AGENDA

- Overview of His-Bundle Pacing
- SelectSecure Lead Overview
- C315 Catheter Family Overview
- His-Bundle Pacing Implant Technique
  - Including locating the His Bundle
  - Considerations for New/Potential Implanters
  - Tips and Tactics
  - Programming
  - Limitations
- Next Steps
DISCLAIMER

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OVERVIEW OF HIS-BUNDLE PACING
OVERVIEW OF HIS-BUNDLE PACING
CONDUCTION SYSTEM REVIEW

Click play on the video below to view an animation of the **Normal Sinus Rhythm Conduction System**.

Click play on the video below to view an animation of the **Left Bundle Branch Conduction System**.
# HIS BUNDLE PACING CLINICAL EVIDENCE
LIMITED DATA WITH NO LARGE RANDOMIZED CLINICAL TRIAL

## Procedure and Follow-Up

- **Procedure and fluoro times**
  - ~20 minute lead implant & 10 minute fluoro\(^1-4\)
  - >75% Implant Success\(^1-4\)

- **Pacing Capture Thresholds**
  - Pacing Capture Threshold\(^1-2\) at implant:
    - Selective His-Bundle Pacing: 2.5V @0.5 ms
    - Non-selective His-Bundle Pacing: 1.5V@0.5 ms
    - Acute Injury Current predicts lower chronic thresholds\(^9\)

- **Exit block**
  - 3.2–5.5% exit block (PCT>5V@0.5ms) at 20±10 m F/U\(^2\)

- **Sensing**
  - Acute 2.9±2.0 – 6.8±5.3 mV\(^1-3\)

## Outcomes

- **Limited data with no large randomized clinical trial**
- **Narrow Paced QRS\(^3-7\)**
- **Improved and preserved LV function\(^3-6\)**
- **Lower HF-related hospitalization in frequently paced (>40%) patients\(^3\)**
- **Corrected LBBB in certain patients\(^7\)**
- **Successfully Paced AVB (infra-nodal and intra-His)\(^9\)**

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2. Zanon, PACE. 2011, 34:399
3. Sharma, Heart Rhythm. 2015, 305
4. Huang. Europace. 2015
7. Lustgarten, Heart Rhythm. 2015, 12:1548
8. Vijayaraman, PACE, 2015, 38:540

Note: To view the studies online, go into presentation mode and click on the study you’d like to view.
HBP IMPLANT TECHNIQUE
CONSIDERATIONS FOR NEW/POTENTIAL IMPLANTERS

There may be risks and benefits with both traditional right ventricular pacing and His bundle pacing. These potential risks may be greater or lesser based on the experience of the implanter and specific challenges posed by patient anatomy. If you are considering His bundle pacing, it is important to understand the potential risks that this approach poses. The following are reported risks and complications based on current limited clinical experience (small single center, non-randomized studies):

- **Complications and Precautions**
  - Occasionally the lead may get attached to the fibrous tissue in the annular region during mapping; a few counter-clock rotations and gentle prolonged traction should free-up the lead\(^1\)
  - Be gentle during mapping. It is very easy to cause transient (8%) and permanent right bundle branch block (2-3%)\(^1\). If you notice RBBB during fixation that is usually a good site. Even if RBBB persists it will correct with pacing (higher output initially and improves as injury-related edema resolves)\(^1\)
  - In patients with AV block and / or LBBB, it is important to be prepared for complete AV block and asystole. Back up pacing should be readily available during implant (prior to mapping his-bundle)\(^2\)
  - Failure to implant (10-20% of patients, infra-His block)\(^3\)
  - High thresholds (10-15% of patients)\(^3\)
  - Lead revisions (~3%)\(^4\)
  - Ventricular undersensing
  - Far-field atrial oversensing
  - Atrial capture

