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(54) Title: LEFT VENTRICULAR CORONARY CONDUIT TO INCREASE CORONARY BLOOD FLOW IN HEART FAILURE PATIENTS

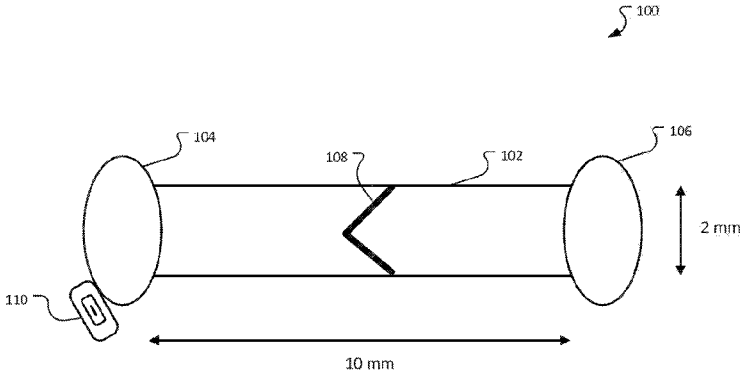

FIG. 1

(57) Abstract: An implantable medical device for increasing coronary blood flow in heart failure patients. The device includes an elongate tubular body having a distal end and a proximal end and a lumen therebetween, a valve disposed within the lumen of the elongate tubular body, and a pressure sensor attached to the elongate tubular body and operatively engaged to the valve, in which the pressure sensor actuates opening and closing of the valve.

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LEFT VENTRICULAR CORONARY CONDUIT TO INCREASE CORONARY BLOOD FLOW IN HEART FAILURE PATIENTS

CROSS REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application Serial No. 62/291,155, filed February 4, 2016, the contents of which are incorporated herein by reference thereto.

FIELD

[0002] The disclosed subject matter relates to a medical device, and in particular, a coronary apparatus for increasing coronary blood flow generally and in particular between the left ventricle and left anterior descending coronary artery.

BACKGROUND

[0003] Heart failure is the leading cause of death worldwide. The disease is characterized by decreased pumping efficiency and blood flow. Current pharmaceutical therapies focus on improving symptoms and preserving quality of life but lose efficacy as the disease progresses. For instance, drug treatments to delay disease progression are available but these are only useful in the early and mid-stages of the disease. Numerous medical devices and surgeries are further available to help maintain cardiac function. However, irreversible tissue damage continues to accumulate. In many cases, the only viable option for end-stage patients to survive is heart transplantation. Unfortunately, heart transplantation is an expensive, risky, and inefficient option for patients in the end stage. This is because heart transplantation requires notoriously scarce donor hearts to complete. In addition, the procedure is highly complicated and invasive, and after the procedure, the organ can still be rejected.

[0004] While artificial hearts have been tested in humans, they typically act as a substitute until a donor organ can be found. The artificial hearts soon wear out, with the current record being four years. Replacement valves have been used, but they are usually employed in specific congenital heart defects and are not typical in heart failure therapies. Thus, there is a need to develop new therapies for combating lowered heart function and blood flow in heart failure in a low cost, minimally invasive, and efficient manner.

SUMMARY

[0005] One aspect of the disclosed subject matter provides an implantable medical device including an elongate tubular body, a valve, and a pressure sensor. The implantable medical device is useful for increasing blood flow and delivering oxygen to cardiac tissue in heart failure. The implantable medical device can be percutaneously placed between the left ventricle and the left anterior descending coronary artery of a patient heart. The device allows blood to flow down from the left ventricle to the left anterior artery descending in times of high demand.

[0006] The elongate tubular body includes a distal end, a proximal end, and a lumen therebetween. The valve is disposed within the lumen of the elongate tubular body. In particular, the valve can be integrated with the inner surface wall of the tubular member. The pressure sensor is attached to the elongate tubular body, *e.g.*, on the outer wall of the tubular member or the inner wall of the tubular member, and operatively engaged to the valve.

