Medtronic

Coding corner

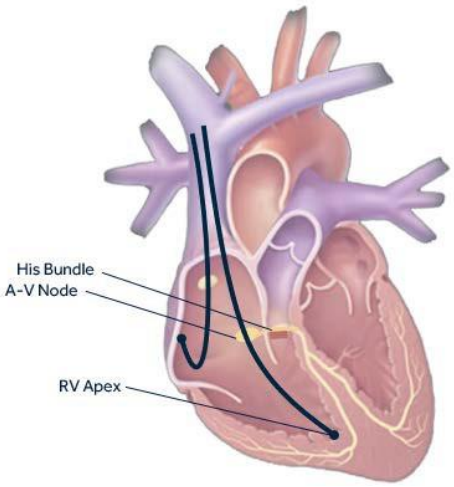
Pacing at the bundle of His

Background

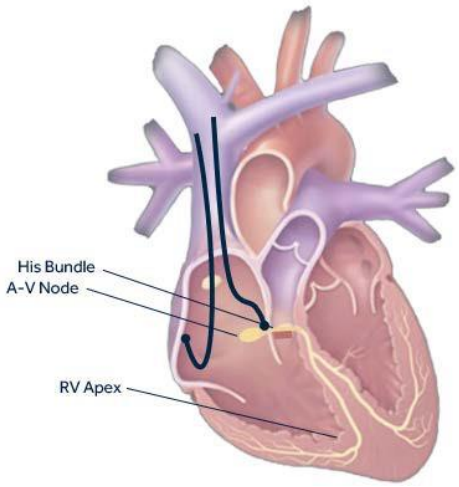
Right ventricular (RV) pacing has been the standard practice for patients requiring permanent ventricular pacing. However, long-term RV apical pacing creates a non-physiologic activation pattern and may lead to worsened systolic and diastolic function in a subset of patients.[1]

His bundle pacing may preserve synchronous ventricular depolarization, which could mitigate ventricular dysfunction relative to RV pacing. The lead that would be intended for ventricular pacing, which would normally be placed in the right ventricle, can be placed on the lower septal part of the right atrium or in the upper septal part of the right ventricle to pace the bundle of His. The lead placement decision is based on the clinician's intent to pace. This document focuses on the special considerations for coding when the lead intended to pace the ventricle is placed at the bundle of His.

The Medtronic C315HIS and the C304HIS delivery catheters are designed for placement of the SelectSecure™ MRI SureScan™ 3830 lead at the bundle of His.



Ventricular lead at the right ventricular apex



Ventricular lead at His bundle‡

Currently, the FDA-approved indications for the SelectSecure MRI 3830 lead state the following:
"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 as an alternative to right ventricular pacing in a single or dual chamber pacing system."[2]

Other indications are either considered not within the current labeling or off-label use.

Possible coding solutions for pacing at the bundle of His – Initial implant

His bundle pacing can be used to treat bradycardia (e.g., AV block, sinus node disease). In these scenarios the RV lead is placed at the bundle of His rather than at the RV apex. The final placement at the bundle of His may be anatomically in either the atrium (floor of atrium near tricuspid valve) or ventricle (at the roof of the ventricle near the tricuspid valve). Therefore, both scenarios are provided below.

Possible CPT®[3] coding solutions for physicians and hospital outpatient setting:

Pacemaker scenario	Bundle of His approach: Atrial anatomical placement
Single Chamber (SC)	**33206** Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial
Dual Chamber (DC)	**33208** Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular

Pacemaker scenario	Bundle of His approach: Ventricular anatomical placement
Single Chamber (SC)	**33207** Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular
Dual Chamber (DC)	**33208** Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular

Possible use of modifier -22:

The use of Modifier -22 (increased procedural service) *may* be appropriate. The use of the modifier -22 is generally considered appropriate when the work and time required to perform the service is more extensive than is typically required for a non-His bundle pacing implant of a single or dual chamber pacemaker. Medicare and/or commercial payers may require additional documentation and justification for billing one of these codes with the modifier -22.

Possible coding solutions for pacing at the bundle of His – Lead replacement

In certain situations, a patient may have a pre-existing single or dual chamber pacemaker. Due to either failure of the existing RV pacing lead or suboptimal clinical response (e.g., pacemaker syndrome), the physician determines that a replacement SelectSecure MRI 3830 transvenous pacing lead should be placed at the His bundle instead of in the RV apex. The existing RV pacing lead is either capped and abandoned or is removed.

