Contraindications: The device is contraindicated for:
- Implantation with unipolar pacing leads
- Concomitant implantation with another bradycardia device
- Concomitant implantation with an implantable cardioverter defibrillator

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Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians and medical professionals)

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 implantation 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.
- Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance.
- ATP therapy is contraindicated in patients with an accessory antegrade pathway.

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 transhoracic defibrillation paddles directly over the device. Use of the device should not change the application of established anticoagulation protocols.

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 Revo MRI SureScan pacing system consisting of a SureScan device and two SureScan leads; patients who have previously implanted devices, or broken or intermittent leads; or patients who have a lead impedance value of < 200 Ω or > 1,500 Ω. Do not scan patients with a SureScan pacing system implanted in sites other than the left and right pectoral region, or patients positioned such that the isocenter (center of MRI bore) is inferior to C1 vertebra and superior to the T12 vertebra.

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, acceleration of tachycardias, and surgical complications such as hematoma, infection, inflammation, and thrombosis. Potential lead complications include but are not limited to, valve damage, fibrosis, 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. The SureScan system has been designed to minimize potential complications in the MRI environment. Potential MRI complications include, but are not limited to, lead electrode and/or device heating which may cause tissue damage, impact the pacing system functionality such as failure to detect/treat irregular heartbeats, or potential for VT/VF induction.

See the device manuals before performing an MRI Scan for detailed information regarding the implant procedure, indications, MRI conditions of use, 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.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Specifically engineered for MRI safety, with reliable lead technology and a proven pacemaker platform – this is state-of-the-art pacing.

Now your patients get proven cardiac care with MRI access.
Meeting the Need for MRI

Pacemaker Implants in an Aging Population

- The number of pacemakers currently implanted in the United States is approximately 1.5 million\textsuperscript{1,2}

### Average Age of Pacemaker Patient

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 25–64</td>
<td>13%</td>
</tr>
<tr>
<td>Age 65+</td>
<td>86%</td>
</tr>
</tbody>
</table>

Elderly patients are the primary users of MRI: individuals over age 65 are twice as likely to need an MRI compared to younger recipients.\textsuperscript{3}
Part of Comprehensive Patient Care

- Now, for the first time, you can implant a state-of-the-art pacing system to provide proven cardiac care AND MRI access when your patients need it.

Number of Comorbidities in Pacemaker Patients

- Given that 85% of all pacemaker patients have one or more comorbidities, facilitating comprehensive multi-specialty care is important in today’s environment.

Medical and Surgical Specialties Rely on MRI for Diagnosis.

- Your choice can affect their decisions and diagnostic capabilities.
Prevalence of Common Comorbidities in the Pacemaker Patient Population

The Prevalence of Common Comorbidities Increases Rapidly Over Age 65

MRI Is the Gold Standard Diagnostic Tool for Neurologists, Oncologists, and Orthopedic Surgeons, Whose Patients Are Often over 65 Years of Age.7

• MRI is unmatched in its ability to accurately visualize soft tissue
• It is estimated that 50 to 75% of pacemaker patients will have a medical need for an MRI over the lifetime of their device.

The Most Common Reasons for MRI Referral Are Musculoskeletal and Neurological Symptoms.8

Medicare records show that in patients > 65 years of age with an implanted pacemaker:

• 34% have spine and intervertebral disc disease9
• 36% have chronic pain of wrist, foot, ankle, or elbow9
• 14% suffer from injury or trauma to the spine, knee, or shoulder9

Prevalence in US Population
Hazards and Risks of MRI with Current Pacing Systems

Since 2008, the safety and risk concerns of MRIs in cardiac device patients have been documented in 17 studies\textsuperscript{10-26}

MRI can put pacemaker patients at risk for any of the following\textsuperscript{25}:

