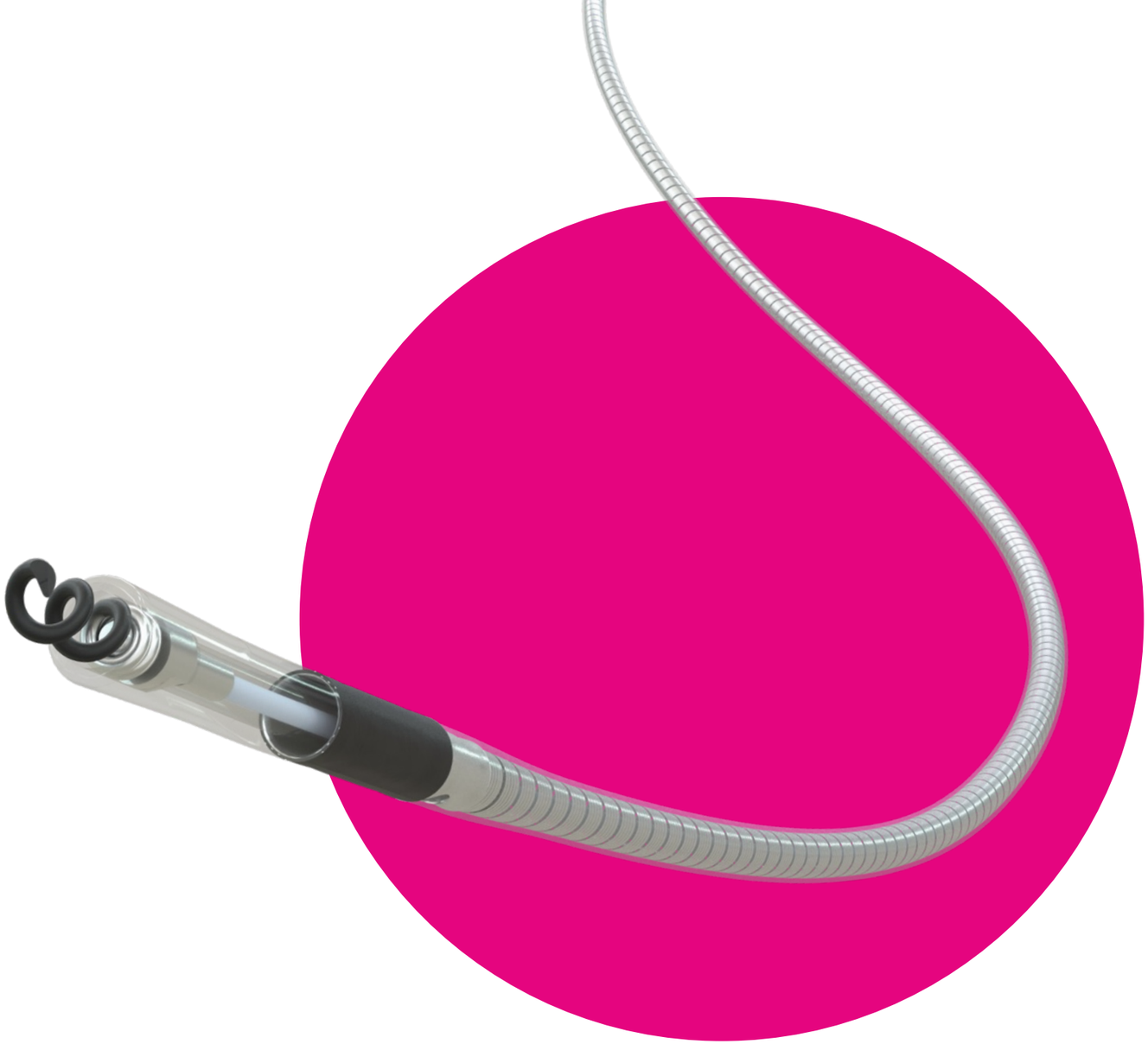
Medtronic

Engineering the extraordinary

Model 3830

Left bundle branch area pacing

indication expansion



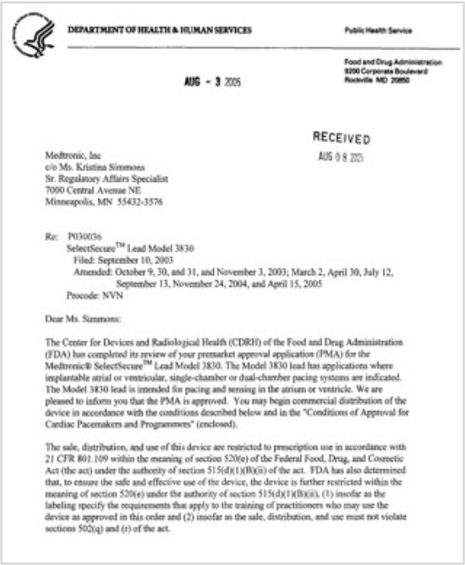
The 3830 left bundle branch area labeling expansion has been approved for bradycardia patients only, as an alternative to right ventricular pacing in a single- or dual-chamber pacing system.

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

Medtronic

FDA approves 3830 lead placement for conduction system pacing



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2005

RECEIVED
AUG 0 8 2005

Medtronic, Inc
c/o Ms. Kristina Simmons
Sr. Regulatory Affairs Specialist
7000 Central Avenue NE
Minneapolis, MN 55432-3576

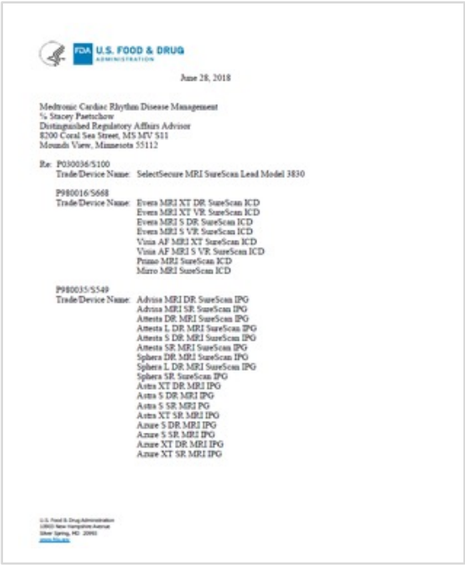
Re: P030036
SelectSecure™ Lead Model 3830
