STEP-BY-STEP INSTRUCTIONS FOR A SUCCESSFUL MRI SCAN

MRI SureScan™ Pacing, ICD and CRT-D Systems

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Purpose:
To define conditions that will allow a patient with a Medtronic SureScan™ Pacing/ICD/CRT-D System to receive an MRI.

Policy:
If a patient with a Medtronic SureScan Pacing/ICD/CRT-D System meets the specific criteria as described in these instructions, they may obtain, at the discretion of a qualified physician, an MRI.

Definitions:
It is recognized that most traditional pacemaker/ICD/CRT-D devices are contraindicated for MRI by the scanner equipment labeling. However, as MR-conditional pacemaker/ICD/CRT-D devices enter the market, there will be requests for scanning these patients since MRI can be a conclusive and/or less invasive way of obtaining important diagnostic information.

MR Specifications:
MR must be a 1.5 T cylindrical bore magnet. The Medtronic SureScan Pacing/ICD/CRT-D System is not approved to use with other magnetic field strengths. Gradient system with maximum gradient slew rate of less than or equal to 200 Tesla per meter per second (T/m/s) must be used. Whole body averaged SAR must be less than or equal to 2 W/kg, head SAR less than or equal to 3.2 W/kg; For Revo MRI™ SAR must be less than 3.2 W/kg.

Equipment Specifications:
Require MR-compatible oximetry or ECG monitoring devices for use in scan room (pacemaker) or for use when SureScan is programmed ON (ICD/CRT-D device). An external defibrillator must be accessible in control area.

Procedure for Approval of Exam:
Before the patient is scheduled for MRI exam, the following must occur:

✓ Interpreting physician (radiologist) approves appropriateness of exam ordered to answer the clinical question.
✓ “Pacemaker/ICD/CRT-D Device Checklist” form (Attachment A) is started for this patient. This form ensures all screening requirements and steps in this procedure are followed.
✓ The patient is not otherwise contraindicated for an MRI. MRI safety screening should be completed per center’s protocol.
✓ Patient’s cardiologist approval and order for pacer settings (Attachment B).

Procedure:
Pre-Scan (day of exam):
Ensure availability of staff to be present during the exam. This should include the MR Technologist and a healthcare professional (not a Medtronic employee) trained to monitor the patient. The patient will arrive to the center 30 minutes before the scheduled scan time.

✓ Standard MRI screening questionnaire and consents will be obtained.
✓ MRI Technologist will discuss scan parameters with the interpreting physician. Any modifications to sequences will be done, when possible, before the patient is in the scan room. Special attention will be made to ensure SAR limits are not exceeded.
✓ All pacemaker/ICD/CRT-D devices will be checked by a Medtronic representative or qualified healthcare professional. (Please note the device programmer is NOT MRI safe.)
  ▪ If pacemaker dependency is unknown, the device will be transiently switched to VVI at a backup rate of 30 to assess for device dependence. Information on battery voltage, lead capture threshold, lead impedance and sensing signal amplitude will be obtained and recorded in a printout and copied to patient’s medical record. While the device is in the SureScan mode, the tachyarrhythmia functions will be disabled (for the ICD or CRT-D device); pacing mode and rate will be set according to the cardiology order (Attachment B).
Healthcare provider will print report from device programmer confirming SureScan mode is turned ON and copied to patient’s medical record.

√ For patients with ICD or CRT-D systems, monitoring of the patient by a qualified health professional is required from the time SureScan is programmed ON to it being programmed OFF. For IPG patients, monitoring is required during the MRI scan.

√ An external defibrillator must be immediately available during the MRI procedure, and for an ICD/CRT-D patient, the entire time SureScan Mode is programmed ON.

√ Patient Monitoring:
  ▪ Pacemaker: Either prior to entering the MRI room or once in the MRI the MR-compatible pulse oximetry or ECG will be attached to the patient and activated. Accurate readings will be confirmed by a trained healthcare professional.
  ▪ ICD/CRT-D: When SureScan is programmed ON, the MR-compatible pulse oximetry or ECG will be attached to the patient and activated. Accurate readings will be confirmed by a trained healthcare professional. Monitoring is required for the duration that SureScan is programmed ON.

MR Scan:
√ The patient will be prepared for the exam according to exam protocol with location guidelines followed.
√ Scanning sequences for MR-conditional IPG/ICD/CRT-D device will be limited or modified to achieve a whole body average SAR less than or equal to 2.0 W/kg and head SAR less than or equal to 3.2 W/kg; For Revo MRI SAR must be less than 3.2 W/kg.
√ Visual and voice communication will be maintained with the patient by the MR tech.
√ Monitoring will be done via pulse oximetry or ECG by a trained healthcare professional. Pre- and post-scan O₂ saturations may be documented on patient chart.

