Medtronic

REVO MRI™ SURESCAN™ RVDR01

Dual Chamber Pacemaker with SureScan™ Technology (OAE-DDDR)

MR Conditional with MVP® Mode, AT/AF Suite Diagnostics and Therapies, and Cardiac Compass® Trends

Implant Manual

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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CapSureFix, CapSureFix MRI, Capture Management, Cardiac Compass, EnRhythm, EnRhythm MRI, Flashback, GEM, GEM III, InCheck, Kappa, MVP, Marker Channel, Marquis, Medtronic, Medtronic AT500, Medtronic CareLink, Paceart, Quick Look, Reactive ATP, Revo MRI, SessionSync, SureScan

Contents

1 Description

The Medtronic Revo MRI SureScan Model RVDR01 implantable pulse generator (IPG) is a multiprogrammable, bipolar, implantable dual chamber device that monitors, detects, and treats atrial tachyarrhythmia episodes. It also provides bradycardia pacing and monitoring of ventricular tachycardia (VT) episodes. The device senses the electrical activity of the patient's heart using the sensing electrodes of the implanted leads. It then analyzes the heart rhythm based on selectable sensing and detection parameters. If the device detects an atrial tachyarrhythmia, it delivers programmed atrial ATP therapy to the patient's heart. If the device identifies a bradyarrhythmia, it delivers bradycardia pacing therapy to the patient's heart.

The Revo MRI SureScan device, along with the SureScan leads, constitutes the implantable portion of the SureScan pacing system.

The Medtronic SureScan pacing system includes a Medtronic SureScan device connected to Medtronic SureScan leads. Labeling for SureScan pacing system components displays the SureScan symbol and the MR Conditional symbol.

SureScan symbol

MR Conditional symbol. The Revo MRI SureScan pacing system is MR Conditional and, as such, is designed to allow implanted patients the ability to undergo an MRI scan under the specified MRI conditions for use.

The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan device to be safely scanned by an MRI machine while the device continues to provide appropriate pacing. When programmed to On, MRI SureScan operation disables arrhythmia detection, magnet mode, and all user-defined diagnostics. **Before performing an MRI scan, refer to the SureScan pacing system technical manual for important information about procedures and MRI-specific warnings and precautions.**

About this manual – This document is primarily an implant manual. Regular patient follow-up sessions should be scheduled after implant. Follow-up procedures such as monitoring battery measurements and confirming therapy parameters are described in the product documentation that is included with the software that supports this device. To obtain additional copies of product documentation, contact a Medtronic representative.

Contents of sterile package – The package contains 1 implantable pulse generator and 1 torque wrench.

Programmer and software – Use the appropriate Medtronic programmer and software to program this device. Programmers from other manufacturers are not compatible with Medtronic devices but will not damage Medtronic devices.

Network connectivity and data exchange – The SureScan pacing system supports network connectivity and the exchange of data between the Medtronic CareLink 2090 programmer and the Medtronic Paceart data management system by using the SessionSync feature, if available.

The SureScan pacing system supports the use of the Medtronic 2290 Analyzer, which allows you to run a device session and an analyzer session at the same time, quickly switch from one to the other without having to end or restart sessions, and export data from the analyzer to the device software application.

Medtronic Model 2696 InCheck Patient Assistant – The patient can use the Model 2696 InCheck Patient Assistant to verify whether the implanted device has detected a suspected atrial arrhythmia, and can initiate recording of cardiac event data in the device memory.

Explanation of IPG code acronyms used on the device package label – The following list of acronyms applies to various IPG products. Refer to the package label for acronyms that apply to this product.

S	Single chamber IPG
D	Dual chamber IPG
SR	Single chamber rate responsive IPG
DR	Dual chamber rate responsive IPG
TR	Triple chamber rate responsive IPG

FCC compliance information – This device complies with Part 15 of the FCC Rules respectively. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

2 Indications

The Medtronic Revo MRI SureScan Model RVDR01 IPG is indicated for use as a system consisting of a Revo MRI SureScan IPG implanted with two CapSureFix MRI SureScan 5086MRI leads. A complete system is required for use in the MRI environment.
The Medtronic 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-degree 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.

3 MRI 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 ≤ 2.0 volts (V) at a pulse width of 0.4 milliseconds (ms)
  - a lead impedance value of ≥ 200 ohms (Ω) and ≤ 1500 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 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 ≤ 200 Teslas per meter per second (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 ≤ 2.0 watts per kilogram (W/kg).
  - The head SAR must be < 3.2 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.

4 Contraindications

The device is contraindicated for the following conditions:

- implant with unipolar pacing leads
- concomitant implant with another bradycardia device
- concomitant implant 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.
- Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance.
- ATP therapy is contraindicated in patients with an accessory antegrade pathway.

5 Warnings and precautions

Before performing an MRI scan, refer to the SureScan pacing system technical manual for MRI-specific warnings and precautions.

5.1 General

Electrical isolation during implant – Do not allow the patient to have contact with grounded equipment that might produce electrical current leakage during implant. Electrical current leakage may induce arrhythmias that may result in the patient's death.

External defibrillation equipment – External defibrillation equipment must be present nearby for immediate use whenever arrhythmias are possible or intentionally induced during device testing, implant procedures, or post-implant testing.

5.2 Handling and storage instructions

Follow these guidelines when handling or storing the device.

Device temperature – Allow the device to reach room temperature before it is programmed or implanted. Device temperature above or below room temperature may affect initial device function.

Dropped device – Do not implant the device if it has been dropped on a hard surface from a height of 30 cm (12 in) or more after it is removed from its packaging.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment. This device is for single use only and is not intended to be resterilized.

Explant and disposal – Consider the following information related to device explant and disposal:

- Explant the implantable device postmortem. In some countries, explanting battery-operated implantable devices is mandatory because of environmental concerns; please check the local regulations. In addition, if subjected to incineration or cremation temperatures, the device may explode.
- Medtronic implantable devices are intended for single use only. Do not resterilize and reimplant explanted devices.
- Please use the Removed Product Information Report to return explanted devices to Medtronic for analysis and disposal.

Inspecting the sterile package – Carefully inspect the package before opening it:

- If the seal or package is damaged, contact a Medtronic representative.
- Do not use the product after the "Use by" date on the package label.
- For instructions on opening the sterile package, see the diagram inside the lid of the shelf box.

Temperature limits – Store and transport the package between –18 °C and +55 °C (0 °F and 131 °F). Electrical reset may occur at temperatures below –18 °C (0 °F). Device longevity may decrease and performance may be affected at temperatures above +55 °C (131 °F).

Use by date – Do not implant the device after the "Use by" date on the package label. Battery longevity may be reduced.

5.3 Lead evaluation and lead connection

Atrial lead maturation – Do not enable AT/AF detection or automatic atrial ATP therapies until the atrial lead has matured (approximately 1 month after implant).

Hex wrench – Use only the torque wrench supplied with the device. The torque wrench is designed to prevent damage to the device from overtightening a setscrew. Other torque wrenches, (for example a blue-handled or right-angled hex wrench) have torque capabilities greater than the lead connector can tolerate.

Lead compatibility – Do not use another manufacturer's leads without demonstrated compatibility with Medtronic devices. If a lead is not compatible with a Medtronic device, the result may be undersensing of cardiac activity, failure to deliver necessary therapy, or a leaking or intermittent electrical connection.

Patients who do not have a complete SureScan pacing system, which includes a SureScan device connected to two SureScan leads, are ineligible for an MRI scan. **Before performing an MRI scan, refer to the SureScan pacing system technical manual for additional information.**

5.4 Device operation

Anti-coagulation – Use of the device should not change the application of established anti-coagulation protocols.

Crosstalk – Crosstalk may cause the device to self-inhibit, which results in no pacing. Program Ventricular Safety Pacing to On to prevent inhibition due to crosstalk.

Electrical reset – Electrical reset can be caused by exposure to temperatures below –18 °C (0 °F) or strong electromagnetic fields. Advise patients to avoid strong electromagnetic fields. Observe temperature storage limits to avoid exposure of the device to cold temperatures. If a partial reset occurs, pacing resumes in the programmed mode with many of the programmed settings retained. If a full reset occurs, the device operates in VVI mode at 65 bpm. Electrical reset is indicated by a programmer warning message that is displayed immediately upon interrogation. To restore the device to its previous operation, it must be reprogrammed. Inform a Medtronic representative if your patient's device has reset.

End of Service (EOS) Indicator – Replace the device immediately if the programmer displays an EOS indicator. The device may not perform adequately after the EOS indicator appears.

Fixed bipolar operation – Use of unipolar leads will result in loss of pacing output and sensing.

Magnets – Placing a magnet over the device suspends tachyarrhythmia detection and initiates asynchronous, fixed-rate bradycardia pacing. The programming head contains a magnet that can cause magnet operation to occur. However, magnet operation does not occur if telemetry between the device and programmer is established.

Pacing and sensing safety margins – Consider lead maturation when selecting pacing amplitudes, pacing pulse widths, and sensing levels. Loss of capture may occur if lead maturation is not considered when selecting settings.

Rate control – Decisions regarding rate controls should not be based on the ability of the device to prevent atrial arrhythmias.

Rate-responsive modes – Do not program rate-responsive modes for patients who cannot tolerate rates above the programmed Lower Rate. Rate-responsive modes may cause discomfort for those patients.

Shipping values – Do not use shipping values or nominal values for pacing amplitude and sensitivity without verifying that the values provide adequate safety margins for the patient.

Single chamber atrial modes – Do not program single chamber atrial modes for patients with impaired AV nodal conduction. Ventricular pacing does not occur in these modes.

Slow retrograde conduction – Slow retrograde conduction may induce pacemaker-mediated tachycardia (PMT) when the VA conduction time is greater than 400 ms. Programming PMT intervention may help prevent PMT when the VA conduction time is less than 400 ms.

Telemetry – Exposure to EMI may briefly interrupt programming and/or telemetry operations. Successful interrogation or programming of the device verifies that reliable communication between the device and the programmer has occurred.

Testing for cross-stimulation – At implant and when atrial ATP therapy is enabled, conduct regular testing at the programmed ATP output settings to ensure that ventricular capture does not occur. This is particularly important when the lead is placed in the inferior atrium.

5.5 Pacemaker-dependent patients

Pacemaker-dependent patients – Always program Ventricular Safety Pacing to On for pacemaker-dependent patients. Ventricular Safety Pacing prevents ventricular asystole due to inappropriate inhibition of ventricular pacing caused by oversensing.

ODO pacing mode – Do not program the ODO mode for pacemaker-dependent patients. Instead, use the Underlying Rhythm Test for brief interruption of outputs.

Underlying Rhythm Test – Use caution when using the Underlying Rhythm Test to inhibit pacing. The patient is without pacing support when pacing is inhibited.

5.6 Medical therapy hazards

Computed tomographic x-ray (CT scan) – If the patient undergoes a CT scan procedure and the device is not directly in the CT scan beam, the device is not affected.

If the device is directly in the CT scan beam, oversensing may occur for the duration of time the device is in the beam. If the device will be in the beam for more than 4 s, take the following precautions to minimize complications:

- Suspend tachyarrhythmia detection using a magnet, or disable tachyarrhythmia detection using the programmer. After the CT scan is complete, remove the magnet or use the programmer to enable tachyarrhythmia detection.
- If appropriate for the patient, program the pacing mode to minimize the effects of oversensing on pacing (for example, false inhibition). For pacemaker-dependent patients, program the device to an asynchronous pacing mode. After the CT scan is complete, program the pacing mode to its original setting.

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

Electrosurgical cautery – Electrosurgical cautery may induce ventricular arrhythmias and fibrillation or may cause device malfunction or damage. If electrosurgical cautery cannot be avoided, observe the following precautions to minimize complications:

- Keep temporary pacing and defibrillation equipment available.
- Program the device to an asynchronous pacing mode for pacemaker-dependent patients.
- Suspend tachyarrhythmia detection using a magnet, or disable detection using the programmer. Do not enable tachyarrhythmia detection until the electrosurgical cautery procedure is complete.
- Use a bipolar electrocautery system if possible. If unipolar cautery is used, position the ground plate so the current pathway does not pass through or near the device and lead system. The current pathway should be a minimum of 15 cm (6 in) away from the device and lead system.
- Avoid direct contact of the cautery equipment with the implanted device or leads.
- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.

External defibrillation – External defibrillation may damage the implanted device. External defibrillation may also temporarily or permanently elevate pacing thresholds or temporarily or permanently damage the myocardium at the electrode tissue interface. Current flow through the device and lead may be minimized by taking the following precautions:

- Use the lowest clinically appropriate defibrillation energy.
- Position the defibrillation patches or paddles a minimum of 15 cm (6 in) away from the device.
- Position the defibrillation patches or paddles perpendicular to the device and lead system.

If an external defibrillation is delivered within 15 cm (6 in) of the device, contact a Medtronic representative.

High-energy radiation – Do not direct high-energy radiation sources such as cobalt 60 or gamma radiation at the device. High-energy radiation may damage the device, however, the damage may not be immediately detectable. If a patient requires radiation therapy near the device, radiation exposure to the device should not exceed 500 rads.

Lithotripsy – Lithotripsy may permanently damage the device if the device is at the focal point of the lithotripter beam. If lithotripsy must be performed, take the following precautions:

- Keep the focal point of the lithotripter beam a minimum of 2.5 cm (1 in) away from the implanted device.
- For pacemaker-dependent patients, program the implanted device to an asynchronous pacing mode or to a single chamber mode without rate response before treatment.

