Implantable extravascular electrical stimulation lead having improved sensing and pacing capability

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Abstract

Implantable medical electrical leads having electrodes arranged such that a defibrillation coil electrode and a pace/sense electrode(s) are concurrently positioned substantially over the ventricle when implanted are described. The leads include an elongated lead body having a distal portion and a proximal end, a connector at the proximal end of the lead body, a defibrillation electrode located along the distal portion of the lead body, wherein the defibrillation electrode includes a first segment and a second segment proximal to the first segment by a distance, a first electrical conductor extending from the proximal end of the lead body and electrically coupling to the first segment and the second segment of the defibrillation electrode, and at least one pace/sense electrode located between the first segment and the second segment of the defibrillation electrode.

Related U.S. Application Data

Provisional application No. 61/984,148, filed on Apr. 25, 2014.
FIG. 3A
FIG. 4
IMPLANTABLE EXTRAVASCULAR ELECTRICAL STIMULATION LEAD HAVING IMPROVED SENSING AND PACING CAPABILITY

[0001] This application claims the benefit of U.S. Provisional Application No. 61/984,148, filed on Apr. 25, 2014, the entire content of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present application relates to electrical stimulation leads and, more particularly, electrical stimulation leads with improved sensing and/or pacing capability for use in extravascular applications.

BACKGROUND OF THE INVENTION

[0003] Malignant tachyarrhythmia, for example, ventricular fibrillation (VF), is an uncoordinated contraction of the cardiac muscle of the ventricles in the heart, and is the most commonly identified arrhythmia in cardiac arrest patients. If this arrhythmia continues for more than a few seconds, it may result in cardiogenic shock and cessation of effective blood circulation. As a consequence, sudden cardiac death (SCD) may result in a matter of minutes.

[0004] In patients at high risk of ventricular fibrillation, the use of an implantable cardioverter defibrillator (ICD) system has been shown to be beneficial at preventing SCD. An ICD system includes an ICD, which is a battery powered electrical stimulation device, that may include an electrical housing electrode (sometimes referred to as a can electrode), that is coupled to one or more electrical stimulation leads. The electrical stimulation leads may be placed within the heart, within vasculature near the heart (e.g., within the coronary sinus), attached to the outside surface of the heart (e.g., in the pericardium or epicardium), or implanted subcutaneously above the ribcage/sternal. If an arrhythmia is detected, the ICD may generate and deliver a pulse (e.g., cardioversion or defibrillation shock) via the electrical stimulation leads to shock the heart and restore its normal rhythm.

SUMMARY

[0005] Subcutaneously implanted electrical stimulation leads or subterminally implanted electrical stimulation leads do not intimately contact the heart, but instead reside in a plane of tissue or muscle between the skin and sternum for subcutaneous, or reside in a plane of tissue or muscle between the sternum and the heart for subternal. Due to the distance between the heart and electrodes of the electrical stimulation leads, to achieve improved pacing, sensing, and/or defibrillation, the pace/sense electrodes and the defibrillation coil electrode should be positioned in the plane of tissue such that the electrodes are located directly above or proximate the ventricular surface of the cardiac silhouette. For example, the electrode(s) used to deliver pacing pulses should be positioned in a vector over substantially the center of the chamber to be paced to produce the lowest pacing capture thresholds for pacing. Likewise, the electrode(s) used to sense cardiac electrical activity of the heart should be positioned over substantially the center the chamber to be sensed to obtain the best sensed signal. For shocking purposes, it is preferred to have the defibrillation coil electrode positioned over substantially the center the chamber to be shocked.

[0006] Current medical electrical lead designs used for subcutaneous defibrillation include a single defibrillation coil electrode located between a first pace/sense electrode distal to the defibrillation coil and a second pace/sense electrode proximal to the defibrillation coil. In such a configuration, it is not possible to concurrently position both the defibrillation coil electrode and one of the first and second pace/sense electrode(s) substantially over the center the ventricle. Electrical stimulation leads described herein are designed such that concurrent positioning of the defibrillation electrode and the pace/sense electrode is possible.

[0007] In one example, this disclosure is directed to an implantable medical electrical lead comprising an elongated lead body having a distal portion and a proximal end, a connector at the proximal end of the lead body, a defibrillation electrode located along the distal portion of the lead body, wherein the defibrillation electrode includes a first segment and a second segment proximal to the first segment by a distance, a first electrical conductor extending from the proximal end of the lead body and electrically coupling to the first segment and the second segment of the defibrillation electrode, and at least one pace/sense electrode located between the first segment and the second segment of the defibrillation electrode.

[0008] In another example, this disclosure is directed to an implantable medical electrical lead comprising an elongated lead body having a distal portion and a proximal end, a connector at the proximal end of the lead body, a defibrillation electrode located along the distal portion of the lead body, wherein the defibrillation electrode includes a first segment and a second segment proximal to the first segment by approximately 1-3 centimeters (cm), and at least one pace/sense electrode located between the first segment and the second segment of the defibrillation electrode.

[0009] In a further example, this disclosure is directed to an extravascular implantable cardioverter-defibrillator system comprising an implantable cardioverter-device (ICD) that includes a therapy module configured to generate and deliver electrical stimulation therapy and an implantable medical electrical lead electrically coupled to the therapy module. The lead includes an elongated lead body having a distal portion and a proximal end, a connector at the proximal end of the lead body, a defibrillation electrode located along the distal portion of the lead body, wherein the defibrillation electrode includes a first segment and a second segment proximal to the first segment by a distance, and at least one pace/sense electrode located between the first segment and the second segment of the defibrillation electrode.

[0010] This summary is intended to provide an overview of the subject matter described in this disclosure. It is not intended to provide an exclusive or exhaustive explanation of the techniques as described in detail within the accompanying drawings and description below. Further details of one or more examples are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the statements provided below.

BRIEF DESCRIPTION OF DRAWINGS

[0011] FIGS. 1A and 1B are conceptual drawings illustrating various views of a patient implanted with an example extravascular implantable cardioverter-defibrillator (ICD) system.
FIG. 2 is a drawing illustrating a distal portion of an example implantable medical electrical lead.

