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

(54) **Title**: DEVICE AND METHOD FOR CARDIAC PACING AND DEFIBRILLATION

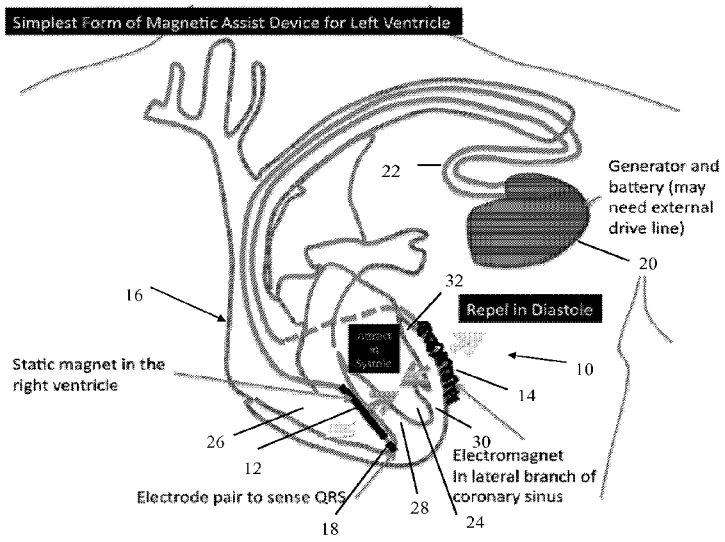

FIG. 1

(57) **Abstract**: An embodiment in accordance with the present invention provides a magnetic assist device to treat congestive heart failure. The device includes at least two magnets disposed on the heart and synchronized to the QRS wave, as sensed by an electrode disposed within the heart. In an embodiment to provide left ventricle assistance, one of the magnets is disposed on the endocardium of the right ventricle and the other magnet is positioned in a lateral branch of the coronary sinus. During systole, the two magnets are attracted to one another to aid in contraction of the heart muscle. During diastole, the two magnets repel one another to aid in relaxation of the heart muscle. A generator disposed transdermally is conductively connected to the two magnets and the electrode, such that the generator powers the two magnets and the electrode. The generator can be powered by an internal battery and/or external drive.

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DEVICE AND METHOD FOR CARDIAC PACING AND DEFIBRILLATION

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 61/501,820, filed June 28, 2011, and is related to U.S. Provisional Patent Application No. 61/666,158, filed June 29, 2012, both of which are incorporated by reference herein, in their entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to cardiac treatment. More particularly, the present invention relates to a device for treatment of congestive heart failure.

BACKGROUND OF THE INVENTION

[0003] Congestive heart failure (CHF) due to systolic and/or diastolic left ventricular dysfunction is a condition associated with significant morbidity and mortality. Patients with CHF are typically identified upon presentation with dyspnea due to pulmonary edema and/or lower extremity swelling. Diagnostic criteria for CHF include history, physical examination, and chest radiographs. A 2010 update from the American Heart Association estimated that there were 5.8 million people with CHF in the United States in 2006. There are an estimated 23 million people with CHF worldwide. Additionally, the prevalence of heart failure increases rapidly with advancing age. In the Framingham Heart Study, the prevalence of heart failure in men was 0.8% at age 50-59 years, but increased to 6.6% by age 80-89 years. It has been estimated that the prevalence of heart failure is 25% higher in the African-American population than in the Caucasian population. Heart failure is the first-listed diagnosis in 875,000 hospitalizations and over 270,000 patients die from heart failure per year.

[0004] Medical therapy for treatment of this disorder has improved significantly but remains limited after onset of the advanced stages of the disease. Medical therapies include

diuretics, beta blockade, and angiotensin converting enzyme inhibitors. These agents improve symptoms and/or outcomes in many patients. However, when presenting with acute decompensated heart failure, treatment remains limited with diuretics, and vasodilator therapy if hemodynamically tolerated. In the case of hemodynamic collapse, inotropic agents are often utilized with modest improvement in contractility, but associated comorbidities including cardiac arrhythmia. Cardiac transplant can be an effective treatment, but the procedure is limited by organ shortages, procedural risks, and the lifelong requirement for immunosuppression.

[0005] Mechanical support therapies including left ventricular assist devices such as the pulsatile-flow Heartmate XVE (HM1; Thoratec Corp., Pleasanton, CA, USA) or continuous-flow Heartmate II (HM2; Thoratec Corp.) can be used as a bridge to transplant or as destination therapy. However, current technologies for mechanical cardiac support are limited by the invasive nature of their implantation (generally requiring open heart surgery), procedural risk, as well as long-term risks after implantation including infections and complications associated with extracorporeal and non-pulsatile flow such as thrombogenicity and gastrointestinal bleeding.