Magnetic resonance imaging (MRI) – Patients with a SureScan pacing system are able to undergo an MRI scan if the requirements provided in the SureScan pacing system technical manual are followed. **Refer to the SureScan pacing system technical manual for additional information.**

Radio frequency (RF) ablation – An RF ablation procedure may cause device malfunction or damage to the device. Radio frequency ablation risks may be minimized by taking the following precautions:

- Keep temporary pacing and defibrillation equipment available.
- Avoid direct contact between the ablation catheter and the implanted system.
- Position the ground plate so the current pathway does not pass through or near the device and lead system. The current pathway should be a minimum of 15 cm (6 in) away from the device and lead system.
- Suspend atrial tachyarrhythmia detection using a magnet, or program atrial detection to Monitor using the programmer. Do not program atrial detection to On until the RF procedure is complete.
- Program the device to an asynchronous pacing mode for pacemaker-dependent patients.

Therapeutic ultrasound – Do not expose the device to therapeutic ultrasound. Therapeutic ultrasound may permanently damage the device.

Susceptibility to radiotherapy – Exposing the device to direct or scattered neutrons may cause reset of the device, errors in diagnostic data, or loss of diagnostic data. To help prevent device reset due to neutron exposure, deliver radiotherapy treatment using photon beam energies less than or equal to 10 MV. Electron beam treatments are not a problem. Using a lead shield during radiotherapy does not protect the device from the effects of the neutrons. Immediately after radiotherapy treatment, Medtronic suggests interrogating the device. In some devices, an alarm in the device sounds when a reset occurs. A device reset requires device parameters to be reprogrammed.

5.7 Home and occupational environments

Cellular phones – This device contains a filter that prevents most cellular telephone transmissions from interacting with device operation. To further minimize the possibility of interaction, take the following precautions:

- Maintain a minimum separation of 15 cm (6 in) between the device and the cellular telephone, even if the cellular telephone is not on.
- Maintain a minimum separation of 30 cm (12 in) between the device and any antenna transmitting above 3 W.
- Hold the cellular telephone to the ear farthest from the device.

This device has been tested using the ANSI/AAMI PC-69 standard to assess the potential for interaction with cellular telephones and other hand-held transmitters with similar power. These transmission technologies represent the majority of cellular telephones used worldwide. The circuitry of this device, when operating under nominal conditions, has been designed to eliminate any significant effects from cellular telephones.

Electromagnetic interference (EMI) – Instruct patients to avoid devices that generate strong EMI. Electromagnetic interference may result in delivery of unneeded therapy. Electromagnetic interference may also cause device malfunction or damage. The patient should move away from the EMI source or turn off the source because this usually allows the device to return to its normal mode of operation. EMI may be emitted from the following sources:

- high-voltage power lines
- communication equipment such as microwave transmitters, linear power amplifiers, or high-powered amateur transmitters
- commercial electrical equipment such as arc welders, induction furnaces, or resistance welders

Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with device operation. There are reports of temporary disturbances caused by electric hand tools or electric razors used directly over the implant site.

Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity to its minimum (most sensitive) setting of 0.15 mV.

Static magnetic fields – Patients should avoid equipment or situations where they would be exposed to static magnetic fields greater than 10 gauss or 1 mT. Static magnetic fields may suspend arrhythmia detection. Sources

of static magnetic fields include, but are not limited to, stereo speakers, bingo wands, extractor wands, magnetic badges, or magnetic therapy products.

Note: The SureScan pacing system has been designed to mitigate the effects of magnetic fields present in 1.5 T MRI machines. **Refer to the SureScan pacing system technical manual for additional information.**

Electronic article surveillance (EAS) – Electronic article surveillance equipment, such as retail theft prevention systems, may interact with devices and result in inappropriate therapy delivery. Advise patients to walk directly through an EAS system and not remain near an EAS system longer than necessary.

6 Potential adverse events

Before performing an MRI scan, refer to the SureScan technical manual for MRI-specific potential adverse events.
Potential adverse events associated with the use of transvenous leads and pacing systems include, but are not limited to, the following events (listed in alphabetical order):

- acceleration of tachyarrhythmias (caused by device)
- air embolism
- bleeding
- body rejection phenomena including local tissue reaction
- cardiac dissection
- cardiac perforation
- cardiac tamponade
- chronic nerve damage
- death
- endocarditis
- erosion
- erosion through the skin
- excessive fibrotic tissue growth
- extrusion
- fibrillation or other arrhythmias
- fluid accumulation
- formation of hematomas or cysts
- heart block
- heart wall or vein wall rupture
- hematoma/seroma
- infection
- keloid formation
- lead abrasion and discontinuity
- lead migration/dislodgment
- muscle stimulation, nerve stimulation, or both
- myocardial damage
- myocardial irritability
- myopotential sensing
- pericardial effusion
- pericardial rub
- pneumothorax
- rejection phenomena (local tissue reaction, fibrotic tissue formation, device migration)
- threshold elevation
- thromboemboli
- thrombolytic and air embolism
- thrombosis
- transvenous lead-related thrombosis
- valve damage (particularly in fragile hearts)
- venous occlusion
- venous or cardiac perforation

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7 Adverse events and clinical trial data

Information regarding clinical studies and adverse events related to this device is available at www.medtronic.com/manuals. To view, download, print, or order the following clinical studies from the Medtronic website, perform the following steps:

1. Navigate your web browser to http://www.medtronic.com/manuals.
2. Select the hyperlink that corresponds to your location.
3. Select the Search field on the left side of the screen and type "RVDR01".
4. Click [Search]. All technical literature for this device is listed.

The following clinical studies are related to this device:

Atrial Septal Pacing Efficacy Trial (ASPECT) – This clinical study, which evaluated the safety and efficacy of the Medtronic AT500 DDDRP Pacing System devices, provides support for the atrial intervention pacing therapies.

Atrial Therapy Efficacy and Safety Trial (ATTEST) – This clinical study, which evaluated the safety and efficacy of the Medtronic AT500 DDDRP Pacing System devices, provides support for the Revo MRI SureScan Model RVDR01 devices.

EnRhythm clinical study – This clinical study, which evaluated the safety and efficacy of the EnRhythm Model P1501DR devices, provides support for MVP mode pacing and the Reactive ATP feature in the Revo MRI SureScan Model RVDR01 devices.

GEM III DR Model 7275 MVP study – This clinical study, which evaluated the performance of MVP mode pacing in the GEM III DR Model 7275 devices, provides support for MVP mode in the Revo MRI SureScan Model RVDR01 devices.

Kappa 700 clinical study – This study, which evaluated the safety and clinical performance of the Kappa 700 pacemakers, provides support for the Right Ventricular Capture Management feature and other bradycardia pacing features.

Marquis MVP download study – This clinical study, which evaluated the performance of MVP mode pacing in the Marquis DR Model 7274 devices, provides support for MVP mode in the Revo MRI SureScan Model RVDR01 devices.

Revo MRI SureScan pacing system clinical study – This clinical study, which evaluated the safety and efficacy of the EnRhythm MRI SureScan pacing system in the clinical magnetic resonance imaging (MRI) environment, provides support for the MRI SureScan feature in the Revo MRI SureScan device.

8 Physician and patient information

In addition to this implant manual, documentation for the Medtronic Revo MRI SureScan Model RVDR01 device includes the following:

- *Revo MRI SureScan RVDR01 Reference Manual*
  Comprehensive reference on system design, operations, programming and clinical use (shipped with software)
- *MRI SureScan Pacemaker Patient Manual*
  Information for the patient, patient's family, and other interested people (shipped with device).
- *Revo MRI SureScan Pacing System Technical Manual*
  Information for cardiologists and radiologists on how to perform a safe MRI scan on patients implanted with a SureScan pacing system.

To obtain additional copies of these documents, contact your Medtronic representative.

8.1 Device registration

Verify device operating characteristics at the time of implant and record them in the patient file. Complete the Device Registration Form and return it to Medtronic as it provides necessary information for warranty purposes and patient tracking.

8.2 Patient counseling

Physicians should consider the following points in counseling the patient about this implanted device:

- Encourage the patient to use the identification card issued by Medtronic and/or the identification bracelets documenting the implanted device system.
- Discuss information in the patient manual so that the patient is fully familiar with the operation of the implanted device.
- Advise the patient how to obtain additional copies of the patient manual.

9 Implant procedure

Proper surgical procedures and sterile techniques are the responsibility of the physician. The following procedures are provided for information only. Each physician must apply the information in these procedures according to professional medical training and experience.

The implant procedure includes the following steps:

- Program the device before implant.
- Verify lead and connector compatibility.
- Position the leads.
- Test the lead system.
- Connect the leads to the device.
- Position and secure the device.
- Program the device.

For information about replacing a previously implanted device, see Section 9.8, "Replacing a device", page 19.

9.1 Programming the device before implant

Caution: Do not implant the device after the "Use by" date. Battery longevity may be reduced.

9.1.1 How to program the device for implant

Before opening the sterile package, prepare the device for implant by performing the following steps.

1. Interrogate the device. Print an initial interrogation report.
   Note: If the programmer reports that an electrical reset occurred, do not implant the device. Contact a Medtronic representative.
2. Check the initial interrogation report or the Quick Look screen to confirm that the battery voltage is at least 2.85 V at room temperature.
   If the device has been exposed to low temperatures, the battery voltage will be temporarily lower. Allow the device to warm to room temperature for at least 48 hours and check the battery voltage again. If an acceptable battery voltage cannot be obtained, contact a Medtronic representative.
   Note: The device measures the battery voltage daily at 2:15 AM based on the device clock. The most recent automatic daily battery voltage measurement is displayed on the Battery and Lead Measurements screen.
3. Set the internal clock of the device.

4. Program the therapy and pacing parameters to values appropriate for the patient. Ensure that tachyarrhythmia detection is disabled.
   Note: Do not enable the Atrial Preference Pacing feature or a rate responsive pacing mode before implanting the device. Doing so may result in a pacing rate that is faster than expected.

9.2 Verifying lead and connector compatibility

Warning: Verify lead and connector compatibility before using a lead with this device. Using an incompatible lead may damage the connector, result in electrical current leakage, or result in an intermittent electrical connection.

Note: The SureScan pacing system includes a SureScan device connected to two SureScan leads. **Before performing an MRI scan, refer to the SureScan pacing system technical manual for additional information.**

Lead adaptors compromise the ability to safely scan the SureScan pacing system. **Refer to the SureScan pacing system technical manual for additional information.**

Select a compatible lead. Refer to the following table.

Table 1. Lead and connector compatibility[a]

Port	Primary Lead	Lead Adaptor
A, V	IS-1[b] bipolar	5866-24M for 5 mm biturcated 5866-40M for Medtronic 3.2 mm low-profile

[a] Lead adaptors have not been tested for MRI safety.
[b] IS-1 refers to the International Connector Standard (see Document No. ISO 5841-3) whereby pulse generators and leads so designated are assured of meeting the electrical and mechanical parameters specified in the IS-1 International Standard.

9.3 Positioning the leads

Warning: When implanting a SureScan pacing system, consider the risks associated with removing previously implanted leads before doing so. Abandoned leads or previously implanted non-SureScan labeled leads compromise the ability to safely scan the SureScan pacing system during MRI scans.

Warning: Proceed with extreme caution if a lead must be removed or repositioned. Chronic repositioning or removal of transvenous leads may be difficult because of fibrotic tissue development on the lead. In most clinical situations, it is preferable to abandon unused leads in place. Return all removed leads, unused leads, or lead sections to Medtronic for analysis.

Note: For active fixation leads, if the helix does not disengage from the endocardium by rotating the connector pin, rotating the lead body counterclockwise may withdraw the helix and decrease the possibility of damage to cardiovascular structures during removal.

- Lead removal may result in avulsion of the endocardium, valve, or vein.
- Lead junctions may separate, leaving the lead tip and bare wire in the heart or vein.
- Chronic repositioning of a lead may adversely affect a steroid lead's low-threshold performance.
- An abandoned lead should be capped so that the lead does not transmit electrical signals.
- Severed leads should have the remaining lead end sealed and the lead body sutured to adjacent tissue.

Warning: Implant transvenous leads according to the supplied instructions unless suitable chronic leads are already in place. Do not use any lead with this device without first verifying connector compatibility. A bipolar atrial lead with closely spaced pacing and sensing electrodes is recommended. Closely spaced bipolar epicardial leads can be used if warranted by the patient's age or medical condition.

If using a subclavian approach, position the lead using a more lateral approach to avoid pinching the lead body between the clavicle and the first rib.

Warning: Pinching the lead can damage the lead conductor or insulation, which may cause unwanted therapies or result in the loss of sensing or pacing therapy.

Note: Only bipolar leads can be used with this device.

9.4 Testing the lead system

For lead testing procedures, refer to the technical manual supplied with the implant support instrument.

Table 2. Acceptable implant values

Measurements required	Acute transvenous leads	Chronic leads[bc]
R-wave amplitude	≥ 5 mV	≥ 3 mV
P-wave amplitude	≥ 2 mV	≥ 1 mV
Slew rate	≥ 0.5 V/s (atrial)	≥ 0.3 V/s (atrial)
	≥ 0.75 V/s (ventricular)	≥ 0.5 V/s (ventricular)
Capture threshold (0.5 ms pulse width)	≤ 1.5 V (atrial)	≤ 3.0 V (atrial)
	≤ 1.0 V (ventricular)	≤ 3.0 V (ventricular)
Typical pacing lead impedance[a]	250 – 1000 Ω	250 – 1000 Ω

[a] The measured pacing lead impedance is a reflection of measuring equipment and lead technology. Refer to the lead technical manual for acceptable impedance values.
[b] Chronic leads are leads implanted for 30 days or more.
[c] During an MRI scan, the MRI conditions for use information in the SureScan pacing system technical manual will supersede these values.

9.4.1 Cross-stimulation testing

Caution: Perform testing at the programmed atrial ATP output settings to ensure that ventricular capture does not occur. This is particularly important when the lead is placed in the inferior atrium.