<table>
<thead>
<tr>
<th>Potential Hazard</th>
<th>Device Field</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lead Heating</strong></td>
<td></td>
</tr>
<tr>
<td>The conductive pacing lead acts as an antenna, picking up radiofrequency energy. A portion of this energy is dissipated as heat in the cardiac tissue nears the tip electrode.</td>
<td>Tissue damage may affect pacing therapy.</td>
</tr>
<tr>
<td><strong>Unintended Cardiac Stimulation</strong></td>
<td></td>
</tr>
<tr>
<td>The gradient and radiofrequency fields will induce voltages in pacemaker leads that will be applied to the pacing lead electrodes. If these voltage pulses are large enough, they may directly stimulate the heart.</td>
<td>May lead to a single or intermittent stimulation, or sustained tachycardia.</td>
</tr>
<tr>
<td><strong>Device Interactions</strong></td>
<td></td>
</tr>
<tr>
<td>The gradient, radiofrequency, and static fields may adversely affect the electrical operation of the pacemaker system if its operation is not protected from the effects of those fields.</td>
<td>Pacemaker malfunction or failure may affect pacing therapy.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MR Conditional Risk Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• A complete Revo MRI SureScan pacing system including a Revo MRI SureScan IPG and two CapSureFix MRI SureScan leads is required for use in the MRI environment</td>
<td></td>
</tr>
<tr>
<td>• Any other pacing system combination may result in a hazard to the patient during an MRI scan</td>
<td></td>
</tr>
<tr>
<td>• When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing</td>
<td></td>
</tr>
<tr>
<td>• Refer to the Revo MRI Pacing System Conditions for Use located in the device manuals prior to scanning a patient. Consult Medtronic’s website at <a href="http://www.medtronic.com">www.medtronic.com</a> or call Medtronic at 1 (800) 328-2518.</td>
<td></td>
</tr>
</tbody>
</table>
Specifically Engineered for MRI Safety

Device Design Solutions

- Input circuits optimized
- Circuit design immune to interference
- SureScan pacing mode
  - Asynchronous pacing
  - High pacing outputs

- The Revo MRI SureScan pacing system has completed clinical evaluation, regulatory review, and FDA approval and is safe for use when used according to the MRI conditions for use as defined in the SureScan manual
- The implanted system must consist solely of a Medtronic Revo MRI SureScan Model RVDR01 device and two CapSureFix MRI SureScan Model 5086MRI leads

Revo MRI SureScan Pacemaker – A Pacemaker Engineered with Multiple Safety Features

- Device verification appears on pacemaker programmer screen
- Automatic testing ensures only appropriate battery and impedance data are collected during MRI
- Dedicated programming mode provides additional security/backup for Power On Reset (POR)
- Hall sensor immune to strong magnetic fields

Easily Identifiable, Radiopaque Icon Confirms SureScan Device Implant

<table>
<thead>
<tr>
<th>Revo MRI Pacing System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
</tr>
<tr>
<td>Weight</td>
</tr>
</tbody>
</table>
Lead Heating Design Solution
- Lead inner conductor coil design mitigates lead heating
- 4 filar to 2 filar increases inductance and reduces heating
- Materials identical to 5076*
- Model 5086MRI lead flex testing
  - Connector/body
  - Lead body
- Model 5086MRI clinical implant experience starting February 2007 (928 leads implanted)

* Exception of MRI Marker band and electrode coating

CapSureFix MRI SureScan Lead Model 5086 – A Lead Designed for MRI Use
- The state-of-the-art 5086 leads are specifically designed and engineered for safety within an MRI environment
- The 5086 lead is based on the CapSureFix® family of leads, which have been implanted in more than 1 million patients worldwide – that’s 2.5 million leads, with 99.5% reliability