[0006] Additionally, patients with CHF and systolic left ventricular dysfunction typically undergo implantable cardioverter defibrillator (ICD) or biventricular pacemaker/ICD implantation for prevention of sudden death and/or for cardiac resynchronization in the setting of left bundle branch block. It is estimated that over 3 million patients in North America are eligible for an ICD, with over 400,000 additional patients meeting the criteria every year. While effective at preventing sudden death, ICDs do not prevent death from pump failure. Biventricular pacing can provide modest improvement in pump function in two thirds of recipients, but over a third of patients derive no symptomatic or survival benefit.

[0007] It would therefore be advantageous to provide a treatment for congestive heart failure that is less invasive and minimizes patient risks, such as infection and thrombogenicity.

SUMMARY OF THE INVENTION

[0008] The foregoing needs are met, to a great extent, by the present invention, wherein in one aspect a device for providing magnetic assistance to a chamber of a heart includes a first magnet positioned adjacent to a first wall of the chamber of the heart and a second magnet positioned adjacent to a second wall of the chamber of the heart. An electrode is configured to sense electrical output in the heart. The electrode is positioned within the chamber of the heart. A generator is coupled to the first magnet, the second magnet, and the electrode, and the generator is in conductive communication with the first magnet, the second magnet, and the electrode. The first magnet and the second magnet are configured to attract during systole and repel during diastole.

[0009] In accordance with an aspect of the present invention the generator includes a battery. The generator can further include an external drive to provide power. Electrical leads can be used to connect the generator to the first and second magnet and the electrode. The first magnet can take the form of a static magnet and said second magnet can take the form of an electromagnet. The electrode can take the form of an electrode pair configured to sense a QRS wave produced by the heart, and further can be configured to produce a bipolar electrogram. The first magnet and the second magnet can be positioned on outer surfaces of opposing walls of the chamber of the heart. More particularly, the first magnet can be positioned on an endocardium of a right ventricle of the heart, and the second magnet can be positioned in a lateral branch of a coronary sinus. A magnitude and a direction of a current applied to the first and second magnets is synchronized to a QRS wave as sensed by the electrode pair.

[0010] In accordance with another aspect of the present invention, a method for providing magnetic assistance to a chamber of a heart includes positioning a first magnet adjacent to a first wall of the chamber of the heart and positioning a second magnet adjacent to a second wall of the chamber of the heart. The method includes positioning an electrode within the chamber of the heart. The electrode is configured to sense electrical waves within the heart. Additionally, the method includes coupling a generator to the first magnet, the second magnet, and the electrode. The generator is in conductive communication with the first magnet, the second magnet and the electrode. The method also includes configuring the first magnet and the second magnet to attract during systole and repel during diastole in synchrony with a QRS wave of the heart.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 illustrates a schematic view of a magnetic assist device for a left ventricle of a heart, according to an embodiment of the present invention.

[0012] FIG. 2 illustrates a graphical view of the force between two groups of four permanent magnets in each group, as a function of distance.

[0013] FIG. 3 illustrates an image of a prototype electromagnet (left) and an image of a static magnet (right), according to an embodiment of the present invention.

[0014] FIG. 4 illustrates an X-ray view of the magnets of FIG. 3, revealing coils embedded within plastic in the electromagnet (left) and 4 static magnets (right), according to an embodiment of the present invention.

DETAILED DESCRIPTION

[0015] The presently disclosed subject matter now will be described more fully hereinafter with reference to the accompanying Drawings, in which some, but not all embodiments of the inventions are shown. Like numbers refer to like elements throughout. The presently disclosed subject matter may be embodied in many different forms and should

not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Indeed, many modifications and other embodiments of the presently disclosed subject matter set forth herein will come to mind to one skilled in the art to which the presently disclosed subject matter pertains having the benefit of the teachings presented in the foregoing descriptions and the associated Drawings. Therefore, it is to be understood that the presently disclosed subject matter is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims.

[0016] An embodiment in accordance with the present invention provides a magnetic assist device to treat congestive heart failure. The device includes at least two magnets implanted on the heart and synchronized to the QRS wave, as sensed by an electrode disposed within the heart. In an embodiment to provide left ventricle assistance, one of the magnets is disposed on the endocardium of the right ventricle and the other magnet is positioned in a lateral branch of the coronary sinus. During systole, the two magnets are attracted to one another to aid in contraction of the heart muscle. During diastole, the two magnets repel one another to aid in relaxation of the heart muscle. A generator, disposed transdermally, is conductively connected to the two magnets and the electrode, such that the generator powers the magnets and the electrode. The generator can be powered by an internal battery and/or external drive. The device described herein has the capacity to aid the systolic and diastolic function of a cardiac chamber using magnetic fields applying ECG synchronized attraction (systolic) and repulsion (diastolic) forces on the outside of cardiac chambers. The device can be implanted using techniques similar to biventricular pacemaker/ICD implantation and may ultimately combine, in one device, the benefits of magnetic assist, pacing, and defibrillation.

