The chart below contains all Medtronic cardiac devices FDA approved for MRI scans under specific conditions for use:

- If the Medtronic pacemaker, ICD or CRT-D system was implanted prior to February 8th, 2011 then it is not FDA approved for MRI scanning.
- If a model number and/or lead length is not listed, then it is not FDA approved for the MR environment.

<table>
<thead>
<tr>
<th>THERAPY</th>
<th>PRODUCT</th>
<th>MODEL NUMBER</th>
<th>MR CONDITIONAL</th>
<th>SURESCAN LEADS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PACEMAKERS</td>
<td>Advisa MRI™</td>
<td>A2DR01, A3SR01</td>
<td>Yes—if complete system is implanted with a SureScan™ pacemaker and SureScan lead(s)</td>
<td>Pacing leads: 5086: 45, 52, 58 cm, 5076: 35, 45, 52, 58, 65, 85 cm</td>
</tr>
<tr>
<td></td>
<td>Revo MRI™</td>
<td>RVDR01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CARDIAC DEFIBRILLATORS</td>
<td>Evera MRI™ XT</td>
<td>DDMB1D4, DVMB1D4</td>
<td>Yes—if complete system is implanted with a SureScan ICD and SureScan lead(s)</td>
<td>Defibrillation leads: 6947M and 6935M, Lengths 55, 62 cm, See above for pacing leads.</td>
</tr>
<tr>
<td></td>
<td>Evera MRI™ S</td>
<td>DDMC3D4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS</td>
<td>Amplia MRI™ Quad CRT-D</td>
<td>DTMB1QQ</td>
<td>Yes—if complete system is implanted with a SureScan CRT-D and SureScan lead(s) or the Model 6725 pin plug</td>
<td>CRT leads: 4196, 4296 and 4396, Lengths: 78 and 88 cm, 4298, 4398 and 4598, Lengths: 78 and 88 cm, See above for defibrillation and pacing leads.</td>
</tr>
<tr>
<td></td>
<td>Amplia MRI™ CRT-D</td>
<td>DTMB1D4</td>
<td></td>
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<tr>
<td></td>
<td>Compia MRI™ Quad CRT-D</td>
<td>DTMC1QQ</td>
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<td></td>
</tr>
<tr>
<td>INSERTABLE CARDIAC MONITORS</td>
<td>Reveal™ XT</td>
<td>9529</td>
<td>Yes</td>
<td>Not Applicable</td>
</tr>
<tr>
<td></td>
<td>Reveal™ DX</td>
<td>9528</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reveal LINQ™</td>
<td>LNQ11</td>
<td>Yes</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

To obtain the MR Conditions for Use, go to [www.manuals.medtronic.com](http://www>manuals.medtronic.com) or [www.mrisurescan.com/productsearch](http://www.mrisurescan.com/productsearch).
The SureScan pacing systems are contraindicated for implantation with unipolar leads and conditions that may or may not be detected early by the RV LIA feature. Boston Scientific Endotak lead as it does when used with a Medtronic Sprint Fidelis lead for patients who have a Medtronic ICD or CRT-D device and a Sprint Fidelis lead minimize right ventricular pacing. Optimization of heart failure medical therapy ≤ 50% and atrioventricular block (AV block) that are expected to require a high NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≥ 130 ms, left ventricular ejection fraction ≤ 30%, and NYHA Functional Class II. Ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. In addition, the dual chamber devices are 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. VVI intolerance (for example, pacemaker syndrome) in the presence of persistent sinus rhythm, or vasovagal syndromes or hypersensitive carotid sinus syndromes. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardia patients with one or more of the above pacing indications.

SureScan 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.

SureScan 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 II or IV and who have a left ventricular ejection fraction ≥ 50% 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 CRT-D systems 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, 6951, and 6930) based on performance data. The RV LIA feature may not perform as well as a St. Jude Medical 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

The SureScan pacing systems are contraindicated for implantation with unipolar pacing leads (Revo MRI only), concomitant implantation with another bradycardia device or an implantable cardioverter defibrillator. 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 symptomatic bilateral bundle branch block, symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders, or bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias. 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. 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, VVI intolerance (for example, pacemaker syndrome) in the presence of persistent sinus rhythm, or vasovagal syndromes or hypersensitive carotid sinus syndromes. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardia patients with one or more of the above pacing indications.

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**Reveal™ Insertable Cardiac Monitors and Patient Assistant 9538**

**Indications**

**Reveal Insertable Cardiac Monitors**

The Reveal Insertable Cardiac Monitor Family are implantable patient-activated and automatically activated monitoring systems that record subcutaneous ECG and are indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain, that may suggest a cardiac arrhythmia

**9538 Reveal™ Patient Assistant**

The Reveal Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management feature in the Reveal Insertable Cardiac Monitor to initiate recording of cardiac event data in the implanted device memory.

**Contraindications**

There are no known contraindications for the implant of Reveal Insertable Cardiac Monitors. However, the patient’s particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

**Warnings/Precautions**

**Reveal Insertable Cardiac Monitors**

Patients with a Reveal Insertable Cardiac Monitor should avoid sources of diathermy, high sources of radiation, electrosurgical cauterity, external defibrillation, lithotripsy, therapeutic ultrasound, and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the Medical procedure and EMI precautions manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal’s Technical Manual.

**Potential Complications**

Potential complications include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

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.

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**9538 Reveal Patient Assistant**

Operation of the Model 9538 Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer monitors, etc., may adversely affect the performance of this device.

**Operation**

Potential complications include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

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