4. Zanon, PACE, 2011
HIS-BUNDLE PACING LEADS & CATHETERS
SELECTSECURE LEAD OVERVIEW
MODEL 3830 LEAD DESIGN

3830 Lead Specifications:
- 4.1 FR lead body diameter
- Bipolar
- Fixed screw helix
- Steroid eluting
- Polyurethane outer insulation
- Cable inner conductor

Cross-sectional view of 3830 lead
SELECTSSECURE LEAD OVERVIEW
3830 LONG-TERM PERFORMANCE WITH VENTRICULAR PLACEMENT

DEVICE SURVIVAL PROBABILITY

3830 SelectSecure™ Ventricular Placement

<table>
<thead>
<tr>
<th>%</th>
<th>1 yr</th>
<th>2 yr</th>
<th>3 yr</th>
<th>4 yr</th>
<th>5 yr</th>
<th>6 yr</th>
<th>at 78.0 mo</th>
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VENTRICULAR PLACEMENT: 97.5% survival probability at 78 months

SELECTSECURE LEAD OVERVIEW
3830 LONG-TERM PERFORMANCE WITH ATRIAL PLACEMENT

DEVICE SURVIVAL PROBABILITY

3830 SelectSecure™ Atrial Placement

<table>
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<tr>
<th></th>
<th>1 yr</th>
<th>2 yr</th>
<th>3 yr</th>
<th>4 yr</th>
<th>5 yr</th>
<th>6 yr</th>
<th>at 78.0 mo</th>
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<tr>
<td>%</td>
<td>99.2</td>
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<td>644</td>
<td>555</td>
<td>403</td>
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</table>

ATRIAL PLACEMENT: 98.6% survival probability at 78 months

## C304 Guide Catheter Family Overview

### C304 Deflectable Catheter Design

<table>
<thead>
<tr>
<th>Spec</th>
<th>C304 Specs</th>
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</thead>
<tbody>
<tr>
<td>Shape</td>
<td>Deflectable</td>
</tr>
<tr>
<td>Introducer</td>
<td>9Fr</td>
</tr>
<tr>
<td>Usable length</td>
<td>30 cm, 40 cm, and 45 cm</td>
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<tr>
<td>Inner diameter</td>
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<tr>
<td>Outer diameter</td>
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<tr>
<td>Integrated valve</td>
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</tr>
<tr>
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<td>Articulation handle</td>
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<tr>
<td>Hydrophilic coating</td>
<td>No</td>
</tr>
<tr>
<td>Braid</td>
<td>Yes, 8 x 8</td>
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</table>

### C304 Deflectable Catheter

![C304 Deflectable Catheter Image](image-url)
## C315 Catheter Family Overview

<table>
<thead>
<tr>
<th>Shape</th>
<th>Description</th>
<th>Compatible 3830 lengths</th>
<th>Lead Location</th>
</tr>
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<tbody>
<tr>
<td>H20</td>
<td>20 cm</td>
<td>49 cm or longer</td>
<td>Apex, triangle of Koch for smaller patients</td>
</tr>
<tr>
<td>J</td>
<td>30 cm</td>
<td>59 cm or longer</td>
<td>Bachmann’s bundle, high atrial septum, lateral free wall, RA appendage</td>
</tr>
<tr>
<td>S4</td>
<td>30 cm</td>
<td>59 cm or longer</td>
<td>Bachmann’s bundle, high atrial septum, low atrial septum</td>
</tr>
<tr>
<td>S5</td>
<td>30 cm</td>
<td>59 cm or longer</td>
<td>Bachmann’s bundle, high atrial septum, low atrial septum</td>
</tr>
<tr>
<td>S10</td>
<td>40 cm</td>
<td>69 cm or longer</td>
<td>Right Ventricular Outflow Tract, mid-ventricular septum</td>
</tr>
<tr>
<td>H40</td>
<td>40 cm</td>
<td>69 cm or longer</td>
<td>Apex, triangle of Koch</td>
</tr>
<tr>
<td><strong>His</strong></td>
<td>43 cm</td>
<td><strong>69 cm or longer</strong></td>
<td><strong>Bundle of His</strong></td>
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## GUIDE CATHETER COMPARISON
### C315 VS C304 SPECIFICATIONS