[0007] In some embodiments, the elongate tubular body can be formed from material including metal or polymer. The elongate tubular body can have a length of about 10 mm and a diameter of about 2 mm. At least one of the proximal and distal ends of the elongate tubular body can have a flange circumferentially and laterally extending from the distal or proximal end.

[0008] In some embodiments, the valve includes leaflets. The valve can be formed from flexible material such as plastic. In some embodiments, the valve can be a one-way check valve. The valve can have its surface coated with anticoagulant.

[0009] In some embodiments, the pressure sensor is attached to an outer surface of the elongate tubular body. In some embodiments, the pressure sensor includes an inductor coil and a pressure-sensitive capacitor. The pressure sensor can further include a body that hermetically seals the inductor coil and pressure-sensitive capacitor. The pressure sensor is capable of recording pressure readings when implanted in a subject. Alternatively, or additionally, the pressure sensor is capable of calculating an average pressure reading over time when implanted in a subject.

[0010] A method of treating a subject, for example, for congestive heart failure or other coronary syndromes in which there is high myocardial demand. The method comprising providing coronary apparatus comprising an elongate tubular member having a length defined by opposing first and second ends, and a valve disposed within the elongate tubular body. Implanting the coronary apparatus between the left ventricle and the left descending artery of the subject. The implantation can occur percutaneously and without the need for surgery. The valve being operatively engaged to a sensor such that the valve is configured to open and close in response to pressure from blood within the tubular member. For example, but not limitation, the first end of the tubular member is disposed at the left ventricle and the second end is disposed at the left descending artery. In some embodiments, the length of the tubular member is about 10 mm, and the outer diameter is about 2 mm.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIGURE 1 is schematic representation of a device in accordance with the disclosed subject matter;

[0012] FIGURE 2 is a schematic representation of a device in accordance with the disclosed subject matter;

[0013] FIGURE 3 is a schematic representation of a device placed in a patient body in accordance with the disclosed subject matter.

DETAILED DESCRIPTION OF SUBJECT MATTER

[0014] In accordance with one aspect of the disclosed subject matter, a device is provided for increasing coronary blood flow, elevating tissue oxygenation, and minimizing tissue damage in heart failure patients. The device is a connection between the main pumping chamber of the heart and the vessels that supply this chamber with blood. The device can be placed in a patient heart via a percutaneous (interventional) approach that does not require surgery. The device is equipped with a valve controlled by a pressure sensor that renders the device active on demand, for example, during periods of high myocardial demand such as congestive heart failure. The device can be customized according to personal needs of each patient. Placement of the device can utilize current catheterization techniques and operations of the device can be based on computer algorithms analogous to standard pacemaker technologies, thus providing great cost-efficiency. Further, the device has a wide range of applications as it can be sized and adjusted to be able to improve blood flow and oxygenation of other well-perfused organs.

[0015] In one embodiment, an implantable medical device 100 for improving blood flow is shown in FIGURE 1. The device 100 includes an elongate tubular body 102, a valve 108, and a

pressure sensor 110. The elongate tubular body 102 has a proximal end 104 and a distal end 106 and a lumen therebetween. At least one of the proximal and distal ends of the elongate tubular body 102 has a flange circumferentially and laterally extending from the distal or proximal end. In some embodiments, the elongate tubular body 102 has a diameter of about 2 mm. Various other suitable diameters are available for the elongate tubular body 102. In some embodiments, the elongate tubular body 102 has a length of about 10 mm. However, the elongate tubular body 102 can have longer or shorter length if desired. In some embodiments, the elongate tubular body 102 is formed from material including but not limited to metal or polymer.

[0016] In some embodiments, the elongate tubular body 102 can be generated using 3D printing technologies, which allows for customization of the elongate tubular body for personal needs of each patient. Personal needs of a patient can be determined based on Magnetic Resonance Imaging (MRI) or other scan of the patient body prior to the insertion of the device 100 into the patient body.

