MEDICAL EDUCATION

Medtronic
Further, Together

PERIOPERATIVE MANAGEMENT OF PATIENTS WITH MEDTRONIC CARDIAC DEVICES*

Preoperative (Magnet Use)

- ✓ Establish the patient has a Medtronic device (pacemaker (PM) or ICD)
- ✓ Determine if magnet placement is appropriate for a surgical procedure: by referencing the HRS/ASA Expert Consensus statement.[1]
  If a magnet cannot be used for the procedure:
  - A Medtronic programmer and competent operator are required.
  - Programming confirmed with the Cardiac Health Provider (a written order in the chart is required).
  - Patient should be properly monitored and connected to an external pacing/defibrillator during the procedure.
  - For ICDs, great care must be taken to ensure that the detections are turned back ON before the patient is unmonitored or leaving the facility.
- ✓ Contact the patient's cardiac physician to determine whether the patient is pacemaker dependent.
- ✓ Review appropriate individual device/clinician manual[2] for specific guidance on proper magnet placement. General guidance on expected device operation when the magnet is placed over the device is available within the Magnet Elearning course on www.MedtronicAcademy.com
- ✓ The presence of a Medtronic representative is not required for Magnet use.[1]

Intraoperative (Magnet Use)

- ✓ Place round blue magnet over Medtronic device.
- ✓ After procedure, remove the magnet. All device functions should resume as programmed within 2 seconds.
- ✓ Patient should be constantly monitored for potential life-threatening arrhythmias before, during and after the procedure.
- ✓ External defibrillation and pacing options should be available to deliver therapy should patient monitoring indicate a need for these therapies.

Postoperative (Magnet Use)

- ✓ In most clinical situations, it is unnecessary to evaluate the device post-operatively after using a magnet.[1] If there is concern that the procedure interfered with device operation:
  - **For PM:** Place a magnet over the PM and verify that pacing is occurring at 85ppm (after ~4-5 beats). A full device interrogation is warranted if there is pacing at 65 ppm.
  - **For ICD:** Place a magnet over the ICD and verify that a constant, steady tone is heard, or no tone occurs if the alerts have been programmed off. The presence of an alternating tone warrants a device interrogation.

***Not applicable to transcatheter pacing systems or pacing systems programmed to MRI SureScan mode.**

Magnet Function with Medtronic Pacemakers/CRT-P∞

Magnets can be used on Medtronic pacemakers to:

- Check device status.
- Inhibit sensing of electrical noise (e.g. EMI for specific medical procedures or a lead fracture).

APPLYING A MAGNET to a **Medtronic pacemaker** results in the following (magnet mode operation):

1. Temporarily changes the pacing mode to an asynchronous mode (i.e., paces) regardless of any intrinsic cardiac events or extraneous noise).
2. Changes the asynchronous pacing rate (e.g., DOO/VOO) based on battery status

Note: Magnet operation does not occur if telemetry between the device and programmer is established or if MRI SureScan is on.

Mode	Normal Device Conditions	Recommended Replacement Time (RRT/ERI)/ Electrical Reset
Single Chamber Modes	VOO/AOO 85 bpm	VOO/AOO 65 bpm
VDD Mode	VOO 85 bpm	VOO 65 bpm
Dual Chamber Modes**	DOO 85 bpm	VOO 65 bpm

- When the magnet shows 65 bpm, the RRT is set or a full electrical reset has occurred. A full device interrogation should be performed. Notify the device care provider immediately.
- If constant magnet mode operation is desired, consideration should be given to securing the magnet.[1]

REMOVING THE MAGNET causes the pacemaker to resume permanently programmed operation within two seconds.

∞ Pacemakers (single/dual chamber), CRT-P (triple chamber), not applicable to transcatheter pacing systems or pacing systems programmed to MRI SureScan mode.

** AAI<=>DDD and AAIR<=>DDDR modes are considered dual chamber modes.

Magnet Function with Medtronic ICDs/CRT-D ϕ

Magnets can be used on Medtronic ICDs to:

- Suspend tachyarrhythmia detection to inhibit detection of electromagnetic interference (EMI) for specific medical procedures or inhibit therapy delivery when inappropriate therapy is suspected.***
- Check device status alerts.

