## Patient Scheduling and Screening

**Q:** Is there any special (other than regular MRI consent) consent form that should be signed by the patient?

**A:** No. The SureScan system is safe when scanned according to the conditions of use.

**Q:** What is a typical scheduling process for a hospital?

**A:** Obtain cardiology order form, schedule with person doing the programming, and schedule monitoring personnel.

**Q:** Do patients need to wait six weeks post-implant prior to having scan?

**A:** For the patient to be able to get scanned, the SureScan pacing system must have been implanted for a minimum of six weeks.

**Q:** What is the process for emergent patients?

**A:** Presence of a complete SureScan system must be confirmed, it must be programmed into the SureScan mode and the conditions of use must be followed. This is true regardless if the patient is emergent or routine.

## Programming

**Q:** Are Medtronic representatives available throughout the entire United States to provide hospital support?

**A:** Medtronic representatives are available throughout the entire country to assist with SureScan programming.

## Monitoring

**Q:** Could we expect that any size facility, including outpatient clinics, would be able to scan a SureScan Pacing System patient?

**A:** Any size facility can scan SureScan patients as long as they meet the requirements in the manual.

**Q:** At sites that are currently scanning patients, are they being monitored by the MR technologist, a physician, or an RN?

**A:** Patients are generally monitored by an RN.

**Q:** What happens if you don’t have monitoring?

**A:** Monitoring of the patient’s heart rate, according to the Conditions of Use, must be provided during the MRI scan.

**Q:** What rescue equipment do you need to have on hand, AED or defib?

**A:** An external defibrillator must be available nearby during the MRI scan.

**Q:** Do you need a nurse present when scanning?

**A:** Not necessarily, as long as the patient is being monitored by a trained HCP.

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*Medtronic SureScan® pacing systems – Advisa MRI™ and Revo MRI® – are MR Conditional and as such, are designed to allow patients to be safely scanned by an MRI machine when used according to the specified MRI conditions for use. A complete SureScan pacing system, including a Medtronic MRI SureScan IPG (Advisa MRI or Revo MRI) and two CapSureFix MRI® SureScan leads are required for use in the MRI environment.*
**System ID and X-Ray**

Q: If a patient had leads left from a previous Pacemaker and a SureScan pacemaker is now implanted, should we not scan the patient?

A: Do not scan patients who have other implanted medical devices, active, passive, or abandoned, that are located within 10 cm of the implanted pacing system components. The interaction between pacing system components and other implantable devices within 10 cm during MRI scans has not been evaluated by Medtronic. The use of lead extenders or lead adaptors is not recommended as they may increase the risk of myocardial tissue damage due to lead tip heating and other MRI field-related hazards.

Q: Are chest x-rays required before the MRI to confirm pacemaker type, and to ensure no old leads/wires are present? How do we know lead extenders were not used?

A: Chest x-ray is not required unless patient history is concerning for inaccuracy or possible old hardware.

Q: Would you recommend a chest x-ray before each procedure?

A: If the presence of a complete SureScan system has been confirmed there should be no need for a radiograph.

Q: Are we likely to see a single lead SureScan pacemaker and if so, has this any implications to scanning?

A: You are not likely to see a SureScan pacemaker with a single lead as the SureScan devices are dual chamber pacemakers. If this should happen, the patient cannot be scanned.

Q: Would the pacemaker interfere with any other ferrous implants, like rods or joint implant? If the patient has a second implant (hip, pump) can you scan them?

A: Confirm that the patient doesn't have other implanted medical devices, active, passive, or abandoned, that are located within 10 cm of the implanted pacing system components. The interaction between pacing system components and other implantable devices within 10 cm during MRI scans has not been evaluated by Medtronic. Scanning patients who have multiple MR Conditional devices present is acceptable as long as the MR labeling conditions for all implants can be satisfied.

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**Scanning Process**

Q: Is there a limit to the number of times a patient can be scanned with a SureScan pacing system?

A: There is no limit as to the number of times that a patient can be scanned.

Q: Is there a time limit for the patient being in the magnet?