Filed: September 10, 2003
Amended: October 9, 30, and 31, and November 3, 2003; March 2, April 30, July 12, September 13, November 24, 2004, and April 15, 2005
Procode: NVN

Dear Ms. Simmons:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Medtronic® SelectSecure™ Lead Model 3830. The Model 3830 lead has applications 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. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval for Cardiac Pacemakers and Programmers" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

2005 | **Initial approval**



U.S. FOOD & DRUG ADMINISTRATION

June 28, 2018

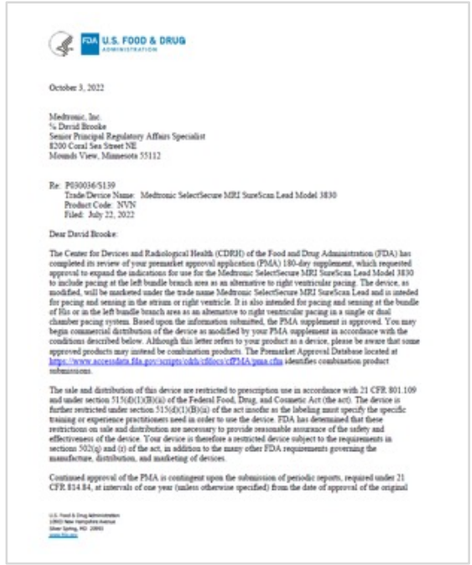
Medtronic Cardiac Rhythm Disease Management
℅ Stacey Paetzhaw
Distinguished Regulatory Affairs Advisor
8200 Coral Sea Street, MS MV 511
Mounds View, Minnesota 55112

