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 leads. Medtronic SureScan pacing systems are indicated for the following:

- Concomitant implantation with an implantable cardioverter defibrillator
- Concomitant implantation with another bradycardia device

Medtronic SureScan pacing systems are contraindicated for:

- Various degrees of AV block to maintain the atrial contribution to cardiac output.
- 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:
  - Persistent atrial fibrillation or flutter
  - Various degrees of AV blocks
  - Symptomatic bilateral bundle branch block
  - Symptomatic atrial anterograde slow node dyssynchrony with or without associated AV Conduct disorder
  - Bradycardia tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
  - VasoVagal syndromes or hypersensitive carotid sinus syndromes.

The systems are also indicated for dual chamber 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.
- AV intolerance (for example, pacemaker syndrome) in the presence of persistent atrial rhythm.
- Antichytriasm pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardic 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.

www.medtronic.com

World Headquarters
Medtronic, Inc.
719 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
CA healthcare provider line for physicians and medical professionals)

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-response modes may be contraindicated in those patients who cannot tolerate pacing rates above the programed Upper 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 of (or likelihood of) competition between paced and intrinsic rhythms.
- Single chamber atrial pacing is contraindicated in patients with an atrial antrigrade pathway.

Warnings and Precautions
Changes in a 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, inappropriately strong shock, or direct damage, inducing 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.

Pacemakers and MRI access are not recommended for the use of MRI.

Medtronic SureScan® MRI Pacing Systems

PACEMAKERS AND MRI ACCESS – FINALLY COMING TOGETHER

SureScan® MRI

Pacing Systems


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

U.S. (1-800-328-2518) www.medtronic.com

SureScan® MRI leads are required for use in the MRI environment.

SureScan® MRI leads are required for use in the MRI environment.

SureScan® MRI leads are required for use in the MRI environment.

SureScan® MRI leads are required for use in the MRI environment.

SureScan® MRI leads are required for use in the MRI environment.

SureScan® MRI leads are required for use in the MRI environment.

SureScan® MRI leads are required for use in the MRI environment.

SureScan® MRI leads are required for use in the MRI environment.

SureScan® MRI leads are required for use in the MRI environment.
When people refer to a pacemaker, they are actually discussing a pacing system, which includes the pacemaker, and leads.

- A **pacemaker** is a small device that is implanted under the skin, typically just below the collarbone. The device delivers therapies to treat irregular interrupted, or slow heartbeats.

  A pacemaker can be programmed in different pacing modes based on the patient’s condition. For example, a patient with complete heart block would be programmed in an “asynchronous” mode and paced at a fixed rate.

- **Leads** are thin, soft, insulated wires about the size of a spaghetti noodle. The leads carry the electrical impulse from the pacemaker to your heart and relay information about the heart’s natural activity back to your pacemaker.

---

### What Is a Pacemaker?

Since 2008, the safety and risk concerns of MRIs in cardiac device patients have been documented in 17 studies. MRI can put pacemaker patients at risk for any of the following:

- **Lead Heating**
  Tissue damage may affect pacing therapy. The conductive pacing lead acts as an antenna, picking up radiofrequency energy. A portion of this energy is dissipated as heat in the cardiac tissue near the tip electrode.

- **Induced Arrhythmias**
  May lead to a single or intermittent stimulation, or sustained tachycardia. The gradient and radiofrequency fields will induce voltages in pacemaker leads that will be applied to the pacing lead electrodes. If these voltage pulses are large enough, they may directly stimulate the heart.

- **Device Interactions**
  Pacemaker malfunction or failure may affect pacing therapy. The gradient, radiofrequency, and static fields may adversely affect the electrical operation of the pacemaker system if its operation is not protected from the effects of those fields.

Lead heating can be associated with change in energy needed to pace the heart (Pacing Capture Threshold) and may cause tissue damage.