A: There is no time limit for the patient to be in the magnet.

Q: Is there any concern when performing multiple studies on a patient if the pacing system moves through isocenter of the bore?

A: No, as long as active scanning does not occur with the scanner's isocenter located between C1 and T12 on the patient.

Q: Do the patients feel anything in the chest during the MRI?

A: Occasionally, patients have reported feeling warmth or a gentle tugging sensation near the pacemaker. This is not a safety concern, but patient comfort should be addressed.

Q: Are there any guidelines for limiting SAR and other parameters? Also, how do these patients impact the schedule?

A: There is an SAR limit with regards to the conditions of use: 2 W/Kg whole body average and 3.2 W/Kg in the head (normal operating mode).

Q: What about gradient intensive imaging (i.e., MERGE or COSMIC)? Will these sequences have any affect on the SureScan pacing system?

A: There is no limitation on the type of gradient pulse sequence as long as the gradient slew rate remains within the labeling guidelines of ≤ 200 T/m/s per axis.
Scanning Process, continued

Q: How would a tech know if the slew rate has been exceeded?
A: That would have to be answered by the particular system vendor.

Q: Are there any positioning restrictions for the patient?
A: You cannot center/landmark below C1 or above T12. Documents are available to assist with successful scans within the position restriction zone.

Q: Are there any parts of the body that cannot be scanned (exclusion zones)?
A: All exams are acceptable as long as the isocenter of the scanner is positioned above C1 or below T12. The scanner’s Field of View (FoV) may be expanded so that images within the C1-T12 region can be obtained.

Image Quality

Q: Do you get a lot of artifact on a cervical spine?
A: As with any metallic implant, the SureScan device produces some image distortion in its immediate vicinity (within a few centimeters). The implanted lead does not produce any significant image distortion.

Reimbursement

Q: Will Medicare reimburse the peri-procedural device evaluation and programming (93286) provided to the patient before and after the MRI scan?
A: Yes, the peri-procedural service may be billed for physician and hospital outpatient procedures. Physician and hospital providers should check with their payers to determine coverage requirements and reimbursement.

Q: At the present time, are there other pacemaker systems that have been approved for use in an MRI environment?
A: SureScan pacemaker systems are the ONLY pacemaker systems FDA-approved for MRI use and covered by Medicare.

Q: Is there incremental reimbursement available when performing an MRI scan on a patient with a SureScan pacemaker?
A: No, there is no additional reimbursement for the MRI scan.

Resources/Checklists

Q: Are SureScan pacemaker systems found in the MRI safety web page?
A: Yes, they are listed on www.mrisafety.com.

Q: Where can I find a workflow process online that was shared earlier in the presentation?
A: The workflow example is available on www.mrisurescan.com.

Q: Are there images of chest scans available on Medtronic’s website?
A: There are some cardiac MRI studies performed on SureScan patients available on www.mrisurescan.com.

SureScan Safety Data and Technical Overview

Q: Have there ever been any adverse events with the use of the Revo pacemaker?
A: In the clinical studies, no MRI related complications have been reported.
How to Scan Different Zones

Q: How does it work if the required area of scanning is within the C1-T12 area? Is it possible to safely continue scanning in regards for instance to thoracic spine imaging?
A: You can scan into that area, you just can’t center the slice group (or FOV) or landmark within that region. Medtronic has documents available with instructions to assist with this task.

Q: It appears that cardiac and abdomen work is not to be done.
A: That is incorrect. There are no restrictions for obtaining images of the chest region as long as the positioning guidelines are followed.

Q: Are there any MRI exams that are considered unsafe?
A: All exams are okay as long as the operator follows the conditions of use.

Q: Not being able to move the table to isocenter for say, a thoracic MRI, would cause lower signal-to-noise ratio (SNR), potentially resulting in reduced image quality. Are there any exams that you recommend not be done at all?
A: This may be limited more by the particular capabilities and condition of the particular MR system. Studies with excellent image quality have obtained images within the C1-T12 area following the centering conditions of use.

Q: So you can actually scan in every plane?
A: Yes.