Re: P030036/S100
Trade/Device Name: SelectSecure MRI SureScan Lead Model 3830

P980016/S668
Trade/Device Name: Evera MRI XT DR SureScan ICD
Evera MRI XT VR SureScan ICD
Evera MRI S DR SureScan ICD
Evera MRI S VR SureScan ICD
Visia AF MRI XT SureScan ICD
Visia AF MRI S VR SureScan ICD
Primo MRI SureScan ICD
Mirro MRI SureScan ICD

P980035/S549
Trade/Device Name: Adviza MRI DR SureScan IPG
Adviza MRI SR SureScan IPG
Attesta DR MRI SureScan IPG
Attesta L DR MRI SureScan IPG
Attesta S DR MRI SureScan IPG
Attesta SR MRI SureScan IPG
Sphera DR MRI SureScan IPG
Sphera L DR MRI SureScan IPG
Sphera SR SureScan IPG
Astra XT DR MRI IPG
Astra S DR MRI IPG
Astra S SR MRI PG
Astra XT SR MRI IPG
Azure S DR MRI IPG
Azure S SR MRI IPG
Azure XT DR MRI IPG
Azure XT SR MRI IPG

2018 | **His bundle pacing**



U.S. FOOD & DRUG ADMINISTRATION

October 3, 2022

Medtronic, Inc.
℅ David Brooke
Senior Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: P030036/S139
Trade/Device Name: Medtronic SelectSecure MRI SureScan Lead Model 3830
Product Code: NVN
Filed: July 22, 2022

Dear David Brooke:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) 180-day supplement, which requested approval to expand the indications for use for the Medtronic SelectSecure MRI SureScan Lead Model 3830 to include pacing at the left bundle branch area as an alternative to right ventricular pacing. The device, as modified, will be marketed under the trade name Medtronic SelectSecure MRI SureScan Lead and 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. Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original

2022 | **Left bundle branch area pacing†**

Indications for use[1]

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.

†Approval based on 3830 LBBAP Real-World Evidence Evaluation.
[1] Model 3830 FDA Instructions for Use M035956C001A.

Medtronic

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 pacing[3]; yet requires precise lead electrode placement that is difficult to achieve with traditional stylet-driven leads.[4]

[1] Abdelrahman M, et al. *J Am Coll Cardiol*. 2018;71:2319-2330.
[2] Tops LF, et al. *J Am Coll Cardiol*. 2009;54:764-776.
[3] Vijayaraman P, et al. *Heart Rhythm*. 2018;15:696-702.
[4] Zanon F, et al. *Europace*. 2018;20:1819-1826.

Medtronic

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

[1] Altman PA, et al. *J Biomed Mater Res.* 1998;43:21-37.
[2] Riley WF, Zachary LW. *Introduction to Mechanics of Materials*. Hoboken, NJ: Wiley; 1989.

Medtronic

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.

Medtronic

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 M035956C001A.

Medtronic

High implant success rate with 3830 at LBBAP[1]

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

[1] SelectSecure 3830 Left Bundle Branch Area Pacing Safety and Efficacy Utilizing RWE. Data on file. Data points from meta-analysis.

Medtronic

Low procedural adverse event rate[1]