<table>
<thead>
<tr>
<th>Comparison</th>
<th>C315</th>
<th>C304</th>
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<tr>
<td>Shape</td>
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</tr>
<tr>
<td>Introducer</td>
<td>7 Fr</td>
<td>9Fr</td>
</tr>
<tr>
<td>Usable length</td>
<td>30 cm, 40 cm &amp; 43 cm</td>
<td>30 cm, 40 cm &amp; 45 cm</td>
</tr>
<tr>
<td>Inner diameter</td>
<td>5.4 Fr</td>
<td>5.7 Fr</td>
</tr>
<tr>
<td>Outer diameter</td>
<td>7.0 Fr</td>
<td>8.4 Fr</td>
</tr>
<tr>
<td>Integrated valve</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Manipulation</td>
<td>No Articulation handle</td>
<td>Articulation handle</td>
</tr>
<tr>
<td>Hydrophilic coating</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Braid</td>
<td>Yes, 16 x 16</td>
<td>Yes, 8 x 8</td>
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</table>
HIS-BUNDLE PACING IMPLANT PROCEDURE*

STEP-BY-STEP INSTRUCTIONS

*Implant Steps Courtesy of Dr. Vijayaraman and Dr. Dandamudi and also described in the paper: Gopi Dandamudi and Pugazhendhi Vijayaraman, How To Perform Permanent His-Bundle Pacing In Routine Clinical Practice, Heart Rhythm, http://dx.doi.org/10.1016/j.hrthm.2016.03.040.

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OVERVIEW OF HIS-BUNDLE PACING
ANATOMY OF HIS-BUNDLE PACING

How to Perform HIS-Bundle Pacing

Courtesy of Dr. Pugazhendhi Vijayaraman, MD

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OVERVIEW OF HIS-BUNDLE PACING
HIS-BUNDLE PACING IMPLANT STEPS¹⁻⁴

Step 1: Obtaining Access

- Obtain access using the preferred method. Two separate venipuncture sites should be considered but are not required.
- The C315HIS sheath can be inserted directly over the .035 guidewire. Using a 7Fr sheath is optional; a 9Fr sheath is required if retaining the guidewire.
- When the C315HIS sheath is in the right atrium near the tricuspid annulus, remove the .035 guidewire and insert the 3830 lead.
- Using the Atrial 5833SL cable, place the Black clip onto the tip electrode and the Red clip onto the patient’s skin, creating a Unipolar Pace/Sense configuration.
  - Use the atrial cables in order to more clearly see the small His potential.
- Set sweep speed to 50 mm/sec and Atrial pulse width to 1.0ms.

OVERVIEW OF HIS-BUNDLE PACING
HIS-BUNDLE PACING IMPLANT STEPS¹-⁴

Step 2: Mapping the His Bundle

▪ Utilizing the Unipolar signal from the atrial cables, carefully advance the 3830 lead outside of the C315HIS catheter, since it is a unipolar connection, only the tip needs to be exposed to record a His potential. Remember that the lead has an exposed helix.

▪ Manipulate the C315HIS catheter until a clear His potential is observable.

▪ After finding the His (as above), advance the C315HIS catheter as far as possible over the 3830 lead. This creates stability for fixating the lead onto the heart.

▪ Recheck the signal to ensure a His potential is still visible.

The His potential seen here is much clearer/larger than most, but it offers a great example of what we desire to see before screwing in the lead.

