

# Medtronic

Engineering the extraordinary

## Medtronic Taps into the Heart's Natural Conduction System with its Newly Approved Lead

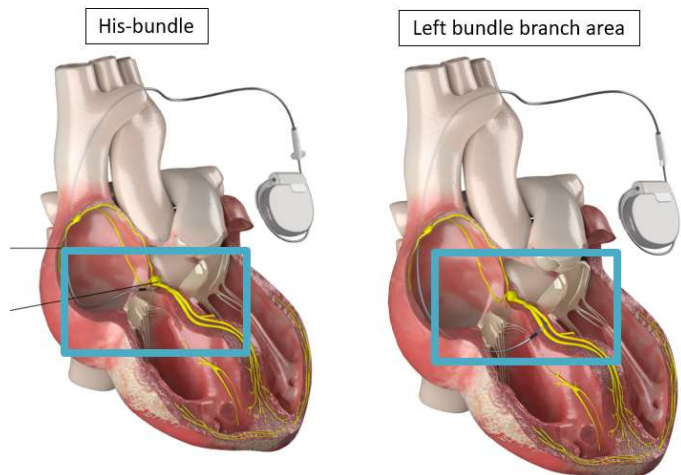
*First and only FDA-approved lead for "Conduction System Pacing" helps patients with slow heart beats*

### Meeting the Need for a Natural Way of Pacing

Bradycardia is characterized by a slow or irregular heart rhythm, usually fewer than 60 beats per minute (normal heart rate is 60 - 100 bpm). At this rate, the heart is unable to pump enough oxygen-rich blood to the body during normal activity or exercise, causing dizziness, fatigue, shortness of breath or fainting spells.

More than half a million U.S. adults over age 65, experience bradycardia<sup>i</sup>, and pacemakers are a common way to treat the condition.

Traditionally, pacemaker leads - long, thin wires that deliver therapy - are implanted into the right ventricle of the heart and attached to a pacemaker situated in a pocket under the skin above the heart. With conduction system pacing, the lead taps into the heart's natural conduction system, either at the bundle of His or the left bundle branch area.



This type of pacing mimics the heart's physiologic contractions, allowing the heart's ventricles to work in coordination. This approach gives patients needed therapy while avoiding complications sometimes associated with traditional pacing methods, such as cardiomyopathy<sup>ii</sup>.

### SelectSecure™ MRI SureScan™ 3830 Lead

#### FIRST AND ONLY



The Model 3830 lead is the first and only MR-conditional lead available on the market and FDA-approved for both His-bundle and left bundle branch area pacing. Left bundle branch area pacing provides another option for patients who require pacing.

The SelectSecure™ Model 3830 lead is a screw-in, catheter-delivered, transvenous lead that comes in various lengths.

Pacing at the bundle of His and left bundle branch area are newer techniques, and the 3830 lead is the only lead to have been evaluated and tested for this use, making it a popular choice for conduction system pacing procedures.

**Regulatory Status**

The U.S Food and Drug Administration (FDA) approved expanded labeling of the Medtronic SelectSecure™ MRI SureScan® 3830 cardiac lead that taps into the heart’s natural electrical system. Now conduction system pacing via left bundle branch area, in addition to pacing from the His-bundle (approved 2018), are approved alternatives to apical pacing in the right ventricle in a single- or dual-chamber pacing system.

Originally indicated in the U.S. for pacing and sensing in the atrium or right ventricle, the MR-conditional, SelectSecure Model 3830 lead has more than 20 years of proven performance and reliability. The expanded indication for left bundle branch area pacing was granted based on evidence from multiple sources spanning more than 20,000 treated patients<sup>iii</sup>.



The SelectSure Model 3830 lead received approval for left bundle branch area based on real-world evidence showing<sup>iv</sup>:

- High procedural success rate at 92%
- Low procedural complication rate at 2.5%
- Low septal perforation rate of less than 2%
- No MRI-related adverse effects

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<sup>i</sup> Cleveland Clinic website, accessed 14 October 2022, <<https://my.clevelandclinic.org/health/diseases/17841-bradycardia#:~:text=Bradycardia%20is%20a%20common%20condition,600%20adults%20over%20age%2065>>.

<sup>ii</sup> Padala SK and Ellenbogen KA. Card Electrophysiol Clin. 2021;13(4):755-84.

<sup>iii</sup> Medtronic data on file.

<sup>iv</sup> Ellenbogen KA, Fagan DH, Zimmerman P, et al. Left bundle branch area pacing using the 3830 lumenless lead: A systematic review and meta-analysis. Accepted at 15th Asia Pacific Heart Rhythm Society Scientific Session. 20 November 2022.