[0017] In some embodiments, the valve 108 is disposed within the lumen of the elongate tubular body. The valve 108 can be made of flexible material capable of opening and closing in response to a computer signal. For example, the valve 108 can be formed from plastic. In some embodiments, the valve 108 includes leaflets. The valve 108 can be a one-way check valve. The valve 108 can have a surface coated with anticoagulant. The anticoagulant may be similar to those used in heart stent applications.

[0018] The pressure sensor 110 is attached to an outer surface of the elongate tubular body 102 and operatively engaged to the valve 108. The pressure sensor 110 can be made using existing technologies that are available in the cardiology field. As shown in FIGURE 2, in some embodiments, the pressure sensor 110 can includes an inductor coil 202 and a pressure-sensitive capacitor 204. The pressure sensor 110 can further include a body 206 that hermetically seals the inductor coil 202 and a pressure-sensitive capacitor 204. The pressure sensor 110 can be

configured to record pressure readings when being implanted in a subject. Further, the pressure sensor 110 can be configured to calculate an average pressure reading over a predetermined period of time when being implanted in a subject.

[0019] FIGURE 3 shows an example intracardiac view and extracardiac view of a patient heart where the implantable medical device 100 is placed. The implantable medical device 100 is percutaneously placed between a left ventricle (LV) 102 and a left anterior descending (LAD) coronary artery 104. The placement of the device 100 can be based on current catheterization technologies for implantation of percutaneous stents and valves, which have been widely used in interventional cardiology practice. Unlike heart transplantation, the placement of the device 100 requires no surgical and therefore is not invasive.

[0020] The device 100 provides communication for blood to flow down from the LV 102 to the LAD 104, providing additional oxygen to cardiac tissue in times of high demand. In particular, the pressure sensor 110 is configured to record continuous pressure readings in the LV 102. The pressure sensor 110 is further configured to calculate average pressure readings (mmHg) over time (second). Operations of the pressure sensor 110 can be controlled based on the same computer algorithms (for example, calibrated algorithm) and computational parameters derived from standard pacemaker technologies, which provides great cost-efficiency for manufacturing and operating the device 100.

[0021] When the pressure sensor 110 detects that pressure in the LV 102 is elevated, for example, when an average pressure reading exceeds a predetermined value, the pressure sensor 110 is configured to send a computer signal to the valve 108. The computer signal triggers the valve 108 to open and allow blood to flow downs its pressure gradient from the LV 102 to the LAD 104. This provides additional oxygen to cardiac tissue during high demand scenarios such as congestive heart failure. By restoring blood flow, the device 100 helps to decrease tissue damage resulting from heart failure and to improve patient prognosis.

[0022] As the device 100 combines both pressure sensing and a fully functioning valve, it has a wide range of applications in treating various diseases. The device 100 can be used to improve blood flow and oxygenation in not only heart but also in other well-perfused organs such as liver, lung, or kidney. Further, the pressure sensor 110 and the valve 108 can be used in monitoring and manipulating systemic blood pressure, especially if percutaneous insertion is made at key vascular junctions. For patients at risk for increased intracranial pressure after head trauma, the device 100 can be used as an artificial shunt that removes exceeding fluid from patient skulls when the pressure sensor 110 records high measurements.

[0023] The elongate tubular member comprises a length of flexible plastic tubing. In some embodiments, the tubing can define a multi-layered unitary tube. Various materials can be used for manufacturing the elongate tubular member, such as but not limited to nylon, polyethylene, PTFE, polyimide, PEEK and PVDF. Multilayered polymeric tubes can also be used formed by coextrusion, dipping processes, or by shrinking tubing layers over one another over a mandrel or by electrostatic deposition and heating. Alternatively, 3-D technique may be utilized to form the elongate tubular member.