¹For References 1-4, see full list of citations on slide 17.
LOCATING THE HIS BUNDLE FOR PACING
IDENTIFY THE HIS BUNDLE POTENTIAL

Mapping with EP catheter

Mapping with the 3830 lead
LOCATING THE HIS BUNDLE FOR PACING
IDENTIFY THE HIS BUNDLE POTENTIAL
OVERVIEW OF HIS-BUNDLE PACING
HIS-BUNDLE PACING IMPLANT STEPS¹-⁴

Step 3: Fixating the Lead

▪ Without letting go of the lead and while applying light forward pressure, rotate the entire lead body clockwise 4 complete times.
  ▪ You may require additional turns based on your sensing the required torque build-up.
  ▪ Upon letting go of the lead you should notice the lead rotates back one to two turns which confirms adequate anchoring in the His region.
  ▪ Depending on the type of tissue (central fibrous body vs myocardium), you may not observe this torque.
▪ Withdraw the C315HIS catheter 2-4 inches to test lead stability.
▪ In the case of dislodgement, remove the 3830 lead and check to ensure there is no tissue stuck in the helix. Tissue in the helix may make further fixation more difficult.

¹For References 1-4, see full list of citations slide 17.
OVERVIEW OF HIS-BUNDLE PACING
HIS-BUNDLE PACING IMPLANT STEPS¹⁻⁴^  

Step 4: Testing the His Bundle Location  
- Test R-wave amplitude. For His bundle pacing, R-waves as low as 1-2mV are acceptable provided you can avoid far-field atrial oversensing.  
- Via 12-lead or other surface ECG, measure the QRS width and V sense time during high output pacing (typically start at 5V @ 1 ms).  
- Run a threshold test, decrementing voltage over time. Note here that you will obtain two thresholds, a His threshold and a RV capture threshold.  
- Set the device up with appropriate safety margins for RV / His capture and sensitivity.  
  - Note that in Advisa MRI™, sensitivity can be as low as 0.45mV. In Adapta™, sensitivity can be as low as 1.0mV.  
  - In selective His bundle pacing, there is no RV myocardial capture.  
  - In non-selective HBP (His-bundle pacing plus local ventricular fusion) His capture threshold may be higher or lower than the RV capture threshold.  
  - It is important to program the output at least 1-2 V above His capture threshold.  

^For References 1-4, see full list of citations on slide 17.
OVERVIEW OF HIS-BUNDLE PACING
HIS-BUNDLE PACING IMPLANT STEPS\(^{1-4}\)

**Step 5: Slit the C315HIS Catheter**
- Using a standard slitting technique, slit the C315HIS catheter and observe lead stability under fluoroscopy.
- It is **extremely important to allow adequate lead slack** similar to or more than an atrial lead before slitting the sheath. The lead may not easily advance forward once the sheath is removed, as it is not steerable with a stylet. Also, avoid excessive slack buildup that may cause the loop of the atrial lead to drop near the tricuspid valve.
- Retest R-wave amplitude and His/RV capture thresholds. Test in both unipolar and bipolar configurations. Ideally select bipolar sensing, but may need to select unipolar based on capture characteristics (generally unipolar thresholds are better than bipolar).
  - When choosing unipolar versus bipolar it is important to consider the pacing dependency in a particular patient. In dependent pts, unipolar sensing is not usually recommended due to risk of oversensing far-field electrograms and myopotentials.
- If HB injury current is noted, the His threshold may improve (even if it is higher at fixation) in the next 10-20 minutes.
- Occasionally unipolar sensing may be better than bipolar both to improve sensing and avoid atrial oversensing.

**Step 6: Place the Atrial Lead and select Appropriate Device**
- For high output situations, consider using a large-capacity battery device such as the Adapta\(^{\text{TM}}\) DR (Model ADDRL1). Check longevity tables if needed.
- For low R-wave situations, consider using an Advisa MRI\(^{\text{TM}}\) DR (model A2DR01) device as it provides higher sensitivity. Ensure that atrial oversensing does not occur. Please note: Visit mrisurescan.com to determine if an implanted system is MR Conditional. As of July 2016, Model 3830 is not labeled for MR Conditional use.