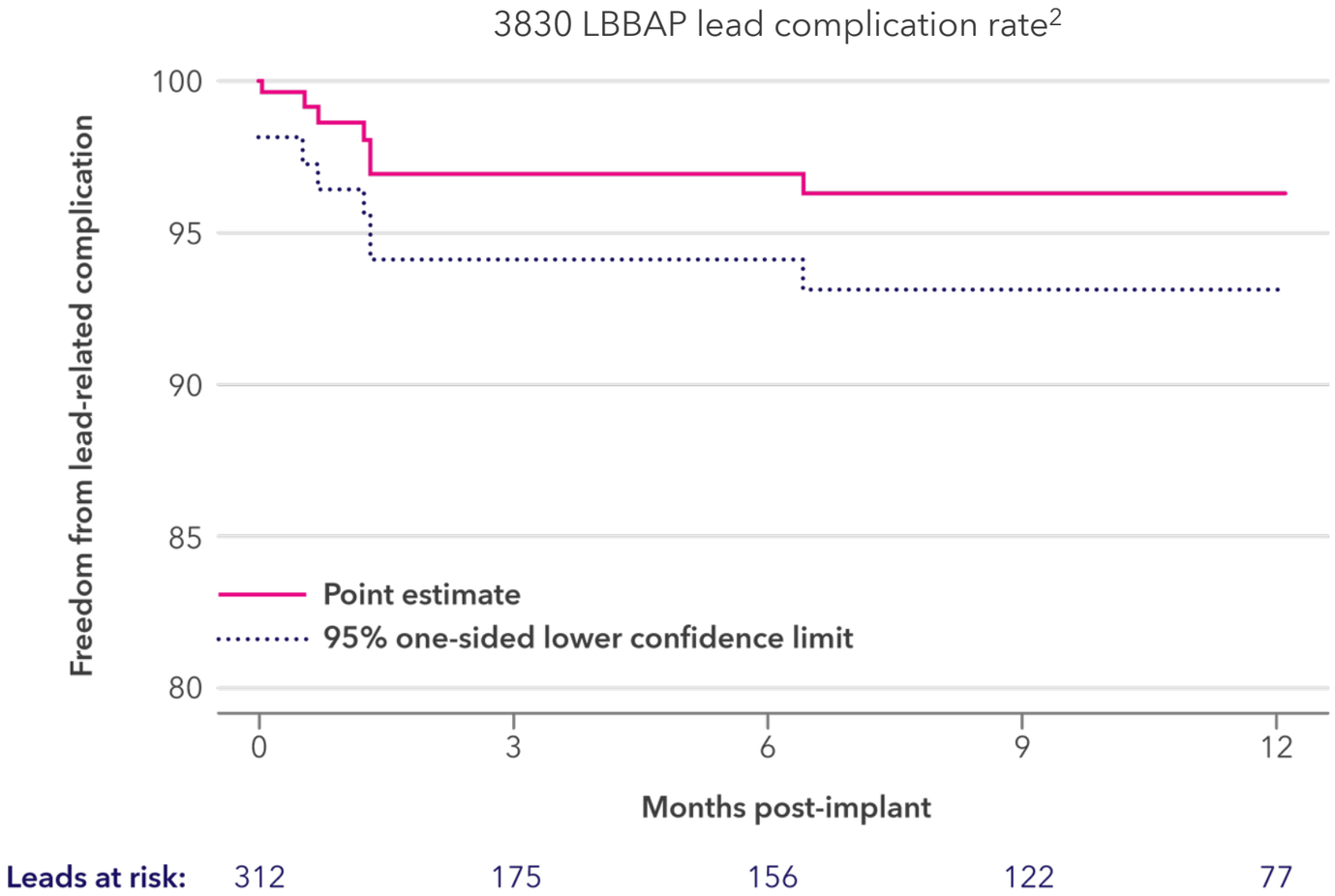
3830 LBBAP real-world evidence evaluation

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



[1] SelectSecure 3830 Left Bundle Branch Area Pacing Safety and Efficacy Utilizing RWE. Medtronic data on file.