FIGS. 3A-3C are conceptual drawings illustrating various views of a patient implanted with an example extravascular ICD system in which a distal portion of the lead is implanted subcutaneously.

FIG. 4 is a block diagram illustrating components of an example ICD.

DETAILED DESCRIPTION

FIGS. 1A and 1B are conceptual diagrams of an extravascular implantable cardioverter-defibrillator (ICD) system 10 subcutaneously implanted within a patient 12. FIG. 1A is a front view of ICD system 10 implanted within patient 12. FIG. 1B is a side view of ICD system 10 implanted within patient 12. ICD system 10 includes an ICD 14 connected to a medical electrical lead 16. FIGS. 1A and 1B are described in the context of an ICD system capable of providing defibrillation and/or cardioversion shocks and, in some instances, pacing pulses. However, the techniques of this disclosure may also be used in the context of other implantable medical devices configured to provide electrical stimulation pulses to stimulate other portions of the body of patient 12.

ICD 14 may include a housing that forms a hermetic seal that protects components of ICD 14. The housing of ICD 14 may be formed of a conductive material, such as titanium or titanium alloy, that may function as a housing electrode (sometimes referred to as a can electrode). ICD 14 may also include a connector assembly (also referred to as a connector block or header) that includes electrical feedthroughs through which electrical connections are made between conductors of lead 16 and electronic components included within the housing of ICD 14. As will be described in further detail herein, housing may house one or more processors, memories, transmitters, receivers, sensors, sensing circuitry, therapy circuitry, power sources and other appropriate components. The housing is configured to be implanted in a patient, such as patient 12. ICD 14 is implanted subcutaneously on the left side of patient 12 above the ribcage. ICD 14 may, in some instances, be implanted between the left posterior axillary line and the left anterior axillary line of patient 12. ICD 14 may, however, be implanted at other subcutaneous locations on patient 12 as described later.

Lead 16 includes an elongated lead body having a proximal end that includes a connector (not shown) configured to be connected to ICD 14 and a distal portion that includes electrodes 24 (formed by electrode segments 24A and 24B), 28, 29, and 30. Lead 16 extends subcutaneously above the ribcage from ICD 14 toward a center of the torso of patient 12, e.g., toward xiphoid process 20 of patient 12. At a location near xiphoid process 20, lead 16 bends or turns and extends superior subcutaneously above the ribcage and/or sternum, substantially parallel to sternum 22. Although illustrated in FIGS. 1A and 1B as being offset laterally from and extending substantially parallel to sternum 22, lead 16 may be implanted at other locations, such as over sternum 22, offset to the right or left of sternum 22, angled lateral from sternum 22 at either the proximal or distal end, or the like.

The elongated lead body of lead 16 contains a plurality of elongated electrical conductors (not illustrated) that extend within the lead body from the connector at the proximal lead end to electrodes 24, 28, 29, and 30 located along the distal portion of lead 16. The elongated lead body may have a generally tubular or cylindrical shape along the length of the lead body. The elongated lead body may have a diameter of between 3 and 9 French (Fr) in some instances. However, lead bodies of less than 3 Fr and more than 9 Fr may also be utilized. In another example, the distal portion (or all of) the elongated lead body may have a flat, ribbon or paddle shape. In this instance, the width across the flat portion of the flat, ribbon or paddle shape may be between 1 and 3.5 mm. Other lead body designs may be used without departing from the scope of this disclosure. The lead body of lead 16 may be formed from a non-conductive material, including silicone, polyurethane, fluoropolymers, mixtures thereof, and other appropriate materials, and shaped to form one or more lumens within which the one or more conductors extend. However, the techniques are not limited to such constructions.

The one or more elongated electrical conductors contained within the lead body of lead 16 may engage with respective electrodes 24, 28, 29, and 30. In one example, each of electrodes 28, 29, and 30 are electrically coupled to a respective conductor within the lead body. Electrode segments 24A and 24B may be electrically coupled to separate conductors, but may be capable of being jumpered, tied or otherwise electrically connected such that segments 24A and 24B may together form an anode or cathode of a therapy vector. Alternatively, electrode segments 24A and 24B may be electrically coupled to the same conductor. In any case, the respective conductors may electrically couple to circuitry, such as a therapy module or a sensing module, of ICD 14 via connections in the connector assembly, including associated feedthroughs. The electrical conductors transmit therapy from a therapy module within ICD 14 to one or more of electrodes 24 (or one of segments 24A and 24B), 28, 29 and 30 and transmit sensed electrical signals from one or more of electrodes 24 (or one of segments 24A and 24B), 28, 29 and 30 to the sensing module within ICD 14.

Defibrillation electrode 24 is located toward the distal portion of defibrillation lead 16, e.g., toward the portion of defibrillation lead 16 extending superior near sternum 22. As indicated above, defibrillation electrode 24 is formed of a first electrode segment 24A and a second electrode segment 24B separated by a distance. In one example, first segment 24A and second segment 24B are each approximately 2.5 cm in length and the proximal end of segment 24A is separated by approximately 1-3 cm from the distal end of segment 24B. The first electrode segment 24A and the second electrode segment 24B of defibrillation electrode 24 may in one example be coil electrode segments. In other embodiments, however, defibrillation electrode 24 may be a flat ribbon electrode, paddle electrode, braided or woven electrode, mesh electrode, directional electrode, patch electrode or other type of electrode that is segmented in the manner described herein. Moreover, in other examples, defibrillation electrode 24 may be constructed of more than two segments.

A total length of defibrillation electrode 24 may vary depending on a number of variables. Defibrillation electrode 24 may, in one example, have a total length (e.g., length of the two segments combined) of between approximately 5-10 centimeters (cm). However, defibrillation electrode 24 may have a total length less than 5 cm and greater than 10 cm in other embodiments. In another example, defibrillation electrode 24 may have a total length of approximately 2-16 cm. In some instances, defibrillation segments 24A and 24B may be approximately the same length. In other instances, one of
defibrillation segments 24A and 24B may be longer or shorter than the other one of the defibrillation segments 24A and 24B.