---

**Dual chamber pacemaker with two leads**
Pacemaker Implants in an Aging Population.

• The number of pacemakers currently implanted in the United States is approximately 1.5 million.\textsuperscript{18,19}

SureScan® Pacing System
Device Design Solutions

• SureScan Pacing Mode technology
• Circuit design immune to interference
• Minimize ferromagnetic content
• Isolated circuit board
• Digital (Hall Sensor) versus mechanical sensor (Reed Switch)

Lead Design

• Lead inner conductor coil design mitigates lead heating

Meeting the Need of MRI

86% Age 65+

Elderly patients are the primary users of MRI: individuals over age 65 are twice as likely to need an MRI compared to younger recipients.\textsuperscript{20}

Average Age of Pacemaker Patient

13% Age 25–64

Specifically Engineered for MRI Safety
SureScan pacing systems have completed clinical evaluation, regulatory review, and FDA approval and are safe for use when used according to the MRI conditions for use as defined in the SureScan manual.

The implanted system must consist solely of a Medtronic Advisa MRI Model A2DR01 or Revo MRI Model RVDR01 SureScan device and two CapSureFix MRI SureScan Model 5086MRI leads. Any other pacing system combination may result in a hazard to the patient during an MRI scan.

When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing.

Refer to the SureScan Pacing System Conditions for Use located in the device manuals prior to scanning a patient. Consult Medtronic’s website at www.medtronic.com/mri or call Medtronic at 1 (800) 328-2518.

**Evidence of Safety**

- **5 years** post-approval worldwide clinical experience*
- **More than 2,700 patients studied** without adverse impact on patient outcomes or pacemaker system functions21-23
- **Thousands of MRI scans** performed in the United States**

Lead heating model analyzed over

- **2 million scanning scenarios** to evaluate risk of tissue damage in MRI environment

* CE Mark received September 2008 and FDA-approval February 2011.
** As of November 2013.

**SureScan Pacing Systems are labeled MR-Conditional**

Under specific conditions of use, there are no known hazards or risks:
- Device conditions
- Cardiology conditions
- Radiology conditions

- SureScan pacing systems have completed clinical evaluation, regulatory review, and FDA approval and are safe for use when used according to the MRI conditions for use as defined in the SureScan manual.
- The implanted system must consist solely of a Medtronic Advisa MRI Model A2DR01 or Revo MRI Model RVDR01 SureScan device and two CapSureFix MRI SureScan Model 5086MRI leads.
- Any other pacing system combination may result in a hazard to the patient during an MRI scan.
- When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing.
- Refer to the SureScan Pacing System Conditions for Use located in the device manuals prior to scanning a patient. Consult Medtronic’s website at www.medtronic.com/mri or call Medtronic at 1 (800) 328-2518.
Schedule a health professional who will monitor patient during MRI exam.

Radiology checklist and Conditions for Use

**MRI Procedure Requirements**

**Step 1: Verify Patient**
- Verify that patient has a complete SureScan Pacing System (consisting of a Revo MRI or Advisa MRI SureScan IPG and two CapSureFix MRI SureScan leads)
- Use the patient records to verify a complete Revo MRI or Advisa MRI SureScan system has been implanted.
- If medical questions or emergency, call: www.medtronic.com/mri or call 1 (800) 551-5544.
- My device may trigger metal detection systems.
- Ensure device is programmed in SureScan mode prior to the MRI examination.

**Step 2: Schedule**
- Confirm that the patient does not have any lead extenders, lead adapters, or abandoned leads.
- 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.

1. Use the patient ID card to identify the device and leads implanted.
2. Call Medtronic at 1 (877) MRI-7677 to verify the patient’s pacing system.
3. Use the patient records to verify a complete Revo MRI or Advisa MRI system has been implanted.
4. Performing an x-ray can help identify radiopaque MRI symbols.
Steps to become a SureScan Center

Visit www.mrisurescan.com
On the website you can:
1. Complete the Radiology training
2. Create a SureScan patient workflow process for your MRI Center
3. Register your MRI center so patients with a SureScan pacing system are able to locate your center when they need an MRI scan

References