The final location of the SelectSecure MRI 3830 lead to pace the His bundle is in the atrium. However, the intent of the lead placement is to pace the ventricle. The lead at the His bundle is the only functioning ventricular pacing lead after the replacement procedure.

Pacemaker scenario	Bundle of His approach: Atrial anatomical placement
His bundle lead is the only functioning ventricular pacing lead after the replacement procedure	**33216** Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
	If removal of the existing lead is performed: **33234** Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular

Possible ICD-10-PCS coding solutions for hospital inpatient setting

The ICD-10-PCS procedure coding would include both a generator insertion code and the appropriate number of codes for insertion of lead(s). For example, a single chamber ventricular system with His bundle placement should report the generator placement (e.g., 0JH604Z) and the atrial lead placement (02H63JZ). A dual chamber system with His bundle placement for the ventricle should report the generator code and the atrial lead code twice, once for the atrium and once for the lead at the bundle of His (assuming an atrial anatomical placement). Note that some coders would view reporting the atrial lead twice as optional and instead would report it only once, particularly since the payment impact is the same.

ICD-10-PCS

Procedure code	Description
Pacemaker generator insertion	
0JH606Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach
0JH605Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach
0JH604Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach
Pacemaker lead insertion	
02H63JZ	Insertion of pacemaker lead into right atrium, percutaneous* approach

*Percutaneous approach is the equivalent of transvenous

Coding for His bundle recording/mapping

Placing a lead appropriately at the His bundle often requires mapping the intracardiac tissue to identify the precise location of the conduction mechanism. It might be reasonably questioned whether two electrophysiology CPT codes for bundle of His recording (CPT code 93600) and intra-atrial pacing (CPT code 93610) might be assigned for this maneuver in conjunction with the code for the lead implant.

While arguments can be made, we do not believe reporting either of these codes separately for mapping prior to placing a lead at the bundle of His – whether using an external EP catheter or using the lead itself – would withstand scrutiny by external reviewers.

By coding convention,[4] identifying the location for leads is included in the lead placement procedure and not separately reported. Further, the introductory language in the CPT manual specifies use of 93600 and other recording/mapping codes as reportable when trying to identify tachyarrhythmias for ablation based on the mapped tachycardias combined with diagnostic information. This indicates that these electrophysiology codes are not used when trying to locate the precise position in which to place a lead, whether in the atrium, apex of the ventricle, or at the bundle of His.

Disclaimer: Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules, and regulations. The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists, and/or legal counsel for interpretation of coding, coverage, and payment policies. This document provides assistance for FDA approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA cleared or approved labeling (e.g., instructions for use, operator's manual, or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service.

References

[1] Mulpuru SK, Cha YM, Asirvatham SJ. Synchronous ventricular pacing with direct capture of the atrioventricular conduction system: Functional anatomy, terminology, and challenges. *Heart Rhythm*. November 2016;13(11):2237-2246.

[2] Medtronic Manual Library, SelectSecure™ MRI SureScan™ 3830 Technical Manual, M983801A001, Accessed November 2021.

[3] CPT ©2021 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to government use. The AMA assumes no liability for the data contained or not contained herein.

[4] American Medical Association. *CPT® Assistant*. April 2004:8.

‡Cardiac Image from https://www.medtronicacademy.com/powerpoint/cardiac-anatomy-and-physiology (slide 33)

Brief Statement
SelectSecure™ 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 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 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 the Medtronic website at medtronic.com *or* mrisurescan.com.

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

C304 SelectSite™ Catheter Brief Statement

Indications (or Intended Use)

The device is indicated to provide a pathway through which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart and for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

Contraindications

Use of the device is contraindicated for patients with obstructed or inadequate vasculature and for right ventricular use in patients with tricuspid valvular disease or a mechanical tricuspid heart valve.