Defibrillation lead 16 also includes electrodes 28, 29 and 30 located along the distal portion of defibrillation lead 16. In the example illustrated in FIGS. 1A and 1B, electrodes 28 and 29 are located between defibrillation electrode segments 24A and 24B and electrode 30 is located distal of defibrillation electrode segment 24A. Electrodes 28 and 29 are illustrated as ring electrodes and electrode 30 is illustrated as a hemispherical tip electrode. However, electrodes 28, 29, and 30 may comprise any of a number of different types of electrodes, including ring electrodes, short coil electrodes, paddle electrodes, hemispherical electrodes, directional electrodes, segmented electrodes, or the like. For example, electrodes 28 and 29 may be formed of a conductive material that only extends around a portion of the circumference of the lead body, e.g., a half-ring electrode, quarter-ring electrode, or other partial-ring electrode. In another example, electrodes 28 and 29 may be formed of conductive material that extends around the entire circumference of the lead body, but may be partially coated with an insulating material to form the half-ring electrode, quarter-ring electrode, or other partial-ring electrode. Likewise, electrode 30 may be formed into a partial-hemispherical electrode in a similar manner as described above with respect to ring electrodes 28 and 29. In still other instances, one or more of electrodes 28, 29, and 30 may be segmented electrodes (e.g., half- or quarter-ring or hemispherical electrodes) with separate conductors connected to each of the segments or a single conductor with a multiplexer or other switch to switch between the segmented electrodes such that the segments may be used as individual electrodes.

Electrodes 28, 29, and 30 of lead 16 may have substantially the same outer diameter as the lead body. In one example, electrodes 28, 29, and 30 may have surface areas between 1.6-150 mm². Electrodes 28 and 30 may, in some instances, have relatively the same surface area or different surface areas.

Electrodes 28 and 29 are spaced apart from one another along the length of the lead. The spacing between electrodes 28 and 29 may be dependent upon the configuration of lead 16. In one example, electrodes 28 and 29 are spaced apart by less than 2 cm. In some instances, electrodes 28 and 29 may be spaced apart by less than 1 cm. In further instances, electrodes 28 and 29 may be spaced apart from one another by more than 2 cm. Electrode 30 is spaced apart from the distal end of defibrillation electrode segment 24A by a distance, which may again be less than 2 cm. However, electrode 30 may be spaced apart from the distal end of defibrillation electrode segment 24A by more than 2 cm.

The example dimensions provided above are exemplary in nature and should not be considered limiting of the embodiments described herein. In other embodiments, lead 16 may include less than three pace/sense electrodes or more than three pace/sense electrodes. In further instances, the pace/sense electrodes may be located elsewhere along the length of lead 16, e.g., distal to defibrillation electrode segment 24A or proximal to defibrillation electrode segment 24B, with one or more of the sense/pace electrodes being located between defibrillation electrode segments 24A and 24B. In other examples, defibrillation electrode may be constructed of more than two segments, such as three segments with electrode 28 located between the proximal segment and middle segment and electrode 29 located between the middle segment and the distal segment.

To achieve improved sensing and/or pacing, it is desirable to have the pace/sense electrodes located substantially over the chamber of heart 26 that is being paced and/or sensed. For example, it is desirable to locate the pace/sense electrodes over a cardiac silhouette of the ventricle as observed via an anterior-posterior (AP) fluoroscopic view of heart 26 for sensing or pacing the ventricle. Likewise, to achieve improved defibrillation therapy, it is desirable to have the defibrillation electrode located substantially over the chamber of heart 26 to which the defibrillation or cardioversion shock is being applied, e.g., over a cardiac silhouette of the ventricle as observed via an AP fluoroscopic view of heart 26. In conventional subcutaneous lead designs, it is only possible to position either the defibrillation electrode or the sense electrode over the relevant chamber, but not both.

Leads designed in accordance with any of the techniques described herein can be implanted to achieve desirable electrode positioning for both defibrillation and pacing/sensing. In particular, lead 16 may be implanted such that electrodes 28 and 29 are substantially located over a cardiac silhouette of the ventricle as observed via an AP fluoroscopic view of heart 26. In other words, lead 16 may be implanted such that one or both of a unipolar pacing/sensing vector from electrode 28 or 29 to a housing electrode of ICD 14 are substantially across the ventricles of heart 26. The therapy vector may be viewed as a line that extends from a point on electrode 28 or 29, e.g., center of electrode 28 or 29, to a point on the housing electrode of ICD 14, e.g., center of the housing electrode. In another example, the spacing between electrodes 28 and 29 as well as the placement of lead 16 may be such that a bipolar pacing vector between electrode 28 and electrode 29 is centered or otherwise located substantially over the ventricle.

Electrode 30 may be located over the cardiac silhouette of the atrium or near the top of the cardiac silhouette of the atrium as observed via an AP fluoroscopic view. As such, electrode 30 may offer an alternate sensing vector and/or provide atrial pacing if needed or desired.

Not only are electrodes 28 and 29 located over the ventricle, but defibrillation electrode segments 24A and 24B are substantially centered over the cardiac silhouette of the ventricle as observed via an AP fluoroscopic view of heart 26. As such, the therapy vector from defibrillation electrode segments 24A and 24B to the housing of ICD 14 is substantially across the ventricles of heart 26.

In some instances, electrodes 24, 28, 29, and/or 30 of lead 16 may be shaped, oriented, designed or otherwise configured to reduce extra-cardiac stimulation. For example, electrodes 24, 28, 29, and/or 30 of lead 16 may be shaped, oriented, designed, partially insulated or otherwise configured to focus, direct or point electrodes 24, 28, 29, and/or 30 toward heart 26. In this manner, pacing pulses delivered via lead 16 are directed toward heart 26 and not outward toward skeletal muscle. For example, electrodes 24, 28, 29, and/or 30 of lead 16 may be partially coated or masked with a polymer (e.g., polyurethane) or another coating material (e.g., tantalum pentoxide) on one side or in different regions so as to direct the pacing signal toward heart 26 and not outward toward skeletal muscle. In the case of a ring electrode, for example, the ring electrode may be partially coated with the polymer or other material to form a half-ring electrode, quarter-ring electrode, or other partial-ring electrode.

