Pace/Sense and Defibrillation Leads– RELIANCE 4–FRONT™

INDICATIONS AND USAGE

This Boston Scientific lead is indicated for use as follows:

• Intended for pacing, rate-sensing, and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator

CONTRAINDICATIONS

Use of this Boston Scientific lead is contraindicated for the following patients:

• Patients who have a unipolar pacemaker

• Patients with a hypersensitivity to a maximum single dose of 1.1 mg dexamethasone acetate

• Patients with mechanical tricuspid heart valves

WARNINGS

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Do not use any component of the lead system to assist in delivery of external-source rescue shocks or extensive tissue damage could occur. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. The lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the lead terminal, other than the terminal pin, even when the lead cap is in place. Implant of the system cannot be performed in an MRI site Zone III (and higher). In order to deliver defibrillation therapy, the single-coil models must be implanted with an additional defibrillation electrode. For DF4-LLHH or DF4-LLHO leads, only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made. Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as for a complete list of MRI-related Warnings and Precautions. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

EXTENDABLE/RETRACTABLE models: The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established. Use fluoroscopy to verify that the lead tip is directed toward the apex when implanted.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage, handling; implantation, hospital and medical environments, follow-up testing

POTENTIAL ADVERSE EVENTS

Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature:
Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Local tissue reaction; Low amplitude VF signals; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., irritability, injury, tissue damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax;

Post-shock rhythm disturbances; Pulse generator and/or lead migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion)

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. Version 1. 046774 AF