\(^{1}\) For References 1-4, see full list of citations on slide 17.
HIS-BUNDLE PACING IMPLANT PROCEDURE ADDITIONAL CONSIDERATIONS*

*Implant Procedure Additional Considerations provided courtesy of Dr. Vijayaraman and Dr. Dandamudi

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**HBP IMPLANT TECHNIQUE¹-⁴**  
**TIPS AND TACTICS**

- Use 12 lead ECG monitoring during implant
- Atrial channel for HB mapping in the PSA
  - Use Maximal gain settings of 0.05mV @ 50 mm/sec sweep speed
  - Printing on the paper may show the His signal better than the PSA monitor – the technician should periodically print and monitor for the His signal to help the implanter
- Consider mapping the His using the lead in the unipolar configuration
- While mapping with the C315HIS sheath:
  - Gentle clockwise rotation will point the lead towards the superior AV septum and more towards the RV region
  - Counterclockwise rotation will direct the lead towards the mid to posterior septum and the atrial region.
- When HB signal cannot be identified, high output pacing (5-10V @ 1 ms) at the AV annular or slightly ventricular location can identify the His region (Pace-mapping) especially in patients with complete heart block. (Varying pacing outputs can show His+RV fusion complexes and pure RV paced complexes)
- Important to feel the torque during/after fixing the lead to achieve stable fixation

¹ For References 1-4, see full list of citations on slide 17.
HBP IMPLANT TECHNIQUE
PROGRAMMING

- About 10% of patients may develop sub-acute increase in HB capture threshold\(^1\)
- Generally, to provide an adequate safety margin, select a pacing voltage twice the chronic stimulation threshold voltage for a given pulse width\(^2\)
- The programmed AV delay should be at-least 40-50 ms shorter than the standard parameters to account for His-Purkinje conduction\(^3\)
- Check for atrial capture during HBP, especially if large atrial electrograms were noted. \(^4\)
- You may experience atrial capture or far-field atrial oversensing and occasionally HB EGM oversensing; therefore, plan sensitivity and pacing output programming accordingly. \(^4\)

FOR ADDITIONAL INFORMATION ABOUT HIS-BUNDLE PACING::

• VISIT MEDTRONICACADEMY.COM

• WATCH THE GLOBAL GRAND ROUNDS FOR AN EXPERT PANEL DISCUSSION OF HIS-BUNDLE PACING

• CONTACT YOUR MEDTRONIC SALES REPRESENTATIVE
BRIEF STATEMENTS

If you are located in the United States, see the device 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.

If you are located outside the United States, see the device manual at manuals.medtronic.com for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.
Brief Statement: IPGs, CRT IPGs, ICDs, and CRT ICDs (cont.)

**Indications**

**Implantable Pulse Generators (IPGs)** are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include various degrees of AV block to maintain the atrial contribution to cardiac output and VVI intolerance (e.g. pacemaker syndrome) in the presence of persistent sinus rhythm. See device manuals for the accepted patient conditions warranting chronic cardiac pacing. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications. For the MR Conditional IPGs, a complete SureScan® pacing system, which consists of an approved combination (see [http://www.mrisurescan.com](http://www.mrisurescan.com)) MRI SureScan device with SureScan lead(s), is required for use in the MR environment.

**Cardiac Resynchronization Therapy (CRT) IPGs** are indicated for NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have a LVEF ≤ 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF ≤ 50%, are on stable, optimal heart failure medical therapy if indicated and have atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post implant. Rate adaptive pacing is provided for those patients developing a bradycardia indication who might benefit from increased pacing rates concurrent with increases in activity. Dual chamber and atrial tracking modes are indicated for patients who may benefit from maintenance of AV synchrony. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications.

