Medtronic

SelectSecure™ MRI SureScan™ 3830 Lead

Electrode configuration

Fixed helix screw

Electrode surface area

Helix	3.6 mm^2
Ring	16.9 mm^2

Helix length

1.8 mm

Other characteristics

Steroid	Beclomethasone dipropionate
Tip-to-ring spacing	9 mm
Unipolar conductor resistance	29 ± 6 Ω (69 cm)
Bipolar conductor resistance	99 ± 22 Ω (69 cm)
Serial prefix	LFF

MR Conditional

MR

Initial implant • Existing implant • 1.5T and 3T full body • MRI scanning

Physical characteristics

Polarity	Bipolar
Shape	Straight
Chamber	Ventricle, atrium, bundle of His, or left bundle branch area†
Standard lengths	59, 69, 74 cm†
Connector	IS-1 BI

†Also available in non-MRI length at 49 cm. As an alternative to apical right ventricular pacing in a single or dual chamber pacing system.

Materials

Insulator	Polyurethane (outer), silicone, and ETFE (inner)
Conductor	MP35N
Helix electrode	Titanium nitride-coated platinum alloy
Ring electrode	Titanium nitride-coated platinum alloy

Diameter

Body	1.4 mm (4.1 Fr)

Guide catheter

Tip design	Working length
Fixed-shape C315 catheters	
C315-H20	20 cm
C315-J C315-S4 C315-S5	30 cm
C315-S10 C315-H40	40 cm
C315-HIS	43 cm
Deflectable C304 catheters	
C304S59	30 cm
C304L69	40 cm
C304XL74	45 cm

Brief Statement
Select Secure and SelectSecure MRI SureScan Pacing and Sensing Lead

Indications
Medtronic SelectSecure family of leads has application where implantable atrial or ventricular, single-chamber or dual-chamber pacing systems are indicated. The Model 3830 lead is intended for pacing and sensing in the atrium or ventricle.

Medtronic SelectSecure MRI family of leads is intended for pacing and sensing in the atrium or right ventricle. It is also intended for pacing and sensing at the bundle of His or in the left bundle branch area as an alternative to right ventricular pacing in a single or dual chamber pacing system.

SelectSecure MRI SureScan™ leads (specified lengths of Model 3830 including 59, 69 and 74 cm) are MR conditional and indicated for pacing and sensing at the bundle of His or in the left bundle branch area as an alternative to right ventricular pacing in a single or dual chamber pacing system. The Model 3830 lead is part of the Medtronic SureScan system. The SureScan system includes a Medtronic SureScan device connected to Medtronic SureScan leads.

Contraindications
SelectSecure lead family is contraindicated for the following:

• Ventricular use in patients with tricuspid valvular disease or a tricuspid mechanical heart valve.

• Patients for whom a single dose of beclomethasone dipropionate may be contraindicated; see manual for specific dosage.

The SelectSecure™ Model 3830 Lead is also contraindicated for the following: Patients with obstructed or inadequate vasculature for intravenous catheterization.

Warnings and Precautions
People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs) and accompanying leads should not receive certain forms of diathermy treatment. Diathermy treatments may result in serious injury or damage to an implanted device and lead system. Some lead models allow the use of therapeutic ultrasound; consult individual lead model technical manuals for more detail.

For Model 3830, total patient exposure to beclomethasone 17,21-dipropionate should be considered when implanting multiple leads. No drug interactions with inhaled beclomethasone 17,21-dipropionate have been described. Drug interactions of beclomethasone 17,21-dipropionate with the Model 3830 lead have not been studied.

Do not use magnetic resonance imaging (MRI) on patients who have non-MR conditional versions/lengths of these leads implanted as part of a complete SureScan System. MRI can induce currents on implanted leads, potentially causing tissue damage and the induction of tachyarrhythmias.

MRI SureScan Leads only: A complete SureScan pacing or defibrillation system is required for use in the MR environment. Before performing an MRI scan, refer to the MRI Technical Manual for MRI-specific warnings and precautions. Patients and their implanted systems must be screened to meet the following requirements for MRI: no implanted lead extenders, lead adaptors, or abandoned leads; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; a SureScan defibrillation system implanted in the left or right pectoral region; pacing capture thresholds of ≤ 2.0 V at a pulse width of 0.4 ms; no diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is programmed to On. Patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging.

Potential Complications
Potential patient-related complications related to the use of transvenous leads include, but are not limited to, valve damage, fibrillation and other arrhythmias, thrombolytic and air embolism, cardiac perforation, heart wall rupture, cardiac tamponade, muscle or nerve stimulation, pericarditis, pericardial rub, infection, myocardial irritability, thrombosis and pneumothorax. Other potential lead-related complications may include exit block, lead dislodgement, lead fracture, insulation failure, and threshold elevation.

Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

See the appropriate Device MRI SureScan Technical Manual before performing an MRI Scan and Lead Technical Manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com or www.mrisurescan.com

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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