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

Policy:
If a patient with a Medtronic SureScan Pacing/ICD 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 pacemakers/ICDs are contraindicated for MRI by the scanner equipment labeling. However, as MR-conditional pacemakers/ICDs 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 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 averaged SAR less than or equal to 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). External defibrillator should 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 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 pacemakers/ICDs 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); 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 ICD patients, 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.

External defibrillation should be immediately available during the MRI procedure, and for an ICD 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: 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 ICD/IPG will be limited or modified to achieve a whole body average SAR less than or equal to 2.0 W/kg and Head average SAR less than or equal to 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 moved from the scan room to the control area by a qualified healthcare professional.
- Pacemaker/ICD 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: 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:

- Online training is provided by Medtronic via www.MRISureScan.com “SureScan MRI System Training” for both radiology and cardiology healthcare providers.
- 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.
# Pacemaker/ICD Checklist Form for MRI

## (Page 1/2)

### Patient Name:

<table>
<thead>
<tr>
<th>Pre-Exam:</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received completed physician’s order for MRI?</td>
<td></td>
</tr>
<tr>
<td>Received completed cardiology clearance form for MRI?</td>
<td></td>
</tr>
<tr>
<td>Pacemaker: has been implanted for more than 6 weeks?</td>
<td></td>
</tr>
<tr>
<td>ICD: is post-lead maturation period (approximately 6 weeks)?</td>
<td></td>
</tr>
<tr>
<td>Threshold check: atrial (if applicable) and ventricular thresholds do not exceed 2.0 V at 0.4 ms</td>
<td></td>
</tr>
<tr>
<td>Confirm that patient does not have any lead extenders, lead adaptors, or abandoned leads.</td>
<td></td>
</tr>
<tr>
<td>Pacemaker/ICD and implanted leads conclusively identified? (Only patients with a complete MRI SureScan™ Pacing/ICD System can undergo an MRI procedure)</td>
<td></td>
</tr>
<tr>
<td>MRI screening questionnaire has been reviewed with patient over the phone?</td>
<td></td>
</tr>
<tr>
<td>If contrast MRI: Renal issues? Diabetes? (If yes, recent Creatinine and GFR required)</td>
<td></td>
</tr>
</tbody>
</table>

## 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 programmed into SureScan™ mode
- External defibrillator is available in the control room
- For ICD: 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

### 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 averaged SAR less than or equal to 3.2 W/kg

### Post-Scan (Outside MRI Suite)

- Post-MRI vital signs will be taken and documented
- Patient’s pacemaker/ICD SureScan setting is programmed OFF (device parameters automatically restored to pre-MRI SureScan configuration).
- Threshold check: update programming outputs if necessary.

(Attachment A)
Medtronic SureScan™ Pacing/ICD System
Cardiology Order Form

Patient Name: ________________________________

DOB: ________________________________

1. Your patient has an MRI ordered. Please confirm that your patient has a Medtronic SureScan Pacing/ICD System, with SureScan lead(s). (Refer to www.MRISureScan.com/productsearch for a current listing of Medtronic MR-conditional products).

☐ YES, my patient has a complete Medtronic SureScan Pacing/ICD 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).

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

2. Please confirm your patient’s leads are electrically intact (For pacemakers: atrial and ventricular lead impedance 200-1,500 ohms. For ICDs: 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.

☐ 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 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)
SureScan™ 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.

Caution:

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; and the system must be implanted in the left or right pectoral region. Patient must have 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 on.

IPG specific: a SureScan pacing system that has been implanted for a minimum of 6 weeks; 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 ≤ 1,500 Ω.

Patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T MRI system with operating frequency of 64 MHz, maximum spatial gradient ≤ 20 T/m, and maximum gradient slew rate performance per axis ≤ 20 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).

For SureScan pacing systems, proper patient monitoring must be provided during the MRI scan.

For SureScan defibrillation systems, continuous patient monitoring is required while MRI SureScan is programmed to On. Do not scan a patient without first programming MRI SureScan to On and do not leave the device in MRI SureScan mode after the scan is complete. 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 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, 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. 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 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.