ICD 14 may obtain sensed electrical signals corresponding with electrical activity of heart 26 via a combination
of sensing vectors that include combinations of electrodes 28, 29, and/or 30 and the housing electrode of ICD 14. For example, ICD 14 may obtain electrical signals sensed using a sensing vector between any two of electrodes 28, 29, and 30 or obtain electrical signals sensed using a sensing vector between any one of electrodes 28, 29, or 30 and the conductive housing electrode of ICD 14. In some instances, ICD 14 may even obtain sensed electrical signals using a sensing vector that includes one or both segments 24A or 24B of defibrillation electrode 24 in combination with electrodes 28, 29, and/or 30, or the housing electrode of ICD 14.

[0032] ICD 14 analyzes the sensed electrical signals obtained from one or more of the sensing vectors of lead 16 to monitor for tachyarrhythmia, such as ventricular tachycardia (VT) or ventricular fibrillation (VF). ICD 14 may analyze the heart rate and/or morphology of the sensed electrical signals to monitor for tachyarrhythmia in accordance with any of a number of techniques known in the art. One example technique for detecting tachyarrhythmia is described in U.S. Pat. No. 7,761,150 to Ghanem et al., entitled “METHOD AND APPARATUS FOR DETECTING ARRRHYTHMIAS IN A MEDICAL DEVICE.” The entire content of the tachyarrhythmia detection algorithm described in Ghanem et al. are incorporated by reference herein in their entirety.

[0033] ICD 14 generates and delivers electrical stimulation therapy in response to detecting tachycardia (e.g., VT or VF). In response to detecting the tachycardia, ICD 14 may deliver one or more cardioversion or defibrillation shocks via defibrillation electrode 24 of lead 16. ICD 14 may deliver the cardioversion or defibrillation shocks using either of the electrode segments 24A and 24B individually or together. ICD 14 may generate and deliver electrical stimulation therapy other than cardioversion or defibrillation shocks, including post-shock pacing using a therapy vector formed from one or more of electrodes 24, 28, 29, 30, and the housing electrode.

[0034] The examples illustrated in FIGS. 1A and 1B are exemplary in nature and should not be considered limiting of the techniques described in this disclosure. In other examples, ICD 14 and lead 16 may be implanted at other locations. For example, ICD 14 may be implanted in a subcutaneous pocket in the right pectoral region. In this example, defibrillation lead 16 may be extended subcutaneously from the device toward the manubrium of sternum 22 and bend or turn and extend inferior from the manubrium to the desired location. In yet another example, ICD 14 may be placed abdominally or intrathoracically. Lead 16 may be implanted in other extravascular locations as well. For instance, as described with respect to FIGS. 3A-3C, lead 16 may be implanted underneath the sternum/ribcage.

[0035] In the example illustrated in FIG. 1, system 10 is an ICD system that provides cardioversion/defibrillation and, in some instances, pacing therapy. However, these techniques may be applicable to other cardiac systems, including cardiac resynchronization therapy defibrillator (CRT-D) systems or other cardiac stimulation therapies, or combinations thereof. For example, ICD 14 may be configured to provide electrical stimulation pulses to stimulate nerves, skeletal muscles, diaphragmatic muscles, e.g., for various neuro-cardiac applications and/or for sleep apnea or respiration therapy. As another example, lead 16 may be placed further superior such that the defibrillation electrode 24 is placed substantially over the atrium of heart 26 to provide a shock or pulse to the atrium to terminate atrial fibrillation (AF). In still other examples, defibrillation lead 16 may include a second defibrillation electrode (e.g., second elongated coil electrode) near a proximal end of lead 16 or near a middle portion of lead 16.

[0036] FIG. 2 is a conceptual diagram illustrating a distal portion of another example implantable electrical lead 40 with improved pacing and/or sensing capability for use in non-vascular, extra-pericardial applications. Lead 40 can include one or more of the structure and/or functionality of lead 16 of FIGS. 1A and 1B (and vice versa). Repetitive description of like numbered elements described in other embodiments is omitted for sake of brevity. Lead 40 may be used in place of lead 16 in ICD system 10 of FIGS. 1A and 1B.

[0037] Lead 40 conforms substantially with lead 16 of FIGS. 1A and 1B, but instead of having ring electrodes 28 and 29 located between defibrillation segments 24A and 24B, lead 40 includes a pace/sense coil electrode 42 between defibrillation segments 24A and 24B and a pace/sense ring electrode 44 proximal to defibrillation electrode segment 24B. Such a configuration may increase the surface area located over the ventricles.

[0038] The length of pace/sense coil electrode 42 may be dependent upon the spacing between defibrillation segments 24A and 24B. In one example, defibrillation segments 24A and 24B may each have lengths approximately equal to 4 cm and be spaced apart by a distance greater than 1 cm. In this case, the pace/sense coil electrode 42 may have a length of approximately 1 cm. However, other spacings and lengths greater than or less than 1 cm may be used, including the ranges provided above with respect to FIGS. 1A and 1B. ICD 14 may be configured to sense and deliver pacing and/or cardioversion/defibrillation using any combination of electrodes 24, 30, 42, 44, and the housing electrode. Lead 40 may be implanted such that electrode 42 and defibrillation electrode 24 is substantially over the ventricular surface of the cardiac silhouette in the same manner as described above with respect to FIGS. 1A and 1B.