Post-Scan:
√ The patient will be transported from the scan room to the control area by a qualified healthcare professional.
√ Pacemaker/ICD/CRT-D function is reassessed and SureScan mode will be switched OFF and pre-scan device settings will be restored by a Medtronic representative or a qualified healthcare professional.
  ▪ Pacemaker: monitor devices will be removed from the patient after final oximetry reading is recorded
  ▪ ICD/CRT-D: monitor devices will be removed from the patient after SureScan has been programmed OFF and pre-scan device settings have been restored
√ Pacing capture threshold is reassessed post-scan by a Medtronic representative or a qualified healthcare professional to ensure the pacing parameters are programmed adequately for the patient based on the threshold.

Education and Training:
Per FDA labeling requirement, all cardiology and radiology healthcare professionals present during the MRI scan must complete online training tutorial prior to the scan.

  ▪ A health professional who has completed cardiology MRI SureScan training must be present during the programming of the MRI SureScan feature
  ▪ A health professional who has completed radiology MRI SureScan training must be present during the MRI scan

Training tutorials have been created for all systems and specifically for Cardiology and Radiology health professionals.

Please visit:

√ Department employees may also receive an in-service by a Medtronic representative. Call 1 (800) Medtronic to contact your local Medtronic representative.

Documentation:
√ Printed device rhythm and threshold reports from the device programmer will become part of the patient’s medical record.
√ Pre- and post-oximetry readings may be recorded.
√ Exceptions to the performance of the routine MR exam will be documented by the technologist or qualified healthcare professional and added to the patient’s chart.
### CHECKLIST FORM FOR MRI

**Pacemaker/ICD/CRT-D Systems**

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#### Patient Name:

#### Pre-Exam:  

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- Received completed physician’s order for MRI?
- Received completed cardiology clearance form for MRI?
- Pacemaker: Has been implanted for more than 6 weeks? (contraindication for pacemakers)
- ICD/CRT-D: Is post-lead maturation period (approximately 6 weeks)? (This is a caution not a contraindication for ICD/CRT-D systems.)
- MRI scans during the lead maturation period (approximately 6 weeks) have not been prospectively studied by Medtronic and are not recommended.
- Threshold check: Pacemaker/ICD: Atrial (if applicable) and right ventricular thresholds do not exceed 2.0 V at 0.4 ms. CRT-D: Right ventricular threshold does not exceed 2.0 V at 0.4 ms for pacemaker dependent patients. (This is a caution not a contraindication for ICD/CRT-D systems.)
- Confirm that patient does not have any lead extenders, lead adaptors, abandoned leads or leads that are not electrically intact.
- Pacemaker/ICD/CRT-D and implanted leads conclusively identified? (Only patients with a complete MRI SureScan™ Pacing/ICD System can undergo an MRI procedure.)

**Note:** Only CRT-D systems may have a 6725 pin plug used in the atrial port as part of an MR-conditional system.

- MRI screening questionnaire has been reviewed with patient over the phone?
- If contrast MRI: Renal issues? Diabetes? (If yes, recent Creatinine and GFR required.)

#### Day of Exam:  

**In Control Room (Outside MRI Suite):**

- MRI Safe ECG or pulse oximeter applied to patient and assessed for accuracy; baseline blood pressure taken.
- Pacemaker/ICD/CRT-D programmed into SureScan mode.
- An external defibrillator is available in the control room.
- For ICD/CRT-D: Patient ECG or oximetry monitoring will be initiated prior to SureScan mode being turned ON and prior to entering the magnet. Monitoring should be continuously done by a qualified staff member until SureScan mode is turned OFF.
- For patients with CRT-D systems, the patient receives no CRT support while SureScan mode is ON. Patient should be monitored for symptoms of dizziness and shortness of breath.

**In MRI Scan Room:**

- Patient ECG or pulse oximetry will be continuously monitored during the scan by qualified staff member.
- Whole **body** averaged SAR must be less than or equal to 2 W/kg, head SAR less than or equal to 3.2 W/kg; For Revo MRI SAR < 3.2 W/kg.

**Post-Scan (Outside MRI Suite):**

- Post-MRI vital signs will be taken and documented.
- Patient’s pacemaker/ICD/CRT-D SureScan setting is programed OFF (device parameters automatically restored to pre-MRI SureScan configuration).
- For CRT-D patients: Be sure to program MRI SureScan mode to OFF as soon as scan is complete to resume CRT support.
- Threshold check: Update programming outputs if necessary.

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*head SAR less than or equal to 3.2 W/kg;*  

*(Attachment A)*
CARDIOLOGY ORDER FORM

Medtronic SureScan™ Pacing, ICD and CRT-D

Patient Name: ________________________________________________________________

DOB: _________________________________________________

1. Your patient has an MRI ordered. Please confirm that your patient has a Medtronic SureScan Pacing/ICD/CRT-D System, with SureScan lead(s). (Refer to www.MRISureScan.com/model lookup for a current listing of Medtronic MR-conditional products. Note: Only CRT-D systems may have a 6725 pin plug used in the atrial port as part of an MR-conditional system.)

