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. The results documented in these cases are unique to these patients. Not every patient responds the same. Results may vary.
Background

• 41-year-old male

• Patient symptoms include increase in neck pain, extremity weakness and numbness over the past six months.

• Revo MRI® SureScan® pacemaker system implanted 6 months prior.

• Neurologist requests MRI scan to rule out cervical myelopathy as a cause of symptoms.
Methods

• 1.5 Tesla GE MRI scanner

• Isocenter positioned at nasion for initial localizer. Isocenter positioned superior to C-1 for remaining series.

• Phased-array spine coil

• Sequences performed
  • 3-plane Localizer
  • FSE Sagittal T1 and T2 weighted imaging
  • FSE Ax T1, T2, and GRE weighted imaging
  • FSE Sagittal and axial T1 weighted images performed post contrast

• SureScan® mode programmed ON prior to scan
Methods

- SAR was kept in “Normal” mode in order to keep SAR < 2 Watts/Kg.
- Isocenter was set at the nasion in the scan room for initial 3 plane localizer. FOV for localizer was set to 34 cm.
- For sagittal imaging, when scanning, FOV was adjusted so the center of the FOV was just superior to C1 with enough coverage inferiorly to include T1. For this patient the FOV was 30 cm.
- For axial imaging, when scanning, the number of slice locations was increased. The center slice in the stack of images was centered superior to C1 with enough coverage inferiorly to T1. For this patient 72 slices, with center slice 36 centered superior to C1.
  - This increased the overall protocol time approximately 10-15 minutes
Localizer Isocenter at Nasion – 34 cm FOV
• Sagittal slice coverage with 30 cm FOV
• Axial increased slice coverage
• Center slice 36 above C1

ISOCENTER
Sagittal Images – 30 cm FOV

T2

T1

ISOCENTER
Axial Images

C5/6 - T2 Weighted

C5/6 – T1 Weighted

C5/6 - MERGE
Diagnostic Results

• Normal
Conclusion

- Positioning of the isocenter superior to C1 with increased Sagittal FOV and Axial slice coverage allowed successful diagnostic imaging of the cervical spine.

- **REMINDER** – Imaging must be performed within the FDA guidelines for this device, to include both FDA-approved isocenter positioning and SAR limits

- **Revo MRI® SureScan® mode** must be programmed ON prior to scan
Revo MRI® Pacing System – Conditions for Use

A complete SureScan® pacing system including a Revo MRI SureScan IPG and two SureScan leads is required for use in the MRI environment. Any other combination may result in a hazard to the patient during an MRI scan. The SureScan feature must be programmed to On prior to scanning a patient according to the specified conditions for use.

**Cardiology requirements**

- Patients and their implanted systems must be screened to meet the following requirements:
  - No previously implanted (active or abandoned) medical devices, leads, lead extenders, or lead adaptors
  - No broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history
  - A SureScan pacing system that has been implanted for a minimum of 6 weeks
  - A SureScan pacing system implanted in the left or right pectoral region
  - Pacing capture thresholds of \( \leq 2.0 \text{ volts (V)} \) at a pulse width of \( 0.4 \text{ milliseconds (ms)} \)
  - A lead impedance value of \( \geq 200 \text{ ohms (Ω)} \) and \( \leq 1,500 \text{ Ω} \)
  - 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 the MRI SureScan is on

**Radiology requirements**

- Horizontal, cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5 Tesla (T) must be used
- Gradient systems with maximum gradient slew rate performance per axis of \( \leq 200 \text{ T/m/s} \) must be used
- The scanner must be operated in Normal Operating mode:
  - The whole-body–averaged specific absorption rate (SAR) must be \( \leq 2.0 \text{ watts per kilogram (W/kg)} \)
  - The head SAR must be \(< 3.2 \text{ W/kg}\)
- The patient must be positioned within the bore such that the isocenter (center of the MRI bore) is superior to the C1 vertebra or inferior to the T12 vertebra
- Proper patient monitoring must be provided during the MRI scan. The methods include visual and verbal contact with the patient, electrocardiography, and pulse oximetry (plethysmography).

**Training requirements**

- A health professional who has completed cardiology SureScan training must be present during the programming of the SureScan feature
- A health professional who has completed radiology SureScan training must be present during the MRI scan
**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 5086MRI 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 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

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.

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. The patient’s age and medical condition, however, may dictate the particular pacing system, mode of operation, and implantation procedure used by the physician.
**Brief Statement (continued)**

- 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 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 region; 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, 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, 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 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 this device to sale by or on the order of a physician.