[0039] FIGS. 3A-3C are conceptual diagrams of patient 12 implanted with another example ICD system 110. FIG. 3A is a front view of patient 12 implanted with ICD system 110. FIG. 3B is a side view of patient 12 implanted with ICD system 110. FIG. 3C is a transverse view of patient 12 with ICD system 110. ICD system 110 can include one or more of the structure and/or functionality of system 10 of FIGS. 1A-1B (and vice versa). ICD system 110 of FIGS. 3A-3C is illustrated with lead 16 for purposes of illustration, but may be utilized with any of leads 16 or 40 or other similar lead. Repetitive description of like numbered elements described in other embodiments is omitted for sake of brevity.

[0040] ICD system 110 conforms substantially to ICD system 10 of FIGS. 1A-1B, except defibrillation lead 16 of system 110 is implanted at least partially underneath sternum 22 of patient 12. Lead 16 extends subcutaneously from ICD 14 toward xiphoid process 20, and at a location near xiphoid process 20 bends or turns and extends superior underneath/ below sternum 22 within anterior mediastinum 36. Anterior mediastinum 36 may be viewed as being bounded laterally by pleurae 39, posteriorly by pericardium 38, and anteriorly by sternum 22. In some instances, the anterior wall of anterior mediastinum 36 may also be formed by the transversus thoracis and one or more costal cartilages. Anterior mediastinum 36 includes a quantity of loose connective tissue (such as areolar tissue), some lymph vessels, lymph glands, substernal musculature (e.g., transverse thoracic muscle), branches of the internal thoracic artery, and the internal thoracic veins. In one example, the distal portion of lead 16 extends along the
posterior side of sternum 22 substantially within the loose connective tissue and/or subternal musculature of anterior mediastinum 36. A lead implanted such that the distal portion is substantially within anterior mediastinum 36 will be referred to herein as a subternal lead. Also, electrical stimulation, such as pacing, cardioversion or defibrillation, provided by lead 16 implanted substantially within anterior mediastinum 36 will be referred to herein as subternal electrical stimulation, subternal pacing, subternal cardioversion, or subternal defibrillation.

The distal portion of lead 16 is described herein as being implanted substantially within anterior mediastinum 36. Thus, points along the distal portion of lead 16 may extend out of anterior mediastinum 36, but the majority of the distal portion is within anterior mediastinum 36. In other embodiments, the distal portion of lead 16 may be implanted in other non-vacular, extra-pericardial locations, including the gap, tissue, or other anatomical features around the perimeter of and adjacent to, but not attached to, the pericardium or other portion of heart 26 and not above sternum 22 or ribcage. As such, lead 16 may be implanted anywhere within the “subternal space” defined by the undersurface between the sternum and/or ribcage and the body cavity but not including the pericardium or other portion of heart 26. The subternal space may alternatively refer to the terms “retrosternal space” or “mediastinum” or “infra-sternal” as is known to those skilled in the art and includes the anterior mediastinum 36. The subternal space may also include the anatomical region described in Baudoin, Y. P., et al., entitled “The superior epigastric artery does not pass through Larrey’s space (trigonum sternocostale),” Surg. Radiol. Anat. 25:3-4 (2003): 259-62 as Larrey’s space. In other words, the distal portion of lead 16 may be implanted in the region around the outer surface of heart 26, but not attached to heart 26.

The distal portion of lead 16 may be implanted substantially within anterior mediastinum 36 such that electrodes 28 and 29 are located near a ventricle of heart 26. To achieve improved sensing and/or pacing, it is desirable to have the pace/sense electrodes located substantially over the chamber of heart 26 that is being paced and/or sensed. For instance, lead 16 may be implanted within anterior mediastinum 36 such that 28 and 29 are located over a cardiac silhouette of one or both ventricles as observed via an AP fluoroscopic view of heart 26. In other words, lead 16 may be implanted such that one or both of a unipolar sensing/pace vector from electrode 28 or 29 to a housing electrode of ICD 14 are substantially across the ventricles of heart 26. In another example, the spacing between electrodes 28 and 29 as well as the placement of lead 16 may be such that a bipolar pacing vector between electrode 28 and electrode 29 is centered or otherwise located over the ventricle.

Likewise, to achieve improved defibrillation therapy, it is desirable to have the defibrillation electrode located substantially over the chamber of heart 26 to which the defibrillation or cardioversion shock is being applied, e.g., over a cardiac silhouette of the ventricle as observed via an AP fluoroscopic view of heart 26. In conventional subcutaneous lead designs, it is only possible to position either the defibrillation electrode or the sense electrode over the relevant chamber, but not both. Thus, not only are electrodes 28 and 29 located over the ventricle, but due to the layout of the electrodes on the lead 16, defibrillation electrode segments 24A and 24B are also substantially centered over the cardiac silhouette of the ventricle as observed via an AP fluoroscopic view of heart 26. In this manner, lead 16 is designed to provide desirable electrode positioning for both defibrillation and pacing/sensing concurrently.

In the example illustrated in FIGS. 3A-3C, lead 16 is located substantially centered under sternum 22. In other instances, however, lead 16 may be implanted such that it is offset laterally from the center of sternum 22. In some instances, lead 16 may extend laterally enough such that all or a portion of lead 16 is underneath/below the ribcage in addition to or instead of sternum 22.

Placing lead 16 in the subternal space may provide a number of advantages. For example, placing lead 16 in the subternal space may significantly reduce the amount of energy that needs to be delivered to defibrillate heart 26. In some instances, ICD 14 may generate and deliver cardioversion or defibrillation shocks having energies of less than 65 Joules (J), less than 60 J, between 35-60 J, and in some cases possibly less than 35 J. As such, placing defibrillation lead 16 within the subternal space, e.g., with the distal portion substantially within anterior mediastinum 36, may result in reduced energy consumption and, in turn, smaller devices and/or devices having increased longevity.