[0017] FIG. 1 illustrates a schematic diagram of a magnetic assist device for a left

ventricle of a heart, according to an embodiment of the present invention. As illustrated in FIG. 1, the device 10 includes a first magnet 12 and a second magnet 14 disposed within a heart 16 of the patient. The device 10 also includes an electrode 18 disposed within the heart 16. A generator 20 is disposed transdermally, and is conductively coupled to the first and second magnets 12, 14 and the electrode 18, via leads 22. The leads 22 can take the form of a single branched lead or can take the form of multiple leads connected to the first and second magnets 12, 14 and the electrode 18.

[0018] As noted above, FIG. 1 illustrates the device 10 configured for left ventricular assist. While this is included as an example, it is not meant to be considered limiting, and such a device can be used to assist any chamber or region of the heart, as is known to or conceivable by one of skill in the art. In the exemplary embodiment of the device 10 configured for left ventricular assist, the first and second magnets 12, 14 are disposed on outer walls of the left ventricle 24. More specifically, the first magnet 12 is disposed in the right ventricle 26, such that it is on a first outer wall 28 of the left ventricle 24. The second magnet 14 is disposed in a lateral branch of the coronary sinus 30, such that it is on a second outer wall 32 of the left ventricle 24. With the first and second magnets 12, 14 disposed on the outer walls 28, 32 of the left ventricle 24, the electrode is also disposed within the right ventricle 26, in order to sense the QRS for the left ventricle. The leads 22 extend from the generator 20 to the first and second magnets 12, 14 and to the electrode 16, through the atria, in a manner similar to a standard lead for pacing or defibrillation. The magnets 12, 14 are configured to attract each other during systole and repel each other during diastole, thus augmenting cardiac work both during contraction and relaxation. The magnets 12, 14 and electrode 16 can be implanted surgically or alternately threaded through the vasculature. More particularly, a subclavian approach can be used for placement of the right ventricular lead, and coronary sinus epicardial lead. The device components can also be implanted in any

other suitable fashion known to one of skill in the art.

[0019] As illustrated in FIG. 1, the first magnet 12 can take the form of a static magnet. Alternately, the first magnet 12 can take the form of any suitable magnet, known to or conceivable by one of skill in the art. The second magnet 14 can take the form of a standard electromagnet or any other suitable magnet known to or conceivable by one of skill in the art. While the first and second magnets 12 and 14 are discussed as singular magnets, they can also take the form of a group of magnets having a number deemed suitable by one of skill in the art. Additionally, the electrode 16, can take the form of a pair of electrodes configured to detect QRS wave in the ventricles or P wave in the atria. The first and second magnets 12, 14 can then be synchronized to attract during systole and repel during diastole. In order for the synchronization to be effective, one or both of the first and second magnets has to take the form of an electromagnet, in conductive communication with the generator 20. Thus, the first and second magnets 12, 14 augment cardiac work during contraction and relaxation. It should be noted that the electrode 16 can be configured to output a bipolar electrogram.

[0020] The generator 20, illustrated in FIG. 1, can include a battery to provide the power necessary to polarize the magnets or can include a driveline for an external battery pack to provide additional power. Such a driveline is commonly used in conventional cardiac assist devices and is known to those skilled in the art. The voltage needed to power the generator 20 is likely greater than that needed for a standard pacemaker or defibrillator. It is also possible that the device as described above could be used to supplement the right ventricle in a case of right ventricular failure, for diffuse atriopathy, or even restoration of the atrial kick in the setting of atrial fibrillation.

[0021] As noted above the magnets can take the form of traditional magnets or electromagnets. The paragraphs below detail exemplary force returns for each of these types,

in the context of the present invention.

Magnetic Forces

[0022] The magnetostatic force between magnets can be used as a first approximation for the arrangement of the opposing magnets, in accordance with the present invention, and is described as $\bar{F} = -\nabla(E)$

where E is the interaction energy. The force between two groups of permanent magnets is described as:

$$F_Z \approx -120\pi K_d R^8 \left[\frac{1}{x^6} + \frac{1}{(x+2t)^6} + \frac{2}{(x+t)^6} \right]$$

Where K_d is magnetostatic energy constant defined as $K_d \equiv \mu_0 M^2 / 2$ (μ_0 is permeability of vacuum which is 1.2566371×10-6 H/m, and M is the saturation magnetization of the magnets in MA/m). For these calculations, K_d = 5 MJ/m^3. R is the radius of each of the magnets, x is the distance between their centers and t is the thickness of the magnets (in meters). As an example, the force between two groups of permanent magnets is calculated as a function of the distance between them. Each of the magnets is, for the purposes of the example, assumed to be 5 mm in diameter and 1 mm thick. Thus a patch of 4 magnets would occupy 4 cm^2 of an over 150 cm^2 of epicardial surface. It is apparent that larger contribution would be offered as the contraction proceeds.

