MRI Procedure Requirements

1. Patient pre-screening requirements
   - Only patients with a complete SureScan® Pacing System (consisting of an Advisa MRI™ or Revo MRI® pacemaker and two SureScan leads) can undergo an MRI procedure
   - System has been implanted for more than 6 weeks
   - Pulse generator was implanted in the pectoral region
   - No lead extenders, lead adaptors, or abandoned leads
   - Leads are electrically intact (impedance between 200 and 1,500 ohms)
   - No broken or abandoned leads or leads with intermittent electrical contact as confirmed by lead impedance history
   - 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

2. Pre-scan pacemaker programming requirements
   - A health professional who has completed cardiology SureScan training must be present during the programming of the SureScan feature
   - Provide order for pacing support needed and the appropriate pacing rate during SureScan operation
     - For patients who require pacing support, the MRI pacing mode must be set to DOO, AOO, or VOO while the MRI SureScan feature is programmed On
     - For patients who do not require pacing support, the MRI pacing mode should be set to ODO while the MRI SureScan feature is programmed On
   - Perform threshold check to confirm that atrial and ventricular thresholds do not exceed 2.00 V at 0.4 ms
   - Confirm SureScan is programmed On prior to scan (see sample device programming on the back)
   - Print SureScan programming report for documentation to accompany patient to the MRI procedure

3. Post-scan pacemaker programming requirements
   - Program SureScan Off after the MRI procedure; device returned to previous settings (see programming steps on the back)
   - Check the pacing thresholds to ensure that there is a proper safety margin

For complete MRI Conditions for Use, operating and programming guidelines and restrictions, refer to the SureScan Pacing System Reference Manual, call 1 (800) 505-4636, or visit www.medtronic.com/MRI.
**SureScan Programming Steps**

**Prior to the MRI procedure**

1. After accessing the Parameters screen, select [Additional Features].
2. Select MRI SureScan programming field to On.
3. From here, you will need to:
   - Program a mode (DOO, VOO, AOO, or ODO)
   - Program a rate (for asynchronous modes only, 30-120)

Touch [PROGRAM] to complete the steps.

Touch [Print...] for documentation.

**After the MRI procedure**

1. Interrogate the device, and you will be automatically brought to the SureScan programming screen.
2. Program SureScan Off. Pre-scan parameters are automatically restored.
3. Check the pacing capture threshold to ensure that there is a proper safety margin.

---

**Radiology Checklist**

**Step 1: Screen Patient**

- Verify that patient has a complete SureScan Pacing System (consisting of a Revo MRI or Advisa MRI SureScan IPG and two MRI SureScan leads) using one or more of the following methods:
  - Use the patient ID card to identify the device and leads implanted
  - Use the patient records to verify a complete SureScan Pacing System has been implanted
  - Perform an x-ray to identify radiopaque MRI symbols, if applicable. The SureScan devices contain a radiopaque marker. The SureScan leads may or may not contain a radiopaque marker.
  - Use the patient information on the programmer. The patient information must be complete and accurate on the programmer if this feature is to be used to determine whether the patient has a SureScan pacing system.
  - Call Medtronic at 1 (877) MRI-7677 to verify the patient’s pacing system.

- Confirm that the patient does not have any lead extenders, lead adaptors, or abandoned leads

**Step 2: Schedule**

- Contact cardiology to obtain clearance documents, including:
  1. SureScan Programming Order.
- Schedule a health professional who will monitor patient during MRI exam.
- Schedule a trained professional who will program the patient’s pacemaker in and out of SureScan mode.
Step 3: Prep Patient for Scan
- Confirm a health professional, who has completed radiology SureScan training, is present
- Ensure device is programmed in SureScan mode prior to the MRI examination

Step 4: Conduct MRI Scan Using the Following Guidelines
- Horizontal cylindrical bore magnet MRI system of 1.5 Tesla must be used in Normal Operating Mode
- Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 Teslas per meter per second (T/m/s) must be used
- Whole body averaged SAR must be ≤ 2W/kg, head averaged SAR must be ≤ 3.2W/kg
- Proper patient monitoring must be provided during the MRI scan. This includes visual and verbal contact with the patient, and monitoring heart rate using instrumentation such as pulse oximetry or electrocardiography. An external defibrillator must be available nearby during the MRI procedure.

Step 5: Manage Patient Post-Scan
- Ensure a trained professional programs patient’s device back to previous settings

Brief Statement: SureScan® Pacing Systems
Medtronic SureScan pacing systems are MR Conditional and as such are designed to allow patients to undergo MRI under the specified conditions for use. A complete SureScan pacing system, which consists of an MRI SureScan device with two SureScan leads, is required for use in the MRI environment. Consult the device manuals to ensure all system components are MR Conditional.

Indications
Medtronic SureScan pacing 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
  - Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias

Note: The Advisa MRI™ pacing system includes the following additional indication:
- Vasovagal syndromes or hypersensitive carotid sinus syndromes

The 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
- Wolff-Parkinson-White (for example, pacemaker syndrome) in the presence of persistent sinus rhythm

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

Contraindications
Medtronic SureScan pacing systems are contraindicated for:
- Concomitant implantation with another bradycardia device
- Concomitant implantation with an implantable cardioverter defibrillator

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.

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