APPLYING A MAGNET to a **Medtronic ICD** results in the following (magnet mode operation):

1. Temporarily suspends tachyarrhythmia detection. This means that the ICD will not deliver tachycardia or defibrillation therapies while the magnet is secured over the ICD.
2. Will NOT affect or change the pacemaker function of the device.
3. May cause an audible tone to emit from the device for 10 seconds when the magnet is first applied correctly over the device.
   - A steady tone indicates proper magnet placement and no alert conditions exist.
   - Beeping or oscillating tones indicate an Alert condition (notify ICD care provider).

REMOVING THE MAGNET causes the ICD to resume permanently programmed operation within two seconds.

ϕ ICDs (single/dual chamber) and CRT-D (triple chamber ICD).

*** The HCP is responsible for ensuring that the patient is constantly monitored for potential life-threatening arrhythmias before, during and after the procedure.

Magnet Use versus Reprogramming for Medtronic Cardiac Devices[1]

	Advantages	Disadvantages
MAGNET	▪ It can be removed to provide normal device operation ▪ Eliminates manual reprogramming to original settings ▪ For Medtronic pacemakers, pacing is ensured for pacemaker dependent patients	▪ A magnet does not provide asynchronous pacing for Medtronic ICD patients that are pacemaker dependent. ▪ There is no continuous audible indication of adequate magnet contact. ▪ There may be situations where stable magnet placement cannot be ensured due to patient body position or habitus.
REPROGRAMMING	▪ Procedure team needs not to be concerned with keeping the magnet in the correct location. ▪ For Medtronic ICD patients that are pacemaker dependent, pacing can be programmed to an asynchronous mode to prevent the device from being inhibited by elecromagnetic interference (EMI).	▪ Changes that are made with the programmer are not readily reversible. ▪ For Medtronic ICDs, there is a risk of human error and failure to re-enable tachycardia therapies after the procedure is completed (this leaves the patient unprotected should ventricular arrhythmias occur).

1. Crossley GH et al., "The HRS/ASA Expert Consensus Statement on the Perioperative Management of Patients with Implantable Defibrillators, Pacemakers and Arrhythmia Monitors: Facilities and Patient Management." Heart Rhythm, 2011 July; 8(7): 1114-1154

2. http://manuals.medtronic.com/manuals/main/region 9466 Tachy Patient Magnet Technical Manual, for implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators. M940929A001C 197773001 Rev C 2005-01-28. Medical Procedure and EMI Precautions, for implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators. M940929A001C 2014-03-10. Medical Procedures and EMI Precautions, for MR Conditional Cardiac Implantable Electronic Devices. M955447A001 2015-04-30, and (non-MR Conditional) Cardiac Implantable Electronic Devices, M962179A001 A 2016-01-27, www.medtronic.com/manuals.

Indications, Safety, and Warnings

If you are located in the United States, please refer to the brief statement(s) below to review applicable indications, safety and warning information. 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 1.763.514.4000 and/or consult www.medtronic.com.

If you are located outside the United States, see the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult www.medtronic.com.

www.medtronic.com/manuals

Consult instructions for use on this website. www.medtronic.com/manuals Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

Important Reminder: This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

Brief Statement: Non-MRI IPGs, CRT IPGs, ICDs, and CRT ICDs

If you are located in the United States

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.

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 de ibrillators (ICDs) are indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. 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. **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.

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.

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.

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.

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Brief Statement for Medtronic SureScan™ Portfolio for 1.5T and 3T MR Conditional Use

Medtronic SureScan products and systems are MR Conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use.

Pacing, ICD, CRT-P and CRT-D Systems: When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. A complete transvenous SureScan system, which is a SureScan device with appropriate SureScan lead(s), is required for use in the MR environment. For ICD and CRT-D Systems, when a single coil SureScan defibrillation lead is used, a Medtronic DF-1 pin plug must be secured in the SVC port to make a complete SureScan DF-1 defibrillation system. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com/. Any other combination may result in a hazard to the patient during an MRI scan.

