### 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 whether 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 defibrillator?
**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.

---

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.
**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 broken, abandoned, or intermittent leads.

**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 there is a concern about inaccurate patient history 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, are there scanning implications?

**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:** Scanning patients who have multiple devices approved for MRI is acceptable as long as the MR labeling conditions for all implants can be satisfied.

**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:** 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 as long as conditions of use are met, but patient comfort should be addressed.

**Q:** Are there any guidelines for limiting SAR and other parameters?

**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 effect 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.

**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:** No

**Q:** Are there any parts of the body that cannot be scanned (exclusion zones)?

**A:** All exams can be performed.

**Q:** Can cardiac and abdomen scanning be performed?

**A:** Yes, cardiac and abdominal scanning can be performed. There are no restrictions for obtaining images of the chest region.

**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.
**Scanning Process, continued**

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

**Q: Can a diffusion weighted scan be done?**
**A:** Yes, the only requirement is to keep the scan in Normal operating mode. All scan types are possible, some may require the operator to adjust parameters.

**Q: With the SureScan pacemaker, can you use a Diffusion Weighted Imaging (DWI) sequence when performing a MRI of the brain?**
**A:** Yes, the only requirement is to keep the scan in Normal operating mode. All scan types are possible, some may require the operator to adjust parameters.

**Q: Does it matter what kind of coil we use?**
**A:** 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.

**Image Quality**

**Q: Do you get a lot of artifact on a cervical spine?**
**A:** As with any metallic implant, the SureScan pacemaker 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 FDA-approved for use in an MRI environment?**
**A:** SureScan pacemaker systems are the ONLY pacemaker systems FDA-approved for full-body MRI scans.

**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 SureScan pacemakers?
A: In the clinical studies, no MRI-related complications have been reported.

How to Scan Different Zones

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.

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

Q: Can a diffusion weighted scan be done?
A: Yes, the only requirement is to keep the scan in Normal operating mode. All scan types are possible, some may require the operator to adjust parameters.

Q: With the SureScan pacemaker, can you use a Diffusion Weighted Imaging (DWI) sequence when performing a MRI of the brain?
A: Yes, the only requirement is to keep the scan in Normal operating mode. All scan types are possible, some may require the operator to adjust parameters.

Q: Does it matter what kind of coil we use?
A: 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.
Brief Statement

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
• 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 tachyarrhythmias, 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 transvenous 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 and two SureScan leads; patients who have broken, abandoned 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.

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.