US Patent & Trademark Office Patent Public Search | Text View

United States Patent

Kind Code

Date of Patent

Inventor(s)

12390654

B2

August 19, 2025

Abraham; Theodore P.

Pericardial implantable cardioverter defibrillator

Abstract

A pericardial implantable cardioverter defibrillator (ICD) may be delivered to the heart through the chest wall using an ultrasound image guided catheter. The ICD may comprise a patch and wire leads which may be secured by a clam shell-like pad at a distal end and comprise a pig-tail shaped securing tail at the other end so that the ICD is firmly attached to the pericardium of a human heart. The ICD may be attached where most needed and serve as either a pacemaker or a defibrillator. In one embodiment, the ICD may emit radio frequency warning signals of heart failure sensed when pacemaker or defibrillator usage is rendered necessary.

Inventors: Abraham; Theodore P. (San Francisco, CA)

Applicant: INNOSCION LLC (San Francisco, CA)

Family ID: 1000008764086

Assignee: INNOSCION LLC (San Francisco, CA)

Appl. No.: 17/308212

Filed: May 05, 2021

Prior Publication Data

Document IdentifierUS 20210260393 A1

Publication Date
Aug. 26, 2021

Related U.S. Application Data

continuation parent-doc US 16016189 20180622 US 11027141 child-doc US 17308212 continuation-in-part parent-doc US 15845756 20171218 US 10772600 20200915 child-doc US 16016189

continuation-in-part parent-doc US 14865151 20150925 US 9855021 20180102 child-doc US 15845756

us-provisional-application US 62590464 20171124

Publication Classification

Int. Cl.: A61B8/00 (20060101); A61B8/08 (20060101); A61B8/12 (20060101); A61B10/04 (20060101); A61N1/368 (20060101); A61N1/39 (20060101); A61N1/05 (20060101); A61N1/37 (20060101); A61N1/375 (20060101)

U.S. Cl.:

CPC **A61N1/3956** (20130101); **A61B8/0841** (20130101); **A61B8/12** (20130101); **A61B10/04**

(20130101); **A61N1/368** (20130101); A61N1/0502 (20130101); A61N1/0504 (20130101); A61N1/0587 (20130101); A61N1/3704 (20130101); A61N1/37512

(20170801); A61N1/3925 (20130101); A61N1/3975 (20130101)

Field of Classification Search

CPC: A61B (8/12); A61B (8/0841); A61N (1/3956); A61N (1/368); A61N (1/37512); A61N

(1/0504); A61N (1/3925); A61N (1/3975)

References Cited

U.S. PATENT DOCUMENTS

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
3556079	12/1970	Omizo	N/A	N/A
3612050	12/1970	Sheridan	N/A	N/A
4092867	12/1977	Matzuk	N/A	N/A
4327709	12/1981	Hanson et al.	N/A	N/A
4540411	12/1984	Bodicky	N/A	N/A
4581025	12/1985	Timmermans	N/A	N/A
4840613	12/1988	Balbierz	N/A	N/A
4849613	12/1988	Eisele	N/A	N/A
4869258	12/1988	Hetz	N/A	N/A
5011469	12/1990	Buckberg et al.	N/A	N/A
5068638	12/1990	Bickely et al.	N/A	N/A
5106368	12/1991	Uldall et al.	N/A	N/A
5159931	12/1991	Pini	N/A	N/A
5181514	12/1992	Solomon et al.	N/A	N/A
5437283	12/1994	Ranalletta et al.	N/A	N/A
5454373	12/1994	Koger et al.	N/A	N/A
5505088	12/1995	Chandraratna et al.	N/A	N/A
5509909	12/1995	Moy	N/A	N/A
5701901	12/1996	Lum et al.	N/A	N/A
5704361	12/1997	Seward et al.	N/A	N/A
5762066	12/1997	Aw et al.	N/A	N/A
5967984	12/1998	Chu et al.	N/A	N/A
5997497	12/1998	Nita et al.	N/A	N/A
6110121	12/1999	Lenker	N/A	N/A