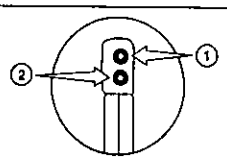
9.5 Connecting the leads to the device

Warning: Verify that the lead connections are secure. Loose lead connections may result in inappropriate sensing and failure to deliver arrhythmia therapy.

Caution: Use only the wrench supplied with the device. The wrench is designed to prevent damage to the device from overtightening a setscrew.

See Figure 1 for information about lead connections.

Figure 1. Lead connections

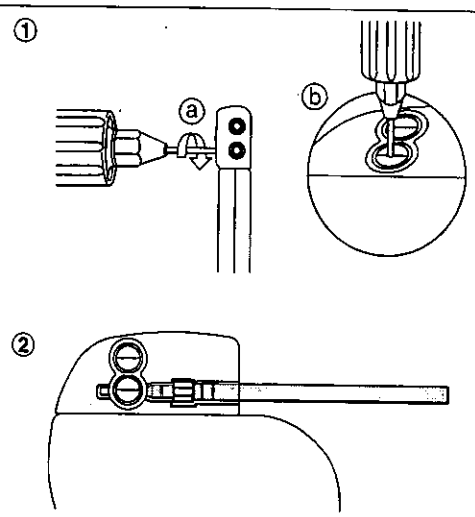


1 IS-1 connector port, A
2 IS-1 connector port, V

9.5.1 How to connect a lead to the device

1. Insert the wrench into a grommet on the connector port.
   a. Check that the setscrew is retracted from the connector port. If the connector port is obstructed, retract the setscrew to clear it. Do not disengage the setscrew from the connector block.
   b. Leave the wrench in the grommet until the lead is secure. This allows a pathway for venting trapped air when the lead is inserted.

Figure 2. Preparing the connector port setscrew



2. Push the lead connector pin into the connector port until the connector pin is visible in the lead viewing area. Sterile water may be used as a lubricant. Sealant is not required.
3. Tighten the setscrew by turning the wrench clockwise until the wrench clicks.

65

4. Repeat these steps for each lead.
5. Gently pull on the lead to confirm the connection.

9.6 Positioning and securing the device

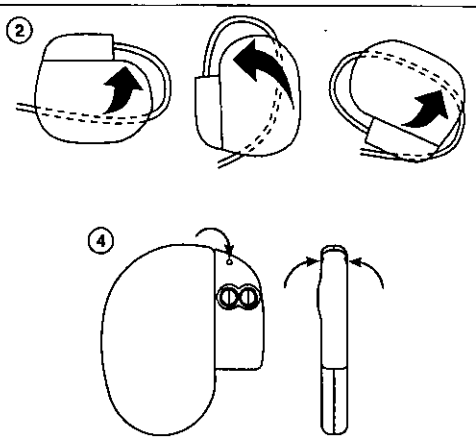
Caution: Ensure that AT/AF detection is programmed to Monitor before closing the pocket to avoid inappropriate therapy delivery while closing the pocket.

Note: Implant the device within 5 cm (2 in) of the surface of the skin to optimize post-implant ambulatory monitoring.

9.6.1 How to position and secure the device

1. Verify that each lead connector pin or plug is fully inserted into the connector port and that all setscrews are tight.
2. To prevent twisting of the lead body, rotate the device to loosely wrap the excess lead length. Do not kink the lead body.
3. Place the device and leads into the surgical pocket.
4. Suture the device securely within the pocket. Use non-absorbable sutures. Secure the device to minimize post-implant rotation and migration. Use a surgical needle to penetrate the suture hole on the device.

Figure 3. Positioning and securing the device



5. Suture the pocket incision closed.

9.7 Programming the device

Caution: Do not program AT/AF detection to On or enable automatic atrial ATP therapies until the atrial lead has matured (approximately 1 month after implant).

9.7.1 How to complete programming the device

1. Program the pacing parameters to values appropriate for the patient.
2. Monitor the patient after the implant, and take x-rays as soon as possible to document and assess the location of the leads.
3. Program patient information.
4. Set up data collection parameters.
5. Initialize data to begin diagnostic data collection.

9.7.2 How to assess the performance of the device and leads

1. Interrogate the device to check for spontaneous episodes to evaluate detection settings.
2. Recheck pacing and sensing values, and adjust if necessary.
3. Interrogate the device and print a Final Report to document the post-operative programmed device status.

9.8 Replacing a device

To retain the ability to safely scan the SureScan pacing system, refer to the SureScan pacing system technical manual for additional information.

Warning: When implanting a SureScan pacing system, consider the risks associated with removing previously implanted leads before doing so. Abandoned leads or previously implanted non-SureScan labeled leads compromise the ability to safely scan the SureScan pacing system during MRI scans.

Warning: Keep external pacing equipment nearby for immediate use. The patient does not receive pacing therapy from the device when the lead is disconnected.

Caution: Disable tachyarrhythmia detection to avoid inappropriate therapy delivery while explanting the device.

Note: To meet the implant requirements, you may need to reposition or replace the chronic leads. Any unused leads that remain implanted must be capped with a lead pin cap to avoid transmitting electrical signals. Contact your Medtronic representative for information about lead pin caps. For more information, see Section 9.3, "Positioning the leads", page 15.

Note: Only bipolar leads can be used with this device. Chronic unipolar leads cannot be used with this device.

9.8.1 How to explant and replace a device

1. Program the device to a mode that is not rate responsive to avoid potential rate increases while handling the device.
2. Dissect the leads and the device free from the surgical pocket. Do not nick or breach the lead insulation.
3. Use a torque wrench to loosen the setscrews in the connector port.
4. Gently pull the leads out of the connector ports.
5. Evaluate the condition of each lead (see Section 9.4, "Testing the lead system", page 16). Replace a lead if the electrical integrity is not acceptable or if the lead connector pin is pitted or corroded.
6. Connect the leads to the replacement device (see Section 9.5, "Connecting the leads to the device", page 16).
   Note: Lead adaptors may be needed to connect the leads to the replacement device. However, lead adaptors compromise the ability to safely scan the SureScan pacing system. Refer to the SureScan pacing system technical manual or contact your Medtronic representative for questions about lead adaptor compatibility with the SureScan pacing system.
7. Use the replacement device to evaluate stimulation thresholds and sensing potentials.
8. After confirming acceptable electrical measurements, position and secure the device in the surgical pocket and suture the pocket incision closed (see Section 9.6, "Positioning and securing the device", page 18).
9. Return the explanted device and any explanted leads to Medtronic for analysis and disposal.

10 Feature summary

See the "Shipped" column of the tables in Section 11.5 for a list of which features are enabled at shipping.

10.1 Tachyarrhythmia operations

Antitachycardia pacing (ATP) therapy – This therapy delivers rapid pacing pulses to overdrive and terminate the detected arrhythmia.

Auto-adjusting sensitivity – This feature automatically adjusts the sensitivity thresholds following certain paced and sensed events to reduce the incidence of oversensing.

Reactive ATP – This feature allows the device to repeat programmed atrial ATP therapies during long AT/AF episodes. Therapies are repeated after a programmed time interval or when the atrial rhythm changes in regularity or cycle length.

10.2 Pacing operations

Atrial Preference Pacing – This atrial rhythm management feature adapts the pacing rate to slightly higher than the intrinsic sinus rate.

Atrial Rate Stabilization – This feature adjusts the pacing rate dynamically to eliminate the long pause that typically follows a premature atrial contraction (PAC).

Mode Switch – This feature prevents tracking of paroxysmal atrial tachycardias by switching from a tracking mode to a non-tracking mode.

MVP (Managed Ventricular Pacing) – This feature promotes intrinsic conduction by reducing unnecessary right ventricular pacing. MVP operates when the programmed mode is either AAIR<=>DDDR or AAI<=>DDD.

Non-Competitive Atrial Pacing (NCAP) – This feature delays an atrial pace from falling within the atrium's relative refractory period.

Pacemaker-Mediated Tachycardia (PMT) Intervention – This feature provides automatic detection and interruption of device-defined PMTs.

Post Mode Switch Overdrive Pacing (PMOP) – This feature applies an elevated DDIR rate for a programmable period following AT/AF reversion.

Premature Ventricular Contraction (PVC) response – This feature extends the atrial refractory period following a PVC to promote dual chamber synchrony.

Rate Adaptive AV (RAAV) – This feature varies the Paced AV (PAV) and Sensed AV (SAV) intervals as the heart rate increases or decreases during dual chamber operation.

Rate Responsive Pacing – This feature varies the pacing rate in response to the patient's physical motion as detected by the activity sensor of the device.

Ventricular Rate Stabilization – This feature adjusts the pacing rate dynamically to eliminate the long pause that typically follows a premature ventricular contraction (PVC).

Ventricular Safety Pacing – This feature prevents inappropriate inhibition of ventricular pacing caused by crosstalk or ventricular oversensing.

10.3 Monitoring operations

Cardiac Compass trends – This report plots long-term trends in heart rhythm and device status for up to 14 months.

Episode data and EGM storage – The device records diagnostic quality electrogram during every detected arrhythmia episode.

Flashback memory – This diagnostic stores interval data for several minutes prior to recent detected arrhythmia episodes, and prior to interrogation.

Heart Rate Histograms – This report shows heart rate range distributions from the most recent follow-up period and previous follow-up period.

Holter telemetry – This function allows the implanted device to continuously transmit an EGM with marker telemetry, with or without applying the programming head, for up to 46 hours.

10.4 Additional operations

MRI SureScan feature – This feature allows patients with an implanted SureScan pacing system to have a safe MRI scan. When programmed to On, MRI SureScan operation disables arrhythmia detection, magnet mode, and all user-defined diagnostics. **Refer to the SureScan pacing system technical manual for additional information.**

11 Product specifications

Note: Functional parameters and electrical characteristics are measured at 37 °C (98.6 °F) with a 500 Ω load on the pacing terminals.

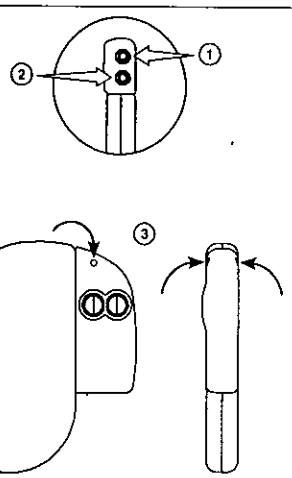
11.1 Physical characteristics

Table 3. Device physical characteristics (nominal)

Volume[a]	12.7 cm^3
Mass	21.5 g
H x W x D[b]	45 mm x 51 mm x 8 mm
Radiopaque IDs	PTA and MRI symbol[c]
Materials in contact with human tissue[d]	Titanium, polyurethane, silicone rubber
Battery	Lithium silver vanadium oxide hybrid

[a] Volume with connector bores unplugged.
[b] Grommets may protrude slightly beyond the can surface.
[c] Refer to the SureScan pacing system technical manual for a description and drawing of the 2 radiopaque symbols.
[d] These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Figure 4. Connector and suture holes



1 IS-1 connector port, A
2 IS-1 connector port, V
3 Suture hole

11.2 Replacement indicators

Battery voltage and messages about replacement status appear on the programmer display and on printed reports. The Recommended Replacement Time (RRT) and the End of Service (EOS) conditions are listed in Table 4.

Table 4. Replacement indicators

Recommended Replacement Time (RRT)	≤ 2.81 V on 3 consecutive daily automatic measurements
End of Service (EOS)	3 months after RRT

RRT date – The Quick Look and Battery and Lead Measurements screens display the date when the battery reached RRT.

Replace at EOS – If the programmer indicates that the device is at EOS, replace the device immediately.

RRT operation – When the device reaches RRT, it automatically changes the value of several parameters as shown in Table 5.

Table 5. Parameter settings after RRT

Pacing Mode	VVI
Lower Rate	65 bpm
RV Amplitude	as programmed
RV Pulse Width	as programmed
Rate Hysteresis	Off
V. Rate Stabilization	Off
AT/AF Detection	Monitor (fixed)[a]
Pre-arrhythmia EGM	Off (fixed)

[a] When AT/AF Detection is set to Monitor, AT/AF therapies are not available.

Prolonged service period – The prolonged service period is the time between the RRT and EOS. This 3-month period between RRT and EOS assumes 100% pacing at these settings, with RV Amplitude set to 3.5 V and RV Pulse Width set to 0.4 ms, and a pacing load of 500 Ω. Reprogramming the pacing parameters may reduce the duration of the RRT to EOS period, as shown in Table 6.

Table 6. Projected prolonged service period in months with 0.4 ms pulse width and 65 bpm pacing rate assuming 100% pacing in VVI mode

	Projected prolonged service period (months)		
	Minimum[a]	**Mean**	**Pacing Parameters**
3.5 V amplitude 500 Ω lead impedance	5.2	6.3	Nominal
5.0 V amplitude 500 Ω lead impedance	2.9	3.6	High pacing output
5.0 V amplitude 300 Ω lead impedance	1.9	2.4	High pacing output Low impedance

[a] Minimum is defined as the length of time that 99.9% of devices are expected to exceed.

11.3 Projected service life

The following service life estimates are based on accelerated battery discharge data and device modeling, as specified.

11.3.1 Considerations

Pacing outputs – If the patient's pacing threshold allows for an appropriate safety margin (at least a factor of 2 after the acute implant period), consider decreasing the pacing outputs. Always consider the patient's access to regular follow-up care in selecting a safety margin for chronic pacing.

Pacing mode – If the patient's intrinsic rhythm allows for appropriate rate support, you can decrease the pacing burden by programming the Mode, Rate Response, and AV Interval parameters to promote intrinsic activation or conduction.

Pre-arrhythmia EGM storage – When Pre-arrhythmia EGM storage is enabled, the device collects up to 10 s of EGM information before the onset or detection of VT Monitor or SVT episodes.

