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(54) Title: IMPROVED SYSTEM FOR PROVIDING ELECTRICAL STIMULATION TO A LEFT CHAMBER OF A HEART

(57) Abstract: A medical electrical lead is disclosed that is adapted for placement in the coronary sinus, or a branch vein thereof. The lead includes a first and second pace/sense electrode. A selection mechanism is provided to select either the first or the second electrode for use as a cathode, with the other electrode being selected as the anode. According to another aspect of the invention, a high-voltage coil electrode may be provided between the first and second electrodes. The coil electrode may be electrically coupled to the anode to increase the shadow area of the coil electrode.

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IMPROVED SYSTEM FOR PROVIDING ELECTRICAL STIMULATION TO A LEFT CHAMBER OF A HEART

FIELD OF THE INVENTION

The present invention relates generally to an implantable medical electrical lead; and more particularly, relates to a medical electrical lead system for implantation in a cardiac vein.

BACKGROUND OF THE INVENTION

It has long been known that implantable medical electrical leads may be positioned transvenously within one or more chambers of the heart to provide electrical stimulation to, and to monitor signals occurring within, the cardiac tissue. In order to achieve reliable sensing of the cardiac electrogram and/or to apply stimulation that effectively paces or cardioverts the heart chamber, it is necessary to accurately position the electrode surface against the endocardium or within the myocardium at the desired site and affix it during an acute post-operative phase until fibrous tissue growth occurs. After implantation, the leads may be coupled to an implantable medical device (IMD) such as a pacemaker or cardioverter/defibrillator so that the desired stimulation may be provided to the cardiac tissue.

More recently, endocardial pacing and cardioversion/defibrillation leads have been developed that are adapted to be advanced into the coronary sinus and branch coronary veins. During this type of implant procedure, a distal end of a lead is advanced through the superior vena cava and the right atrium, and through the ostium of the coronary sinus. The lead may further be advanced within the coronary sinus into one of the branch veins.

Placement of leads within the coronary sinus and branch veins is important because these leads can be located adjacent to the left ventricle or the left atrium of the heart. Electrical stimulation can then be provided to the left chambers of the heart without actually placing one or more leads into these chambers. Because the left side of the heart accounts for the majority of the heart's hemodynamic output, various pathologies may be better treated through such left-heart stimulation. For example, in patients experiencing conditions associated with heart failure, electrical stimulation of both the

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right and left sides of the heart can be used to re-synchronize the depolarization of the left and right ventricles in a manner that increases the cardiac output.

In addition to providing important benefits to heart failure patients, the location of electrodes within the coronary sinus and branch veins can also reduce defibrillation thresholds. That is, when a shocking electrode is positioned within a left-sided cardiac vein and used in conjunction with other shocking electrodes placed in more traditional locations, a lower shock energy may be required during cardioversion and/or defibrillation therapy. This can reduce the discomfort associated with these therapies.

Several challenges are posed by providing both pacing and defibrillation electrodes within the coronary vasculature. Because of the small vessel size, positioning multiple leads within the vasculature is difficult. Additionally, the size of coil electrodes of the type needed for high-voltage therapies may be limited based on the size of the vessels, thereby limiting the area of the tissue through which current flows during the therapy. This may limit the efficacy of high-voltage therapies. Finally, locating the leads at a precise location needed to provide adequate tissue stimulation may be difficult given the problems associated with navigating the torturous vessels such as the coronary sinus and branch veins.

What is needed, therefore, is an improved system that may be used to provide both pacing and high-voltage therapy to the left chambers of the heart and that may be reliably fixed within a branch vein of the coronary sinus.

SUMMARY OF THE INVENTION

According to one embodiment of the current invention, a medical electrical lead is disclosed that is adapted for placement in the coronary sinus, or a branch vein of the coronary sinus. The lead includes a first electrode located in proximity to the distal end of the lead. A second electrode is located distal to the first electrode. A selection mechanism is provided to select either the first or the second electrode for use as a cathode, with the other electrode being selected as the anode. In one embodiment, the selection mechanism may include a configurable circuit. Alternatively, the selection mechanism may include selectable electrical configurations provided by an adaptor module. After the selection is complete, relative low-voltage electrical stimulation, including pacing pulses, may then be delivered between the anode and cathode to a left chamber of the heart.

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The lead of the current invention may include means to aid in the positioning of the lead within the coronary sinus or branch veins. For example, the lead may include a lumen formed within the lead body, or adjacent to an exterior surface of the lead. The lumen is adapted to receive a guidewire or stylet for use in delivering the lead to a target location during implant. In one embodiment, the lumen is formed of a collapsible tube such as tubing formed of a porous PTFE tubing material. The tube is carried adjacent to at least a portion of the outer surface of the lead body.

According to yet another aspect of the current invention, a coil electrode may be positioned between the first and second electrodes. The coil electrode is adapted to deliver relatively high-voltage therapy such as cardioversion/defibrillation shocks to the heart. In one embodiment, the coil electrode may be electrically coupled to the electrode selected as the anode to increase the shadow area of the coil electrode during high-voltage stimulation therapy.

In another embodiment of the invention, a method of delivering electrical stimulation to a heart is provided. The method includes the step of delivering a lead to a branch vein of the coronary sinus, wherein the lead includes first and second pace/sense electrodes coupled to a distal end of the lead. The method further includes selecting one of the first or the second pace/sense electrode as a cathode, and delivering electrical stimulation between the cathode and the other pace/sense electrode to a left chamber of the heart. The lead may further include a coil electrode for delivering relatively high-voltage stimulation to the heart. In this embodiment, the method may further include electrically coupling one of the pace/sense electrodes to the coil electrode prior to the delivery of the high-voltage therapy to increase the shadow area of the coil electrode.

In still another embodiment of the invention, a system is provided delivering electrical stimulation to a heart. The system includes a lead having first and second pace/sense electrodes, and a coil electrode. The system may further include an adapter for selecting one of the first and the second pace/sense electrodes as a cathode for delivery of pacing therapy. The adapter may further couple the other one of the pace/sense electrodes to the coil electrode for use as the anode, and further for delivery of relatively high-voltage stimulation. As an alternative to the adapter, the system may include an implantable

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medical device having means for selectably configuring the electrodes in the afore-mentioned manner.

Other scopes and aspects of the current invention will become apparent to those skilled in the art from the following description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a plan view of one embodiment of the inventive lead system.

Figure 2 is a side cutaway view of one embodiment of the distal portion of the lead.

Figure 3 is a posterior view of the heart illustrating the inventive lead system implanted within a branch vein of the coronary sinus.

Figure 4 is a block diagram of an IMD configuration including a programmable switch as may be used with the lead system of the current invention.

Figure 5 is a side view of a lead that is similar to that shown in Figure 2 including a multi-pin connector as may be used with the current invention.

Figure 6 is an end view of the connector of Figure 5.

Figure 7 is an end view illustrating a mating interface for use with the connector of Figure 6.

Figure 8 is a side view illustrating use of the mating interface of Figure 7 incorporated within an adapter that includes a standard DF-1 connector.

Figure 9 is a side view illustrating use of mating interface incorporated within an adapter that includes a standard IS-1 connector.

Figure 10 illustrates an adapter as shown in Figure 9 coupled to a lead including the connector shown in Figure 5.

Figure 11 illustrates an adapter such as shown in Figure 9 being coupled to a lead of a type as shown in Figure 5.

Figure 12 is an end view of the connector of Figure 5 being temporarily configured for threshold testing.

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