162179 12/1999 Moore N/A N/A 16190353 12/2000 Makower et al. N/A N/A N/A 6236336 12/2000 Ouchi N/A N/A N/A 6248081 12/2000 Nishtalas et al. N/A N/A 6254573 12/2000 Haim et al. N/A N/A 6261234 12/2000 Lin N/A N/A 6360697 12/2000 Park et al. N/A N/A 6368280 12/2001 Cermak et al. N/A N/A 636319 12/2001 Cermak et al. N/A N/A 6572551 12/2002 Simkin et al. N/A N/A 6572551 12/2002 Simkin et al. N/A N/A 6582390 12/2002 Simkin et al. N/A N/A 6582390 12/2002 Simker et al. N/A N/A 6582390 12/2002 Sanderson N/A N/A 6592559 12/2002 Lenker N/A N/A 66896548 12/2003 Flaherty et al. N/A N/A 6689648 12/2003 Flaherty et al. N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A N/A 6726677 12/2004 Fonseca et al. N/A N/A N/A 6726677 12/2006 Lamson et al. N/A N/A N/A 7191015 12/2006 Lamson et al. N/A N/A N/A 7211054 12/2006 Francis et al. N/A N/A 73186655 12/2007 Garibotto et al. N/A N/A 7318806 12/2007 Garibotto et al. N/A N/A 7318806 12/2009 Saadat N/A N/A N/A 7482389 12/2008 Saorsa et al. N/A N/A N/A 74860556 12/2009 Saadat N/A N/A N/A 7480556 12/2009 Saadat N/A N/A N/A 74805656 12/2009 Saadat N/A N/A N/A 74805656 12/2009	6149598	12/1999	Tanaka	N/A	N/A
6190353 12/2000					
6238336 12/2000 Ouchi N/A N/A 6248081 12/2000 Nishtalas et al. N/A N/A 6254573 12/2000 Lin N/A N/A 6261234 12/2000 Lin N/A N/A 6306097 12/2001 Park et al. N/A N/A 6368280 12/2001 Ang et al. N/A N/A 6372551 12/2002 Smith et al. N/A N/A 6572558 12/2002 Smith et al. N/A N/A 6582550 12/2002 Sanderson N/A N/A 6592556 12/2002 Pakter et al. N/A N/A 6689062 12/2003 Flaherty et al. N/A N/A 6689062 12/2003 Flaherty et al. N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6726677 12/2004 Fonseca et al. N/A N/A 7191015 12/2006 Lamson et al.<					
6248081 12/2000 Nishtalas et al. N/A N/A 6254573 12/2000 Haim et al. N/A N/A 6362034 12/2000 Park et al. N/A N/A 6368280 12/2001 Cermak et al. N/A N/A 6376319 12/2002 Simkin et al. N/A N/A 6505088 12/2002 Simkin et al. N/A N/A 6572588 12/2002 Smith et al. N/A N/A 6572588 12/2002 Sanderson N/A N/A 6592550 12/2002 Lenker N/A N/A 6592551 12/2002 Pakter et al. N/A N/A 6685648 12/2003 Haberty et al. N/A N/A 6685648 12/2003 Haberty et al. N/A N/A 6726677 12/2003 Haberty et al. N/A N/A 6726677 12/2004 Fonseca et al. N/A N/A 7191015 12/2004					
6254573 12/2000					
6261234 12/2000 Lin N/A N/A 6306097 12/2001 Park et al. N/A N/A 6368280 12/2001 Ang et al. N/A N/A 6372519 12/2002 Simkin et al. N/A N/A 6505088 12/2002 Smith et al. N/A N/A 6572588 12/2002 Bierman et al. N/A N/A 6582390 12/2002 Sanderson N/A N/A 6592526 12/2002 Lenker N/A N/A 6592559 12/2002 Pakter et al. N/A N/A 6689648 12/2003 Flaherty et al. N/A N/A 6726677 12/2003 Mesallum N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7191015 12/2005 Stevens et al. N/A N/A 7191015 12/2006 Francis et al. N/A N/A 721054 12/2006 Francis et a					
6306097 12/2000 Park et al. N/A N/A 636280 12/2001 Cermak et al. N/A N/A 6376319 12/2002 Simkin et al. N/A N/A 6505088 12/2002 Smith et al. N/A N/A 6572581 12/2002 Bierman et al. N/A N/A 6582390 12/2002 Sanderson N/A N/A 659256 12/2002 Lenker N/A N/A 6592559 12/2002 Pakter et al. N/A N/A 6685648 12/2003 Halberty et al. N/A N/A 6685648 12/2003 Mesallum N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2005 Stevens et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7210634 12/2006 <t< td=""><td></td><td></td><td></td><td></td><td></td></t<>					
6368280 12/2001 Cermak et al. N/A N/A 6376319 12/2001 Ang et al. N/A N/A 6505088 12/2002 Simkin et al. N/A N/A 6572551 12/2002 Bierman et al. N/A N/A 6572588 12/2002 Bierman et al. N/A N/A 6582526 12/2002 Lenker N/A N/A 6692559 12/2002 Pakter et al. N/A N/A 6689648 12/2003 Flaherty et al. N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2005 Stevens et al. N/A N/A 7191015 12/2006 Francis et al. N/A N/A 721054 12/2006 Francis et al. N/A N/A 7270634 12/2006 Scampini et al. N/A N/A 7318806 12/2007 </td <td>6306097</td> <td>12/2000</td> <td>Park et al.</td> <td>N/A</td> <td></td>	6306097	12/2000	Park et al.	N/A	
6505088 12/2002 Simkin et al. N/A N/A 6572551 12/2002 Bierman et al. N/A N/A 6572588 12/2002 Bierman et al. N/A N/A 6592526 12/2002 Lenker N/A N/A 6592559 12/2002 Pakter et al. N/A N/A 6685648 12/2003 Flaherty et al. N/A N/A 6689062 12/2003 Flaherty et al. N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2005 Stevens et al. N/A N/A 711015 12/2006 Lamson et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7211054 12/2006 Scampini et al. N/A N/A 731806 12/20	6368280	12/2001	Cermak et al.	N/A	N/A
6505088 12/2002 Simkin et al. N/A N/A 6572551 12/2002 Bierman et al. N/A N/A 6572588 12/2002 Bierman et al. N/A N/A 6582390 12/2002 Lenker N/A N/A 6592526 12/2002 Pakter et al. N/A N/A 6685648 12/2003 Haberty et al. N/A N/A 6685648 12/2003 Hesallum N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2005 Stevens et al. N/A N/A 711015 12/2006 Francis et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 721065 12/2007 Garibotto et al. N/A N/A 731806 12/2007	6376319	12/2001	Ang et al.	N/A	N/A
6572588 12/2002 Bierman et al. N/A N/A 6582390 12/2002 Sanderson N/A N/A 6592526 12/2002 Lenker N/A N/A 6592559 12/2003 Flaherty et al. N/A N/A 6685648 12/2003 Flaherty et al. N/A N/A 6685670 12/2003 Mesallum N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7190614 12/2005 Stevens et al. N/A N/A 7191015 12/2006 Lamson et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7210634 12/2006 Francis et al. N/A N/A 7318806 12/2007 Garibotto et al. N/A N/A 748288 12/2008 Warren 600/509 A61B 5/283 7662089 12/2009 </td <td>6505088</td> <td>12/2002</td> <td>_</td> <td>N/A</td> <td>N/A</td>	6505088	12/2002	_	N/A	N/A
6582390 12/2002 Sanderson N/A N/A 6592526 12/2002 Lenker N/A N/A 6592559 12/2002 Pakter et al. N/A N/A 6685648 12/2003 Flaherty et al. N/A N/A 6689062 12/2003 Mesallum N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2005 Stevens et al. N/A N/A 710054 12/2006 Lamson et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7270634 12/2006 Furia N/A N/A 7318806 12/2007 Kohno N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7662089 12/2009 Waren 600/509 A61B 5/283 7662089 12/2009 Saadat </td <td>6572551</td> <td>12/2002</td> <td>Smith et al.</td> <td>N/A</td> <td>N/A</td>	6572551	12/2002	Smith et al.	N/A	N/A
6592526 12/2002 Lenker N/A N/A 6592559 12/2002 Pakter et al. N/A N/A 6685648 12/2003 Flaherty et al. N/A N/A 6689062 12/2003 Flaherty et al. N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2005 Stevens et al. N/A N/A 7191015 12/2006 Lamson et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7270634 12/2006 Francis et al. N/A N/A 7316655 12/2007 Garibotto et al. N/A N/A 7318806 12/2007 Kohno N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7662089 12/2009 Saadat N/A N/A 7860555 12/2009	6572588	12/2002	Bierman et al.	N/A	N/A