Q: Can a diffusion weighted scan be done?
A: Yes.

Q: What is the center point landmark when scanning a thoracic spine?
A: You cannot center/landmark below C1 or above T12, landmark/center just above or at C1 for a thoracic spine MR exam.

Q: I have a Philips with a 1.5T magnet. If I scanned a breast where would I center?
A: One option would be to isocenter at T12.

Q: One of my customers has a patient who needs an MRI of her breast. They are concerned about the quality of the scan due to the restrictions of the isocenter C1-T12. Can you help us relieve their concerns? Do you recommend using a breast coil?
A: A breast coil is highly recommended. The quality of the image is dependent on the capabilities of the particular MR system being used.

Q: How would you do a renal MRA for centering?
A: Recommend placing isocenter at T12.

Q: How is MRA of carotids performed using a GE scanner if the patient is suspected of having Subclavian Steal Syndrome or stenosis?
A: There should be no issue with image quality (assuming the system is well maintained as is performing within manufacturer specifications).

Q: With the SureScan pacemaker, can you use a Diffusion Weighted Imaging (DWI) sequence when performing a MRI of the brain?
A: Yes.

Q: Is it safe to scan the shoulder and humerus given they are in the exclusion zone?
A: Yes. You can scan into the C1-T12 area, you just can’t place isocenter in that region.

Q: What about scanning the shoulder joints, with off-set FOV to right or left?
A: There should be no issue with image quality (assuming the system is well maintained as is performing within manufacturer specifications).

Q: What about liver and MRCP exams?
A: There should be no issue with image quality (assuming the system is well maintained as is performing within manufacturer specifications).
Scanning Process

Q: If the scan area of interest is between C1-T12, can you use a send/receive coil over that area?
A: A transmit/receive coil cannot be positioned between C1 and T12. Outside of this region, there are no restrictions on the use of transmit/receive coils as long as the patient positioning and centering criteria are followed. Additionally, there are no restrictions on the placement of receive-only coils.

Q: Does it matter what kind of coil we use?
A: As long as the patient positioning and centering criteria are followed, there are no restrictions on the use of local transmit/receive coils for imaging of the head or of the extremities, and there are no restrictions on the placement of receive-only coils.

Q: Does it matter how a patient enters room on table?
A: No, it does not.

Q: Does it matter head first or feet first?
A: No, it does not.

Q: When centering a patient for an MRI scan, we cannot center between C1 and T12, but can the pacemaker PASS THROUGH that area? For example, centering for a lumbar spine with the patient going in head first?
A: Yes, as long as the scanner is not actively scanning when the patient’s C1-T12 region passes through isocenter.

Q: Are there instructions/protocols if it is realized a patient was positioned in the hazardous C1-T12 area during a scan/series? (Even if patient appears fine.)
A: No. Simply follow the normal post-scan procedure.
Brief Statement

Medtronic SureScan® pacing systems, including the Advisa DR MRI™ and Revo MRI® SureScan pacing systems, are MR Conditional and as such are designed to allow patients to undergo MRI under the specified conditions for use.

Indications

A complete SureScan pacing system is required for use in the MRI environment.

- The Advisa DR MRI SureScan Model A2DR01 IPG is indicated for use as a SureScan pacing system consisting of an Advisa DR MRI SureScan IPG implanted with two CapSureFix MRI® SureScan 5086MRI leads
- The Revo MRI SureScan Model RVDR01 IPG is indicated for use as a SureScan pacing system consisting of a Revo MRI SureScan IPG with two CapSureFix MRI SureScan 5086MRI leads

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

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
- 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.

Contraindications

Medtronic SureScan pacing systems are contraindicated for:

- 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 implant 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
- Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms
- 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 transsthoracic 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 Medtronic SureScan pacing system consisting of a SureScan device (Advisa MRI or Revo MRI) and two CapSureFix® SureScan leads; patients who have 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 or 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.

When scanning patients with a Revo MRI SureScan pacing system, the isocenter cannot be between C1 and T12. This positioning restriction does not apply to patients with an Advisa MRI SureScan pacing system.

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.