Electromagnetic Forces

[0023] Electromagnets are coils that develop a magnetic field when an electrical current is passed. Mumetal cores have high relative permeability (20,000) and can increase the magnetic field created by the solenoid substantially. For example, a single coil of similar dimensions as one of the permanent magnets analyzed above can generate 0.1 Tesla flux with a 2000 turn solenoid and a 1 A current. This field strength would be comparable to that

estimated from the small magnet model in the previous paragraph.

[0024] Therefore, at 3 cm distance (typical left ventricular dimension), it is estimated that permanent magnets with 5 mm diameter and 1 mm thickness would generate 5 N (500 grams or 1 lb of force), with increasing force as the distance between the magnets decreased in systole, as illustrated in FIG. 2. More particularly, FIG. 2 illustrates a force between two groups of four permanent magnets each (5mm diameter and 1mm thickness) as a function of the distance.

[0025] Notably, the magnets are most effective at the apex where open chest cardiac massage has been shown to be most effective. Near the apex, even is dilated hearts, the magnet distance is typically less than 3 cm. Additionally, the magnets can be implanted in a hinge configuration which maximizes the generated force due to the proximity of the more apical magnets. The forces (exceeding 1 lb) calculated by this conservative estimate would augment a failing heart in great excess of the added force by using intravenous inotropic agents. In contrast to the proposed device, effective intravenous inotropy is arrhythmogenic and patients develop rapid tachyphylaxis. Importantly, to be clinically beneficial, generation of enough force for complete left ventricular contraction or relaxation is not necessary. Current clinically utilized devices and agents that result in mild augmentation of the contraction or relaxation process often improve symptoms significantly.

[0026] FIGS. 3 and 4 illustrate exemplary implantable magnets, according to an embodiment of the present invention. However, these exemplary magnets are not to be considered limiting, and it is expected that the electromagnets can be miniaturized to enable future versions for minimally invasive implantation. As illustrated in FIGS. 3 and 4, the magnets are embedded in a soft, biocompatible plastic material that allows the magnets to be sutured to the cardiac muscle of the heart and more particularly to the epicardial surface. The magnets need not be embedded in the plastic, and the embodiment illustrated in FIGS. 3 and

4 is simply an example of a device according to the present invention that is capable of being sutured to the epicardial surface. Further, FIG. 3illustrates an image of electromagnet (left) and a group of static magnet (right), and FIG. 4 illustrates an X-ray of the electromagnet (left) and the group of 4 static magnets right, also illustrated in FIG. 3.

[0027] Alternately, if the device is implanted using a minimally invasive approach such as demonstrated in FIG. 1, and described above, and is not secured to the cardiac muscle with sutures, the magnets cannot be utilized for the first few months. It typically takes 3 months before fibrotic tissue envelopes develop around the device leads, thus fully securing the components to the cardiac muscle. Activation of the magnets prior to fibrosis and endothelialization may lead to dislodgement. However, based upon lead extraction experience, after the first 3 months, the device will be secure enough to withstand the generated forces without dislodgement. Such a time limitation would not apply to endoscopic approaches for device placement by electrophysiologists or device placement by cardiac surgeons.

[0028] An additional element of the present invention is the power requirement for the device, which will likely require a driveline for continuous use. However, incorporation of inductive charging by utilization of an electromagnetic field to transfer energy to the subcutaneous generator can obviate the need for a driveline. In such a scenario, an induction coil would be utilized to create an alternating electromagnetic field from within a charging base station, and a second induction coil in the implanted generator to receive power from the electromagnetic field and convert it back into electrical current to charge the battery. Any other suitable means of powering the device known to or conceivable by one of skill in the art could also be used.

[0029] The many features and advantages of the invention are apparent from the detailed specification, and thus, it is intended by the appended claims to cover all such

features and advantages of the invention which fall within the true spirit and scope of the invention. Further, since numerous modifications and variations will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation illustrated and described, and accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the invention.

What is claimed is:

1. A device for providing magnetic assistance to a chamber of a heart comprising:

a first magnet positioned adjacent to a first wall of the chamber of the heart;

a second magnet positioned adjacent to a second wall of the chamber of the heart;

an electrode configured to sense electrical waves within the heart, said electrode being positioned within the chamber of the heart;

a generator coupled to the first magnet, the second magnet, and the electrode, wherein the generator is in conductive communication with the first magnet, the second magnet, and the electrode; and

wherein the first magnet and the second magnet are configured to attract during systole and repel during diastole in synchrony with a QRS wave of the heart.