6592559 12/2002 Pakter et al. N/A N/A 6685648 12/2003 Flaherty et al. N/A N/A 6689062 12/2003 Mesallum N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2006 Lonson et al. N/A N/A 7191015 12/2006 Lonson et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 721054 12/2006 Francis et al. N/A N/A 7270634 12/2006 Scampini et al. N/A N/A 7318806 12/2007 Garibotto et al. N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7662089 12/2009 Okada et al. N/A N/A 7800556 12/2009 Brock et al. N/A N/A 8036622 12/201	6582390	12/2002	Sanderson	N/A	N/A
6685648 12/2003 Flaherty et al. N/A N/A 6689062 12/2003 Mesallum N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2006 Lamson et al. N/A N/A 710154 12/2006 Francis et al. N/A N/A 7241267 12/2006 Furia N/A N/A 7270634 12/2006 Scampini et al. N/A N/A 7316655 12/2007 Garibotto et al. N/A N/A 7318806 12/2007 Kohno N/A N/A 7488289 12/2008 Warren 600/509 A61B 5/283 7662080 12/2009 Okada et al. N/A N/A 7713190 12/2009 Saadat N/A N/A 7860556 12/2009 Saadat N/A N/A 8147414 12/2011 Abraham	6592526	12/2002	Lenker	N/A	N/A
6689062 12/2003 Mesallum N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2005 Stevens et al. N/A N/A 7191015 12/2006 Lamson et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7241267 12/2006 Furia N/A N/A 7270634 12/2006 Scampini et al. N/A N/A 7316655 12/2007 Garibotto et al. N/A N/A 7318806 12/2007 Kohno N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7662036 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860556 12/2009 Saadat N/A N/A 8147414 12/2011 Abrah	6592559	12/2002	Pakter et al.	N/A	N/A
6689062 12/2003 Mesallum N/A N/A 6726677 12/2003 Flaherty et al. N/A N/A 6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2005 Stevens et al. N/A N/A 7191015 12/2006 Lamson et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7241267 12/2006 Furia N/A N/A 7270634 12/2006 Scampini et al. N/A N/A 7316655 12/2007 Garibotto et al. N/A N/A 7318806 12/2007 Kohno N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7662036 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860556 12/2009 Saadat N/A N/A 8147414 12/2011 Abrah	6685648	12/2003	Flaherty et al.	N/A	N/A
6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2006 Stevens et al. N/A N/A 7191015 12/2006 Lamson et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7241267 12/2006 Furia N/A N/A 7270634 12/2006 Scampini et al. N/A N/A 7318806 12/2007 Garibotto et al. N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7627367 12/2008 Warren 600/509 A61B 5/283 7662089 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 803622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8199685 12/2011 Hwa	6689062	12/2003	=	N/A	N/A
6855115 12/2004 Fonseca et al. N/A N/A 7100614 12/2006 Stevens et al. N/A N/A 7191015 12/2006 Lamson et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7241267 12/2006 Furia N/A N/A 7270634 12/2006 Scampini et al. N/A N/A 7318806 12/2007 Garibotto et al. N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7627367 12/2008 Warren 600/509 A61B 5/283 7662089 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 803622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8199685 12/2011 Hwa	6726677	12/2003	Flaherty et al.	N/A	N/A
7191015 12/2006 Lamson et al. N/A N/A 7211054 12/2006 Francis et al. N/A N/A 7241267 12/2006 Furia N/A N/A 7270634 12/2006 Scampini et al. N/A N/A 7316655 12/2007 Garibotto et al. N/A N/A 7318806 12/2007 Kohno N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7662089 12/2009 Okada et al. N/A N/A 7662089 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 7860556 12/2009 Saadat N/A N/A 8036622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8199685 12/2011 Abraham N/A N/A 8403859 12/2011 Abraham N/A<	6855115	12/2004	_	N/A	N/A
7211054 12/2006 Francis et al. N/A N/A 7241267 12/2006 Furia N/A N/A 7270634 12/2006 Scampini et al. N/A N/A 7316655 12/2007 Garibotto et al. N/A N/A 7318806 12/2008 Suorsa et al. N/A N/A 7488289 12/2008 Warren 600/509 A61B 5/283 7662089 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 7860556 12/2009 Saadat N/A N/A 8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8199685 12/2011 Hwang N/A N/A 8403858 12/2011 Abraham N/A N/A 8403859 12/2012 Abraham	7100614	12/2005	Stevens et al.	N/A	N/A
7241267 12/2006 Furia N/A N/A 7270634 12/2006 Scampini et al. N/A N/A 7316655 12/2007 Garibotto et al. N/A N/A 7318806 12/2007 Kohno N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7627367 12/2008 Warren 600/509 A61B 5/283 7662089 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 8235903 12/2011 Abraham N/A N/A 8403858 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A <td>7191015</td> <td>12/2006</td> <td>Lamson et al.</td> <td>N/A</td> <td>N/A</td>	7191015	12/2006	Lamson et al.	N/A	N/A
7270634 12/2006 Scampini et al. N/A N/A 7316655 12/2007 Garibotto et al. N/A N/A 7318806 12/2007 Kohno N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7627367 12/2008 Warren 600/509 A61B 5/283 7662089 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 8235903 12/2011 Hwang N/A N/A 8403858 12/2012 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149257 12/2014 Steffen N/A <td>7211054</td> <td>12/2006</td> <td>Francis et al.</td> <td>N/A</td> <td>N/A</td>	7211054	12/2006	Francis et al.	N/A	N/A
7316655 12/2007 Garibotto et al. N/A N/A 7318806 12/2007 Kohno N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7627367 12/2008 Warren 600/509 A61B 5/283 7662089 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 8199685 12/2011 Hwang N/A N/A 8403858 12/2011 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A N/A 9149257 12/2001 Haddock N/A	7241267	12/2006	Furia	N/A	N/A
7316655 12/2007 Garibotto et al. N/A N/A 7318806 12/2007 Kohno N/A N/A 7488289 12/2008 Suorsa et al. N/A N/A 7627367 12/2008 Warren 600/509 A61B 5/283 7662089 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 8199685 12/2011 Hwang N/A N/A 8403858 12/2011 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149257 12/2014 Abraham N/A N/A 902/0077568 12/2001 Haddock N/A	7270634	12/2006	Scampini et al.	N/A	N/A
7488289 12/2008 Suorsa et al. N/A N/A 7627367 12/2008 Warren 600/509 A61B 5/283 7662089 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 81499685 12/2011 Hwang N/A N/A 8403858 12/2011 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A N/A 9149257 12/2014 Abraham N/A N/A 2002/0077568 12/2001 Haddock N/A N/A 2003/0139677 12/2002 Fonseca et al. N/A	7316655	12/2007		N/A	N/A
7627367 12/2008 Warren 600/509 A61B 5/283 7662089 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 81499685 12/2011 Hwang N/A N/A 8403858 12/2012 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A N/A 9149257 12/2014 Abraham N/A N/A 2002/0077568 12/2001 Haddock N/A N/A 2002/0123698 12/2001 Garibotto et al. N/A N/A 2003/0199767 12/2002 Cespedes et al.	7318806	12/2007	Kohno	N/A	N/A
7662089 12/2009 Okada et al. N/A N/A 7713190 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 7860556 12/2009 Saadat N/A N/A 8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 8147414 12/2011 Hwang N/A N/A 8199685 12/2011 Hwang N/A N/A 8235903 12/2011 Abraham N/A N/A 8403858 12/2012 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A N/A 9149257 12/2014 Abraham N/A N/A 2002/0077568 12/2001 Haddock N/A N/A <	7488289	12/2008	Suorsa et al.	N/A	N/A
