Model 3830

Left bundle branch area pacing

indication expansion
The 3830 left bundle branch area labeling expansion has been approved for bradycardia patients only, as an alternative to right ventricular pacing in a single- or dual-chamber pacing system.

Conduction system pacing as an alternative to CRT for patients with prolonged QRS duration is considered off-label. Any unsolicited requests must be referred to the Medtronic Office of Medical Affairs (OMA).

United States OMA
Phone: 1-877-359-6415
Email: RS.omachrf@medtronic.com
FDA approves 3830 lead placement for conduction system pacing

Indications for use

The Model 3830 lead 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.

2005 | Initial approval
2018 | His bundle pacing
2022 | Left bundle branch area pacing†

†Approval based on 3830 LBBAP Real-World Evidence Evaluation.
† Model 3830 FDA Instructions for Use M035956C001A.
Opportunity to improve patient outcomes with conduction system pacing

Studies have reported deleterious effects of right ventricular pacing, including increased risk of pacing-induced cardiomyopathy, heart failure,¹ and ventricular dyssynchrony.²

Conduction system pacing allows for a more physiologic alternative to right ventricular pacing³; yet requires precise lead electrode placement that is difficult to achieve with traditional stylet-driven leads.⁴

SelectSecure™ Model 3830 MRI leads

Proven safe. Proven effective. Proven design.

**Fixed helix**
- Increased helix stability at implant relative to extendable/retractable helix leads\(^1\)
- Reduced fracture risk relative to extendable/retractable helix leads\(^1\)

**Lumenless design**
- 4.1 French, isodiametric lead body design
- Central cable minimizes lead mechanical stress relative to stylet-delivered lead designs\(^2\)
- Portfolio of fixed and steerable catheters to facilitate reaching targeted anatomical sites

**MR Conditional**
- 3830 is now the only left bundle branch area lead approved for use with MR Conditional systems

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The 3830 LBBAP real-world evidence evaluation

Three analyses\(^1\) encompassing > 20K global patients

**Systematic review, meta-analysis**
- 6,061 patients
- 45 centers
- Implant success rate, procedure adverse events from 53 original research manuscripts

**Medtronic Product Surveillance Registry**
- 312 patients
- 25 centers
- Retrospective analysis of electrical performance and lead complications

**Medtronic CareLink™**
- 14,933 patients
- 887 centers
- Retrospective analysis of electrical performance

\(^1\) SelectSecure 3830 Left Bundle Branch Area Pacing Safety and Efficacy Utilizing RWE. Medtronic data on file.
The Model 3830 lead is safe and effective for LBBAP pacing in bradycardia-indicated patients

3830 LBBAP real-world evidence evaluation

High implant success rate\(^1\)
92.7% average implant success rate among bradycardia-indicated patients (meta-analysis)

Low procedural adverse event rate\(^1\)
2.5% total procedural adverse event rate at implant; 1.6% total procedural septal perforation rate at implant, yet none with clinical sequela (meta-analysis)

Low and stable pacing thresholds\(^1\)
The average pacing threshold remained < 1.0 V after 18 months of follow-up (PSR)

Conclusion\(^2\)
These real-world data demonstrate with reasonable assurance the safety and effectiveness of the Model 3830 lead when placed in the left bundle branch area.

\(^1\) SelectSecure 3830 Left Bundle Branch Area Pacing Safety and Efficacy Utilizing RWE. Medtronic data on file.
\(^2\) Model 3830 FDA Instructions for Use M035955C001A.
High implant success rate with 3830 at LBBAP\textsuperscript{1}

\textbf{3830 LBBAP real-world evidence evaluation}

92.7\% implant success rate among bradycardia-indicated patients

11.3 average minutes fluoroscopy time

84.4 minutes total procedure time

117 ms average paced QRS duration at implant

\textsuperscript{1} SelectSecure 3830 Left Bundle Branch Area Pacing Safety and Efficacy Utilizing RWE. Data on file. Data points from meta-analysis.
Low procedural adverse event rate\textsuperscript{1}

3830 LBBAP real-world evidence evaluation

2.5\% total procedural adverse event rate at implant (meta-analysis)

1.6\% total procedural septal perforation rate at implant, yet none with clinical sequela (meta-analysis)

97.0\% patients free from 3830 LBBAP complication through six months follow-up (PSR)

Three infections, two dislodgements, one elevated threshold

\textsuperscript{1} SelectSecure 3830 Left Bundle Branch Area Pacing Safety and Efficacy Utilizing RWE. Medtronic data on file.
Electrical performance of 3830 LBBAP

3830 LBBAP real-world evidence evaluation

Pacing thresholds

< 1.0 V average at ≤ 1.0 ms pulse width through 12 months (PSR) and 18 months (CareLink™) follow-up\(^1\)

R-wave sensing

> 12.0 mV average through 12 months (PSR) and 18 months (CareLink™) follow-up\(^1\)

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\(^1\) SelectSecure 3830 Left Bundle Branch Area Pacing Safety and Efficacy Utilizing RWE. Medtronic data on file.
Robust mechanical performance supports Model 3830 for LBBAP procedures

Test methodology developed from clinical CT data sets for 10-year simulated mechanical testing (> 400 M cycles)

Use conditions

IMAGE-LBB study included n = 43 patients with 3830 in LBB

• Acute stresses at implant
• Lead tip depth in septum
• Lead bending in vivo

Fatigue testing

Replicated LBB use conditions in benchtop fatigue tests

• Torque pre-conditioning
• Tested at 95th percentile stress condition

Statistical modeling

Modeled reliability predicts equivalent performance to standard RV pacing

The road to conduction system pacing with SelectSecure™ 3830

SelectSecure 3830 pacing lead
> 350,000\(^1\) leads implanted, sold in 99\(^1\) countries, 71 published manuscripts\(^\dagger\)

\(^1\)Includes manuscripts with primarily bradycardia patients, does not include case reports, and is through May 2022.
\(^\dagger\) 3830 Milestones. Units Sold and Countries of Sale. Medtronic data on file.
SelectSecure™ MRI SureScan™ 3830 Lead

Approved for LBBAP

Proven safe. Proven effective. Proven design.
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 valvarul disease or a tricuspid mechanical heart valve.
- Patients for whom a single dose of beclomethasone dipropionate may be contraindicated; see manual for specific dosage.

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 have 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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