2. The device of claim 1 wherein the generator further comprises a battery.

3. The device of claim 1 wherein the generator further comprises an external drive to provide power.

4. The device of claim 1 further comprising electrical leads connecting the generator to the first and second magnet and the electrode.

5. The device of claim 1 further comprising said first magnet comprising a static magnet and the second magnet comprising an electromagnet.

6. The device of claim 1further comprising said electrode comprising an electrode pair configured to sense a QRS wave produced by the heart.

7. The device of claim 6 wherein said electrode pair is further configured to produce a bipolar electrogram.

8. The device of claim 1 further comprising said first magnet and said second magnet are positioned on outer surfaces of opposing walls of the chamber of the heart.

9. The device of claim 1 further comprising said first magnet being positioned on an endocardium of a right ventricle of the heart.

10. The device of claim 1 further comprising said second magnet being positioned in a lateral branch of a coronary sinus.

11. The device of claim 1 wherein a magnitude and a direction of a current applied to the first and second magnets are synchronized to the QRS wave sensed by the electrode pair.

12. The device of claim 1 wherein the first magnet is disposed in a housing formed from a soft, biocompatible material, configured to be sutured to a surface of the heart.

13. The device of claim 12 wherein the soft, biocompatible material comprises a plastic.

14. The device of claim 1 wherein the second magnet is disposed in a housing formed from a soft, biocompatible material, configured to be sutured to a surface of the heart.

15. The device of claim 14 wherein the soft, biocompatible material comprises a plastic.

16. A method for providing magnetic assistance to a chamber of a heart comprising:

positioning a first magnet adjacent to a first wall of the chamber of the heart;

positioning a second magnet adjacent to a second wall of the chamber of the heart;

positioning an electrode within the chamber of the heart, wherein said electrode is configured to sense electrical waves within the heart;

coupling a generator to the first magnet, the second magnet, and the electrode, wherein the generator is in conductive communication with the first magnet, the second magnet and the electrode;

configuring the first magnet and the second magnet to attract during systole and repel during diastole in synchrony with a QRS wave of the heart.

17. The method of claim 16 further comprising suturing the first magnet to the first wall of the chamber of the heart.

18. The method of claim 16 further comprising suturing the second magnet to the second wall of the chamber of the heart.

19. The method of claim 16 further comprising positioning the first magnet in the right ventricle.

20. The method of claim 16 further comprising threading the second magnet to a left ventricular epicardial branch of a coronary sinus of the heart.

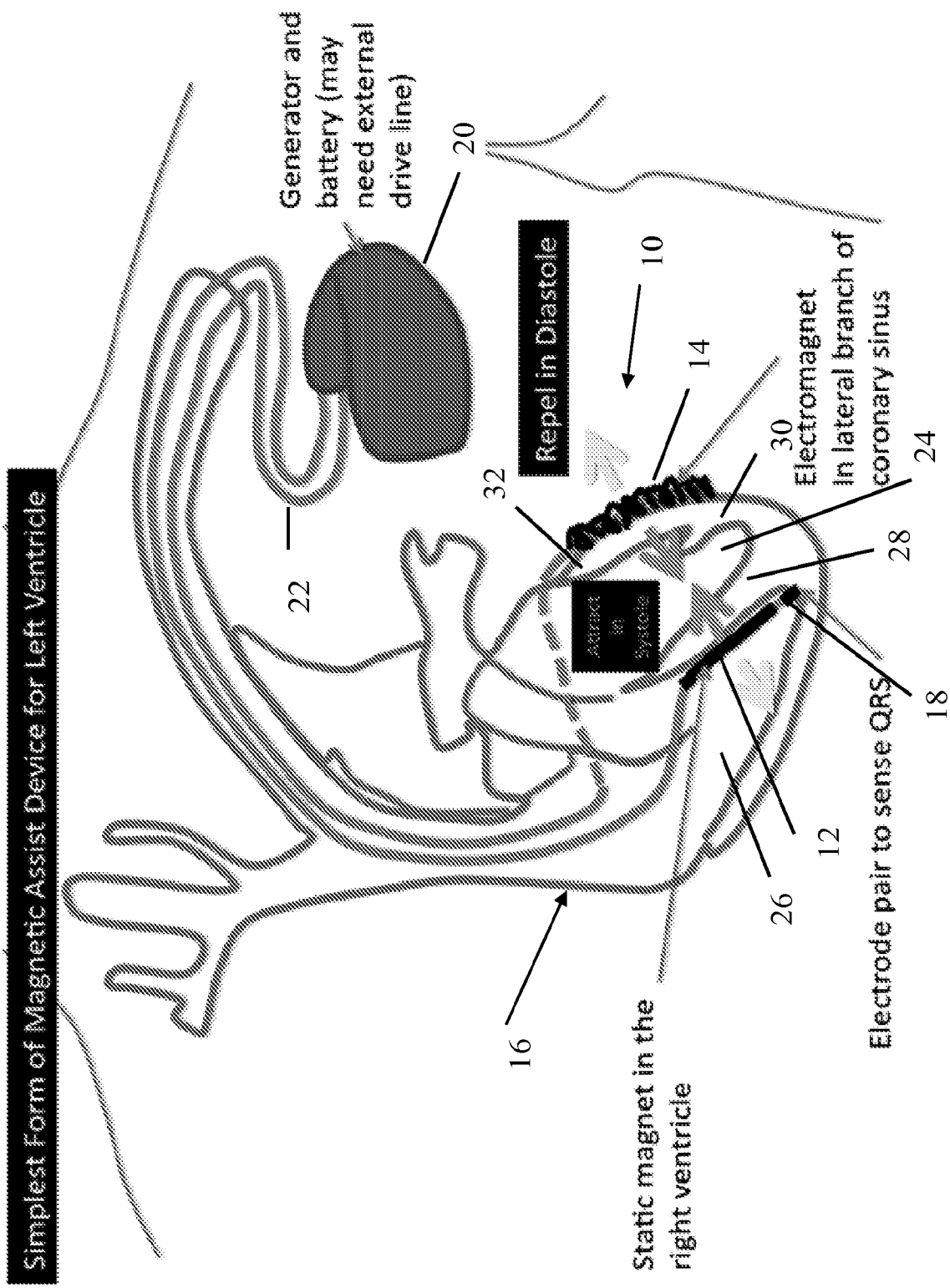
Simplest Form of Magnetic Assist Device for Left Ventricle
Generator and battery (may need external drive line)
20
22
Repel in Diastole
10
14
32
30
Electromagnet in lateral branch of coronary sinus
24
28
Attract in Systole
16
Static magnet in the right ventricle
26
12
Electrode pair to sense QRS
18