7713190 12/2009 Brock et al. N/A N/A 7860555 12/2009 Saadat N/A N/A 7860556 12/2009 Saadat N/A N/A 8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 8199685 12/2011 Hwang N/A N/A 8235903 12/2011 Abraham N/A N/A 8403858 12/2012 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A N/A 9149257 12/2014 Abraham N/A N/A 2001/0023323 12/2001 Haddock N/A N/A 2002/0077568 12/2001 Garibotto et al. N/A N/A 2003/0139677 12/2002 Fonseca et al. N/A	7627367	12/2008	Warren	600/509	A61B 5/283
7860555 12/2009 Saadat N/A N/A 7860556 12/2009 Saadat N/A N/A 8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 8199685 12/2011 Hwang N/A N/A 8235903 12/2011 Abraham N/A N/A 8403858 12/2012 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A N/A 9149257 12/2014 Abraham N/A N/A 2001/0023323 12/2001 Haddock N/A N/A 2002/0077568 12/2001 Garibotto et al. N/A N/A 2003/0139677 12/2002 Fonseca et al. N/A N/A 2003/029286 12/2002 Lenker N/A	7662089	12/2009	Okada et al.	N/A	N/A
7860556 12/2009 Saadat N/A N/A 8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 8199685 12/2011 Hwang N/A N/A 8235903 12/2011 Abraham N/A N/A 8403858 12/2012 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A N/A 9149257 12/2014 Abraham N/A N/A 2001/0023323 12/2000 Nishtala et al. N/A N/A 2002/0077568 12/2001 Garibotto et al. N/A N/A 2003/013698 12/2001 Garibotto et al. N/A N/A 2003/0199767 12/2002 Cespedes et al. N/A N/A 2003/0229286 12/2002 Lenker	7713190	12/2009	Brock et al.	N/A	N/A
8038622 12/2010 Abraham N/A N/A 8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 8199685 12/2011 Hwang N/A N/A 8235903 12/2011 Abraham N/A N/A 8403858 12/2012 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A N/A 9149257 12/2014 Abraham N/A N/A 2001/0023323 12/2000 Nishtala et al. N/A N/A 2002/0077568 12/2001 Haddock N/A N/A 2003/0139677 12/2002 Fonseca et al. N/A N/A 2003/029286 12/2002 Cespedes et al. N/A N/A 2003/0233129 12/2002 Lenker N/A N/A 2003/0233129 12/2002 Matos 607/5 A61N 1/0476	7860555	12/2009	Saadat	N/A	N/A
8147413 12/2011 Abraham N/A N/A 8147414 12/2011 Abraham N/A N/A 8199685 12/2011 Hwang N/A N/A 8235903 12/2011 Abraham N/A N/A 8403858 12/2012 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A N/A 9149257 12/2014 Abraham N/A N/A 2001/0023323 12/2000 Nishtala et al. N/A N/A 2002/0077568 12/2001 Haddock N/A N/A 2003/0139677 12/2002 Fonseca et al. N/A N/A 2003/0199767 12/2002 Cespedes et al. N/A N/A 2003/0229286 12/2002 Lenker N/A N/A 2003/0233129 12/2002 Matos 607/5 A61N 1/0476	7860556	12/2009	Saadat	N/A	N/A
8147414 12/2011 Abraham N/A N/A 8199685 12/2011 Hwang N/A N/A 8235903 12/2011 Abraham N/A N/A 8403858 12/2012 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A N/A 9149257 12/2014 Abraham N/A N/A 2001/0023323 12/2000 Nishtala et al. N/A N/A 2002/0077568 12/2001 Haddock N/A N/A 2002/0123698 12/2001 Garibotto et al. N/A N/A 2003/0139677 12/2002 Fonseca et al. N/A N/A 2003/029286 12/2002 Cespedes et al. N/A N/A 2003/0233129 12/2002 Lenker N/A N/A 2003/0233129 12/2002 Matos 607/5 A61N 1/0476	8038622	12/2010	Abraham	N/A	N/A
819968512/2011HwangN/AN/A823590312/2011AbrahamN/AN/A840385812/2012AbrahamN/AN/A840385912/2012AbrahamN/AN/A914925112/2014SteffenN/AN/A914925712/2014AbrahamN/AN/A2001/002332312/2000Nishtala et al.N/AN/A2002/007756812/2001HaddockN/AN/A2002/012369812/2001Garibotto et al.N/AN/A2003/013967712/2002Fonseca et al.N/AN/A2003/019976712/2002Cespedes et al.N/AN/A2003/022928612/2002LenkerN/AN/A2003/023312912/2002Matos607/5A61N 1/0476	8147413	12/2011	Abraham	N/A	N/A
8235903 12/2011 Abraham N/A N/A 8403858 12/2012 Abraham N/A N/A 8403859 12/2012 Abraham N/A N/A 9149251 12/2014 Steffen N/A N/A 9149257 12/2014 Abraham N/A N/A 2001/0023323 12/2000 Nishtala et al. N/A N/A 2002/0077568 12/2001 Haddock N/A N/A 2002/0123698 12/2001 Garibotto et al. N/A N/A 2003/0139677 12/2002 Fonseca et al. N/A N/A 2003/029286 12/2002 Cespedes et al. N/A N/A 2003/0233129 12/2002 Matos 607/5 A61N 1/0476	8147414	12/2011	Abraham	N/A	N/A
840385812/2012AbrahamN/AN/A840385912/2012AbrahamN/AN/A914925112/2014SteffenN/AN/A914925712/2014AbrahamN/AN/A2001/002332312/2000Nishtala et al.N/AN/A2002/007756812/2001HaddockN/AN/A2002/012369812/2001Garibotto et al.N/AN/A2003/013967712/2002Fonseca et al.N/AN/A2003/019976712/2002Cespedes et al.N/AN/A2003/022928612/2002LenkerN/AN/A2003/023312912/2002Matos607/5A61N 1/0476	8199685	12/2011	9	N/A	N/A
840385912/2012AbrahamN/AN/A914925112/2014SteffenN/AN/A914925712/2014AbrahamN/AN/A2001/002332312/2000Nishtala et al.N/AN/A2002/007756812/2001HaddockN/AN/A2002/012369812/2001Garibotto et al.N/AN/A2003/013967712/2002Fonseca et al.N/AN/A2003/019976712/2002Cespedes et al.N/AN/A2003/022928612/2002LenkerN/AN/A2003/023312912/2002Matos607/5A61N 1/0476	8235903	12/2011	Abraham	N/A	N/A
914925112/2014SteffenN/AN/A914925712/2014AbrahamN/AN/A2001/002332312/2000Nishtala et al.N/AN/A2002/007756812/2001HaddockN/AN/A2002/012369812/2001Garibotto et al.N/AN/A2003/013967712/2002Fonseca et al.N/AN/A2003/019976712/2002Cespedes et al.N/AN/A2003/022928612/2002LenkerN/AN/A2003/023312912/2002Matos607/5A61N 1/0476	8403858	12/2012	Abraham	N/A	N/A
9149257 12/2014 Abraham N/A N/A 2001/0023323 12/2000 Nishtala et al. N/A N/A 2002/0077568 12/2001 Haddock N/A N/A 2002/0123698 12/2001 Garibotto et al. N/A N/A 2003/0139677 12/2002 Fonseca et al. N/A N/A 2003/0199767 12/2002 Cespedes et al. N/A N/A 2003/0229286 12/2002 Lenker N/A N/A 2003/0233129 12/2002 Matos 607/5 A61N 1/0476	8403859	12/2012	Abraham	N/A	N/A
2001/0023323 12/2000 Nishtala et al. N/A N/A 2002/0077568 12/2001 Haddock N/A N/A 2002/0123698 12/2001 Garibotto et al. N/A N/A 2003/0139677 12/2002 Fonseca et al. N/A N/A 2003/0199767 12/2002 Cespedes et al. N/A N/A 2003/0229286 12/2002 Lenker N/A N/A 2003/0233129 12/2002 Matos 607/5 A61N 1/0476	9149251	12/2014	Steffen	N/A	N/A
2002/0077568 12/2001 Haddock N/A N/A 2002/0123698 12/2001 Garibotto et al. N/A N/A 2003/0139677 12/2002 Fonseca et al. N/A N/A 2003/0199767 12/2002 Cespedes et al. N/A N/A 2003/0229286 12/2002 Lenker N/A N/A 2003/0233129 12/2002 Matos 607/5 A61N 1/0476	9149257	12/2014	Abraham	N/A	N/A
2002/0123698 12/2001 Garibotto et al. N/A N/A 2003/0139677 12/2002 Fonseca et al. N/A N/A 2003/0199767 12/2002 Cespedes et al. N/A N/A 2003/0229286 12/2002 Lenker N/A N/A 2003/0233129 12/2002 Matos 607/5 A61N 1/0476	2001/0023323		Nishtala et al.	N/A	N/A
2003/0139677 12/2002 Fonseca et al. N/A N/A 2003/0199767 12/2002 Cespedes et al. N/A N/A 2003/0229286 12/2002 Lenker N/A N/A 2003/0233129 12/2002 Matos 607/5 A61N 1/0476	2002/0077568	12/2001	Haddock	N/A	N/A
2003/0199767 12/2002 Cespedes et al. N/A N/A 2003/0229286 12/2002 Lenker N/A N/A 2003/0233129 12/2002 Matos 607/5 A61N 1/0476	2002/0123698	12/2001	Garibotto et al.	N/A	N/A
2003/0229286 12/2002 Lenker N/A N/A 2003/0233129 12/2002 Matos 607/5 A61N 1/0476	2003/0139677	12/2002	Fonseca et al.	N/A	N/A
2003/0233129 12/2002 Matos 607/5 A61N 1/0476		12/2002	Cespedes et al.	N/A	N/A
	2003/0229286	12/2002	Lenker		N/A
2004/0015193 12/2003 Lamson et al. N/A N/A		12/2002	Matos	607/5	A61N 1/0476
· · · · · · · · · · · · · · · · · · ·	2004/0015193	12/2003	Lamson et al.	N/A	N/A