Note: The Pre-arrhythmia EGM feature does not apply to AT/AF episodes. The device stores up to 5 s of EGM prior to AT/AF detection, regardless of the Pre-arrhythmia EGM setting.

Using Pre-arrhythmia EGM storage reduces longevity by approximately 34% or by 4 months per year.[1] In a patient who uniformly repeats the same onset mechanisms, the greatest clinical benefit of Pre-arrhythmia EGM storage is achieved after a few episodes are captured.

To maximize the effectiveness of the Pre-arrhythmia EGM feature and optimize device longevity, consider these programming options:

- Enable Pre-arrhythmia EGM to capture possible changes in the onset mechanism following significant clinical adjustments, for example, device implant, medication changes, and surgical procedures.
- Disable Pre-arrhythmia EGM once you have successfully captured the information of interest.

Note: When Pre-arrhythmia EGM is disabled, the device starts storing EGM information for VT Monitor and SVT episodes after the third tachyarrhythmia event occurs. However, the device still records up to 20 s of information before the onset or detection of the episode, including interval measurements and Marker Channel annotations. In addition, the most recent tachyarrhythmia episodes also provide Flashback interval data.

11.3.2 Projected service life

Delivery of atrial antitachycardia pacing therapy does not appreciably alter the service life of the device, when considered with the inhibition of atrial pacing during the AT/AF episode.

Table 7. Projected service life in years with 0.4 ms pulse width and 60 bpm pacing rate[a]

Pacing	Pre-arrhythmia EGM storage[b]	300 Ω pacing impedance		500 Ω pacing impedance		1000 Ω pacing impedance	
		2.5 V	5.0 V	2.5 V	5.0 V	2.5 V	5.0 V
DDD, 0%	Off	12.6	12.6	12.6	12.6	12.6	12.6
	On	12.4	12.4	12.4	12.4	12.4	12.4
DDD, 15%	Off	11.7	9.2	12.0	10.2	12.4	11.3
	On	11.4	9.0	11.8	10.0	12.1	11.1
DDD, 50%	Off	9.9	5.5	10.8	7.0	11.8	9.0
	On	9.7	5.4	10.6	6.9	11.5	8.8
AAI<=>DDD, 50% atrial, 5% ventricular	Off	10.8	7.4	11.4	8.7	12.0	10.2
	On	10.6	7.2	11.2	8.5	11.7	10.0
DDD, 100%	Off	8.1	3.5	9.4	4.8	11.0	7.0
	On	7.9	3.4	9.3	4.7	10.7	6.8

[a] The service life projections in this table assume less than 75 hours of total MRI SureScan feature use throughout the device lifetime.

[b] The data provided for programming Pre-arrhythmia EGM On assumes that it is enabled for a period of 6 months following the implant of the device. Additional use of Pre-arrhythmia EGM reduces projected service life by approximately 34% or 4 months per year.

11.4 Magnet application

When a magnet is placed near the device, the device responds as shown in Table 8. When the magnet is removed, the device returns to its programmed operations.

[1] Based on device modeling with 50% atrial pacing and 5% ventricular pacing.

Table 8. Effects of magnet application on the device[a]

Pacing mode	The device changes to an asynchronous pacing mode. The specific mode depends on the programmed pacing mode: • DOO if the programmed mode is AAIR<=>DDDR, AAI<=>DDD, DDDR, DDD, DDIR, DDI, or DOO • VOO if the programmed mode is VVIR, VVI, or VOO • AOO if the programmed mode is AAIR, AAI, or AOO
Pacing rate and interval	The device applies a fixed pacing rate. The specific rate depends on the status of the device. • 85 bpm (700 ms) if device conditions are normal • 65 bpm (920 ms) if RRT or an electrical reset occurred
Tachyarrhythmia detection	The device suspends detection.

[a] Tachyarrhythmia detection and the programmed pacing mode and rate resume if telemetry between the device and the programmer is established and the application software is running.

11.5 Functional parameters

Programmable parameters are determined by the software used in the programmer. If the programmer displays a message that an electrical reset has occurred, contact your Medtronic representative.

The ◆ symbol in parameter tables indicates the Medtronic nominal value for that parameter.

11.5.1 Emergency settings

Table 9. Emergency VVI settings

Parameter	Selectable values
Pacing Mode	VVI
Lower Rate	70 bpm
RV Amplitude[a]	6 V
RV Pulse Width	1.5 ms
V. Blank Post VP	240 ms
Rate Hysteresis	Off
V. Rate Stabilization	Off
MRI SureScan	Off

[a] Peak pacing amplitude. When tested per CENELEC standard EN 45502-2-1:2003, the tolerance is applied not to the programmed setting, but to the calculated amplitude A, which depends upon the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 - (W_p \times 0.145\ ms^{-1})]$.

11.5.2 Tachyarrhythmia detection parameters

Table 10. Tachyarrhythmia detection parameters

Parameter	Programmable values	Shipped	Reset
AT/AF Detection	On; Monitor◆	Monitor	Monitor
Zones	1◆; 2	1	1
AT/AF Interval[a]	150; 160 ... 350◆ ... 450 ms	350 ms	350 ms

Table 10. Tachyarrhythmia detection parameters (continued)

Parameter	Programmable values	Shipped	Reset
Fast AT/AF Interval[a]	150; 160 ... 200◆ ... 250 ms	200 ms	200 ms
VT Monitor	Monitor◆; Off	Monitor	Off
VT Monitor Interval[a]	280; 290 ... 400◆ ... 500 ms	400 ms	400 ms
RV Sensitivity[b,c]	0.45; 0.6; 0.9◆; 1.2; 1.5; 2.1 mV	0.9 mV	0.9 mV
Atrial Sensitivity[c,d]	0.15 mV; 0.3◆; 0.45; 0.6; 0.9; 1.2; 1.5; 2.1 mV	0.3 mV	0.3 mV

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.
[b] With a 40 ms sine^2 waveform. When using the CENELEC waveform, the sensing threshold value will be 1.5 times the rated sine^2 sensing threshold.
[c] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.
[d] With a 20 ms sine^2 waveform. When using the CENELEC waveform, the sensing threshold value will be 1.4 times the rated sine^2 sensing threshold.

11.5.3 Atrial tachyarrhythmia therapy parameters

Table 11. Atrial tachyarrhythmia therapy parameters

Parameter	Programmable values	Shipped	Reset
AT/AF Rx Status	On; Off◆	Off	Off
Therapy Type	Ramp; Burst+ Rx1: Ramp◆ Rx2: Burst+◆ Rx3: Ramp◆	—	—
Fast AT/AF Rx Status	On; Off◆	Off	Off
Therapy Type	Ramp; Burst+ Rx1: Ramp◆ Rx2: Burst+◆ Rx3: Ramp◆	—	—
Burst+ parameters			
Initial # S1 Pulses	1; 2 ... 15◆; 20; 25	—	—
A-S1 Interval (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91◆; 94; 97%	—	—
S1-S2 (%AA)	Off; 28; 31; 34; 38; 41 ... 59; 63; 66; 69 ... 84◆; 88; 91; 94; 97%	—	—
S2-S3 Decrement	Off; 0; 10◆; 20 ... 80 ms	—	—
Interval Decrement	0; 10◆; 20; 30; 40 ms	—	—
# Sequences	1; 2 ... 6◆ ... 10	—	—

Table 11. Atrial tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
Ramp parameters			
Initial # S1 Pulses	1; 2 ... 6◆ ... 15; 20; 25	—	—
A-S1 Interval (% AA)	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91◆; 94; 97%	—	—
Interval Decrement	0; 10◆ ... 40 ms	—	—
# Sequences	1; 2 ... 8◆; 9; 10	—	—
Shared atrial therapy parameters			
Duration to Stop	12; 24; 48◆; 72 hr; None	48 hr	48 hr
Disable all atrial therapies if atrial lead position is suspect?	Yes◆; No	No	No
Disable Atrial ATP if it accelerates V. rate?	Yes◆; No	Yes	Yes
Episode Duration Before ATP	0; 1◆; 2; 3; 4; 5; 7; 10; 15; 20; 25; 30; 40; 50 min; 1; 2; 3; 4; 5; 6; 12; 24 hr	1 min	1 min
Reactive ATP Rhythm Change	On◆; Off	On	On
Reactive ATP Time Interval	Off; 2; 4; 7◆; 12; 24; 36; 48 hr	Off	Off
A-A Minimum ATP Interval[b]	100; 110; 120; 130◆ ... 400 ms	150 ms	150 ms
A. Pacing Amplitude[a]	1; 2 ... 6◆; 8 V	6 V	6 V
A. Pacing Pulse Width	0.1; 0.2 ... 1.5◆ ms	1.5 ms	1.5 ms
VVI Backup Pacing	Off; On (Always); On (Auto-Enable)◆	On (Auto- Enable)	On (Auto- Enable)
VVI Backup Pacing Rate	60; 70◆ ... 120 bpm	70 bpm	70 bpm

[a] Peak pacing amplitude. When tested per CENELEC standard EN 45502-2-1:2003, the tolerance is applied not to the programmed setting, but to the calculated amplitude A, which depends upon the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 - (W_p \times 0.145\ ms^{-1})]$.

[b] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

11.5.4 Bradycardia pacing parameters

Table 12. Bradycardia pacing parameters

Parameter	Programmable values	Shipped	Reset
Mode	DDDR; DDD; AAIR<=>DDDR◆; AAI<=>DDD; DDIR; DDI; AAIR; AAI; VVIR; VVI; DOO; AOO; VOO; ODO	AAI<=>DDD	VVI
Mode Switch	On◆; Off	On	Off
Lower Rate[a]	30; 35 ... 60◆; 70; 75 ... 150 bpm	60 bpm	65 bpm
Upper Tracking Rate	80; 85 ... 130◆ ... 150 bpm	130 bpm	120 bpm
Upper Sensor Rate	80; 85 ... 130◆ ... 150 bpm	130 bpm	120 bpm
Paced AV	30; 40 ... 180◆ ... 350 ms	180 ms	180 ms
Sensed AV	30; 40 ... 150◆ ... 350 ms	150 ms	150 ms
PVARP	Varied; 150; 160 ... 310◆ ... 500 ms	310 ms	310 ms
A. Refractory Period	150; 160 ... 310◆ ... 500 ms	310 ms	310 ms
RV Amplitude[b]	0.5; 1 ... 3◆; 3.5; 4; 5; 6 V	3 V	6 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4◆ ... 1.5 ms	0.4 ms	1.5 ms
RV Sensitivity[c,d]	0.45; 0.6; 0.9◆; 1.2; 1.5; 2.1 mV	0.9 mV	0.9 mV
Atrial Amplitude[b]	0.5; 1 ... 3◆; 3.5; 4; 5; 6 V	3 V	4 V
Atrial Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4◆ ... 1.5 ms	0.4 ms	0.4 ms
Atrial Sensitivity[d,e]	0.15 mV; 0.3◆; 0.45; 0.6; 0.9; 1.2; 1.5; 2.1 mV	0.3 mV	0.3 mV
PVAB Interval	10; 20 ... 150◆ ... 300 ms	150 ms	150 ms
PVAB Method	Partial◆; Partial+; Absolute	Partial	Partial
A. Blank Post AP	150; 160 ... 200◆ ... 250 ms	200 ms	240 ms
A. Blank Post AS	100◆; 110 ... 170 ms	100 ms	100 ms
V. Blank Post VP	150; 160 ... 200◆ ... 320 ms	200 ms	240 ms
V. Blank Post VS	120◆; 130 ... 170; 200; 220; 250; 280; 300; 320 ms	120 ms	120 ms
Rate Response Pacing parameters			
Rate Response	1; 2 ... 7◆ ... 10	7	7
Activity Threshold	Low; Medium Low◆; Medium High; High	Medium Low	Medium Low
Activity Acceleration	15; 30◆; 60 s	30 s	30 s
Activity Deceleration	Exercise◆; 2.5; 5; 10 min	5 min	5 min
Rate Adaptive AV parameters			
Rate Adaptive AV	On; Off◆	Off	On
Start Rate	50; 55 ... 80◆ ... 145 bpm	80 bpm	60 bpm
Stop Rate	55; 60 ... 130◆ ... 150 bpm	130 bpm	120 bpm

Table 12. Bradycardia pacing parameters (continued)

Parameter	Programmable values	Shipped	Reset
Minimum Paced AV	30; 40 ... 140◆ ... 200 ms	140 ms	140 ms
Minimum Sensed AV	30; 40 ... 110◆ ... 200 ms	110 ms	110 ms
Arrhythmia Intervention parameters			
A. Rate Stabilization	On; Off◆	Off	Off
Maximum Rate	80; 85 ... 100◆ ... 150 bpm	100 bpm	100 bpm
Interval Percentage Increment	12.5; 25◆; 50%	25%	25%
A. Preference Pacing	On; Off◆	Off	Off
Maximum Rate	80; 85 ... 100◆ ... 150 bpm	100 bpm	100 bpm
Interval Decrement	30; 40; 50◆ ... 100; 150 ms	50 ms	50 ms
Search Beats	5; 10◆ ... 25; 50	10	5
Post Mode Switch	On; Off◆	Off	Off
Overdrive Rate	70; 75; 80◆ ... 120 bpm	80 bpm	65 bpm
Overdrive Duration	0.5; 1; 2; 3; 5; 10◆; 20; 30; 60; 90; 120 min	10 min	10 min
V. Rate Stabilization	On; Off◆	Off	Off
Maximum Rate	80; 85 ... 120◆ bpm	120 bpm	120 bpm
Interval Increment	50; 60 ... 150◆ ... 400 ms	150 ms	150 ms
Additional pacing features			
Non-Comp Atrial Pacing	On◆; Off	On	On
NCAP Interval	200; 250; 300◆; 350; 400 ms	300 ms	300 ms
Rate Hysteresis	Off◆; 30; 40 ... 80 bpm	Off	Off
PMT Intervention	On; Off◆	Off	Off
PVC Response	On◆; Off	On	On
V. Safety Pacing	On◆; Off	On	On
MRI SureScan	Off◆; On	Off	Off
MRI Pacing Mode	DOO; AOO; VOO; ODO	—	—
MRI Pacing Rate	30; 35 ... 60; 70; 75 ... 120 bpm	—	—

[a] The corresponding Lower Rate Interval can be calculated as follows: Lower Rate Interval (ms) = 60,000/Lower Rate. The tolerance for Lower Rate Interval is (+30; –2 ms).