Another advantage of placing lead 16 in the subternal space is that pacing, such as anti-tachycardia pacing (ATP), post-shock pacing and, in some cases, bradycardia pacing, may be provided by system 110. For example, ICD 14 may deliver one or more sequences of ATP in an attempt to terminate a detected VT without delivering a defibrillation shock. The ATP may be delivered via one or more therapy vectors of lead 16, e.g., unipolar therapy vector, bipolar pacing vector or multipolar pacing vector, formed using electrodes 28, 29, or 30, housing electrode of ICD 14, and/or defibrillation electrode 24 or individual defibrillation electrode segments 24A or 24B. If the one or more sequences of ATP are not successful, it is determined that ATP is not desired (e.g., in the case of VF), or ICD 14 is not configured to deliver ATP, ICD 14 may deliver one or more cardioversion or defibrillation shocks via defibrillation electrode 24 of lead 16. ICD 14 may deliver the cardioversion or defibrillation shocks using either of the electrode segments 24A and 24B individually or together. ICD 14 may generate and deliver electrical stimulation therapy other than ATP, cardioversion or defibrillation shocks, including post-shock pacing, bradycardia pacing, or other electrical stimulation therapy using a therapy vector formed from one or more of electrodes 24, 28, 29, 30, and the housing electrode.

FIG. 4 is a functional block diagram of an example configuration of electronic components of an example ICD 14. ICD 14 includes a control module 60, sensing module 62, therapy module 64, communication module 68, and memory 70. The electronic components may receive power from a power source 66, which may be a rechargeable or non-rechargeable battery. In other embodiments, ICD 14 may include more or fewer electronic components. The described modules may be implemented together on a common hardware component or separately as discrete but interoperable hardware or software components. Depiction of different features as modules is intended to highlight different functional aspects and does not necessarily imply that such modules must be realized by separate hardware or software components. Rather, functionality associated with one or more modules may be performed by separate hardware or software components, or integrated within common or separate hardware or software components. FIG. 4 will be described in the
context of ICD being coupled to lead 16 for exemplary purposes only. However, ICD 14 may be coupled to other leads, such as lead 40 described herein, and thus other electrodes, such as electrodes 42 and 44.

**[0048]** Sensing module 62 is electrically coupled to some or all of electrodes 24 (or separately to segments 24A and/or 24B), 28, 29, and 30 via the conductors of lead 16 and one or more electrical feedthroughs, or to the housing electrode via conductors internal to the housing of ICD 14. Sensing module 62 is configured to obtain signals sensed via one or more combinations of electrodes 24 (or segments 24A and/or 24B), 28, 29, and 30 and the housing electrode of ICD 14 and process the obtained signals.

**[0049]** The components of sensing module 62 may be analog components, digital components or a combination thereof. Sensing module 62 may, for example, include one or more sense amplifiers, filters, rectifiers, threshold detectors, analog-to-digital converters (ADCs) or the like. Sensing module 62 may convert the sensed signals to digital form and provide the digital signals to control module 60 for processing or analysis. For example, sensing module 62 may amplify signals from the sensing electrodes and convert the amplified signals to multi-bit digital signals by an ADC. Sensing module 62 may also compare processed signals to a threshold to detect the existence of atrial or ventricular depolarizations (e.g., P- or R-waves) and indicate the existence of the atrial depolarization (e.g., P-waves) or ventricular depolarizations (e.g., R-waves) to control module 60.

**[0050]** Control module 60 may process the signals from sensing module 62 to monitor electrical activity of heart 26 of patient 12. Control module 60 may store signals obtained by sensing module 62 as well as any generated EGM waveforms, marker channel data or other data derived based on the sensed signals in memory 70. Control module 60 may analyze the EGM waveforms and/or marker channel data to detect cardiac events (e.g., tachycardia). In response to detecting the cardiac event, control module 60 may control therapy module 64 to deliver the desired therapy to treat the cardiac event, e.g., defibrillation shock, cardioversion shock, AIT, post-shock pacing, or bradycardia pacing.

**[0051]** Therapy module 64 is configured to generate and deliver electrical stimulation therapy to heart 26. Therapy module 64 may include one or more pulse generators, capacitors, and/or other components capable of generating and/or storing energy to deliver as pacing therapy, defibrillation therapy, cardioversion therapy, cardiac resynchronization therapy, other therapy or a combination of therapies. In some instances, therapy module 64 may include a first set of components configured to provide pacing therapy and a second set of components configured to provide defibrillation therapy. In other instances, therapy module 64 may utilize the same set of components to provide both pacing and defibrillation therapy. In still other instances, therapy module 64 may share some of the defibrillation and pacing therapy components while using other components solely for defibrillation or pacing.

**[0052]** Control module 60 may control therapy module 64 to deliver the generated therapy to heart 26 via one or more combinations of electrodes 24 (or separately to segments 24A and/or 24B), 28, 29, and 30 of lead 16 and the housing electrode of ICD 14 according to one or more therapy programs, which may be stored in memory 70. In instances in which control module 60 is coupled to a different lead, e.g., lead 40, other electrodes may be utilized, such as electrodes 42 and 44. Control module 60 controls therapy module 64 to generate electrical stimulation therapy with the amplitudes, pulse widths, timing, frequencies, electrode combinations or electrode configurations specified by a selected therapy program.

**[0053]** Therapy module 64 may include a switch module to select which of the available electrodes are used to deliver the therapy. The switch module may include a switch array, switch matrix, multiplexer, or any other type of switching device suitable to selectively couple electrodes to therapy module 64. Control module 60 may select the electrodes to function as therapy electrodes, or the therapy vector, via the switch module within therapy module 64. In instances in which defibrillation segments 24A and 24B are each coupled to separate conductors, control module 60 may be configured to selectively couple therapy module 64 to either one of segments 24A or 24B individually or couple to both of segments 24A and 24B concurrently. In some instances, the same switch module may be used by both therapy module 64 and sensing module 62. In other instances, each of sensing module 62 and therapy module 64 may have separate switch modules.