2004/0102804	12/2003	Chin	N/A	N/A
2004/0138526	12/2003	Guenst	N/A	N/A
2005/0090709	12/2004	Okada et al.	N/A	N/A
2005/0096642	12/2004	Appling et al.	N/A	N/A
2005/0143664	12/2004	Chen et al.	N/A	N/A
2006/0058738	12/2005	Ponzi et al.	N/A	N/A
2006/0106315	12/2005	Edens	N/A	N/A
2007/0293724	12/2006	Saadat et al.	N/A	N/A
2008/0171993	12/2007	Beran	N/A	N/A
2008/0183080	12/2007	Abraham	N/A	N/A
2009/0088648	12/2008	Jaffe et al.	N/A	N/A
2009/0299447	12/2008	Jensen	607/130	A61N 1/0587
2011/0213459	12/2010	Garrison et al.	N/A	N/A
2012/0197205	12/2011	Peters	N/A	N/A
2016/0008165	12/2015	Baelden et al.	N/A	N/A

FOREIGN PATENT DOCUMENTS

Patent No.	Application Date	Country	CPC
2376103	12/2000	CA	N/A
19939791	12/2000	DE	N/A

OTHER PUBLICATIONS

Int Search Report and Written Op mailed May 4, 2021, for Int Application No. PCT/US2021/12132, filed Jan. 5, 2021 (11 pages). cited by applicant Non-Final Office Action issued in U.S. Appl. No. 16/247,046, date of mailing: Sep. 18, 2020 (18 pages). cited by applicant

Primary Examiner: Brutus; Joel F

Attorney, Agent or Firm: Brown Rudnick LLP

Background/Summary

(1) This application is a continuation of U.S. patent application Ser. No. 16/016,189, filed Jun. 22, 2018, which is a continuation-in-part of U.S. patent application Ser. No. 15/845,756 filed Dec. 18, 2018, which is a continuation-in-part of U.S. patent application Ser. No. 14/865,151 filed Sep. 25, 2015 by the same inventor (now U.S. Pat. No. 9,855,021 issued Jan. 18, 2018) and U.S. patent application Ser. No. 15/845,756 claims the right of priority to U.S. Provisional Patent Application Ser. No. 62/526,170 filed Jun. 28, 2017, U.S. Provisional Patent Application Ser. No. 62/527,865 filed Jun. 30, 2017, and U.S. Provisional Patent Application Ser. No. 62/590,464 filed Nov. 24, 2017

TECHNICAL FIELD

(1) The present invention relates generally to medical devices and, more particularly, to a device that functions as a pacemaker and/or an implantable cardioverter defibrillator for detecting heart arrhythmias and regularizing heart rhythm.

BACKGROUND OF THE INVENTION

(2) Over 450,000 individuals die suddenly every year in the United States before they can get to a hospital or in the emergency room. Even if rescued by Cardio Pulmonary Resuscitation (CPR) in the field, survival rates are about 3% if there is more than a few minutes delay in starting CPR after

the patient collapses. An implantable cardioverter defibrillator (ICD) has been life-saving in millions of patients since it detects potentially life-threatening heart rhythms and delivers an electric shock to the heart to regularize the rhythm. Modem ICDs also function as pacemakers.

- (3) Cardioversion and defibrillation both refer to the administration of an electric shock to the heart to treat arrhythmias. Cardioversion refers to a shock that is synchronized to a specific moment of the cardiac cycle. Cardioversion is used to normalize an irregular heart rate that occurs with atrial flutter, atrial fibrillation or ventricular tachycardia with pulse. Defibrillation, on the other hand, refers to a high-energy electric shock that may be administered at any time and is not synchronized to the heart's rhythm. Defibrillation is typically administered as an emergency resuscitative procedure to restore a normal heartbeat in cases of cardiac arrest, pulseless ventricular tachycardia, or ventricular fibrillation.
- (4) Early ICDs were placed surgically in the abdomen with wires attached to the epicardium, or on the surface of the heart. Other types of ICDs were placed under the skin below the clavicle with wires inserted through the subclavian vein into the right side of the heart in the right ventricle.
- (5) Early ICDs were associated with several risks. When ICDs are placed in the blood stream and attached to the heart muscle there are concerns about infection, clot formation and wire fracture. Long-term wires adhere to blood vessels, so removing them for complications is challenging and high-risk.
- (6) More recently, new devices are placed under the armpit (sub-axillary) with wires only running below the skin. Wireless ICD devices (Nanostim) are small capsules placed in the ventricle.
- (7) Wired internal devices have risk of blood clots, blood stream infection and wire fracture. They are longer lasting and can pace the heart.
- (8) Sub-cutaneous devices do not have any wires going into the heart so there is no chance of clot, blood stream infection or wire fracture. However, they are larger, shorter shelf life, cannot pace the heart, and need to deliver a larger shock when needed.
- (9) Certain new small devices are placed inside the ventricle of the heart. Internal nano devices are placed inside the heart but they lack wires, so there is no chance of clots, blood stream infection, or wire fracture while the device is in place. However, since the device is inside the heart, if there are problems with the device and the device must be removed, there is a small chance of clots, malfunction and difficulty removing the device.
- (10) The present invention has several advantages over existing ICDs. The present invention is a relatively small device because its battery needs are closer to older versions of ICDs. Because the device is implanted close to the heart, it requires less energy for cardioversion (electrically converting the heart rhythm to normal). The device does not go through the blood stream, so there is no chance of blood clots or infection. The electrode patches may be placed at any location on the heart that needs to be monitored. So, the device can pace either the right or left ventricle and it can defibrillate the ventricles or the atria. The wire moves minimally on the pericardium, so there is little to no chance of wire fracture. The device is easier to remove than existing ICDs. The device is fully deployed using an image guided catheter-based delivery system, so there is minimal or no use of X-rays for implanting the device. This is an advantage because of lower costs and less radiation exposure to the patient and the surgeon.