[b] Peak pacing amplitude. When tested per CENELEC standard EN 45502-2-1:2003, the tolerance is applied not to the programmed setting, but to the calculated amplitude A, which depends upon the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times \{0.9 - (W_p \times 0.145\ ms^{-1})\}$.

[c] With a 40 ms sine^2 waveform. When using the CENELEC waveform, the sensing threshold value will be 1.5 times the rated sine^2 sensing threshold.

[d] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

[e] With a 20 ms sine^2 waveform. When using the CENELEC waveform, the sensing threshold value will be 1.4 times the rated sine^2 sensing threshold.

11.5.5 Data collection parameters

Table 13. Data collection parameters

Parameter	Programmable values	Shipped	Reset
EGM 1 Source	Vtip to Vring; Atip to Aring◆; Atip to Vring; Aring to Vring	Atip to Aring	Atip to Aring
EGM 1 Range	±2; ±4; ±8◆; ±16 mV	±8 mV	±8 mV
EGM 2 Source	Vtip to Vring (fixed)	Vtip to Vring	Vtip to Vring
EGM 2 Range	±2; ±4; ±8◆; ±16 mV	±8 mV	±8 mV
Pre-arrhythmia EGM	Off◆; On – 1 month; On – 3 months; On Continuous	Off	Off
Device Date/Time[a]	(enter time and date)	—	—
Holter Telemetry	Off◆; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr	Off	Off

[a] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

11.5.6 System test parameters

Table 14. System test parameters

Parameter	Selectable values
Pacing Threshold Test parameters	
Test Type	Amplitude; Pulse Width
Chamber	RV; Atrium
Decrement after	2; 3 ... 15 pulses
Mode[a] (RV test)	VVI; VOO; DDI; DDD; DOO
Mode[a] (Atrium test)	AAI; AOO; DDI; DDD; DOO
Lower Rate	30; 35 ... 60; 70; 75 ... 150[b] bpm
RV Amplitude[c]	0.5; 1 ... 4; 5; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2 ... 1.5 ms
A. Amplitude[c]	0.5; 1 ... 4; 5; 8 V
A. Pulse Width	0.03; 0.06; 0.1; 0.2 ... 1.5 ms
AV Delay	30; 40 ... 350 ms
RV Pace Blanking	150; 160 ... 320 ms
A. Pace Blanking	150; 160 ... 250 ms
PVARP	150; 160 ... 500 ms

Table 14. System test parameters (continued)

Parameter	Selectable values
Sensing Test parameters	
Mode[a]	AAI; DDD; DDI; VVI; ODO
AV Delay	30; 40 ... 350 ms
Lower Rate	30; 35 ... 60; 70; 75 ... 120 bpm

[a] The selectable values for this parameter depend on the programmed pacing mode.
[b] The maximum Lower Rate value is 145 bpm if you perform the test in DDD mode.
[c] Peak pacing amplitude. When tested per CENELEC standard EN 45502-2-1:2003, the tolerance is applied not to the programmed setting, but to the calculated amplitude A, which depends upon the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 - (W_p \times 0.145\ ms^{-1})]$.

11.5.7 EP study parameters

Table 15. EP Study parameters

Parameter	Selectable values
Fixed Burst Induction parameters	
Resume at Burst	Enabled◆; Disabled
Chamber	RV; Atrium
Interval	100; 110 ... 600◆ ms
Amplitude[a]	0.5; 1 ... 4◆; 5; 6; 8 V
Pulse Width	0.1; 0.2 ... 0.5◆ ... 1.5 ms
VVI Backup (for atrial Fixed Burst)[c]	On; Off◆
Pacing Rate	60; 70◆ ... 120 bpm
RV Amplitude[a,b]	0.5; 1 ... 4; 5; 6; 8 V
RV Pulse Width[b]	0.1; 0.2 ... 1.5 ms
PES Induction parameters	
Resume at Deliver	Enabled◆; Disabled
Chamber	RV; Atrium
#S1	1; 2 ... 8◆ ... 15
S1S1	100; 110 ... 600◆ ... 2000 ms
S1S2	Off; 100; 110 ... 400◆ ... 600 ms
S2S3	Off◆; 100; 110 ... 600 ms
S3S4	Off◆; 100; 110 ... 600 ms
Amplitude[a]	0.5; 1 ... 4◆; 5; 6; 8 V
Pulse Width	0.1; 0.2 ... 0.5◆ ... 1.5 ms
VVI Backup (for atrial PES)[c]	On; Off◆
Pacing Rate	60; 70◆ ... 120 bpm
RV Amplitude[a,b]	0.5; 1 ... 4; 5; 6; 8 V
RV Pulse Width[b]	0.1; 0.2 ... 1.5 ms

Table 15. EP Study parameters (continued)

Parameter	Selectable values
General manual ATP therapy parameters	
Minimum Interval (atrial ATP)	100; 110; 120; 130◆ ... 400 ms
Minimum Interval (ventricular ATP)	150; 160 ... 200◆ ... 400 ms
Amplitude[a]	0.5; 1 ... 4; 5; 6◆; 8 V
Pulse Width	0.1; 0.2 ... 1.5◆ ms
VVI Backup (for atrial ATP therapy)[c]	On; Off◆
Pacing Rate	60; 70◆ ... 120 bpm
RV Amplitude[a,b]	0.5; 1 ... 4; 5; 6; 8 V
RV Pulse Width[b]	0.1; 0.2 ... 1.5 ms
Manual Ramp therapy parameters	
Chamber	RV; Atrium
RV Ramp therapy parameters	
# Pulses	1; 2 ... 6◆ ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88; 91; 94; 97◆%
Dec/Pulse	0; 10◆; 20; 30; 40 ms
Atrial Ramp therapy parameters	
# Pulses	1; 2 ... 6◆ ... 15; 20; 30 ... 100
%AA Interval	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91; 94; 97◆%
Dec/Pulse	0; 10◆; 20; 30; 40 ms
Manual Burst therapy parameters	
# Pulses	1; 2 ... 8◆ ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88◆; 91; 94; 97%
Manual Ramp+ therapy parameters	
# Pulses	1; 2; 3◆ ... 15
R-S1 (%RR)	50; 53; 56; 59; 63; 66 ... 75◆ ... 84; 88; 91; 94; 97%
S1-S2 (%RR)	50; 53; 56; 59; 63; 66; 69◆ ... 84; 88; 91; 94; 97%
S2-SN (%RR)	50; 53; 56; 59; 63; 66◆ ... 84; 88; 91; 94; 97%
Manual Burst+ therapy parameters	
# S1 Pulses	1; 2 ... 6◆ ... 15; 20; 30 ... 100
%AA Interval	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91◆; 94; 97%

Table 15. EP Study parameters (continued)

Parameter	Selectable values
S1S2	Off; 28; 31; 34; 38; 41 ... 59; 63; 66 ... 84Φ; 88; 91; 94; 97%
S2S3 Dec	Off; 0; 10; 20Φ ... 80 ms

[a] Peak pacing amplitude. When tested per CENELEC standard EN 45502-2-1:2003, the tolerance is applied not to the programmed setting, but to the calculated amplitude A, which depends upon the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 - (W_p \times 0.145\ ms^{-1})]$.
[b] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[c] Crosstalk may occur when atrial pacing amplitude is greater than 6 V.

11.5.8 Nonprogrammable parameters

Table 16. Nonprogrammable parameters

Parameter	Value
Premature threshold	69%
Fixed blanking periods	
Atrial blanking after a paced ventricular event	30 ms
Ventricular blanking after a paced atrial event	30 ms
Fixed bradycardia pacing parameters	
Ventricular Safety Pacing Intervals	110 ms 70 ms[a]
PVC Response (PVARP extension)[b]	Extended to 400 ms
PVC Response (NCAP extension)[c]	Extended to 400 ms
PMT Intervention (PVARP extension)[b]	Extended to 400 ms
PMT Intervention (NCAP extension)[c]	Extended to 400 ms
Fixed tachyarrhythmia detection parameters	
Ventricular events to detect AT/AF	32
VT Monitor initial beats to detect	16
Stability criterion interval	90 ms
AF/Afl criterion	On
Sinus Tach criterion	On
Fixed automatic atrial ATP therapy parameters	
VVI Backup Pacing amplitude[d]	6 V
VVI Backup Pacing pulse width	1.5 ms

Table 16. Nonprogrammable parameters (continued)

Parameter	Value
Hardware parameters	
Atrial rate limit[e] (protective feature)	171 bpm
Ventricular rate limit[e] (protective feature)	171 bpm
Input impedance	150 kΩ minimum

[a] The shorter VSP interval takes effect when the pacing rate exceeds the results of the following formula: 60,000/2 x (Ventricular Pace Blanking + 110) per minute.
[b] PVARP is extended to 400 ms only if the current PVARP (either the programmed PVARP value or the current Varied PVARP value) is less than 400 ms.
[c] The NCAP extension applies only if NCAP is enabled.
[d] Peak pacing amplitude. When tested per CENELEC standard EN 45502-2-1:2003, the tolerance is applied not to the programmed setting, but to the calculated amplitude A, which depends upon the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 - (W_p \times 0.145\ ms^{-1})]$.
[e] Does not apply during therapies, programmed high rates, or ventricular safety pacing.

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Medtronic

CAPSUREFIX MRI™ SURESCAN™ 5086MRI

MR Conditional, steroid-eluting, bipolar, implantable, screw-in, ventricular/atrial, transvenous lead

Technical Manual

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

The following are trademarks of Medtronic:
CapSureFix, CapSureFix MRI, Medtronic, Quick Twist, Revo MRI, SureScan

Contents

1 Description

The Medtronic CapSureFix MRI SureScan Model 5086MRI steroid-eluting, bipolar, implantable, screw-in, ventricular/atrial, transvenous lead is designed for pacing and sensing applications in either the atrium or ventricle. The lead has been designed for use in the MRI environment when used with the Revo MRI SureScan IPG. The platinum alloy tip and ring electrodes feature a high-active surface area of titanium nitride microstructure. This electrode configuration contributes to low polarization.

The lead has a helical tip electrode made of platinum alloy that can be actively fixed in the endocardium. The helix electrode can be extended or retracted by rotating the lead connector pin with either the Quick Twist tool attached to the lead or with the white fixation tool. An active fixation lead is particularly beneficial for patients who have smooth or hypertrophic hearts where lead dislodgement may be a potential problem. The lead also has a second, larger electrode proximal to the helical tip electrode and an IS-1 Bipolar (BI) connector[1] with one terminal pin. It features MP35N nickel alloy conductors and silicone rubber insulation. The outer insulation of the lead has been treated to facilitate ease of implant.

The distal tip contains a nominal dosage of 692 µg of dexamethasone acetate. Upon exposure to body fluids, the steroid elutes from the lead tip. The steroid is known to suppress the inflammatory response that is believed to cause threshold rises typically associated with implanted pacing electrodes.

The Medtronic SureScan pacing system includes a Medtronic SureScan device connected to Medtronic SureScan leads. Labeling for SureScan pacing system components displays the SureScan symbol and the MR Conditional symbol.

SureScan symbol

MR Conditional symbol. The Revo MRI SureScan pacing system is MR Conditional and, as such, is designed to allow implanted patients the ability to undergo an MRI scan under the specified MRI conditions for use.

The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan device to be safely scanned by an MRI machine while the device continues to provide appropriate pacing. When programmed to On, MRI SureScan operation disables arrhythmia detection, magnet mode, and all user-defined diagnostics. **Before performing an MRI scan, refer to the SureScan pacing system technical manual for important information about procedures and MRI-specific warnings and precautions.**

1.1 Package contents

Leads and accessories are supplied sterile. Each package contains the following items:

- 1 lead with radiopaque anchoring sleeve, stylet, and Quick Twist tool
- 1 white fixation tool
- 1 vein lifter
- extra stylets
- product literature

1.2 Accessory descriptions

Anchoring sleeve – An anchoring sleeve secures the lead to prevent it from moving and protects the lead insulation and conductors from damage caused by tight sutures.

White fixation tool – The white fixation tool facilitates connector pin rotation.

Quick Twist tool – The Quick Twist tool facilitates both connector pin rotation and stylet insertion into the lead. This tool comes attached to the lead.

Stylet – A stylet provides additional stiffness and controlled flexibility for maneuvering the lead into position. Each stylet knob is labeled with the stylet diameter and length.

Vein lifter – A vein lifter facilitates lead insertion into a vein.

2 Indications

The Medtronic CapSureFix MRI SureScan 5086MRI lead is indicated for use as a system consisting of a Medtronic Revo MRI SureScan Model RVDR01 IPG implanted with two SureScan leads. A complete system is required for use in the MRI environment. This lead has application where implantable dual chamber MR Conditional pacing systems are indicated.

[1] IS-1 BI refers to an International Connector Standard (ISO 5841-3) whereby pulse generators and leads so designated are assured of a basic mechanical fit.

3 Contraindications

- Use of ventricular transvenous leads is contraindicated in patients with tricuspid valvular disease.
- Use of ventricular transvenous leads is contraindicated in patients with mechanical tricuspid heart valves.
- Use of steroid-eluting transvenous leads is contraindicated in patients for whom a single dose of 1.0 mg dexamethasone acetate may be contraindicated.

