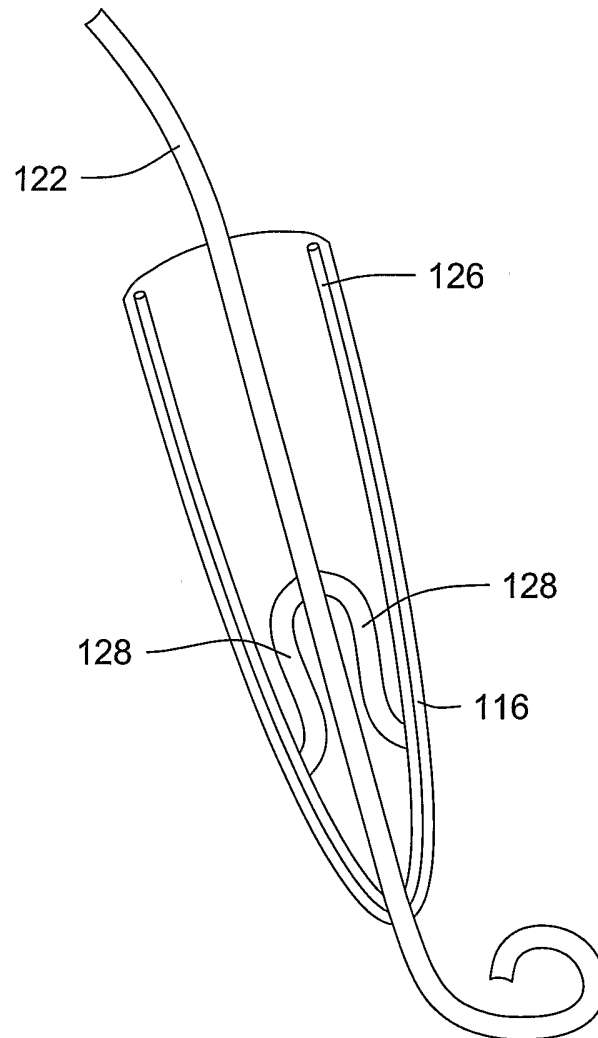
28. The method of claim 27, wherein the desired position is a left ventricle.
29. The method of claim 28, further comprising the step of pushing the pump from the percutaneous catheter.
30. The method of claim 29, wherein the pump includes an elongate member.
31. The method of claim 30, wherein the pump includes a flexible wall defining a pumping chamber.
32. The method of claim 31, wherein the pump includes a plurality of support struts attached to the flexible wall.

*Figure 1*

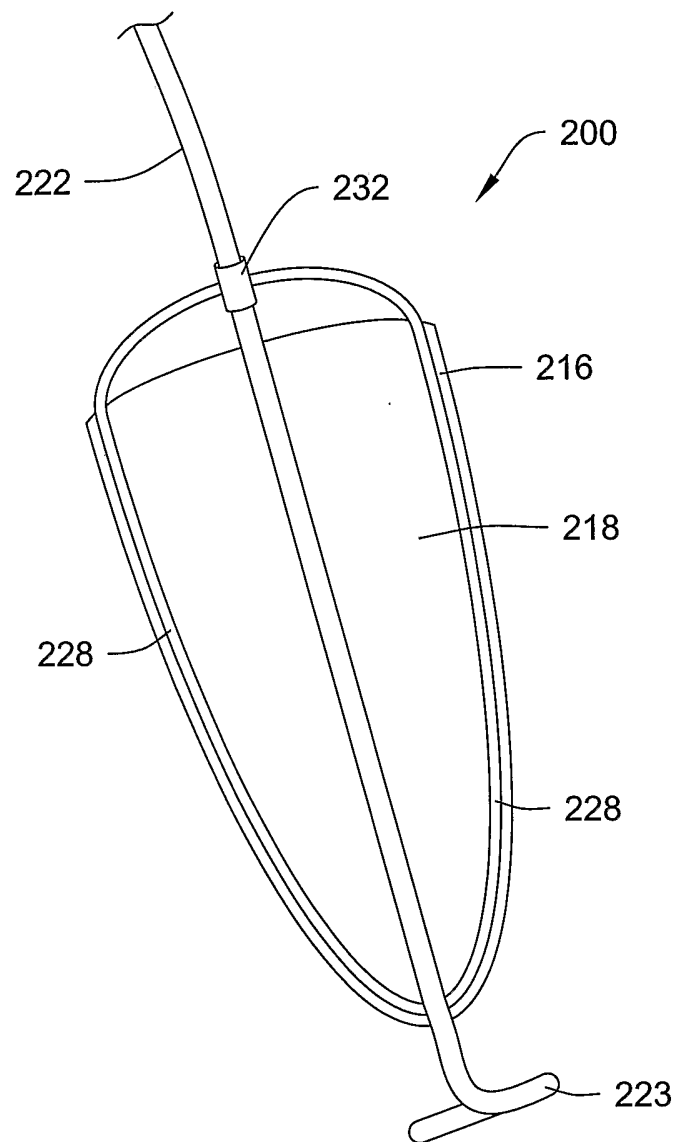
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*Figure 2*