SUMMARY OF THE INVENTION

- (11) The present invention is an implantable cardioverter-defibrillator (ICD) and/or pacemaker that monitors the heart rhythm via electrodes, detects abnormalities, and delivers pacing, cardioversion, and/or defibrillation when appropriate. The device may also comprise additional diagnostic technologies, such as ultrasound to detect fluid, biochemistry diagnostics such as, for example, Raman spectroscopy, and/or a mechanism for detecting ST elevation for early detection of a myocardial infarction.
- (12) The proposed invention includes a multi-component/multi-device platform that will provide a single, integrated platform for delivery of the ICD into the heart with real-time ultrasound and other

image guidance. In an image-guided catheter such as represented by U.S. Pat. No. 9,149,257 entitled "Image Guided Catheters and Methods of Use" issued Oct. 6, 2015 (the '257 patent) by the same inventor, per FIG. 3A, an ultrasound beam generated by a transducer element 210 of an ultrasound imaging channel **214** provides a cone-shaped imaging zone **301** which can display a needle **208** or guide wire or sheath or other tool extending from the distal (patient) end or provide device delivery and be directed parallel to the ultrasound beam and may be located within a sheath or lumen or plurality of lumens. (The '257 patent should be deemed to be incorporated by reference as to its entire contents). On the other hand, the needle **208**, a guide wire, sheath, delivery system for a filter or a prosthesis or tool being deployed parallel to the cone-shaped ultrasonic beam imaging zone **301**, may be difficult to see in the imaging zone **301** because the needle, guide wire, sheath or lumen is very thin in diameter, may comprise a smooth surface, and may extend in the same direction as the ultrasound beam is projected (parallel to the sonic beam) from the thin, minimally invasive image-guided catheter limiting the amount of desired ultrasound echo. This can be improved by providing echogenicity by sanding, engraving or otherwise causing ultrasound beams to be reflected back to the source so that the sonic beam will tend to follow the angles of impingement and reflection and are intended to project from the needle, sheath or tool in a direction deeper into, for example, a human body in which the image guided catheter of FIG. 3A is inserted and so may be captured by surface-mounted or implanted ultrasound transducers. The image guided catheter may be inserted by directing an introducer needle through the skin surface and guides the image guided catheter under ultrasound vision to site of interest. Ultrasound waves may be echoed or returned to the ultrasound transducer source or scattered toward the human body surface. Also, it is desirable to visualize the needle, sheath or tool itself (via echogenicity) to determine the direction of its movement within the human body from the point of entry of the human body to an area of interest such as the human heart. In one embodiment, the needle or sheath may be hollow (in another, solid) and may be removed or moved forward via a lumen extending the length of the catheter once the catheter is located at a site of interest and may be replaced in real time with a guide wire or tool such as a micromechanical motor system (MEMS). In another embodiment, the tool may be used simultaneously (in its own lumen) with the needle or sheath to bend or guide the needle, guide wire or sheath to the region of interest from a patient's skin surface.

- (13) The following additional U.S. Patents and published applications of Dr. Theodore Abraham should be deemed to be incorporated by reference as to their entire subject matter and refer to similar image guided catheters, implanted ultrasound devices, wired or wireless ultrasound devices and the like which may receive signals from echogenic needles, sheaths or tools and surrounding human tissue or blood or other fluids of interest at a site of interest for a minimally invasive surgical procedure: U.S. Pat. No. 8,038,622 issued Oct. 18, 2011: U.S. Pat. Nos. 8,147,413 and 8,147,414, issued Apr. 13, 2012: U.S. Pat. Nos. 8,403,858 and 8,403,859 issued Mar. 26, 2013, and U.S. 2016/008,1658 published Mar. 24, 2016. Most recently, U.S. Ser. No. 15/636,328 entitled "Image Guided Catheters and Methods of Use" was filed by the present inventor on Jun. 28, 2017 and U.S. Provisional Patent Application Ser. No. 62/526,170) entitled "Echogenic Needle, Sheath or Tool" was filed by the present inventor also on Jun. 28, 2017.
- (14) The device of the present invention is deployed into the body through the skin using an image guided catheter-based delivery system. The device is attached to either the inside lining or the outside lining of the pericardium. The device can pace the heart's rhythm from either the pericardium or the outside of the heart muscle (epicardium) through a wire attached to the epicardium. It may also function as a defibrillator by delivering an electric shock to the heart to treat life-threatening dysrhythmia.
- (15) The ICD/pacemaker of the present invention comprises a wire with one or two coils implanted on the pericardium. At least coil is required for the pacemaker function, while at least two coils are required for defibrillation and cardioversion. The coils function as electric conductors for

delivering shocks to the heart. The defibrillation and cardioversion functions of the device are administered by transmitting an electric shock between two coils. The coils also detect electrical energy corresponding to the heart's rhythm and transmit the reading to a microprocessor implanted between the patient's ribs. The microprocessor uses algorithms to detect whether the patient is experiencing a life-threatening arrhythmia. If so, the microprocessor will generate a rhythm for the pacemaker or a signal for the coils to deliver an electric shock to the heart. In a single-coil embodiment of the present invention, one coil is delivered to the pericardium and the microprocessor serves as a second coil.

- (16) Coils may be in the form of exposed coiled wire, or in the form of coiled wire embedded inside a patch or wafer comprising a flat piece of metal or plastic. The patch may be a round, square, or rectangular shape.
- (17) The wire and coils of the present invention are delivered to the pericardium by an image-guided catheter. The coils, a pericardial pad, and a chest wall pad are pre-loaded and pre-crimped inside of a curved delivery needle, and each component is deployed when the needle is withdrawn out of the body over the wire.
- (18) In one embodiment of the present invention, the coils are placed on the visceral (inner) surface of the pericardium. In an alternative embodiment, the coils are placed on the parietal (outer) surface of the pericardium.
- (19) To implant the device, an image-guided catheter is inserted through the chest wall and then through pericardium into the pericardial cavity. Then, the delivery needle is advanced into the pericardial cavity through the image-guided catheter. The curved delivery needle is further advanced out of the pericardium at a second site, creating a pathway for the coils to be deployed inside the pericardial cavity.
- (20) The delivery needle is then slowly withdrawn back through the catheter, leaving a retention mechanism outside the pericardium. When the needle is withdrawn completely out of the pericardium, the wire remains in place and the coil/patch expands inside of the pericardial cavity. Then, the catheter is withdrawn from the pericardial cavity and the wire is pulled to place the coil immediately adjacent to the inner surface of the pericardium. A pericardial pad is deployed outside of the pericardium to maintain the tension on the wire and keep the coil in close contact with the inner surface of the pericardium.
- (21) The needle and the catheter are then withdrawn out of the chest wall, the wire extends out from the chest wall and a pad is deployed outside the chest wall. After exiting the chest wall, the wire with a proximal connector at its end is exposed. The proximal connector plugs into the microprocessor, which in turn receives signals from the coils, and generates a pulse rhythm for the pacemaker function of the device or electric shocks for the defibrillation/cardioversion function. The microprocessor is implanted subcutaneously (under the skin) between the patient's ribs. The microprocessor is powered by a lithium battery, and also detects when the battery is low. (22) When the device is deployed in the body, the coils are placed near the areas of the heart where the particular patient has problems to monitor those areas. Typically, problems with the ventricles are most likely to be life-threatening, so coils would be deployed near the ventricles to detect any irregular cardiac rhythm in the ventricles. However, some patients have atrial problems. For those patients, the coils would be deployed near the atria.