Medtronic

Electrical performance of 3830 LBBAP

3830 LBBAP real-world evidence evaluation

Pacing thresholds

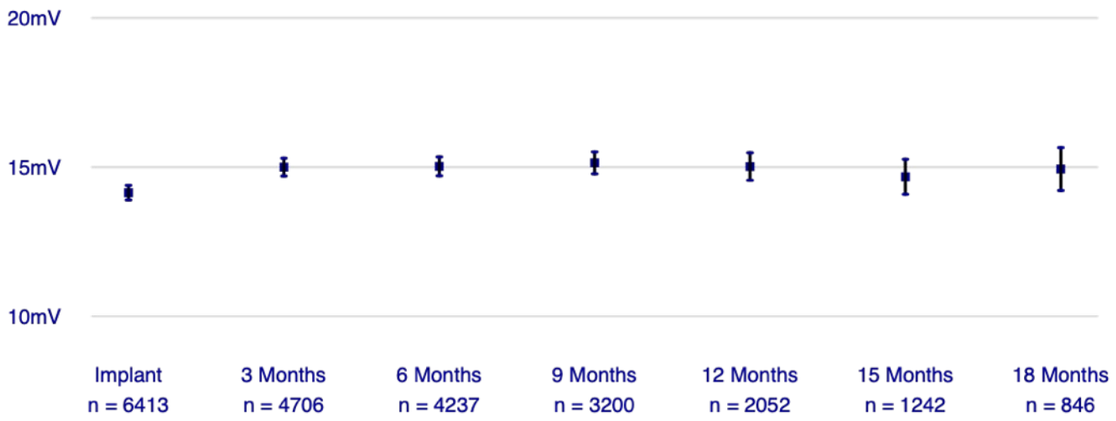
< 1.0 V average at ≤ 1.0 ms pulse width through 12 months (PSR) and 18 months (CareLink™) follow-up[1]

R-wave sensing

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

Average pacing thresholds with 99% confidence intervals

Average sensed R-wave with 99% confidence intervals



[1] SelectSecure 3830 Left Bundle Branch Area Pacing Safety and Efficacy Utilizing RWE. Medtronic data on file.

Medtronic

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)[1]