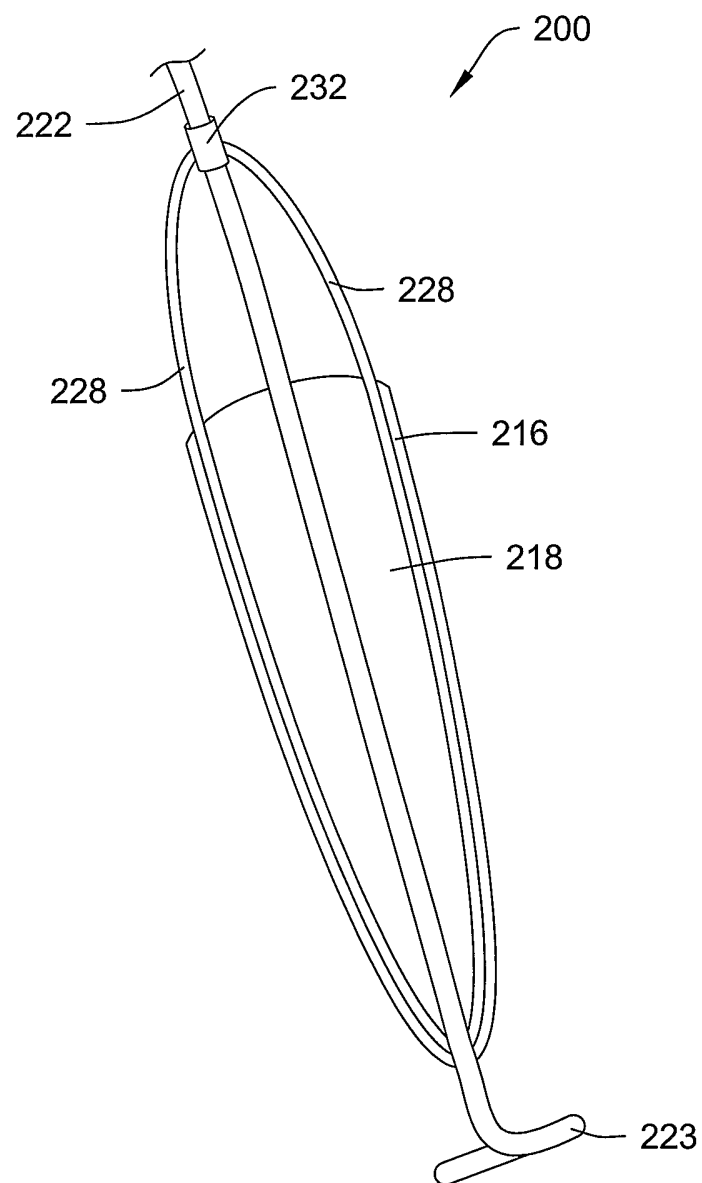
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*Figure 3*