**[0054]** In the case of pacing therapy being provided from the substernal space, e.g., ATP, post-shock pacing, and/or bradycardia pacing provided via electrodes 28, 29, and/or 30 (and possibly defibrillation electrode 24 or segments 24A or 24B thereof) of lead 16, control module 60 controls therapy module 64 to generate and deliver pacing pulses with any of a number of shapes, amplitudes, pulse widths, or other characteristic to capture heart 26. For example, the pacing pulses may be monophasic, biphasic, or multi-phasic (e.g., more than two phases). The pacing thresholds of heart 26 when delivering pacing pulses from the substernal space, e.g., from electrodes 28, 29, and/or 30 substantially within anterior mediastinum 36, may depend upon a number of factors, including location, type, size, orientation, and/or spacing of electrodes 28, 29, and 30, location of ICD 14 relative to electrodes 28, 29, and 30, physical abnormalities of heart 26 (e.g., pericardial adhesions or myocardial infarctions), or other factor(s).

**[0055]** The increased distance from electrodes 28, 29, and 30 of lead 16 to the heart tissue may result in heart 26 having increased pacing thresholds compared to transvenous pacing thresholds. To this end, therapy module 64 may be configured to generate and deliver pacing pulses having larger amplitudes and/or pulse widths than conventionally required to obtain capture via leads implanted within the heart (e.g., transvenous leads) or leads attached directly to heart 26. In one example, therapy module 64 may generate and deliver pacing pulses having amplitudes of less than or equal to 8 volts and pulse widths between 0.5-3.0 milliseconds. In another example, therapy module 64 may generate and deliver pacing pulses having amplitudes of between 5 and 10 volts and pulse widths between approximately 3.0 milliseconds and 10.0 milliseconds. In another example, therapy module 64 may generate and deliver pacing pulses having pulse widths between approximately 2.0 milliseconds and 8.0 milliseconds. In a further example, therapy module 64 may generate and deliver pacing pulses having pulse widths between approximately 0.5 milliseconds and 20.0 milliseconds. In another example, therapy module 64 may generate and deliver pacing pulses having pulse widths between approximately 1.5 milliseconds and 20.0 milliseconds.

**[0056]** Pacing pulses having longer pulse durations than conventional transvenous pacing pulses may result in lower
energy consumption. As such, therapy module 64 may be configured to generate and deliver pacing pulses having pulse widths or durations of greater than two (2) milliseconds. In another example, therapy module 64 may be configured to generate and deliver pacing pulses having pulse widths or durations of between greater than two (2) milliseconds and less than or equal to three (3) milliseconds. In another example, therapy module 64 may be configured to generate and deliver pacing pulses having pulse widths or durations of greater than or equal to three (3) milliseconds. In another example, therapy module 64 may be configured to generate and deliver pacing pulses having pulse widths or durations of greater than or equal to five (5) milliseconds. In another example, therapy module 64 may be configured to generate and deliver pacing pulses having pulse widths or durations of greater than or equal to ten (10) milliseconds. In a further example, therapy module 64 may be configured to generate and deliver pacing pulses having pulse widths or durations of greater than or equal to fifteen (15) milliseconds. In yet another example, therapy module 64 may be configured to generate and deliver pacing pulses having pulse widths or durations of greater than or equal to twenty (20) milliseconds.

[0057] Depending on the pulse widths, ICD 14 may be configured to deliver pacing pulses having pulse amplitudes less than or equal to twenty (20) volts, deliver pacing pulses having pulse amplitudes less than or equal to ten (10) volts, deliver pacing pulses having pulse amplitudes less than or equal to five (5) volts, deliver pacing pulses having pulse amplitudes less than or equal to two and one-half (2.5) volts, deliver pacing pulses having pulse amplitudes less than or equal to one (1) volt. In other examples, the pacing pulse amplitudes may be greater than 20 volts. Typically the lower amplitudes require longer pacing widths as illustrated in the experimental results. Reducing the amplitude of pacing pulses delivered by ICD 14 reduces the likelihood of extracardiac stimulation and lower consumed energy of power source 66. Some experimental results are provided later illustrating some example combinations of pacing amplitudes and widths.

[0058] For pacing therapy provided from the subcutaneous placement of lead 16 above the sternum and/or ribcage, pacing amplitudes and pulse widths may vary.

[0059] In the case of cardioversion or defibrillation therapy, e.g., cardioversion or defibrillation shocks provided by defibrillation electrode segments 24A and/or 24B (individually or together), control module 60 controls therapy module 64 to generate cardioversion or defibrillation shocks having any of a number of waveform properties, including leading-edge voltage, tilt, delivered energy, pulse phases, and the like. Therapy module 64 may, for instance, generate monophasic, biphasic or multiphasic waveforms. Additionally, therapy module 64 may generate cardioversion or defibrillation waveforms having different amounts of energy. As with pacing, delivering cardioversion or defibrillation shocks from the substernal space, e.g., from electrode 24 substantially within anterior mediastinum 36, may reduce the amount of energy that needs to be delivered to defibrillate heart 26. When lead 16 is implanted in the substernal space, therapy module 64 may generate and deliver cardioversion or defibrillation shocks having energies of less than 65 J, less than 60 J, between 40-50 J, between 35-60 J, and in some instances less than 35 J. When lead 16 is implanted subcutaneously, ICD 14 may generate and deliver cardioversion or defibrillation shocks having energies around 65-80 J.

[0060] Therapy module 64 may also generate defibrillation waveforms having different tilts. In the case of a biphasic defibrillation waveform, therapy module 64 may use a 65/65 tilt, a 50/50 tilt, or other combinations of tilt. The tilts of each phase of the biphasic or multiphasic waveforms may be the same in some instances, e.g., 65/65 tilt. However, in other instances, the tilts of each phase of the biphasic or multiphasic waveforms may be different, e.g., 65 tilt on the first phase and 55 tilt on the second phase. The example delivered energies, leading-edge voltages, phases, tilts, and the like are provided for example purposes only and should not be considered as limiting the scope of the waveform properties that may be utilized to provide subthreshold defibrillation via defibrillation electrode 24.