Description

BRIEF DESCRIPTION OF THE DRAWING

(1) FIG. **1**A, FIG. **1**B, and FIG. **1**C depict the harness, wire, and coil/patch of the present invention. FIG. **1**A depicts a round patch, FIG. **1**B depicts a square patch, and FIG. **1**C depicts a rectangular patch.

- (2) FIG. 2A, FIG. 2B, FIG. 2C, and FIG. 2D show deployment of a patch and wire inside the pericardium via an image-guided catheter and a delivery needle.
- (3) FIG. **2**A depicts an image guided catheter (also referred to herein as a PeriPort) placed through the pericardium at a first site, with a curved deliver needle extending into the pericardial cavity and out of the pericardium through a second site, and a retaining portion of the wire extending out from the delivery needle.
- (4) FIG. **2**B depicts the delivery needle being withdrawn into the pericardial cavity out of the second site in the pericardium, deploying the retaining portion and the wire.
- (5) FIG. **2**C depicts the delivery needle further withdrawn to deploy the coil or patch, which was pre-crimped and pre-loaded on the delivery needle.
- (6) FIG. **2**D depicts the delivery needle and the catheter completely withdrawn from the pericardial cavity, and the wire pulled or cinched to bring the coil or patch close to the inside of the pericardium.
- (7) FIG. **3**A depicts the pericardial pad, also pre-loaded on the delivery needle, deployed outside of the pericardium.
- (8) FIG. **3**B depicts the device fully deployed in the pericardium, the catheter withdrawn out of the chest wall, and the chest wall pat deployed against the chest wall.
- (9) FIG. **4** depicts the wire extending out of the chest wall with a proximal connector, and the proximal connector connected to a microprocessor that is implanted subcutaneously between the ribs.
- (10) FIG. **5** is a diagram showing the communication pathways between the pericardial electrode, the microprocessor, and the lithium battery.

DETAILED DESCRIPTION

- (11) The aspects summarized above can be embodied in various forms. The following description shows, by way of illustration, combinations and configurations in which the aspects can be practiced. It is understood that the described aspects and/or embodiments are merely examples. It is also understood that other aspects and/or embodiments can be utilized, and that structural and functional modifications can be made, without departing from the scope of the present disclosure. (12) The present invention is an implantable cardioverter-defibrillator (ICD) and/or pacemaker that monitors the heart's activity, detects abnormalities and arrhythmias, and delivers pacing, cardioversion, and/or defibrillation when needed. The device can pace the heart's rhythm from either the pericardium or the outside of the heart muscle (epicardium) through a wire attached to the epicardium. It may also function as a defibrillator by delivering an electric shock to the heart to treat life-threatening dysrhythmia.
- (13) The ICD/pacemaker device of the present invention comprises a wire with at least one electrode fastened to the surface of the pericardium. The wire extends out of the pericardium and connects to a microprocessor that is implanted subcutaneously between the patient's ribs. The electrodes of the device may be placed at one or more sites on the pericardium near the areas of the heart that require monitoring. Typically, the electrodes are placed near the ventricles because ventricular arrhythmias are more likely to be life-threatening and require defibrillation. However, for patients with atrial problems, the electrodes may be positioned near the atria to detect any atrial arrhythmias.
- (14) Referring to FIG. 1A, an electrode in the form of a circular patch 120A is shown attached to a wire 110 and harness (not shown). In FIG. 2B, the electrode appears in the form of a square patch 120B. In FIG. 2C, the electrode appears in the form of a rectangular patch 120C. The electrodes may comprise a flat metal patch or a plastic patch with a coil, metal, or other conducting element embedded inside the patch, in various shapes including but not limited to those depicted in FIG. 1A, FIG. 1B and FIG. 1C. The electrode may also consist of a stand-alone metallic wire coil that is not embedded in a flat patch (not shown). The electrode 120 may be interchangeably referred to herein as a coil, a patch, or an electrode and it should be understood that these terms refer to the

- same component of the present invention.
- (15) The patch **120** may also comprise additional diagnostic technologies, such as ultrasound elements which may, for example, detect fluid or a pressure transducer. The patch **120** may further comprise biochemistry diagnostics such as, for example, Raman spectroscopy, and/or a mechanism for detecting ST elevation for early detection of a myocardial infarction.
- (16) The wire and coil/patch of the present invention are delivered to the pericardium by an image-guided catheter-based delivery system. The coil/patch, a pericardial pad, and a chest wall pad are pre-loaded and pre-crimped inside of a curved delivery needle, which is introduced into the pericardium through an image-guided catheter, also referred to herein as a Peri-Port. The delivery needle threads the wire, harness, electrode and pads through an entry site and an exit site on the pericardium. The device is then deployed when the needle is withdrawn out of the body over the wire.
- (17) FIG. 2A, FIG. 2B, FIG. 2C, and FIG. 2D depict the procedure for delivering a wire and electrode to the inner (visceral) surface of the pericardium closes to the heart. It should be understood, however, that the electrodes of the present invention may be deployed on either the visceral surface of the pericardium or the outer (parietal) surface. The procedure is shown in these figures by way of example, and it may be modified to deliver the device to the parietal surface of the epicardium.
- (18) Referring to FIG. 2A, an image-guided catheter (Peri-Port) 210 is introduced first through the chest wall (not shown) and then through an entry site 260 of the pericardium 220. A curved delivery needle 230 is advanced through the Peri-Port and then advanced further through an exit site 270 of the pericardium 220. The curved delivery needle 230 delivers and/or creates a pathway for the harness 240, the wire (not shown), and the patch (not shown) through the pericardium 220. When the delivery needle 230 is withdrawn slightly, the harness 240 is exposed.
- (19) As depicted in FIG. **2**A, the harness **240** consists of a pigtail wire on the opposite surface from the electrode. The purpose of the harness **240** is to retain the patch or coil on the surface of the pericardium **220**. The harness may consist of tines or pigtails as shown in FIG. **2**A. The harness **240** may also comprise a hook at the tip of the wire protruding from the exit site **270**, with the hook inserted into the pericardium **220** to hold the patch in place. The harness **240** may also comprise a corkscrew or corkscrew that is screwed into the pericardium at the exit site **270** to hold the patch in place. Alternatively, the harness **240** may comprise a clamshell-like coil or patch that is delivered on both sides of the pericardium **220** at the exit site **270**.
- (20) Referring to FIG. **2B**, the delivery needle **230** is slowly withdrawn out of the exit site **270** on the pericardium **220** back into the pericardia} cavity, deploying the harness **240** outside the pericardial cavity and further deploying and exposing the wire **250**. In an alternative embodiment with a clamshell harness, withdrawing the delivery needle **230** into the pericardia} cavity deploys an outer clamshell portion at the exit site **270** on the outer surface of the pericardium **220**, and an inner clamshell portion at the exit site **270** on the inner surface of the pericardium **220** such that the clamshell surrounds the pericardium and holds the wire **250** in place.
- (21) Referring to FIG. **2**C, the delivery needle **230** is further withdrawn to deploy the coil/patch **120** which was pre-crimped and pre-loaded on the delivery needle **230**. Withdrawal of the delivery needle **230** covering the coil/patch **120** expands the coil or patch **120** to its final shape.
- (22) Referring to FIG. **2D**, after the coil/patch **120** is deployed, the delivery needle **230** and the Peri-Port **210** are withdrawn from the entry site **260** of the pericardium **220**. The harness **240** secures the wire **250** at the exit site **270** of the pericardium **220**. After the Peri-Port **210** and the delivery needle **230** are withdrawn from the pericardium **220**, the wire **250** is pulled out from the entry site **260** to bring the coil/patch **120** in close proximity to the inner surface of the pericardium **220**.
- (23) Referring to FIG. **3**A, a pericardial pad **310**, also pre-loaded in the delivery needle **230**, is deployed on the outer surface of the pericardium **220** by further withdrawing the delivery needle