4 Warnings and precautions

Before performing an MRI scan, refer to the SureScan pacing system technical manual for MRI-specific warnings and precautions.

Line-powered and battery-powered equipment – An implanted lead forms a direct current path to the myocardium. During lead implant and testing, use only battery-powered equipment or line-powered equipment specifically designed for this purpose to protect against fibrillation that may be caused by alternating currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

Vessel and tissue damage – Use care when positioning the lead. Avoid known infarcted or thin ventricular wall areas to minimize the occurrence of perforation and dissection.

Single use – The lead is for single use only.

Inspecting the sterile package – Inspect the sterile package with care before opening it.

- Contact a Medtronic representative if the seal or package is damaged.
- Do not store this product above 40 °C (104 °F).
- Do not use the product after its expiration date.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment. This lead is for single use only and is not intended to be resterilized.

Steroid use – It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of this highly localized, controlled-release lead. For a list of potential adverse effects, refer to the *Physicians' Desk Reference*.

Handling the steroid tip – Avoid reducing the amount of steroid available before implanting the lead. Reducing the available amount of steroid may adversely affect low-threshold performance.

- Do not allow the electrode surface to come in contact with surface contaminants.
- Do not wipe or immerse the electrode in fluid, except blood, at the time of implant.

Handling a screw-in lead – Handle the lead with care at all times.

- Do not implant the lead if it is damaged. Return the lead to a Medtronic representative.
- Protect the lead from materials that shed small particles such as lint and dust. Lead insulators attract these particles.
- Handle the lead with sterile surgical gloves that have been rinsed in sterile water or a comparable substance.
- Do not severely bend, kink, or stretch the lead.
- Do not immerse the lead in mineral oil, silicone oil, or any other liquid, except blood, at the time of implant.
- Do not use surgical instruments to grasp the lead or connector pin.
- Do not force the lead if resistance is encountered during lead passage.
- Exercise the helix electrode before implanting the lead. On initial extension, more rotations may be required to extend and retract the helix electrode, or the helix electrode may extend suddenly when torque is built up.
  Note: The estimated number of rotations (using the fixation tool) needed to initially extend or retract the helix electrode is stated in Table 3, page 12.
- Ensure helix is retracted prior to implant.
- The number of turns required to extend and subsequently retract the helix may be different. Verify helix electrode extension and retraction using fluoroscopy during implant (Figure 7). Overrotation of the connector pin may result in fracture or distortion of the inner conductor or retraction of the helix electrode out of its channel.

Handling the stylet – Handle the stylet with care at all times.

- Curve the stylet before inserting it into the lead to achieve a curvature at the lead's distal end. Do not use a sharp object to impart a curve to the distal end of the stylet.
- Do not use excessive force or surgical instruments when inserting the stylet into the lead.
- Avoid overbending or kinking the stylet.
- Use a new stylet when blood or other fluids accumulate on the stylet. Accumulated blood or other fluids may damage the lead or cause difficulty in passing the stylet into the lead.

Necessary hospital equipment – Keep external defibrillation equipment nearby for immediate use during acute lead system testing, the implant procedure, or whenever arrhythmias are possible or intentionally induced during post-implant testing.

Concurrent devices – Output pulses, especially from unipolar devices, may adversely affect device sensing capabilities. If a patient requires a separate stimulation device, either permanent or temporary, allow enough space between the leads of the separate systems to avoid interference in the sensing capabilities of the devices. Previously implanted pulse generators and

implantable cardioverter defibrillators should generally be explanted.

Chronic lead removal and the SureScan pacing system – When implanting a SureScan pacing system, consider the risks associated with removing previously implanted leads before doing so. Abandoned leads or previously implanted non-SureScan labeled leads compromise the ability to safely scan the SureScan pacing system during MRI scans.

Chronic repositioning or removal of a screw-in lead – Proceed with extreme caution if a lead must be removed or repositioned. Chronic repositioning or removal of screw-in transvenous leads may not be possible because of blood or fibrotic tissue development into the helix mechanism on the lead. In most clinical situations, it is preferable to abandon unused leads in place. Return all removed leads, unused leads, or lead sections to Medtronic for analysis.

Note: If a helix electrode does not disengage from the endocardium by rotating the connector pin, rotating the lead body counterclockwise may withdraw the helix electrode and decrease the possibility of damage to cardiovascular structures during removal.

- Lead removal may result in avulsion of the endocardium, valve, or vein.
- Lead junctions may separate, leaving the lead tip and bare wire in the heart or vein.
- Chronic repositioning of a lead may adversely affect the low-threshold performance of a steroid lead.
- An abandoned lead should be capped so that the lead does not transmit electrical signals.
- Severed leads should have the remaining lead end sealed and the lead body sutured to adjacent tissue.

5 Potential adverse events

The potential complications (listed in alphabetical order) related to the use of transvenous leads include, but are not limited to, the following patient-related conditions that can occur when the lead is being inserted or repositioned:

- cardiac perforation
- cardiac tamponade
- fibrillation and other arrhythmias
- heart wall rupture
- infection
- muscle or nerve stimulation
- myocardial irritability
- pericardial rub
- pericarditis
- pneumothorax
- thrombotic and air embolism
- thrombosis
- valve damage (particularly in fragile hearts)

Other potential complications related to the screw-in lead and the programmed parameters include, but are not limited to, the complications listed in the following table. Symptoms of the following potential complications include loss of capture or intermittent or continuous loss of capture or sensing:[2]

Complication	Corrective action to be considered
Lead dislodgement	Reposition the lead.
Lead conductor or helix electrode fracture or insulation failure	Replace the lead. In some cases with a bipolar lead, the implantable device may be programmed to a unipolar configuration or the lead may be unipolarized.
Threshold elevation or exit block[a]	Adjust the implantable device output. Replace or reposition the lead.

[a] Evidence indicates that there is a higher frequency of exit block in the ventricle when using a screw-in lead. This should be considered when selecting a screw-in lead for use in the ventricle.

Potential acute or chronic complications associated with screw-in lead placement that may require lead replacement to correct include, but are not limited to, the following:

Implant technique	Potential complication
Forcing the lead through the introducer	Screw electrode damage, insulation damage
Use of too medial of an approach with venous introducer resulting in clavicle and first rib binding	Conductor coil fracture, insulation damage, helix engagement issues
Puncturing the periosteum and/or tendon when using subclavian introducer approach	Conductor coil fracture, insulation damage
Advancing the lead into the venous insertion site and/or through the veins without the stylet fully inserted	Tip distortion, insulation perforation
Bending the lead or manually pinching the lead body during extension or retraction of the helix electrode	Delayed torque transfer

In addition, prolonged implant procedures or repositioning the lead multiple times may allow blood or body fluids to build up on the helix mechanism. This may result in an increased number of rotations needed to extend or retract the helix electrode, which may damage the lead.

[2] Transient loss of capture or sensing may occur for a short time following implant until lead stabilization takes place. If stabilization does not occur, lead dislodgement may be suspected.

6 Implant procedure

Warning: When implanting a SureScan pacing system, consider the risks associated with removing previously implanted leads before doing so. Abandoned leads or previously implanted non-SureScan labeled leads compromise the ability to safely scan the SureScan pacing system during MRI scans.

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. Some implant techniques vary according to physician preference and the patient's anatomy or physical condition.

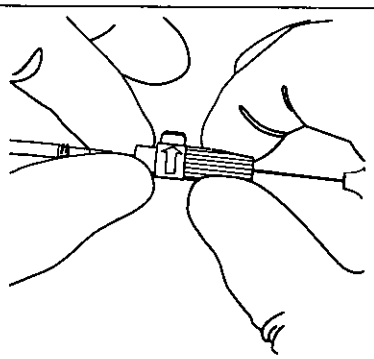
6.1 Verifying the mechanical functioning of the helix electrode

Note: The package includes 2 tools, the Quick Twist tool attached to the lead and the white fixation tool. Either tool may be used to verify the mechanical functioning of the helix electrode. The choice of tool is left to the discretion of the physician.

Before implant, verify the mechanical functioning of the helix electrode using the following steps:

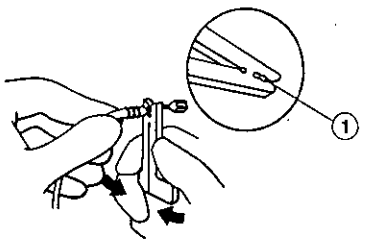
1. Attach either the Quick Twist tool or the white fixation tool to the lead. Ensure that the stylet is inserted into the lead and proceed as indicated, according to the tool being used.
   a. **Quick Twist tool:** Push the Quick Twist tool onto the connector pin (Figure 1).

Figure 1.



   b. **White fixation tool:** Press both legs of the white fixation tool together and place the most distal hole on the connector pin (Figure 2).

Figure 2.



1 The most distal hole of the white fixation tool.

2. Keep the lead body and the IS-1 connector sleeve as straight as possible (Figure 2). Ensure that the stylet is fully inserted, then rotate the selected fixation tool clockwise until the helix electrode is fully extended (Figure 3 or Figure 4). When the helix electrode is fully extended, approximately 1.5 to 2 helix coils are exposed.

Figure 3.

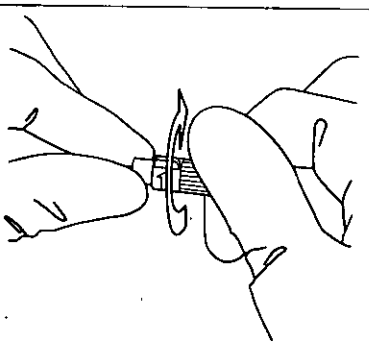
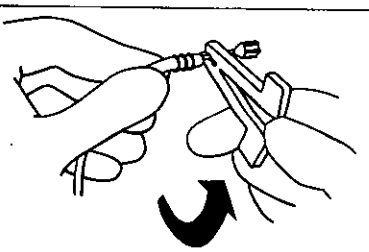


Figure 4.



Caution: Do not severely bend the IS–1 connector sleeve or the lead body while extending the helix electrode.
Caution: Overrotating the connector pin after the helix electrode is fully extended may damage the lead.

The number of rotations required to extend the helix electrode increases proportionately with the length of the lead. Additional curvatures made to the stylet may increase the number of rotations needed to extend or retract the helix electrode. Refer to Table 3, page 12 for the estimated number of rotations required to extend or retract the helix electrode.

Note: The number of rotations required to extend the helix electrode is variable depending on the lead path. During the initial helix electrode extension, the helix electrode may extend suddenly due to accumulated torque in the lead, or the helix electrode may require additional rotations for extension.

3. Disconnect the selected fixation tool from the connector pin and release the proximal end of the lead body. Allow several seconds for relief of the residual torque in the lead.
4. After allowing for relief of the residual torque, reattach the selected fixation tool and rotate it counterclockwise until the helix electrode tip is retracted into the sheath.

6.2 Inserting the lead

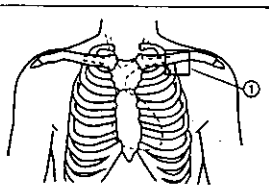
Caution: Use care when handling the lead during insertion.

- Do not severely bend, kink, or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector pins.

Insert the lead using the following techniques:

1. Select a site for lead insertion. The lead may be inserted by venotomy through several different venous routes, including the right or left cephalic vein or the external or internal jugular vein. Use the cephalic vein whenever possible to avoid lead damage in the first rib or clavicular (thoracic inlet) space.
   Cautions:
   - Certain anatomical abnormalities, such as thoracic outlet syndrome, may also precipitate pinching and subsequent fracture of the lead.
   - When using a subclavian approach, avoid techniques that may damage the lead.
   - Place the insertion site as far lateral as possible to avoid clamping the lead body between the clavicle and the first rib (Figure 5).

Figure 5.



1 Suggested entry site

   - Do not force the lead if significant resistance is encountered during lead passage.
   - Do not use techniques such as adjusting the patient's posture to facilitate lead passage. If resistance is encountered, it is recommended that an alternate venous entry site be used.
2. Insert the tapered end of a vein lifter into the incised vein and gently push the lead tip underneath and into the vein (Figure 6).
   Note: A percutaneous lead introducer (PLI) kit may be used to facilitate insertion. If a slittable introducer is used, it should be at least 2.6 mm (8 French). Refer to the technical manual packaged with an appropriate percutaneous lead introducer for further instructions.

Figure 6.

3. Advance the lead into the right atrium using a straight stylet to facilitate movement through the veins.

6.3 Positioning a screw-in ventricular lead

Caution: Use care when handling the lead during positioning:

- Do not severely bend, kink, or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector pin.

1. Insert the tapered end of a vein lifter into the incised vein and gently push the lead tip underneath and into the vein. A vein lifter facilitates lead insertion.
2. Advance the lead into the right atrium using a straight stylet to facilitate movement through the veins.
3. Advance the lead through the tricuspid valve. Replacing the straight stylet with a gently curved stylet may add control in maneuvering the lead through the tricuspid valve. Then, advance the lead directly through the tricuspid valve, or project the lead tip against the lateral atrial wall and retract the curved portion of the lead body through the tricuspid valve until the lead tip enters the ventricle.
4. Position the lead in the ventricle using the following techniques. Accurate positioning of the helix electrode is essential for stable pacing.
   Caution: If there is reason to believe the patient has an unusually thin wall at the apex of the right ventricle, you may want to consider another site for placement of the lead.
   Caution: If placing the lead in or near the right ventricular apex, use caution if passing the distal end of the lead directly from the valve to the apex. This technique may result in excessive tip pressure.
   Caution: If an awake patient feels a twinge of pain, this may be an early sign of perforation.