[0061] Communication module 68 includes any suitable hardware, firmware, software or any combination thereof for communicating with another device, such as a programmer, patient monitoring device, or the like. For example, communication module 68 may include appropriate modulation, demodulation, frequency conversion, filtering, and amplifier components for transmission and reception of data with the aid of antenna 72. Antenna 72 may be located within connector block of ICD 14 or within housing ICD 14.

[0062] The various modules of ICD 14 may include any one or more processors, controllers, digital signal processors (DSPs), application specific integrated circuits (ASICs), field-programmable gate arrays (FPGAs), or equivalent discrete or integrated circuitry, including analog circuitry, digital circuitry, or logic circuitry. Memory 70 may include computer-readable instructions that, when executed by control module 60 or other component of ICD 14, cause one or more components of ICD 14 to perform various functions attributed to those components in this disclosure. Memory 70 may include any volatile, non-volatile, magnetic, optical, or electrical media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), static non-volatile RAM (SRAM), electrically-erasable programmable read-only memory (EEPROM), flash memory, or any other non-transitory computer-readable storage media.

[0063] Various examples have been described. These and other examples are within the scope of the following claims.

1. An implantable medical electrical lead comprising:
   a. an elongated lead body having a distal portion and a proximal end;
   b. a connector at the proximal end of the lead body;
   c. a defibrillation electrode located along the distal portion of the lead body, wherein the defibrillation electrode includes a first segment and a second segment proximal to the first segment by a distance;
   d. a first electrical conductor extending from the proximal end of the lead body and electrically coupling to the first segment and the second segment of the defibrillation electrode;
   e. and at least one pace/sense electrode located between the first segment and the second segment of the defibrillation electrode.

2. The lead of claim 1, wherein the at least one pace/sense electrode comprises a first pace/sense electrode and a second pace/sense electrode located between the first segment and the second segment, the implantable medical electrical lead further comprising:
a second electrical conductor extending from the connector at the proximal end of the lead body and electrically coupling to the first pace/sense electrode; and a third electrical conductor extending from the connector at the proximal end of the lead body and electrically coupling to the second pace/sense electrode.

3. The lead of claim 2, wherein the first and second pace/sense electrodes located between the first segment and the second segment comprise one or a combination of ring electrodes, hemispherical electrodes, coil electrodes, partial-ring electrodes, partial-hemispherical electrodes, partial-coil electrodes.

4. The lead of claim 1, further comprising at least one pace/sense electrode located distal to the first segment of the defibrillation electrode.

5. The lead of claim 1, further comprising at least one pace/sense electrode located proximal to the second segment of the defibrillation electrode.

6. The lead of claim 1, wherein the at least one pace/sense electrode located between the first segment and the second segment of the defibrillation electrode comprises a coil electrode or partial-coil electrode.

7. The lead of claim 1, wherein the distance between the first segment and the second segment is between approximately 1-3 centimeters (cm).

8. The lead of claim 1, wherein the distal portion of the lead is arranged such that when the lead is implanted the at least one pace/sense electrode and the defibrillation electrode are both substantially centered over a ventricle of a heart of the patient.

9. An implantable medical electrical lead comprising:
an elongated lead body having a distal portion and a proximal end;
a defibrillation electrode located along the distal portion of the lead body, wherein the defibrillation electrode includes a first segment and a second segment proximal to the first segment by approximately 1-3 centimeters (cm); and
at least one pace/sense electrode located between the first segment and the second segment of the defibrillation electrode.

10. The lead of claim 9, further comprising an electrical conductor extending from the proximal end of the lead body and electrically coupling to the first segment and the second segment of the defibrillation electrode.

11. The lead of claim 9, further comprising:
a first electrical conductor extending from the proximal end of the lead body and electrically coupling to the first segment of the defibrillation electrode; and
a second electrical conductor extending from the proximal end of the lead body and electrically coupling to the second segment of the defibrillation electrode.

12. The lead of claim 9, wherein the at least one pace/sense electrode comprises at least two pace/sense electrodes located between the first segment and the second segment.

13. The lead of claim 9, wherein the at least one pace/sense electrode located between the first segment and the second segment of the defibrillation electrode comprises a coil electrode.

14. The lead of claim 9, further comprising at least one of a pace/sense electrode located distal to the first segment of the defibrillation electrode and a pace/sense electrode located proximal to the second segment of the defibrillation electrode.

15. The lead of claim 9, wherein the distal portion of the lead is configured such that when the lead is implanted the at least one pace/sense electrode and the defibrillation electrode are both substantially centered over a ventricle of a heart of the patient.

16. An implantable cardioverter-defibrillator system comprising:
an implantable cardioverter-device (ICD) that includes a therapy module configured to generate and deliver electrical stimulation therapy; and
an implantable medical electrical lead electrically coupled to the therapy module, wherein the lead comprises:
an elongated lead body having a distal portion and a proximal end;
a connector at the proximal end of the lead body;
a defibrillation electrode located along the distal portion of the lead body, wherein the defibrillation electrode includes a first segment and a second segment proximal to the first segment by a distance; and
at least one pace/sense electrode located between the first segment and the second segment of the defibrillation electrode.

17. The system of claim 16, wherein the lead further comprises an electrical conductor extending from the proximal end of the lead body and electrically coupling to the first segment and the second segment of the defibrillation electrode.

18. The system of claim 16, wherein the lead further comprises:
a first electrical conductor extending from the proximal end of the lead body and electrically coupling to the first segment of the defibrillation electrode; and
a second electrical conductor extending from the proximal end of the lead body and electrically coupling to the second segment of the defibrillation electrode, and the ICD further comprises a switching array configured to selectively couple the therapy module to any one of just the first segment of the defibrillation electrode, just the second segment of the defibrillation electrode, and both the first and second segments of the defibrillation electrode simultaneously.

19. The system of claim 16, wherein the distance between the first segment and the second segment is between approximately 1-3 centimeters (cm).

20. The system of claim 16, wherein the distal portion of the lead is arranged such that when the lead is implanted the at least one pace/sense electrode and the defibrillation electrode are both substantially centered over a ventricle of a heart of the patient.

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