- **230**. The pericardia} pad **310** keeps the tension on the wire and holds the electrode **120** in close contact with the inside of the pericardium.
- (24) Referring to FIG. **3**B, the Peri-Port **210** and the delivery needle **230** are further withdrawn out of the chest wall **330**, exposing additional wire **250** as they are withdrawn. After the Peri-Port **210** and the delivery needle **230** exit the chest wall **330**, a chest wall pad, also pre-loaded on the delivery needle, is deployed outside the chest wall.
- (25) Referring to FIG. **4**, after exiting the chest, the wire **250** is exposed with a proximal connector **410** at its end. The connector **410** plugs into a socket in the microprocessor **420** that is implanted subcutaneously between the ribs **430**. Thus, the electrode **120** is connected to the microprocessor **420** through the wire **250**, and electrical signals are transmitted between the electrode **120** and the microprocessor **420**. The microprocessor **420** may be implanted at different sites between the ribs, either near the apex or axillary. The size of the microprocessor **420** is small and the shape may be altered to conform to the intercostal space.
- (26) Referring to FIG. 5, the microprocessor 420 receive signals from the pericardia} electrode 120, communicates with the electrode 120 through wires, and controls the pacing and defibrillation/cardioversion functions of the present invention. The pericardia} electrode 120 receives electrical signals from a proximal area of the heart indicating its function, then transmits that signal as an input signal 510 to the pre-amplifier 511. The signal is processed by the pre-amplifier 511, the filter 512, and the amplifier 513, and then transmitted to the microprocessor 420. The microprocessor 420 includes a 2-way memory device 514 in which data may be stored, retrieved, and written. Algorithms for detecting cardiac arrhythmias and other abnormalities are stored on the 2-way memory device 514. When the microprocessor 420 received the filtered and amplified signal from the amplifier 513, it analyzes the signal using algorithms retrieved from the 2-way memory 514. The 2-way memory 514 also contains algorithms for determining whether and how to treat an abnormality by administering pacing or a shock to the heart through the electrode 120.
- (27) If cardiac arrest or another condition that requires defibrillation or cardioversion is detected, the microprocessor may send a charge 517 to a capacitor 519 which will administer a shock 519 through the electrode 120. Defibrillation is achieved by sending an electric shock between two electrodes 120 or between a single electrode 120 and the microprocessor 420. To achieve the pacemaking function of the device, the microprocessor 420 may generate a pulse 520 to deliver pacing 521 through one or more electrode 120. The microprocessor 420 and capacitor 518 are powered by a lithium battery 516. The microprocessor 420 can detect when the lithium battery 516 is low. The microprocessor 420 further comprises a RF transceiver 515 for receiving and transmitting radio signals. The RF transceiver 515 may alert the patient, the physician, and/or another caregiver when the lithium battery 516 must be replaced. The RF transceiver 515 may also send an alert to the physician and/or caregiver when the patient is experiencing a life-threatening emergency.
- (28) The wire and electrode **120** may be deployed at one or more sites on the pericardium as needed, with the wires from each electrode connecting to the microprocessor **420**. Multiple coils/wires/patches may be deployed at different sites to get multiple leads for more robust and reliable arrhythmia detection algorithms and capabilities. When the electrode **120** is deployed near the ventricles, the device may provide pacing to a single ventricle or dual ventricles. Electrodes **120** may also be delivered closer to the left or right atrium to allow atrial pacing and atrial defibrillation.
- (29) At least one electrode **120** must be deployed in the pericardium to effectuate the device's pacing and defibrillation functions. The electrodes **120** function as conductors for delivering shocks to the heart. The defibrillation and cardioversion functions of the device are administered by transmitting an electric shock between two coils. In an alternative embodiment with only one electrode **120** deployed in the pericardia} cavity, the device may administer a shock between the

electrode 120 and the microprocessor 420.

- (30) All documents mentioned herein are incorporated by reference herein as to any description which may be deemed essential to an understanding of illustrated and discussed aspects and embodiments of devices and methods herein.
- (31) Although the devices and methods discussed above and primarily illustrated and described herein provide instruments that also can be adapted for performing minimally invasive diagnostic or therapeutic procedures on humans, it will be appreciated by those skilled in the art that such instruments and methods also are adaptable for use in other surgical procedures as well as in performing various veterinary surgeries. Further, while several preferred embodiments have been described using specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims.

Claims

- 1. A heart defibrillator for attachment to the pericardium of the heart at least at one location on the pericardium proximate to a chamber of the heart, the heart defibrillator comprising: at least one electrode configured to attach to a portion of an inner surface of the pericardium proximate to the chamber without entering a heart muscle, wherein the electrode is not attached to a visceral surface of the pericardium; and a controller in communication with the electrode, the controller configured to receive electrical signals corresponding to a heart rhythm from the at least one electrode, and to transmit an electrical pulse to the electrode to stimulate a regular heartbeat when needed.
- 2. The heart defibrillator of claim 1, comprising at least two electrodes.
- 3. The heart defibrillator of claim 1, wherein the controller comprises a memory operable to store a record of the received electrical signals over time.
- 4. The heart defibrillator of claim 1, wherein the controller comprises a memory operable to store a record of transmission of the electrical pulse.
- 5. The heart defibrillator of claim 1, further comprising a radio frequency transceiver.
- 6. The heart defibrillator of claim 5, wherein the controller is operable to broadcast a signal when a battery for powering the defibrillator requires replacement.
- 7. The heart defibrillator of claim 5, wherein the controller is operable to broadcast a signal when electrical signals received from the heart indicate a life-threatening emergency.
- 8. The heart defibrillator of claim 7, wherein the signal is broadcast via the transceiver to one or more of a physician and a caregiver.
- 9. The heart defibrillator of claim 1, wherein the controller further comprises a microprocessor configured to analyze the electrical signals, via one or more algorithms to detect a cardiac rhythm abnormality.
- 10. The heart defibrillator of claim 1, wherein the at least one electrode comprises a wire coil or a circular, rectangular or square patch with an embedded wire coil.