[0024] The valve mounted within the tubular member formed by the sidewall can comprises leaflets, e.g., two, three or more, or alternatively, comprise a flap. The valve can be formed of active materials, such as thermoelastic, piezoelectric, magnetostrictive, multiferroic, and shape memory. To prevent overflow in the heart, the valve in-built with the tubular member automatically opens when a predetermined threshold pressure is experienced. The threshold pressure can be adjusted to cater for vessels or hearts of differing size.

[0025] It is understood that the subject matter described herein is not limited to particular embodiments described, as such may, of course, vary. For example, the exemplary embodiments describe above are not limited to applications in heart failure. Instead the disclosed subject matter is applicable to increase oxygen supply in other organs and in other vasculature

conditions. Accordingly, nothing contained in the Abstract or the Summary should be understood as limiting the scope of the disclosure. It is also understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting. Where a range of values is provided, it is understood that each intervening value between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the disclosed subject matter.

[0026] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosed subject matter belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present disclosed subject matter, this disclosure may specifically mention certain exemplary methods and materials.

[0027] As used herein and in the appended claims, the singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise.

[0028] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present disclosed subject matter.

CLAIMS

What is claimed is:

1. An implantable medical device:

an elongate tubular body having a distal end, a proximal end, and a lumen therebetween,

a valve mounted to a sidewall within the lumen of the elongate tubular body, and

a sensor mounted to a sidewall of the elongate tubular body and operatively engaged to the valve, wherein the sensor detects pressure when implanted and actuates opening and closing of the valve mounted to the lumen of the elongate tubular body.

2. The implantable medical device of claim 1, wherein the valve includes leaflets.

3. The implantable medical device of claim 1, wherein the valve is formed from active material.

4. The implantable medical device of claim 1, wherein the valve is a one-way check valve.

5. The implantable medical device of claim 1, wherein the valve has a surface coated with anticoagulant.

6. The implantable medical device of claim 1, wherein the elongate tubular body is formed from metal or polymeric tubing.

7. The implantable medical device of claim 1, wherein the elongate tubular body has a length of about 10 mm.

8. The implantable medical device of claim 1, wherein the elongate tubular body has an inner diameter of about 1 to 2 mm.

9. The implantable medical device of claim 1, wherein the elongate tubular body has an outer diameter of about 2mm.

10. The implantable medical device of claim 1, wherein at least one of the distal or proximal ends of the elongate tubular body has a flange circumferentially and laterally extending from the distal or proximal end.

11. The implantable medical device of claim 1, wherein the pressure sensor is attached to an outer surface of the elongate tubular body.

12. The implantable medical device of claim 1, wherein the pressure sensor includes an inductor coil and a pressure-sensitive capacitor.

13. The implantable medical device of claim 12, wherein the pressure sensor includes a body that hermetically seals the inductor coil and pressure-sensitive capacitor.

14. The implantable medical device of claim 1, wherein the pressure sensor is capable of recording pressure readings when implanted in a subject.

15. The implantable medical device of claim 1, wherein the pressure sensor is capable of calculating an average pressure reading over time when implanted in a subject.

16. A method of treating a subject,

providing coronary apparatus comprising an elongate tubular member having a length defined by opposing first and second ends, and a valve disposed within the elongate tubular body, the valve operatively engaged to a sensor such that the valve is

configured to open and close in response to pressure from blood within the tubular member and

implanting the coronary apparatus between the left ventricle and the left descending artery.

17. The method of claim 16, wherein the first end is disposed at the left ventricle and the second end is disposed at the left descending artery.

18. The method of claim 16, wherein the length of the tubular member is about 10 mm, and the outer diameter is about 2 mm.