**Implantable cardioverter defibrillators (ICDs)** are indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Notes on some features in ICDs: The clinical value of the OptiVol fluid monitoring diagnostic feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure. Additional notes for DR ICDs: The use of the device has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias. The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 17%, and in terminating device classified atrial fibrillation (AF) was found to be 16.8%, in the VT/AT patient population studied. The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 11.7%, and in terminating device classified atrial fibrillation (AF) was found to be 18.2% in the AF-only patient population studied.
BRIEF STATEMENT

Product Safety Information

Brief Statement: IPGs, CRT IPGs, ICDs, and CRT ICDs (cont.)

**CRT ICDs** are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications: New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction < 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration > 130 ms, left ventricular ejection fraction < 30%, and NYHA Functional Class II. NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤ 50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post implant. Some ICDs and CRT ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias. The RV Lead Integrity Alert (LIA) feature is intended primarily for patients who have a Medtronic ICD or CRT-D device and a Sprint Fidelis lead (Models 6949, 6948, 6931, and 6930), based on performance data. The RV LIA feature may not perform as well with a St. Jude Riata/Durata lead or a Boston Scientific Endotak lead as it does when used with a Medtronic Sprint Fidelis lead. This is because different lead designs may have different failure signatures and conditions that may or may not be detected early by the RV LIA feature.

**Contraindications**

IPGs and CRT IPGs are contraindicated for concomitant implant with another bradycardia device and concomitant implant with an implantable cardioverter defibrillator. There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient’s age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician. Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate. Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance. Anti-tachycardia pacing (ATP) therapy is contraindicated in patients with an accessory antegrade pathway.

ICDs and CRT ICDs are contraindicated in patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis; patients who have a unipolar pacemaker implanted, patients with incessant ventricular tachycardia (VT) or ventricular fibrillation (VF), and patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.
**BRIEF STATEMENT**

Product Safety Information

Brief Statement: IPGs, CRT IPGs, ICDs, and CRT ICDs (cont.)

**Warnings/Precautions**
Changes in a patient’s disease and/or medications may alter the efficacy of the device’s programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset or device damage. Do not place transthoracic defibrillation paddles directly over the device. Additionally, for CRT ICDs and CRT IPGs, certain programming and device operations may not provide cardiac resynchronization. Also for CRT IPGs, Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and / or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set. Use of the device should not change the application of established anticoagulation protocols. For MR Conditional IPG Systems, before performing an MRI scan, refer to the SureScan pacing system technical manual for additional information, patients and their implanted systems must be screened to meet the MRI Conditions of Use. Do not scan patients who do not have a complete SureScan pacing system consisting of an approved combination MRI SureScan device with SureScan lead(s); patients who have broken, abandoned or intermittent leads; or patients who have a lead impedance value of < 200 Ω or > 1,500 Ω.

**Potential complications**
Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis. An additional complication for ICDs and CRT ICDs is the acceleration of ventricular tachycardia. SureScan systems have been designed to minimize potential complications in the MRI environment. 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 device 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.

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.

Updated Nov 10 2015
**BRIEF STATEMENT**

**Product Safety Information**

**Brief Statement: Medtronic Leads**

**Indications**
Medtronic leads are used as part of a cardiac rhythm disease management system. Leads are intended for pacing and sensing and/or defibrillation. Defibrillation leads have application for patients for whom implantable cardioverter defibrillation is indicated.

**Contraindications**
Medtronic leads are 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 1.0 mg of dexamethasone sodium phosphate or dexamethasone acetate may be contraindicated. (includes all leads which contain these steroids)
- Epicardial leads should not be used on patients with a heavily infarcted or fibrotic myocardium.

The SelectSecure Model 3830 Lead is also contraindicated for the following:
- patients for whom a single dose of 40.µg of beclomethasone dipropionate may be contraindicated.
- patients with obstructed or inadequate vasculature for intravenous catheterization.

**Warnings/Precautions**
People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, or the need to reprogram or replace the device.

For the SelectSecure Model 3830 lead, 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.
BRIEF STATEMENT

Product Safety Information

Brief Statement: Medtronic Leads (cont.)

Potential Complications

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

See the device 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.

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