This chart encompasses all Medtronic cardiac devices FDA-Approved as MR Conditional and included in the MRI SureScan™ portfolio. If a device and/or model number is not listed, then it is not approved for the MRI environment.

Visit www.medtronic.com/mrc to search for a specific device or model number.

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<td>PACEMAKERS</td>
<td>Advisa MRI™ A2DR01</td>
<td>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>
<td>Coils allowed:  • Integrated body coil  • Local receive coils  • Local transmit/receive coils for imaging of the head or extremities</td>
<td>Normal Operating Mode:  • Whole body SAR ≤ 2.0 W/kg  • Head SAR ≤ 3.2 W/kg</td>
<td>≤ 200 T/m/s</td>
<td>NA</td>
<td>Maintain visual and verbal contact with the patient  Monitor heart rate using pulse oximetry or ECG</td>
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<tr>
<td></td>
<td>Revo MRI™ RVDR01</td>
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<td></td>
<td>Advisa MRI and Revo MRI are approved for use with all SureScan leads. Please refer to device manuals for all conditions for use and cardiology training requirements.</td>
</tr>
<tr>
<td></td>
<td>Evera MRI™ S and XT</td>
<td>DDMB1 D4, DVMB1 D4, DDMC3 D4.</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: 6947Mand 6935M Lengths 55, 62 cm</td>
<td>Coils allowed:  • Integrated body coil  • Local receive coils  • Local transmit/receive coils for imaging of the head or extremities</td>
<td>Normal Operating Mode:  • Whole body SAR ≤ 2.0 W/kg  • Head SAR ≤ 3.2 W/kg</td>
<td>≤ 200 T/m/s</td>
<td>NA</td>
<td>Maintain visual and verbal contact with the patient  Monitor heart rate using pulse oximetry or ECG the entire time when SureScan is programmed to On</td>
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<tr>
<td></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 6715 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</td>
<td>Coils allowed:  • Integrated body coil  • Local receive coils  • Local transmit/receive coils for imaging of the head or extremities</td>
<td>Normal Operating Mode:  • Whole body SAR ≤ 2.0 W/kg  • Head SAR ≤ 3.2 W/kg</td>
<td>≤ 200 T/m/s</td>
<td>NA</td>
<td>Maintain visual and verbal contact with the patient  Monitor heart rate using pulse oximetry or ECG the entire time when SureScan is programmed to On</td>
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<tr>
<td></td>
<td>Compia MRI™ Quad CRT-D</td>
<td>DTMC1QQ</td>
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<td>All Amplia MRI and Compia MRI devices, including quadripolar and bipolar, are approved for use with all SureScan leads. Please refer to the device’s MRI Technical Manual for all conditions for use and cardiology training requirements.</td>
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<tr>
<td></td>
<td>Compia MRI™ CRT-D</td>
<td>DTMC1D4</td>
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December 2015
### Advisa DR MRI™ and Advisa SR MRI™ SureScan™ Pacing Systems

The Advisa DR MRI and Advisa SR MRI SureScan pacing systems are MR Conditional, and as such designed to allow patients to undergo MRI under the specified conditions for use. A complete SureScan pacing system, which consists of an approved combination (see [http://www.mrisurescan.com/](http://www.mrisurescan.com/)) MRI SureScan device with SureScan lead(s), is required for use in the MRI environment. Consult the device manuals to ensure all system components are MR Conditional.

### Indications

The Advisa DR MRI SureScan Model A2DR01 and Advisa SR MRI SureScan Model A3SR01 IPGs are indicated for use as a system. A complete SureScan pacing system, including an Advisa DR MRI or Advisa SR MRI SureScan IPG and SureScan lead(s), are required for use in the MRI environment.

The Advisa DR MRI and Advisa SR MRI SureScan systems are indicated for the following:

- **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
  - Bradyarrhythmia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias

The Advisa DR MRI device is 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
- 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

### Contraindications

The Advisa DR MRI and Advisa SR MRI SureScan systems are contraindicated for:
- Concomitant implantation with another bradycardia device
- Concomitant implantation 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**

### 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, 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. 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 induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

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](http://www.medtronic.com).

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.
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 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’s Technical Manual.

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.

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.

Read the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/ adverse events. If further information is needed, 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.

The Revo MRI™ “SureScan™” pacing system is MR Conditional and as such is designed to allow patients to undergo MRI under the specified conditions for use. A complete SureScan pacing system, which consists of an approved combination (see http://www.mrisurescan.com/) MRI SureScan device with SureScan lead(s), is required for use in the MRI environment. Consult the device manuals to ensure all system components are MR Conditional.

Indications
The Revo MRI SureScan Model RVDR01 IPG is indicated for use as a system consisting of a Medtronic Revo MRI SureScan IPG implanted with two SureScan leads. A complete system is required for use in the MRI environment.

The Revo MRI SureScan Model RVDR01 IPG is indicated for the following:
- 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 atrioventricular block
  - Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders
  - Bradyarrhythmia-tachyarrhythmia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias

The device is 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

Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardia patients with one or more of the above pacing indications.

Contraindications
The device is contraindicated for:
- Implantation with unipolar pacing leads
- Concomitant implantation with another bradycardia device
- Concomitant implantation 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 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 transthoracic 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, abandoned 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 or right pectoral region.

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, 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. 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 induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.
The Evera MRI SureScan™ defibrillation system 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 Evera MRI SureScan system is 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. Notes:
- The ICD features of the device functions the same as other approved Medtronic market-released ICDs.
- The following notes are applicable based on the features available in the specific Evera MRI model.
- 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.

A complete SureScan defibrillation system is required for use in the MR environment, which is an Evera MRI SureScan device with a SureScan defibrillation lead in the right ventricle and if using a dual chamber ICD, a SureScan atrial pacing 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.

Contraindications
The Evera MRI SureScan 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. 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: 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; pacing capture thresholds of ≤ 2.0 V at a pulse width of 0.4 ms; 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.

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 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.
The Amplia MRI™/Amplia MRI™ Quad CRT-D SureScan™ Implantable Cardioverter Defibrillator (ICD) 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, or those patients who are at significant risk for developing atrial tachyarrhythmias 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.

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

- The Amplia 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.

Lead Integrity Alert
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.

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, 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 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.
The Compia MRI CRT-D SureScan™ Implantable Cardioverter Defibrillator with Cardiac Resynchronization System (CRT-D MRI System)

The Compia MRI CRT-D SureScan Model DTMC1D4 and Compia MRI Quad CRT-D SureScan Model DTMC1QQ, hereafter referred to collectively as the Compia 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 Compia MRI CRT-D system is 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 as indicated, and meet any of the following classifications: New York Heart Association (NYHA) Functional Class II or III, and who have a left ventricular ejection fraction ≤ 30%, and NYHA Functional Class II, 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.

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.

Lead Integrity Alert

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 as 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

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.

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 transvenous 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 MR 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.

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