19. The method of claim 16, wherein the subject is treated for heart failure.

20. The method of claim 16, wherein the subject is treated for high myocardial demand.

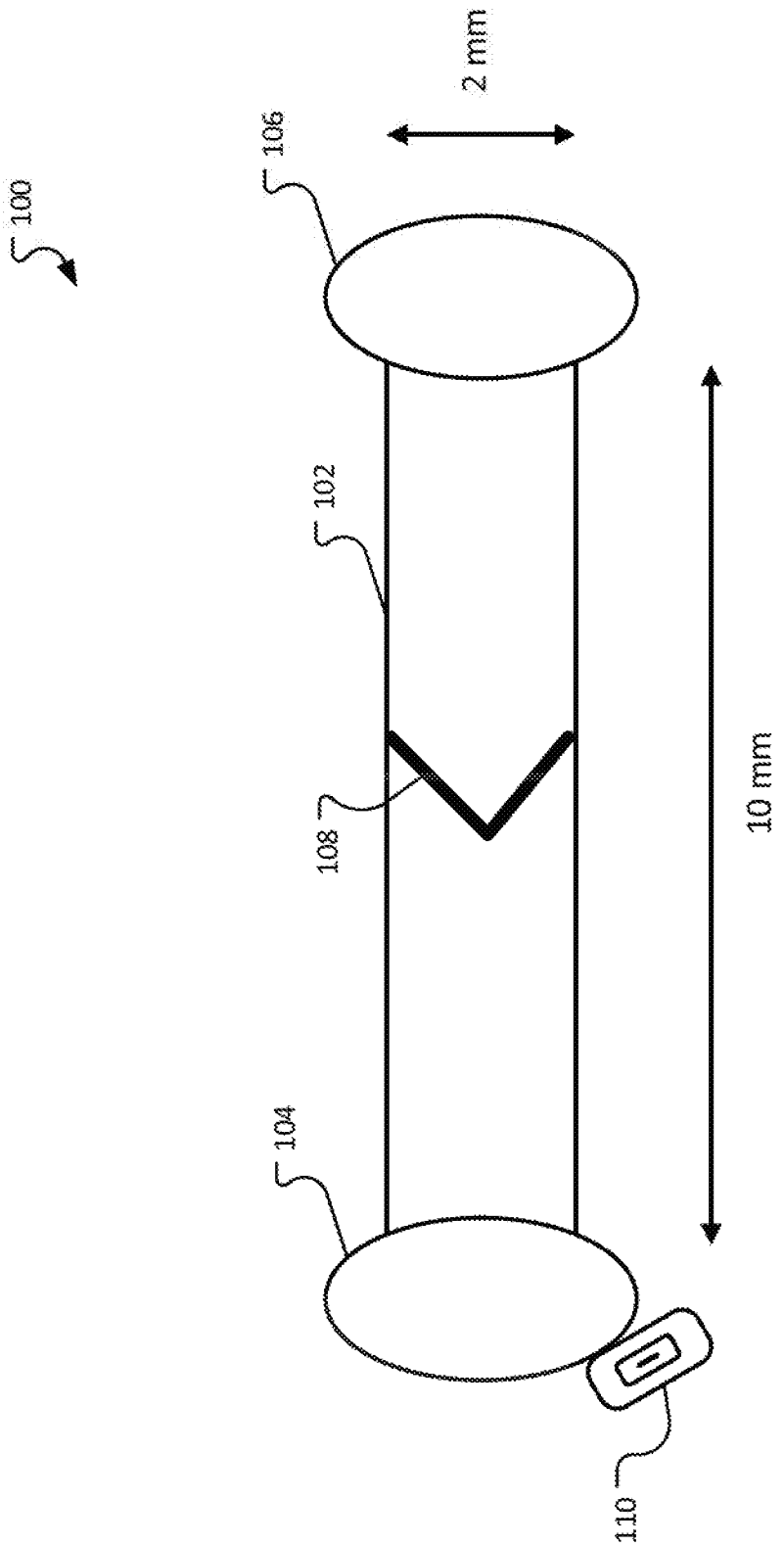

FIG. 1

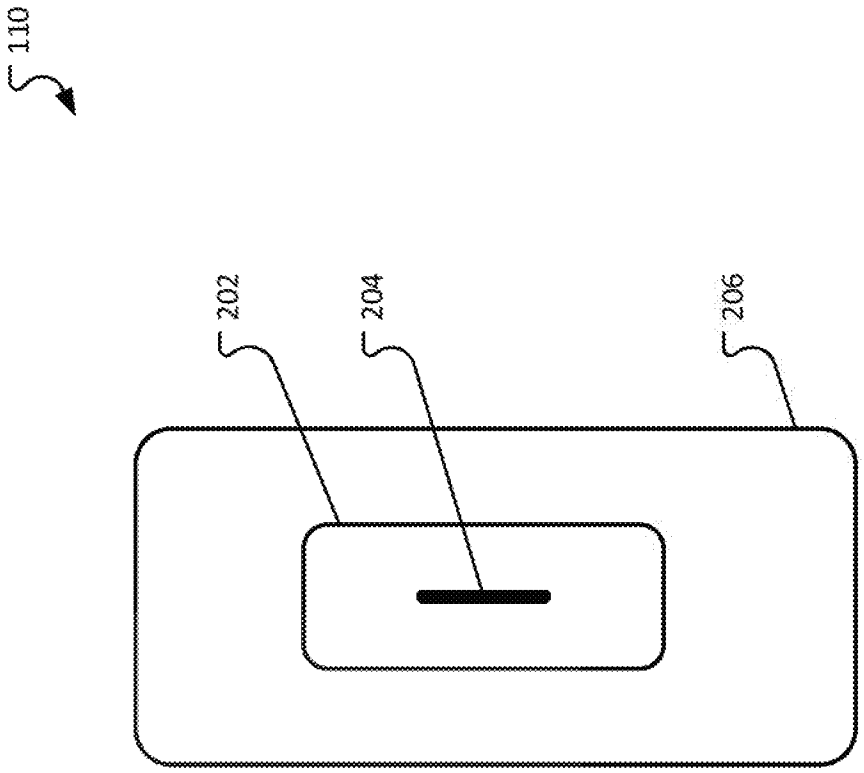

FIG. 2

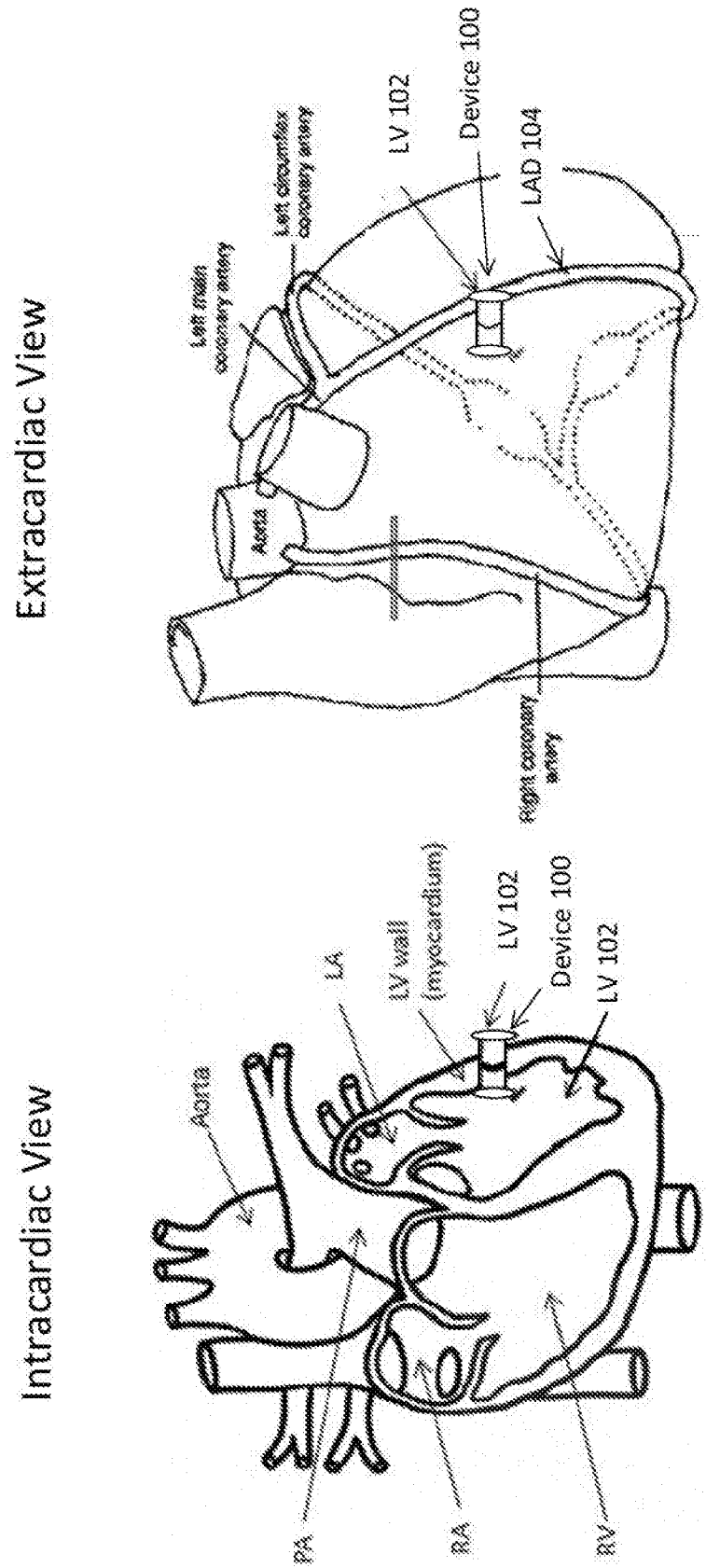
Extracardiac View
Left main coronary artery
Left circumflex coronary artery
LV 102
Device 100
LAD 104
Aorta
Right coronary artery
Intracardiac View
Aorta
LA
LV wall (myocardium)
LV 102
Device 100
LV 102
PA
RA
RV

FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US17/16518