Indications

The SureScan MRI transvenous pacing systems are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Dual chamber SureScan pacing systems are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony.
The SureScan MRI defibrillation systems are indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. In addition, the dual chamber devices are indicated for use in the above patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias.

Indications cont'd

The SureScan MRI CRT-D systems 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. Claria/Amplia only: Some CRT-D system are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

The SureScan CRT-P Systems 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.

Micra Model MC1VR01 is indicated for patients with symptomatic paroxysmal or permanent high grade AV block in the presence of AF. It is also indicated in the absence of AF as an alternative to dual chamber pacing, or symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia/sinus pauses) when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy.

The Reveal LINQ Insertable Cardiac Monitor (ICM) is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated for patients with clinical syndromes or situations at increased risk of cardiac arrhythmias, or patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain that may suggest a cardiac arrhythmia.

Contraindications

The SureScan transvenous pacing and CRT-P systems are contraindicated for implantation with unipolar pacing leads (Revo MRI only), concomitant implantation with another bradycardia device or an implantable cardioverter defibrillator.

Micra IPG is contraindicated for patients who have the following types of medical devices implanted: an implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician, an implanted inferior vena cava filter, a mechanical tricuspid valve, or an implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra device or for patients who have the following conditions: femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity), morbid obesity that prevents the implanted device from obtaining telemetry communication within ≤12.5 cm (4.9 in), or known intolerance to the materials listed in the Instruction for Use, or to heparin, or sensitivity to contrast media that cannot be adequately pre-medicated.

SureScan defibrillation and CRT-D systems are contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes, or patients with incessant VT or VF. For dual chamber and CRT-D devices, the device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF. For single chamber devices, the device is contraindicated for patients whose primary disorder is atrial tachyarrhythmia.

Reveal LINQ: There are no known contraindications for the implant of the Reveal LINQ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Warnings and Precautions

Changes in 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-D devices, certain programming and device operations may not provide cardiac resynchronization. Use of the device should not change the application of established anticoagulation protocols.
Patients and their implanted systems must be screened to meet the following requirements for MRI:

- SureScan transvenous systems: no lead extenders, lead adaptors or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; and the system must be implanted in the left or right pectoral region. For pacemaker-dependent patients, it is not recommended to perform an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at 0.4 ms. A higher pacing capture threshold may indicate an issue with the implanted lead. 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 on. It is not recommended to perform MRI scans during the lead maturation period (approximately 6 weeks).
- SureScan Pacemaker and CRT-P specific: pace polarity parameters set to Bipolar for programming MRI SureScan to On (Advisa MRI and CRT-P [atrial and RV] only); or a SureScan pacing system with a lead impedance value of ≥ 200 Ω and ≤ 1500 Ω (Advisa MRI and Revo MRI only). Revo MRI patients must have pacing capture thresholds of ≤ 2.0 V at a pulse width of 0.4 ms and a SureScan pacing system that has been implanted for a minimum of 6 weeks.
- Micra: no abandoned leads are present; device is operating within the projected service life; pacing amplitude is ≤ 4.5 V at the programmed pulse width; no diaphragmatic stimulation is observed when MRI SureScan is programmed to On.

MR Scanning Conditions:

Micra, Reveal LINQ, and transvenous system patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging. Revo MRI pacemakers can only be scanned using 1.5T systems.

Potential Adverse Events

Potential complications include, but are not limited to, rejection phenomena, device migration, infection, or erosion through the skin. Potential complications associated with cardiac rhythm devices include muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachycardia, and surgical complications such as hematoma, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibrillation, thrombosis, thrombotic and air embolism, cardiac perforation, heart wall rupture, cardiac tamponade, 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. Other potential complications related to Micra are access site hematoma, AV fistulae, and vessel spasm, 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 MR-induced stimulation on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse. Potential complications of the Reveal LINQ device include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

See the appropriate product MRI SureScan Technical Manual before performing an MRI Scan and see the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, 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 these devices to sale by or on the order of a physician.

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