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

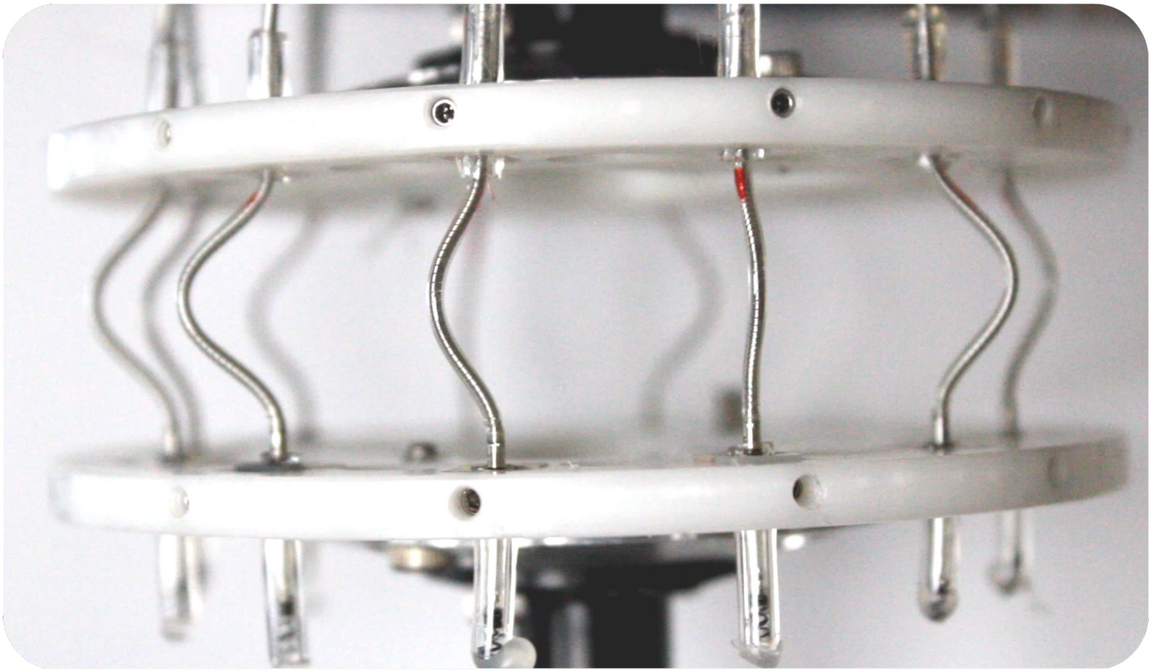
Fatigue testing

Replicated LBB use conditions in benchtop fatigue tests

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

Statistical modeling

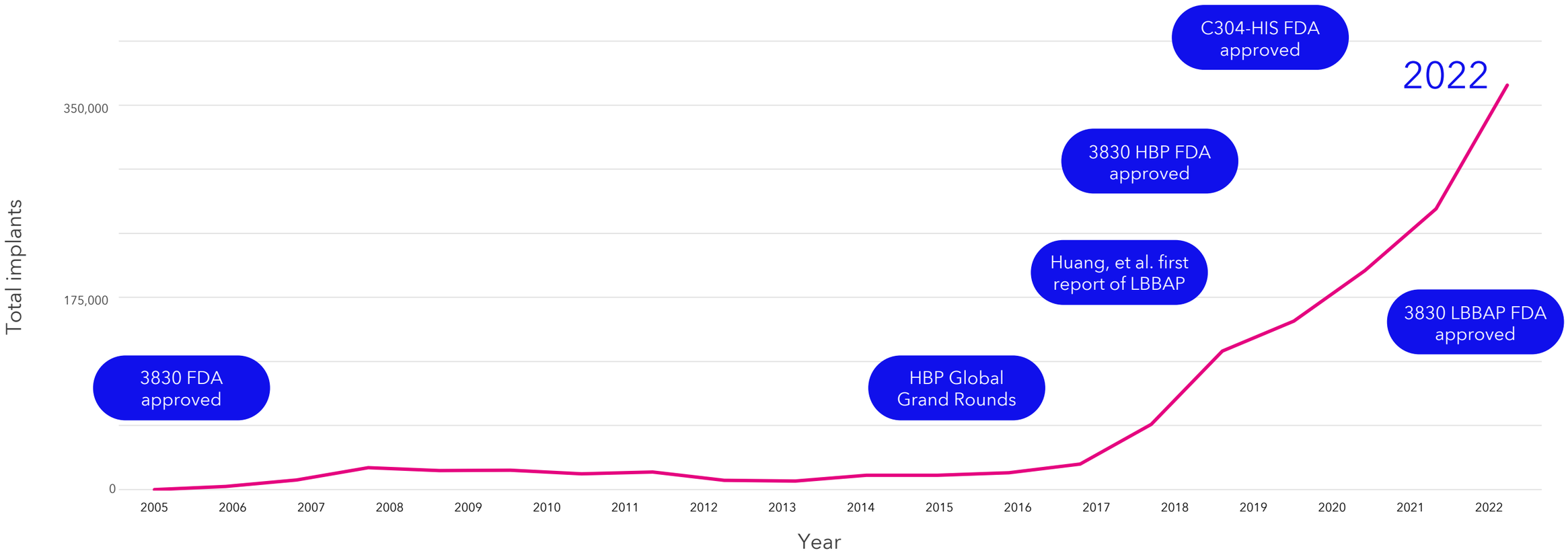
Modeled reliability predicts equivalent performance to standard RV pacing



[1] SelectSecure 3830 Left Bundle Branch Area Pacing Reliability for Conductor Fracture – Estimated 10-Year Survival. Medtronic data on file.

Medtronic

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[†]

[†]Includes manuscripts with primarily bradycardia patients, does not include case reports, and is through May 2022.
[1] 3830 Milestones. Units Sold and Countries of Sale. Medtronic data on file.

Medtronic

SelectSecure™ MRI SureScan™ 3830 Lead

Approved for LBBAP

Proven safe. Proven effective. Proven design.

Medtronic

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.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

Medtronic