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M27/00, A61F2/04, A61F2/06, A61B17/00, A61B17/11, A61B5/021, A61B5/0215 (2017.01)
CPC - A61M27/002, A61F2/04, A61F2/06, A61M1/36, A61M1/3613, A61B17/11, A61B5/02, A61B5/6847, A61F2/2493

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0107733 A1 (FAUL, J et al.) 19 May 2005; figures 4-6; paragraphs 19, 21, 27-28, 37, 56-61, 63; claim 19	1, 2, 4-8, 10
Y		3, 9, 11-20
Y	US 2008/0125690 A1 (DELAPORTE, S) 29 May 2008; paragraphs 12-13, 27-28	3
Y	WO 2001/017582 A2 (CORVASCULAR, INC.) 15 March 2001; page 10, lines 16-19	9, 18
Y	US 2009/0156960 A1 (MAUGE, C et al.) 18 June 2009; figure 3; paragraphs 40, 51	11
Y	US 2014/0243703 A1 (SCHMIDT, S et al.) 28 August 2014; paragraphs 7, 9, 31-32, 35	12-13
Y	US 2013/0303942 A1 (DAMASER, M et al.) 14 November 2013; paragraphs 19-20, 30	14-15
Y	US 2006/0122554 A1 (WILK, P) 8 June 2006; figures 5-5C; paragraphs 17, 105, 121	16-20

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

* Special categories of cited documents:
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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 March 2017 (29.03.2017)	17 APR 2017

Name and mailing address of the ISA/	Authorized officer
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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