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.
   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 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.

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. 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 85 ppm (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.
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.

<table>
<thead>
<tr>
<th>Mode</th>
<th>Normal Device Conditions</th>
<th>Recommended Replacement Time (RRT/ERI)/ Electrical Reset</th>
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</thead>
<tbody>
<tr>
<td>Single Chamber Modes</td>
<td>VOO/AAO 85 bpm</td>
<td>VOO/AAO 65 bpm</td>
</tr>
<tr>
<td>VDD Mode</td>
<td>VOO 85 bpm</td>
<td>VOO 65 bpm</td>
</tr>
<tr>
<td>Dual Chamber Modes**</td>
<td>DOO 85 bpm</td>
<td>VOO 65 bpm</td>
</tr>
</tbody>
</table>

* 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.

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

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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.

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**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 Use versus Reprogramming for Medtronic Cardiac Devices

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAGNET</td>
<td></td>
</tr>
<tr>
<td>It can be removed to provide normal device operation</td>
<td>A magnet does not provide asynchronous pacing for Medtronic ICD patients that are pacemaker dependent.</td>
</tr>
<tr>
<td>Eliminates manual reprogramming to original settings</td>
<td>There is no continuous audible indication of adequate magnet contact.</td>
</tr>
<tr>
<td>For Medtronic pacemakers, pacing is ensured for pacemaker dependent patients</td>
<td>There may be situations where stable magnet placement cannot be ensured due to patient body position or habitus.</td>
</tr>
<tr>
<td>REPROGRAMMING</td>
<td>Changes that are made with the programmer are not readily reversible.</td>
</tr>
<tr>
<td>Procedure team needs not to be concerned with keeping the magnet in the correct location.</td>
<td>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).</td>
</tr>
<tr>
<td>For Medtronic ICD patients that are pacemaker dependent, pacing can be programmed to an asynchronous mode to prevent the device from being inhibited by electromagnetic interference (EMI).</td>
<td></td>
</tr>
</tbody>
</table>

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**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 increased pacing rates in the presence of persistent atrial arrhythmias. 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 arrhythmias. ATP is also indicated for ventricular antitachycardia pacing and ventricular defibrillation for automatic treatment of life-threatening ventricular arrhythmias. Non-MRI IPGs may be used for rate adaptive pacing in patients who may 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 arrhythmias.

**Cardiac Resynchronization Therapy (CRT) IPGs** are indicated for NYHA Class II or III patients who have left ventricular ejection fraction of 30-45% and a prolonged QRS duration for NYHA Class I II or III patients who have left ventricular ejection fraction of 40-55% and a prolonged QRS duration. CRT IPGs are also indicated for patients with atrial arrhythmias and AV block who may benefit from improved AV synchrony.

**Contraindications**

IPGs and CRT IPGs are contraindicated for concomitant implant with another bradyarrhythmia device and concomitant implant with an implantable cardioverter defibrillator. These are known contraindications for the use of pacings 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 pacings is contraindicated in patients with chronic or persistent atrial arrhythmias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence of a high likelihood of ventricular fibrillation in patients with atrial fibrillation or flutter.

ICDs and CRT-ICDs are contraindicated in patients experiencing tachyarrhythmias with transient or reversable causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electrical shock, sepsis, hypoxic or sepsis, hypotension, and neuroleptic or sedative administered. Patients with a history of ventricular fibrillation and/or 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 transcutaneous defibrillation pads 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, Electrode Replacement Indicator (ERI) results in the device switching to VVI pacing at 40 bpm. In this mode, patients may experience loss of cardiac resynchronization, device deactivation due to loss of atrial signals, or failure to detect and/or terminate arrhythmia episodes and surgical complications such as hematoma, infection, inflammation, and thrombosis.

**Potential complications**

Potentially serious 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 1-800-338-2518 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 Sep 16 2016

**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 MR under the specified conditions for use. For more information, please consult 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.

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**Potential complications**

Potentially serious 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.

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Updated Sep 16 2016
Indications cont’d

The SureScan 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.

Potential Adverse Events

Potential complications include, but are not limited to, ejection 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 hematomas, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibrillation, thorax, and intra-atrial and/or chamber perforation, heart wall rupture, cardiac tamponade, pericardial rub, infection, myocardial infarction, and/or embolism. 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 hematomas, 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 in both, or Micra-induced stimulation or leads resulting in continuous capture, VVT, 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 access 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 1.800.528.2518 and/or consult Medtronic’s website at www.medtronic.com or www.mrisurescan.com.

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