☐ YES, my patient has a complete Medtronic SureScan Pacing/ICD/CRT-D System and it has been implanted longer than 6 weeks in the pectoral region (IPG) or post-lead maturation period of approximately 6 weeks (ICD/CRT-D).

☐ NO, my patient does not have a complete SureScan IPG/ICD/CRT-D System.

2. Please confirm your patient’s leads are electrically intact. (For pacemakers: atrial and ventricular lead impedance 200–1,500 ohms. For ICDs and CRT-D devices: pacing lead 200–3,000 ohms, defibrillation lead impedance 20–200 ohms.)

☐ YES, I confirm that my patient’s lead(s) are electrically intact.

☐ NO, my patient’s lead(s) are not electrically intact.

3. Confirm your patient’s pacing threshold(s) do not exceed 2.0 V at 0.4 ms for Pacing/ICD system, or right ventricular pacing threshold does not exceed 2.0 V at 0.4 ms for pacemaker dependent patients for CRT-D system.

☐ YES, I confirm that my patient’s threshold(s) do not exceed 2.0 V at 0.4 ms.

☐ NO, my patient’s threshold(s) exceed 2.0 V at 0.4 ms.

4. Before the scan, your patient’s IPG/ICD/CRT-D will be placed in a SureScan mode. How would you like your patient’s device to be programmed? Please select a pacing rate to avoid competitive pacing. (Note that post-scan, device programming will be restored to original settings.)

☐ DOO Pacing rate:______bpm ☐ AOO Pacing rate:______bpm

☐ VOO Pacing rate:______bpm ☐ ODO or OVO

(no pacing, for patients who do not require pacing support)

Physician Signature: __________________________________________________________________

Physician Name: _____________________________________________________________________

Date: ____________________________________________________________________________

(Attachment B)
Potential complications include, but are not limited to, acute myocardial infarction, drug intoxication, tachyarrhythmias with transient or reversible causes including, persistent supraventricular tachycardias, including atrial fibrillation or flutter. Dual chamber and CRT-D devices are contraindicated for patients whose primary disorder is atrial tachyarrhythmia. 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 leads(s), is required to verify that the patient’s implantable devices 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:** The SureScan pacing systems are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity detection. Conditions warranting chronic cardiac pacing include symptomatic paroxysmal or permanent second- or third-degree AV block, symptomatic bundle branch block, symptomatic paroxysmal or transient sinus node dysfunction 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, ventricular defibrillation for autonomous 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 for 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 III or IV who have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration ≥ 150 ms, left ventricular ejection fraction ≤ 30%, and CHA2DS2-VASc score ≥ 2 or NYHA Functional Class II, NYHA Functional Class II, NYHA Functional Class II, NYHA Functional Class II, or 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 system is also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias. The RV LIA 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 Lead Integrity Alert (LIA) feature is intended primarily for patients who are at significant risk for developing atrial tachyarrhythmias. The RV Lead Integrity Alert (LIA) feature is intended primarily for patients who may benefit from atrial tracking in bradycardia patients (LBBB) with a QRS duration ≥ 150 ms, left ventricular ejection fraction ≤ 30%, and NYHA Functional Class II. NYHA Functional Class II, NYHA Functional Class II, NYHA Functional Class II, or 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 system is also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias. The RV LIA feature may not perform as well with a St. Jude Medical Riata/®/Durata® lead or a Boston Scientific Definitive lead and ventricular defibrillation thresholds with a Medtronic MyoTemp 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 into patients with Medicare implantable cardioverter defibrillator. Rate-responsive modes may be contraindicated in patients whose primary disorder is atrial tachyarrhythmia. In addition, if the device is programmed to an asynchronous pacing mode when MRI SureScan is on. IPG specific: a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is on. IPG specific: a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is on. IPG specific: a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is on. In addition, if the device is programmed to an asynchronous paced 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 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, insufflation failure, threshold elevation, or exit block. Potential MRI complications include, but are not limited to, reduction of sensing or capture or both, MR-induced stimulation on leads 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. If a SureScan pacing system is implanted in a patient with a prior history of 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. Dual chamber and CRT-D devices, the device is contraindicated for patients whose primary disorder is atrial tachyarrhythmia with no conduction disturbance (whole body averaged specific absorption rate (SAR) ≤ 2.0 W/kg, head SAR ≤ 3.2 W/kg). For SureScan pacing systems, proper patient monitoring must be provided during the MRI scan.

**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 interference with the device’s function. Indications, contraindications, warnings, and/or potential complications/adverse effects. 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.