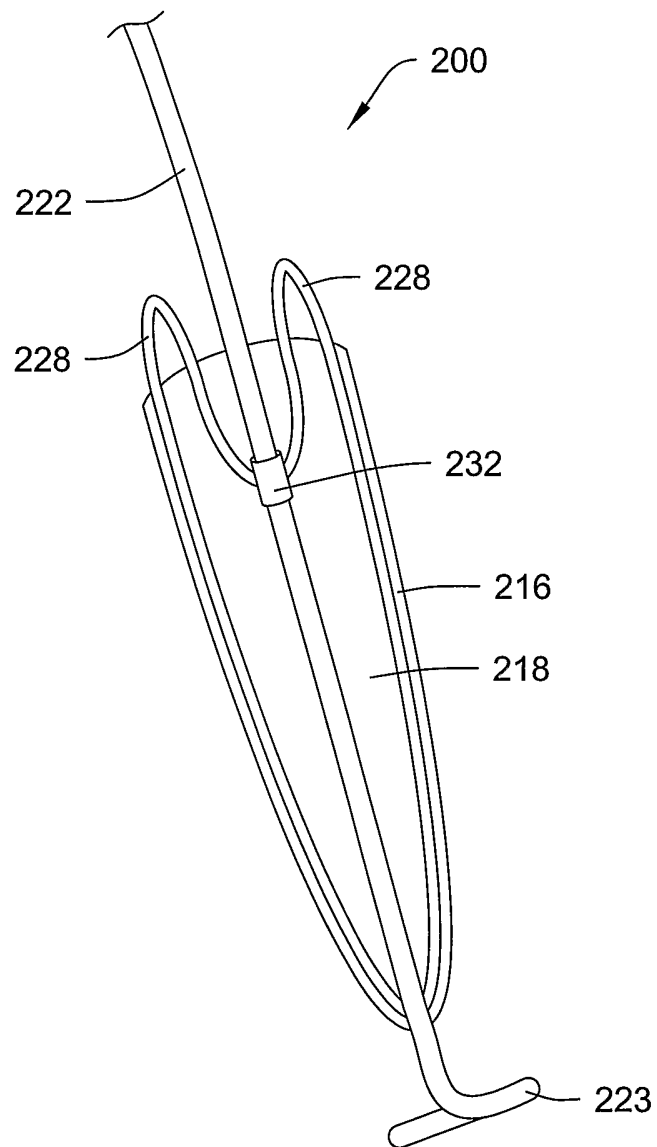
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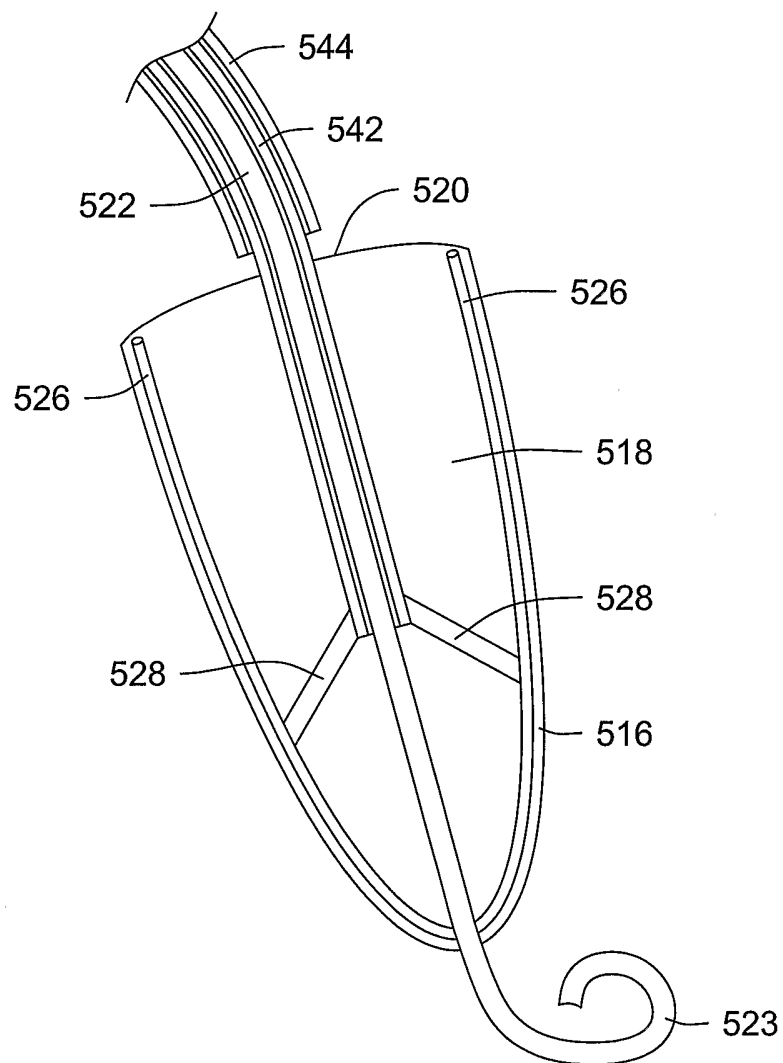
*Figure 4*

5/9

*Figure 5A*

6/9

*Figure 5B*

*Figure 8*

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/009061

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M1/10

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/18508 A (DOBAK, JOHN, D., III; GHAERZADEH, KAMBIZ) 7 May 1998 (1998-05-07)	1,2, 6-11, 18-22, 24,25
Y	page 9, line 2 - page 10, line 13 page 11, line 8 - line 9 figures 3-6,16 page 19, line 7 - line 9	26
X	US 5 827 171 A (DOBAK, III ET AL) 27 October 1998 (1998-10-27) column 7, line 35 - column 8, line 54; figures 2-5 ----- -/-	2,4, 6-11, 18-22

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

20 July 2005

Date of mailing of the international search report

27/07/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Böttcher, S

INTERNATIONAL SEARCH REPORT

Inter.al Application No
PCT/US2005/009061

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 522 195 A (SCHIFF ET AL) 11 June 1985 (1985-06-11) column 8, line 7 - column 9, line 43 column 12, line 16 - line 27; figures 4,5	1,8-16, 18,19, 24,25
X	EP 0 567 788 A (INDIANA UNIVERSITY FOUNDATION) 3 November 1993 (1993-11-03) column 6, line 50 - column 7, line 13 column 7, line 54 - line 59; figures 2,3	1,4,11, 17
Y	US 3 860 968 A (SHAPIRO ET AL) 21 January 1975 (1975-01-21) column 3, line 50 - line 62; figure 1	26

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 27-32

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

Claims 27 - 32 relate to a method for installing a pump in the vascular system of a patient and include explicitly the surgical step "moving the percutaneous catheter proximate a desired position in the intravascular system".

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/009061

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 27-32
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Claims 27 - 32 relate to a method for installing a pump in the vascular system of a patient and include explicitly the surgical step "moving the percutaneous
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2005/009061

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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