Revo MRI™ Pacing System
Engineered with SureScan® Technology

MRI Procedure Requirements

1. Patient pre-screening requirements
- Only patients with a complete Revo MRI SureScan Pacing System (consisting of a Revo MRI SureScan IPG and two CapSureFix MRI™ SureScan leads) can undergo an MRI procedure (see ID card and radiopaque images at right to verify)
- Confirm that the patient does not have any other previously implanted (active or abandoned) medical devices, leads, lead extenders, or lead adaptors

2. Pre-scan pacemaker programming requirements
- Patient must have cardiology clearance and SureScan programming order
- Confirm SureScan is programmed On prior to the MRI procedure (see sample device programming below)
- The health professional has completed cardiology SureScan training

3. MRI procedure protocols
- A health professional who has completed radiology SureScan training must be present during the MRI examination
- 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 < 3.2W/kg
- Isocenter cannot be between C1 and T12. Patient positioning guidelines can be found in the SureScan Pacing system reference manual
- During the MRI procedure, patient must be continuously monitored, including the following methods: visual and verbal contact with the patient, electrocardiography, and pulse oximetry. An external defibrillator must be available nearby during the MRI procedure.

4. Post-scan pacemaker programming requirements
- Confirm SureScan is programmed Off and device returned to previous settings

Verification of SureScan Programming

After the device has been programmed into the SureScan mode, these reports can be printed from the device programmer to document pacemaker configuration.

For complete MRI Conditions for Use, operating and programming guidelines and restrictions, refer to the SureScan Pacing System Reference Manual, call 1 (877) MRI-7677, or visit www.medtronic.com/MRI.

The Revo MRI SureScan pacing system is MR Conditional designed to allow patients to undergo MRI under the specified conditions for use. A complete system, consisting of a Medtronic Revo MRI SureScan IPG implanted with two CapSureFix MRI SureScan leads is required for use in the MRI environment.
**Brief Statement**

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.

**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 CapSureFix™ MRI® SureScan leads. A complete system is required for use in the MRI environment.

- 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 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
- VT/VF intolerance (for example, pacemaker syndrome) in the presence of persistent sinus rhythm

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

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in bradycardia patients with atrial septal lead placement and 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. If 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 antiarrhythmic 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 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 and right pectoral regions or patients positioned such that the isocenter (center of MRI bore) is inferior to C1 vertebra and superior to the T12 vertebra.

**Potential Complications**

Potential complications include, but are not limited to, injection 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 hemaoma, 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 and/or device heating which may cause tissue damage, impact the pacing system functionality such as failure to detect/treat irregular heartbeats, or potential for VT/VF induction.

See the device manual s before performing an MRI Scan for detailed information regarding the instructions for use, indications, MRI conditions of use, 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.