Warnings and Precautions

- The device is for single use only and is not intended to be resterilized.
- Use the deflectable catheter only with compatible transvenous devices. No test data is available to demonstrate compatibility of the deflectable catheter with any device not manufactured by Medtronic. For the C304 Catheters, no test data is available to demonstrate compatibility of the transvenous devices with an outer diameter larger that 1.5mm (4.6Fr), with the exception of the 1.85mm (5.6Fr) dilator included with the device package. Consequences of using the deflectable catheter with incompatible devices may include the inability to deliver the transvenous device or damage to the transvenous device during delivery.
- Thrombogenicity evaluations were conducted using a heparinized model. If your patient cannot be adequately anticoagulated, it is unknown whether thrombus formation may occur with this product.
- Handle the deflectable catheter with care at all times. Do not kink, stretch, or severely bend the deflectable catheter. Do not use surgical instruments to grasp the deflectable catheter. Avoid contact with liquids other than isopropyl alcohol, blood, saline, or contrast solution.
- Use the valve to impede the back flow of venous blood during the implant procedure. Ensure that the flush port stopcock is closed before attaching the valve to the deflectable catheter hub.
- Keep external defibrillation and backup pacing readily available during implant. Use of the device, transvenous devices, or both may cause heart block.

Potential Adverse Events or Potential Complications

Potential adverse events related to the use of the deflectable catheter may include, but are not limited to, the following events: air embolism, allergic reaction to contrast media, arteriovenous fistula formation, bleeding at the insertion site, brachial plexus injury, cardiac tamponade, dislodgement, dissection, endocarditis, heart block, hematoma formation, hemothorax, infection, irregular heart beat, mediastinal widening, perforation, pneumothorax, subclavian artery puncture, thrombophlebitis, thrombosis, valve damage, vascular occlusion, vessel damage.

See the device instructions for use for detailed information regarding the procedural instructions, 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.

C315 Catheter Brief Statement

Indications (or Intended Use)

The C315 is indicated for the introduction of various types of pacing or defibrillator leads and catheters.

Contraindications

Use of the C315 percutaneous catheter is contraindicated in patients with obstructed or inadequate vasculature.

Warnings and Precautions

- This device is intended only to be used once for a single patient. Do not reuse, reprocess, or resterilize this device for purpose of reuse. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device or create a risk of contamination of the device that could result in patient injury, illness, or death.
- Keep external defibrillation equipment nearby for immediate use during insertion, placement, acute lead system testing, or whenever arrhythmias are possible or intentionally induced. Backup pacing should be readily available during implant. Use of a delivery system and/or leads may cause heart block. For further information about this and other potential adverse events or complications, refer to the technical manual packaged with the appropriate product.
- Use care when passing a catheter through vessels and tissue. Avoid damage, such as perforations and dissections, to vessels and cardiac tissue, during catheter passage and positioning. Do not push, pull, or rotate the catheter against resistance. If resistance is met, discontinue movement, determine the reason for resistance, and take appropriate action before continuing. Damage to the catheter may prevent it from performing with accurate torque response and control, and may cause vessel damage.
- Use the catheter only with compatible transvenous devices. No test data is available to demonstrate compatibility of any non-Medtronic device with the catheter. Consequences of using the catheter with incompatible devices may include the inability to deliver the transvenous device or damage to the transvenous device or catheter during delivery. Slitting evaluations on this product were conducted using Medtronic Universal II or Medtronic Adjustable Slitters. These are the only slitters recommended for use with the C315 catheter.
- Handle the catheter with care at all times. Do not kink, stretch, or severely bend the catheter. Do not use surgical instruments to grasp the catheter. Do not use excessive force when inserting a catheter into a vessel. Ensure the catheter is thoroughly flushed and free of air prior to use. Avoid contact with liquids other than blood, saline, or contrast solution. Use in conjunction with fluoroscopic guidance and proper anticoagulation agents.
- Use the side port on the hub to flush the catheter. The catheter must be thoroughly flushed and free of air prior to use. When using the side port, consider sealing the proximal opening of the hemostatic valve with a thumb or forefinger.

Potential Adverse Events or Potential Complications

Air embolism, allergic reaction to contrast media, arteriovenous fistula formation, bleeding at the insertion site, brachial plexus injury, cardiac tamponade, dislodgement, dissection, endocarditis, heart block, hematoma formation, hemothorax, infection, irregular heart beat, mediastinal widening, perforation, pneumothorax, subclavian artery puncture, thrombophlebitis, thrombosis, valve damage, vascular occlusion, vessel damage.

See the device instructions for use for detailed information regarding the procedural instructions, 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.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

Medtronic