Using one of the following techniques may help minimize transmission of pressure directly toward the tip of the lead:

- Partially withdraw the stylet so that the stylet tip is proximal to the electrode ring while positioning the lead, to minimize tip stiffness. The stylet can then be gently advanced to the tip of the lead before securing the electrode in the endocardium.
- A curved stylet may be used during positioning to minimize direct pressure on the apex.
- Using a curved stylet, or partially withdrawing the stylet to allow the lead to be carried by blood flow, the lead may be curved up toward the outflow tract and then allowed to fall gently into position near the apex by pulling back on the lead body.

Use fluoroscopy (lateral position) to ensure that the tip is not in a retrograde position or is not lodged in the coronary sinus.

5. After placing the lead in a satisfactory position, extend the helix electrode by following the procedure in Section 6.5, "Securing the helix electrode into the endocardium", page 8.

6.4 Positioning a screw-in atrial lead

Caution: Use care when handling the lead during positioning:

- Do not severely bend, kink, or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector pin.

The following procedure is suggested for atrial placement of the lead:

1. Insert the tapered end of a vein lifter into the incised vein and gently push the lead tip underneath and into the vein. A vein lifter facilitates lead insertion.
2. Advance the lead into the right atrium using a straight stylet to facilitate movement through the veins. After the lead tip is passed into the atrium, replace the straight stylet with a gently curved stylet or one of the J-shaped stylets supplied with the lead.
3. Direct the lead tip into an appropriate position. Accurate positioning of the helix electrode is essential for stable pacing and sensing.
   Generally, a satisfactory position has the lead tip situated against the atrial endocardium in or near the apex of the appendage. As viewed on the fluoroscope (A-P view), the lead tip points medially and forward toward the left atrium. A successful position is usually achieved with an anterior, medial, or lateral tip location.

Caution: If an awake patient feels a twinge of pain, this may be an early sign of perforation.

After placing the lead tip in a satisfactory position, extend the helix electrode by following the procedure in Section 6.5, "Securing the helix electrode into the endocardium", page 8.

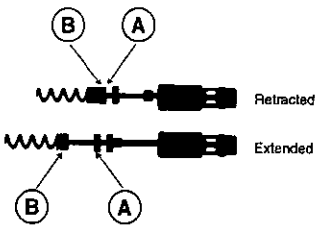
6.5 Securing the helix electrode into the endocardium

Note: The package includes 2 tools, the Quick Twist tool attached to the lead and the white fixation tool. Either tool may be used to secure the helix electrode into the endocardium. The choice of tool is left to the discretion of the physician.

Secure the helix electrode using the following techniques:

1. Attach either the Quick Twist tool or the white fixation tool to the lead. Ensure that the stylet is inserted into the lead and proceed as indicated, according to the tool being used.
   a. **Quick Twist tool:** Push the Quick Twist tool onto the connector pin (Figure 1, page 6).
   b. **White fixation tool:** Press both legs of the white fixation tool together and place the most distal hole on the connector pin (Figure 2, page 6).
2. Press the lead tip against the endocardium using the appropriate technique:
   a. **Ventricular placement:** Press the lead tip against the endocardium by gently pushing the stylet and lead at the vein entry site.
   b. **Atrial placement:** With the lead tip advanced into the atrium and a J-shaped or gently curved stylet in the lead, press the lead tip against the endocardium by gently pulling the stylet and the lead at the vein entry site.
3. Rotate the selected fixation tool clockwise until the helix electrode is fully extended.
   Caution: Do not severely bend the IS-1 connector sleeve or the lead body while extending the helix electrode.
4. Use fluoroscopy to verify helix electrode extension. This is the only reliable method to confirm extension. Extension of the space between the indicator ring (A) and the drive mechanism (B) implies complete exposure of the helix electrode (Figure 7). The top view illustrates no gap between the indicator ring and the drive mechanism (retracted) and the bottom view illustrates a gap (extended).
   Cautions:
   - The estimated number of rotations required to fully extend or retract the helix electrode is variable. Refer to Table 3, page 12, for the estimated number of rotations.
   - Prolonged implant procedures or repositioning the lead multiple times may allow blood or body fluids to build up on the helix mechanism. This may result in an increased number of rotations required to extend or retract the helix electrode, which may damage the lead.

Figure 7.



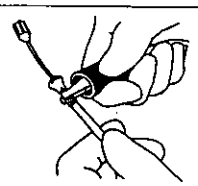
5. Remove the selected fixation tool from the IS-1 connector pin and release the proximal end of the lead body. Allow several seconds for relief of the residual torque in the lead.
6. Partially withdraw the stylet.
7. Verify that the lead is affixed.
   a. **For a lead placed in the ventricle:** Gently pull back on the lead and check for resistance to verify affixation. A properly affixed helix electrode will remain in position. If the helix electrode is not properly affixed, the lead tip may become loose in the right ventricle.
   b. **For a lead placed in the atrial appendage:** After the lead tip is fixed, allow lead slack to build up in the atrium. Lead slack helps prevent tip dislodgement. Enough slack is assumed present if, under fluoroscopy, the lead assumes an "L" shape during deep inspiration. Avoid excessive slack buildup that may cause the loop of the lead to drop near the tricuspid valve.
8. If repositioning is required, reattach the selected fixation tool and rotate counterclockwise until the helix electrode is retracted. Use fluoroscopy to verify withdrawal of the helix electrode before attempting to reposition (Figure 7).
   Caution: Do not rotate the selected fixation tool more than the number of rotations required to fully retract the helix electrode.
9. After final positioning, remove the stylet and the Quick Twist tool completely. When removing the Quick Twist tool, grip the lead firmly just below the connector pin to help prevent lead dislodgement.
10. Obtain final electrical measurements.

6.6 Taking electrical measurements

Take electrical measurements:

1. Attach the clip of a surgical cable to the notch on the stylet guide (Figure 8).

Figure 8.



Note: A unipolar lead requires the use of an indifferent electrode.

2. Use an implant support instrument to obtain electrical measurements. Medtronic recommends using a pacing system analyzer. For information on the use of the implant support instrument, see the product literature for that device. Satisfactory lead placement is indicated by low stimulation thresholds and adequate sensing of intracardiac signal amplitudes. Refer to Table 1 for recommended stimulation threshold and sensing amplitude measurements at implant.
   - A low stimulation threshold provides for a desirable safety margin, allowing for a possible rise in thresholds that may occur within 2 months following implant.
   - Adequate sensing amplitudes ensure that the lead is properly sensing intrinsic cardiac signals. Minimum signal requirements depend on the device's sensitivity capabilities. Acceptable acute signal amplitudes for the lead must be greater than the minimum device sensing capabilities, including an adequate safety margin to account for lead maturity.

Table 1. Recommended measurements at implant

	Ventricle	Atrium
Recommended maximum acute stimulation thresholds[a]	1.0 V 3.0 mA	1.5 V 4.5 mA
Minimum acute sensing amplitudes	5.0 mV	2.0 mV

[a] At pulse duration setting of 0.5 ms.

3. If electrical measurements do not stabilize to acceptable levels, repositioning the lead and repeating the testing procedure may be necessary.
   Note: Initial electrical measurements may deviate from the recommendations because of acute cellular trauma. If such a deviation occurs, wait 5 to 15 min and repeat the testing procedure. Values may vary depending upon lead type, device settings, cardiac tissue condition, and drug interactions.

6.6.1 Checking diaphragmatic stimulation for screw-in leads

Diaphragmatic stimulation should also be checked by pacing at 10 V and observing on fluoroscopy whether the diaphragm contracts with each paced stimulus. If diaphragmatic stimulation occurs, reposition the lead.

6.6.2 Taking pacing impedance (or resistance) measurements

Pacing impedance (or resistance) is used to assess device function and lead integrity during routine device patient follow-up sessions and to assist in troubleshooting suspected lead failures. Additional troubleshooting procedures include ECG analysis, visual inspection, measurement of thresholds, and electrogram characteristics.

Pacing impedance values are affected by many factors including lead position, electrode size, conductor design and integrity, insulation integrity, and the patient's electrolyte balance. Apparent pacing impedance is also significantly affected by the measurement technique. Comparison of pacing impedance should be done using consistent methods of measurements and equipment.

An impedance higher or lower than the typical values is not necessarily a conclusive indication of a lead failure. Other causes must be considered as well. Before reaching a conclusive diagnosis, the full clinical picture must be considered. The full clinical picture includes pacing artifact size and morphology changes in 12-lead analog ECGs, muscle stimulation with bipolar leads, sensing and/or capture problems, patient symptoms, and device characteristics.

Recommendations for clinically monitoring and evaluating leads in terms of impedance characteristics are listed below.

Consider the following recommendations for devices with telemetry readout of impedance:

- Routinely monitor and record impedance values at implant and follow-up sessions using consistent output settings. **Note:** Impedance values may be different at different programmable output settings (for example, pulse width or pulse amplitude) of the device or pacing system analyzer.
- Establish a baseline chronic impedance value once the impedance has stabilized, generally within 6 to 12 months after implant.
- Monitor for significant impedance changes and abnormal values.
- Where impedance abnormalities occur, closely monitor the patient for indications of pacing and sensing problems. The output settings used for measuring impedance should be the same as those used for the original measurements.
- For patients at high risk, such as implantable device-dependent patients, you may want to consider further action such as increased frequency of monitoring, provocative maneuvers, and ambulatory ECG monitoring.

Consider the following recommendations for devices without telemetry:

- Record the impedance value at implant. Also record the measurement device, its output settings, and the procedure used.
- At the time of device replacement, if pacing system analyzer-measured impedance is abnormal, carefully evaluate lead integrity (including thresholds and physical appearance) and patient condition before electing to reuse the lead.
- Impedances below 250 Ω may result in excessive battery current drain, which may seriously compromise device longevity, regardless of lead integrity.

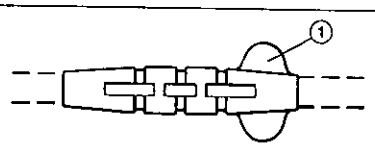
For more information on obtaining electrical measurements, consult the product literature supplied with the testing device.

6.7 Anchoring the lead

Cautions:

- Use care when anchoring the lead.
- Use an anchoring sleeve with all leads.
- Do not use absorbable sutures to anchor the lead.
- Do not secure the sutures so tightly that they damage the vein, lead, or anchoring sleeve.
- Do not use the anchoring sleeve tabs for suturing (Figure 9).
- Do not tie a suture directly to the lead body (Figure 10).
- Do not dislodge the lead tip.
- Do not attempt to remove or cut the anchoring sleeve.
- Do not remove the tabs on anchoring sleeves. Tabs are provided to minimize the possibility of the sleeve entering the vein.
- If a large diameter percutaneous lead introducer (PLI) sheath is used, take extreme care to prevent passage of the anchoring sleeve into the PLI lumen or the venous system.

Figure 9.



1 Anchoring sleeve tab

Figure 10.

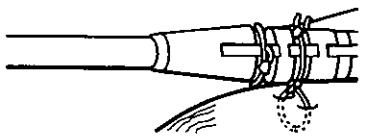
With a triple groove anchoring sleeve, generally 2 or 3 of the grooves may be used with the following procedure.

Note: The anchoring sleeves contain a radiopaque substance, which allows visualization of the anchoring sleeve on a standard x-ray and may aid in follow-up examinations.

Anchor the lead:

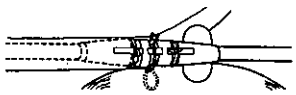
1. Position the anchoring sleeve close to the lead's connector pin to prevent inadvertent passage of the sleeve into the vein.
2. Insert the anchoring sleeve partially into the vein.
3. Use the most distal suture groove to secure the anchoring sleeve to the vein.
4. Use the middle groove to secure the anchoring sleeve to the fascia and lead (Figure 11):
   a. Create a base by looping a suture through the fascia underneath the middle groove and tying a knot.
   b. Firmly wrap the suture around the middle groove and tie a second knot.

Figure 11.



5. If anchoring with all 3 grooves, use the third and most proximal groove to secure the anchoring sleeve to the lead body (Figure 12).

Figure 12.



6.8 Connecting the lead

Caution: Always remove the stylet and stylet guide before connecting the lead to the device. Failure to remove the stylet and stylet guide may result in lead failure.

Connect the lead to the device according to the instructions in the product literature supplied with the device.

Connect the lead to the device:

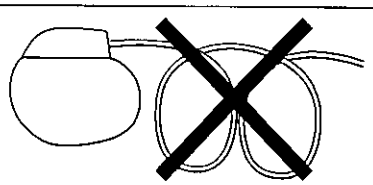
1. Carefully and completely remove the stylet and stylet guide. **Note:** When removing the stylet and stylet guide, firmly grip the lead just below the connector pin to help prevent possible lead dislodgement.
2. Obtain final electrical measurements.
3. Insert the lead connector into the connector block on the device. For instructions on proper lead connections, see the product literature supplied with the device.

6.9 Placing the device and lead into the pocket

Cautions:

- Use care when placing the device and lead into the pocket.
- Ensure that the lead does not leave the device at an acute angle.
- Do not grip the lead or device with surgical instruments.
- Do not coil the lead (Figure 13). Coiling the lead can twist the lead body and may result in lead dislodgement.

Figure 13.

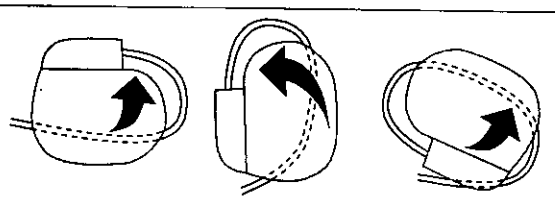


Caution: To prevent undesirable twisting of the lead body, wrap the excess lead length loosely under the device and place both the device and the lead into the subcutaneous pocket.

Place the device and lead into the pocket:

1. Rotate the device to loosely wrap the excess lead length under the device (Figure 14).

Figure 14.