FIG. 1

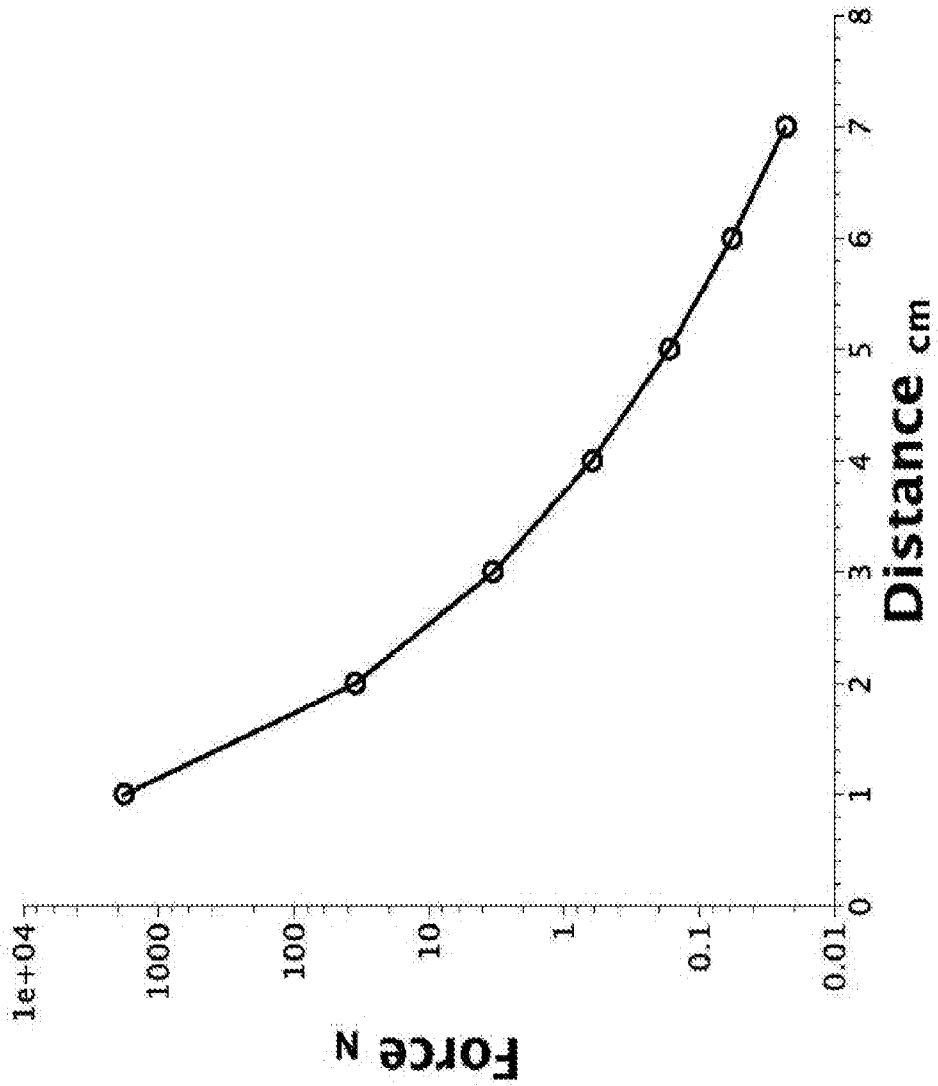

FIG. 2

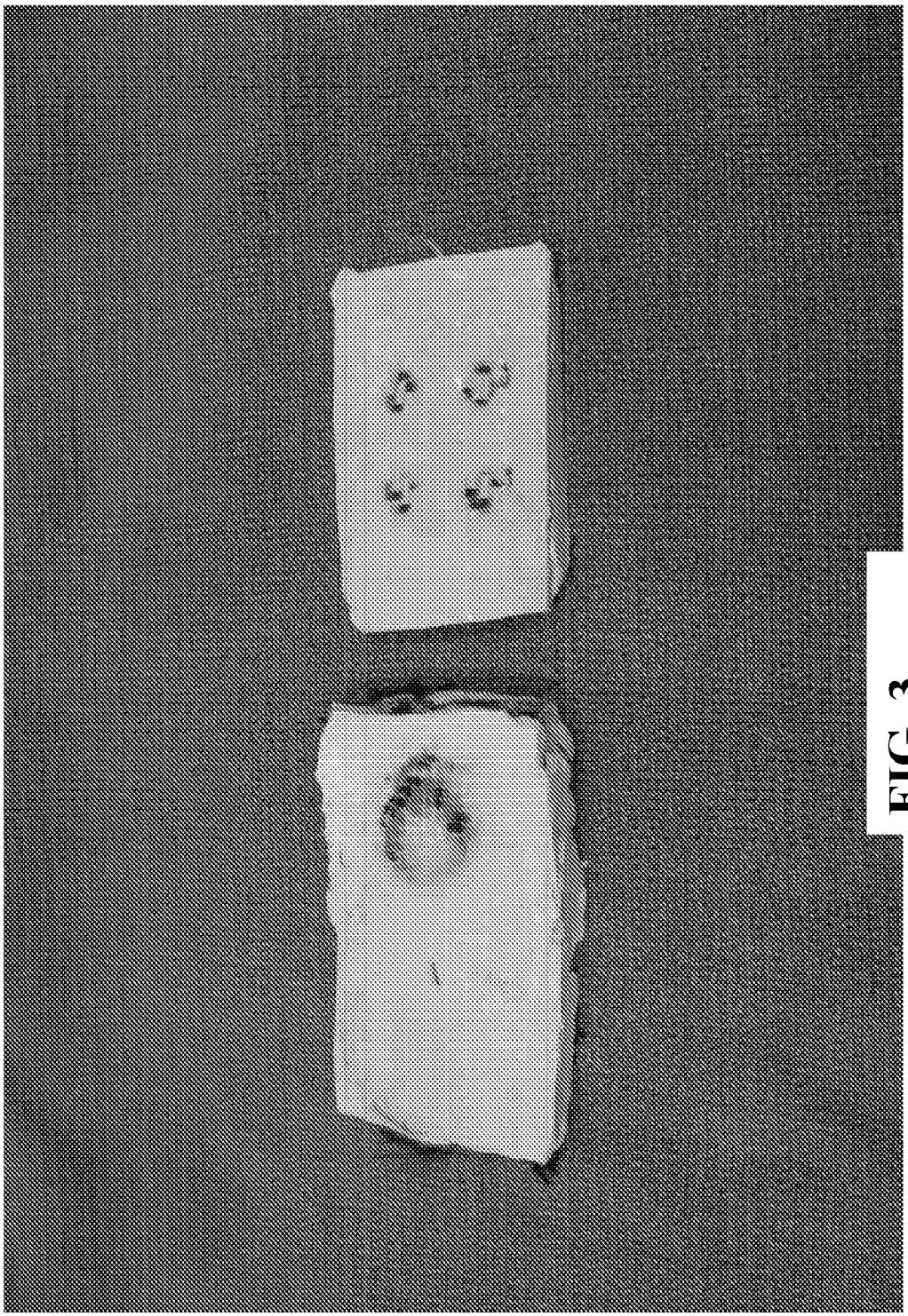

FIG. 3

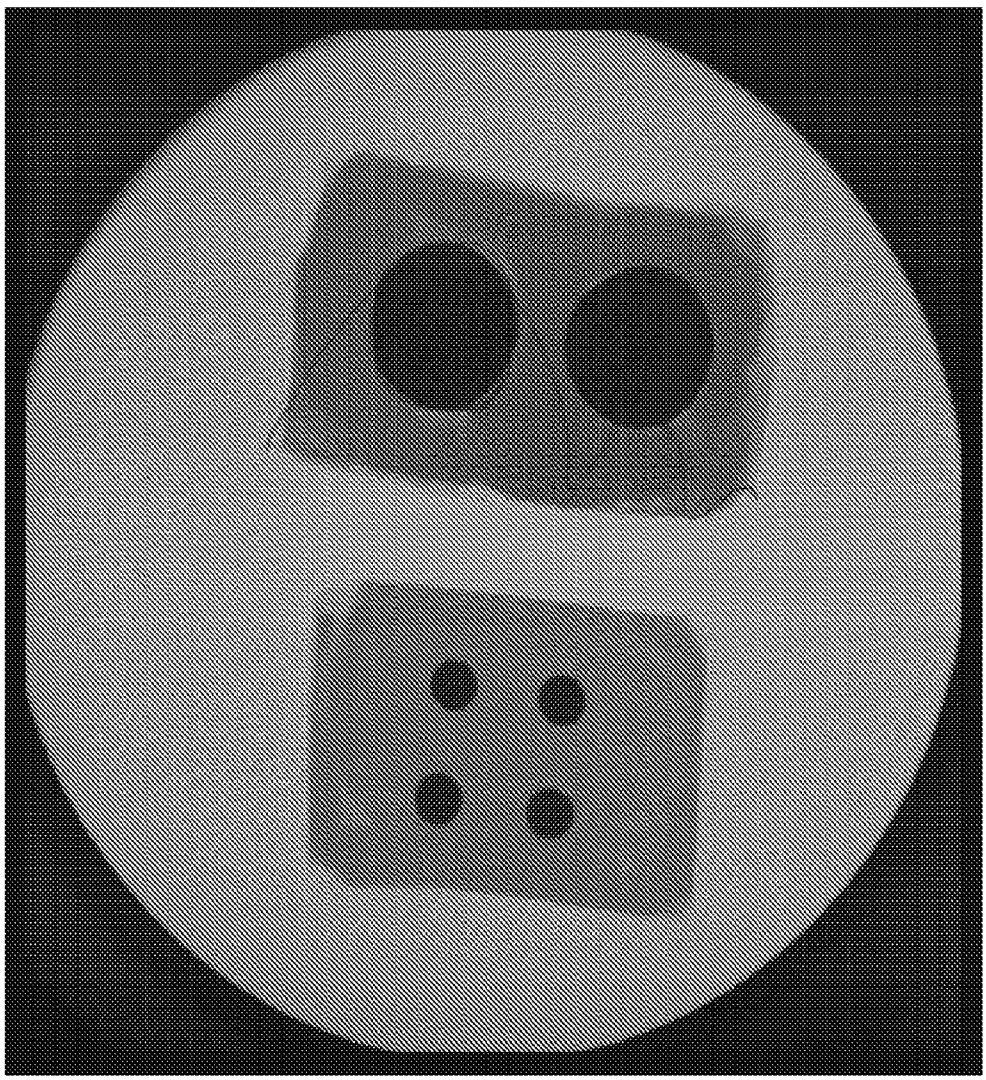

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/048859

A. CLASSIFICATION OF SUBJECT MATTER

A61N 1/39(2006.01)i, A61N 1/36(2006.01)i, A61N 1/04(2006.01)i

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)
A61N 1/39; A61N 1/362; A61M 1/12; A61N 1/368; A61N 1/00; A61N 1/365; A61N 1/04

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: magnetic assistance, heart, magnet, electrode, electrical wave, generator, synchrony, QRS wave

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6099460 A (DENKER, S.) 8 August 2000 See abstract; claims 1-20; figures 1-6.	1-15
Y	WO 2004-093986 A1 (MEDTRONIC, INC.) 4 November 2004 See abstract; claims 1-4; figures 1-2.	1-15
A	WO 2008-034005 A2 (BOSTON SCIENTIFIC SCIMED, INC.) 20 March 2008 See abstract; claims 1-23; figures 1-11.	1-15
A	US 2008-0319502 A1 (SUNAGAWA, K. et al.) 25 December 2008 See abstract; claim 14; figures 6-10.	1-15
A	US 2004-0116769 A1 (JASSAWALLA, J. S. et al.) 17 June 2004 See abstract; claim 1; figure 1A.	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family 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 application or patent 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 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	Date of mailing of the international search report
15 October 2013 (15.10.2013)	**16 October 2013 (16.10.2013)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/048859

Box No. 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.: 16-20
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 16-20 pertain to methods for treatment of the human and thus relate to a subject-matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

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 No. 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 addtional 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 and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/048859

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