Easily Identifiable, Radiopaque Icon Confirms SureScan Device Implant

<table>
<thead>
<tr>
<th>CapSureFix MRI Model 5086</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Polarity</td>
<td>Bipolar</td>
</tr>
<tr>
<td>Shape</td>
<td>Straight</td>
</tr>
<tr>
<td>Fixation</td>
<td>Screw-in</td>
</tr>
<tr>
<td>Inner/Outer Insulator</td>
<td>Silicone</td>
</tr>
<tr>
<td>Body</td>
<td>7 Fr</td>
</tr>
<tr>
<td>Recommended Introducer Size</td>
<td>8 Fr (without guide wire)</td>
</tr>
<tr>
<td>Tip-to-Ring Spacing</td>
<td>10 mm</td>
</tr>
<tr>
<td>Standard Lengths</td>
<td>45 cm, 52 cm, 58 cm</td>
</tr>
</tbody>
</table>

Lead Heating
Model 5076 versus Model 5086MRI

- the x-axis represents 50 anatomically relevant leads paths
- the results demonstrate significant variability in lead tip heating as a function of the lead path
- overall the 5086MRI lead heats approximately 3 times less than the 5076 for most lead paths
Preclinical Research Demonstrates the Safety of Revo MRI Pacing System

Testing Summary
Extensive preclinical evaluation was based on clinically relevant as well as worst-case scan conditions, using in vitro (bench) testing, in vivo (animal) testing, and computer simulations (modeling).

MRI-Induced Lead Heating
Simulations in Human Body Models Using Different Lead Combinations

- Human body models encompassed 2nd to 97th percentile of all human bodies, with ten different lead paths
- Over 400,000 different lead/body combinations were analyzed to derive a minimal probability of a 0.5 V threshold

MRI-Induced Unintended Cardiac Stimulation (UCS)
- Analysis combined a prediction for the induced voltage pulse widths and amplitudes and an in vivo canine study to evaluate the stimulation threshold to these pulses
- The risk of reaching the gradient stimulation range is 1/1,000,000 – which remains outside the capture range
- Results confirmed that patient risk from UCS is at an acceptable level

Gradient Stimulation Strength Duration Curve
Clinical Trial Demonstrates the Safety of Revo MRI SureScan

Study Design

- Multicenter, randomized, controlled clinical trial designed to evaluate the safety of the Revo MRI SureScan pacing system, including any MRI-related complications, as well as to analyze pacing capture thresholds and sensing amplitude.
- 464 patients received a Revo MRI SureScan pacing system and were then randomized to elective MRI or no MRI, approximately 9-12 weeks post-implant.
- MRI imaging intended to represent commonly used, clinically relevant scans.

Methods – Visit Schedule

Key Results

- 100% were free of MRI-related complications (n = 211, p < 0.001).
- No sustained atrial or ventricular arrhythmias, no asystole, no pacemaker output inhibition, and no electrical resets in the group receiving MRI.
- Minimal changes in pacing capture thresholds, as shown on the following chart.

Primary Effectiveness End Point: Atrial and Ventricular Capture Threshold

Threshold changes pre-MRI/control visit to 1-month post-MRI/control visit.

No discernible difference between the MRI and control groups.
Builds upon Medtronic Innovations

MVP – Managed Ventricular Pacing
- Exclusive technology that used Atrial Pacing (AAIR) primarily with DDD pacing only when necessary
- MVP reduces unnecessary RV pacing by 99%\(^{27}\)

ACC/AHA/HRS guidelines\(^ {28}\) state the need to reduce unnecessary pacing as much as possible. The following studies support the guidelines:

**MOST\(^ {29}\):** Every incremental 1% of unnecessary VP increases the risk for heart failure hospitalizations by 5.4% and for AF by 1%.

**Danish II\(^ {30}\):** Even with long AV delays, the risk of AF doubles with DDD(R) pacing compared to AAI(R) with DDD(R) backup.

**Gardiwal\(^ {31}\):** Patients with 72% RV pacing are at increased risk for VT/VF.

**CareLink\(^ {\text{®}}\) Network\(^ {\ast}\)**
- The leading Internet-based remote monitoring service for implanted devices\(^ {12}\)
- Serving nearly 500,000 patients in 3,000 clinics in the United States

\(^{\ast}\) Not all devices are available on the CareLink Network.
References


24. Medtronic CareLink Metrics Database.