The chart below contains all Medtronic cardiac devices FDA approved for MRI scans under specific conditions for use. 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>MR SYSTEM</th>
<th>SURESCAN LEADS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PACEMAKERS</td>
<td>Micra™</td>
<td>MC1VR01</td>
<td>Yes</td>
<td>Horizontal cylindrical bore magnet 1.5 or 3T</td>
<td>Not Applicable</td>
</tr>
<tr>
<td></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>Horizontal cylindrical bore magnet 1.5T only</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>
<td></td>
</tr>
<tr>
<td>CARDIAC DEFIBRILLATORS</td>
<td>Visia AF MRI™</td>
<td>DVFB1D4</td>
<td>Yes — If complete system is implanted with a SureScan ICD and SureScan lead(s)</td>
<td>Horizontal cylindrical bore magnet 1.5T only</td>
<td>Defibrillation leads: 6947M and 6935M Lengths 55, 62 cm See above for pacing leads.</td>
</tr>
<tr>
<td></td>
<td>Evera MRI™ XT</td>
<td>DDMB1D4 DVMB1D4</td>
<td></td>
<td>Horizontal cylindrical bore magnet 1.5 or 3T</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evera MRI™ S</td>
<td>DDMC3D4</td>
<td></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>Horizontal cylindrical bore magnet 1.5T only</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>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Compia MRI™ Quad CRT-D</td>
<td>DTMC1QQ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INSERTABLE CARDIAC MONITORS</td>
<td>Reveal LINQ™</td>
<td>LNQ11</td>
<td>Yes</td>
<td>Horizontal cylindrical bore magnet 1.5 or 3T</td>
<td>Not Applicable</td>
</tr>
<tr>
<td></td>
<td>Reveal™ XT</td>
<td>9529</td>
<td>Yes</td>
<td>Closed bore, cylindrical magnet 1.5 or 3T</td>
<td></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).
Brief Statement

Transvenous SureScan™ Pacing and Defibrillation Systems

The SureScan transvenous pacing and defibrillation systems are MR Conditional, and as such are designed to allow patients to undergo MRI under the specified conditions. 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 SureScan system, which is a SureScan device with appropriate SureScan lead(s), is required for use in the MR environment. 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

SureScan pacing systems are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Accepted patient conditions warranting chronic cardiac pacing include symptomatic paroxysmal or permanent second- or third-degree AV block, 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.

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.

Contraindications

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 an AV conduction disturbance. ATP therapy is contraindicated in patients with an accessory antegrade pathway.

SureScan defibrillation systems are contraindicated for 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. The device is contraindicated for patients who have a unipolar pacemaker implanted. The device is contraindicated for patients with incessant VT or VF. For dual chamber 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.

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. Patients and their implanted systems must be screened to meet the following requirements for MRI:

All 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; the device must be operating within the projected service life, 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. Patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is on must have no diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms. It is not recommended to perform MRI scans during the lead maturation period (approximately 6 weeks).

IPG specific: pace polarity parameters set to Bipolar for programming MRI SureScan to On (Advisa MRI only) or a SureScan pacing system with a lead impedance value of < 200 Ω and ≤ 1500 Ω. 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.

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 tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibration, 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. 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.

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.
Amplia MRI™/Amplia MRI™ Quad CRT-D SureScan™ Implantable Cardioverter Defibrillator with Cardiac Resynchronization System (CRT-D MRI System)

The Amplia MRI CRT-D SureScan Model DTMB1D4 and Amplia MRI Quad CRT-D SureScan Model DTMB1QQ, hereafter referred to collectively as the Amplia MRI CRT-D device, is MR Conditional and, as such is designed to allow patients to be safely scanned by an MRI machine when used according to the specified MRI conditions for use. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing.

Indications for Use

The Amplia MRI CRT-D system is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias, for use in patients with atrial tachyarrhythmias and/or hemodynamic collapse. Use in patients with atrial tachyarrhythmias and/or hemodynamic collapse is recommended for patients with incessant VT or VF whose primary disorder is chronic atrial tachyarrhythmia with no concomitant left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, 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, 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.

Contraindications

The Amplia MRI CRT-D system is contraindicated for 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. The device is contraindicated for patients who have a unipolar pacemaker implanted. The device is contraindicated for patients with incessant VT or VF. The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

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. Certain programming and device operations may not provide cardiac resynchronization.

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; 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.

Additionally 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.

Patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T MRI system with operating frequency of 64MHz, maximum spatial gradient ≤ 20 T/m, and maximum gradient slew rate performance per axis ≤ 200 T/m/s. Scanner must be operated in Normal Operating Mode (whole body averaged specific absorption rate (SAR) ≤ 2.0 W/kg, head SAR ≤ 3.2 W/kg).

Continuous patient monitoring is required while MRI SureScan is programmed to On. While MRI SureScan is programmed to On, arrhythmia detection and therapies are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. In addition, if the device is programmed to an asynchronous pacing mode, arrhythmia risk may be increased.

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 tachyarrhythmia episodes, acceleration of ventricular tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis. 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 heating and tissue damage resulting in loss of sensing or capture or both, or MRI-induced stimulation on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

See the MRI SureScan Technical Manual before performing an MRI Scan and 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 or www.mrisurescan.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
The Reveal XT Insertable Cardiac Monitor is an implantable patient-activated and ventricular pacing and 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 (AVB) 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.

A complete SureScan defibrillation system is required for use in the MR environment. A complete SureScan CRT-D system includes the following components:

- The Compia MRI CRT-D device
- A SureScan right atrial pacing lead or a Model 6725 pin plug for the right atrial port
- A SureScan left ventricular pacing lead
- A SureScan defibrillation lead

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.

The RV Lead Integrity Alert 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 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.

The Compia MRI CRT-D system is contraindicated for 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. The device is contraindicated for patients who have a unipolar pacemaker implanted. The device is contraindicated for patients with incessant VT or VF. The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

The RV Lead Integrity Alert 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 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.

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 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.

See the MRI SureScan Technical Manual before performing an MRI Scan and 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 or www.mrisurescan.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
REVEAL LINQ™ LNQ11 Insertable Cardiac Monitor

The Reveal LINQ™ Insertable Cardiac Monitor is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is 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

The device has not been tested specifically for pediatric use.

Contraindications

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

Warnings/Precautions

REVEAL LINQ LNQ11 Insertable Cardiac Monitor

Patients with the Reveal LINQ Insertable Cardiac Monitor should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, 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 LINQ MRI Technical Manual.

Micra™ Transcatheter Pacing System VVIR Single Chamber with SureScan™ MRI Indications

Micra Model MC1VR01 is indicated for patients with:

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

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.

Contraindications

Micra Model MC1VR01 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.

The device is contraindicated 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 premedicated.

Steroid use — Do not use in patients for whom a single dose of 1.0 mg of dexamethasone acetate cannot be tolerated.

Warnings and Precautions

End of Service (EOS) — When the EOS condition is met, the clinician has the option of permanently programming the device to Off and leaving it in the heart, or retrieving the device, provided the device has not yet become encapsulated. Removal of the Micra device after it has become encapsulated may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician who has expertise in the removal of implanted leads.

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.

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 these devices to sale by or on the order of a physician.

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