2. Insert the device and lead into the pocket.
3. Suture the pocket closed.
4. Monitor the patient's electrocardiogram until the patient is discharged. If a lead dislodges, it usually occurs during the immediate postoperative period.

7 Specifications (nominal)

Table 2. Specifications (nominal)

Parameter		Model 5086MRI
Type		Bipolar
Chamber		Atrium/Ventricle
Fixation		Screw-in
Lengths		45, 52, 58 cm
Connector		IS-1 BI
Materials	Conductor:	MP35N nickel alloy
	Insulation:	Treated silicone rubber
	Connector pin:	Stainless steel
	Connector ring:	Stainless steel
Electrode materials	Helix electrode:	Titanium nitride coated platinum alloy
	Ring electrode:	Titanium nitride coated platinum alloy
Electrode surface area	Helix:	4.2 mm^2
	Ring:	22 mm^2
Tip to ring spacing		10 mm
Diameter	Lead body:	2.3 mm
Lead introducer (recommended size)		
	without guide wire:	2.7 mm (8 French)
	with guide wire:	3.7 mm (11 French)

Table 2. Specifications (nominal) (continued)

Parameter		Model 5086MRI
Helix length (fully extended)		1.8 mm
Resistance	Unipolar:	70.0 Ω (58 cm)
	Bipolar:	105.0 Ω (58 cm)
Steroid	Type:	Dexamethasone acetate
Nominal dosage of steroid		692 µg
Steroid binder		Silicone

Table 3. Estimated number of rotations required to extend or retract the helix electrode for initial placement[a]

Lead length	Straight stylet	J-shaped stylet
45 cm	12	18
52 cm	13	20
58 cm	14	21

[a] The number of rotations required to extend the helix electrode is variable depending on the lead path. In addition, the number of turns required to extend and subsequently retract the helix may be different. Verify extension and retraction with fluoroscopy.

8 Medtronic disclaimer of warranty

For complete disclaimer of warranty information, see the accompanying disclaimer of warranty document.

9 Service

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REVO MRI™ SURESCAN™ PACING SYSTEM CLINICAL STUDY

Summary of clinical results

Clinical study

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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Table of Contents

Summary of Clinical Results

The Revo MRI SureScan pacing system clinical study which evaluated the safety and effectiveness of the EnRhythm MRI SureScan pacing system in the clinical MRI environment provides support for the Revo MRI SureScan pacing system. This study is also referred to as the EnRhythm MRI SureScan pacing system clinical study.

1 Study Purpose

The study purpose was to confirm the results of earlier pre-clinical bench and animal testing and to assess whether the Revo MRI SureScan pacing system is safe and effective for human use in the MRI environment under the specified MR Conditions of Use.

2 Study Scope, Design and Methods

The clinical study was designed as a prospective, randomized, controlled, unblinded, global multi-center study of typical Class I or II indicated pacemaker patients comparing outcomes between those with and without exposure to a single investigational protocol MR scan.

Pacemaker function and adverse events were assessed at implant, two-months post-implant, before and after MRI at 9-12 weeks post-implant (Control group subjects had a waiting period), at 3, 4 and 6 months post-implant (one week, one month and 3 months after MRI) and every 6 months thereafter. Data from the 9-12 week visit and the visit occurring one month later were used for the primary endpoints.
Up to 470 subjects at 75 centers were planned for implant and follow-up.

3 Subject Inclusion and Exclusion Criteria

Patients who met all inclusion and no exclusion criteria were eligible.

Inclusion Criteria

- Subjects who have a Class I or II indication for implantation of a dual chamber pacemaker according to the ACC/AHA/NASPE guidelines[1].
- Subjects must be able to undergo a pectoral implant.
- Subjects who are able and willing to undergo elective MRI scanning without sedation.
- Subjects who are geographically stable and available for follow-up at the study center for the length of the study.

[1] Gregoratos G, Abrams J, Epstein AE, Freedman RA, Hayes DL, Hlatky MA, Kerber RE, Naccarelli GV, Schoenfeld NH, Silka MJ, Winters SL. ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee on Pacemaker Implantation). 2002. Available at: www.acc.org/clinical/guidelines/pacemaker/Pacemakerclean.pdf.

Exclusion Criteria

- Subjects who require a legally authorized representative to obtain consent.
- Subjects with a mechanical tricuspid heart valve.
- Subjects with a history of tricuspid valvular disease.
- Subjects for whom a single dose of 1.0 mg dexamethasone acetate may be contraindicated.
- Subjects who have a previously implanted pacemaker or implantable cardioverter defibrillator (ICD) (abandoned pacemaker and/or defibrillator leads not permitted; however, subjects with complete system explants are not excluded).
- Subjects who are immediate candidates for an ICD.
- Subjects currently indicated or expected to be indicated for another MRI-scan procedure other than those specifically described in the study during the period of required study follow-up.
- Subjects with previously implanted active medical devices.
- Subjects with non-MRI compatible device (such as ICDs or neurostimulators) or material implant (e.g. non-MRI compatible sternal wires, neurostimulator, biostimulator, metals or alloys).
- Subjects with medical conditions that preclude the testing required by the protocol or limit study participation.
- Subjects who are enrolled or intend to participate in another clinical trial (of an investigational drug or device, new indication for an approved drug or device, or requirement of additional testing beyond standard clinical practice) during this clinical study.
- Pregnant women, or women of child bearing potential and who are not on a reliable form of birth control.
- Subjects with exclusion criteria required by local law (e.g. age, breastfeeding).

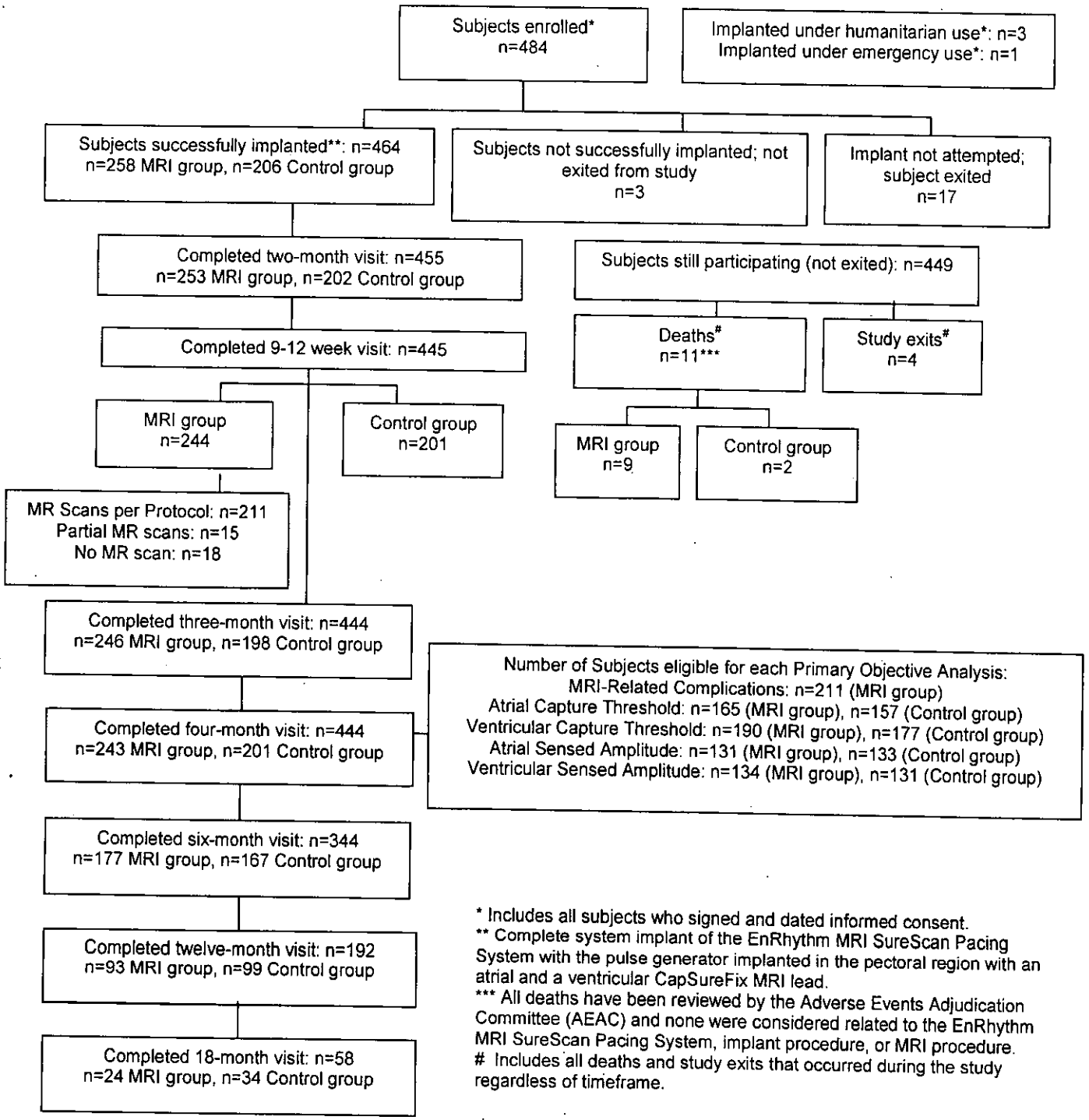
4 Results

The first enrollment occurred 5 February 2007. Enrollment was between February 2007 and July 2008. Follow up continued through November 2008 for an average duration of 11.2 months. These results include any visit or event that occurred on or before 21 November 2008 and received by December 18, 2008 (all data) or by September 14, 2009 (adverse event updates).

Patient Accountability

A total of 484 subjects were enrolled at 42 centers, including 113 (23%) enrollments at 13 centers in the US and 371 (77%) enrollments at 29 centers outside of the US. The enrollments outside of the US included 302 enrollments at 21 centers in Europe, 68 enrollments at seven centers in Canada, and one enrollment at one center in Saudi Arabia. Of the 484 enrolled subjects, 464 subjects were successfully implanted with the EnRhythm MRI pacing system and randomized. Among these, 99 (21%) subjects were from the US and 365 (79%) subjects were from the outside of the US. Figure 1: Subject Distribution shows a study flow chart which accounts for subject withdrawal due to death or exits and denotes missing follow-up visit data. (Note: although a subject can miss a follow-up visit, they can contribute to data at a subsequent follow-up visit).

Figure 1: Subject Distribution



* Includes all subjects who signed and dated informed consent.
** Complete system implant of the EnRhythm MRI SureScan Pacing System with the pulse generator implanted in the pectoral region with an atrial and a ventricular CapSureFix MRI lead.
*** All deaths have been reviewed by the Adverse Events Adjudication Committee (AEAC) and none were considered related to the EnRhythm MRI SureScan Pacing System, implant procedure, or MRI procedure.
# Includes all deaths and study exits that occurred during the study regardless of timeframe.

Subject Demographics

Table 1 and Table 2 summarize baseline clinical characteristics, including subject demographics and the primary indication for successfully implanted subjects.

Table 1: Baseline Clinical Characteristics

Demographic	MRI Group (n=258)	Control Group (n=206)
Age at Implant (years) Mean ± SD	69.3 ± 12.9	68.0 ± 12.6
Male	154 (59.7%)	135 (65.5%)
Atrial Tachyarrhythmias	130 (50.4%)	82 (39.8%)

Table 2: Primary Indication for Implant

Primary Indication for Implant	MRI Group (n=258)	Control Group (n=206)
Atrial tachyarrhythmias	19 (7.4%)	15 (7.3%)
AV block	95 (36.8%)	84 (40.8%)
Cardial sinus hypersensitivity	5 (1.9%)	4 (1.9%)
Sinus node dysfunction	122 (47.3%)	90 (43.7%)
Vasovagal syncope	4 (1.6%)	4 (1.9%)
Sick Sinus Syndrome	2 (0.8%)	6 (2.9%)
Other*	11 (4.3%)	3 (1.5%)

* Includes His ablation with pacemaker implant (1 MRI group), AV ablation with pacemaker implant (1 MRI group), binodal disease (2 MRI group), bradycardia with junctional rhythm (1 MRI group), complete heart block (1 MRI group), observed asystole (1 MRI group), possible cardiac sarcoidosis (1 Control group), rapid SVT (1 MRI group), sinus arrest (1 MRI group), symptomatic bradycardia (1 Control group), syncope with bifascicular block (1 Control group), AV node dysfunction (1 MRI group), and tachy-brady syndrome (1 MRI group).

Summary of Missing Data

The number of subjects analyzed for each primary endpoint was lower than the number of subjects randomized (n=464) in the study. Table 3 summarizes the missing data for each primary objective.

Table 3: Summary of Missing/Excluded Data in Primary Objectives

	Missing data n (%)	
	MRI Group (n = 258)	Control (n=206)
MRI-Complications	47 (18.2%)	N/A
Pacing Capture Threshold		
• Atrial	93 (36%)	49 (24%)
• Ventricular	68 (26%)	29 (14%)
Sensed Amplitudes		
• Atrial	127 (49%)	73 (35%)
• Ventricular	124 (48%)	75 (36%)

Subjects were missing or excluded from the primary objective analyses for the following reasons:

- Follow-up visits missed or outside of follow-up window (30)
- PCT increase exceeding 0.5 V from 2 months to 9-12 weeks (6)
- Atrial arrhythmia at follow up and therefore no threshold obtained (45)
- Incomplete sensing test at 9-12 weeks or four-month visit (26 atrial, 51 ventricular)
- Sensing values less than 1.5 mV (atrial) or 5.0 mV (ventricular) at 9-12 weeks (38 atrial, 53 ventricular)
- MRI scan not conducted (18), for reasons including:
    - High PCT (3)
    - Unknown PCT (2)
    - Non-MRI compatible stent (1)
    - Pacemaker stimulation of the diaphragm (2)
    - Presence of an MRI-incompatible lead (1)
    - Pregnancy (1)
    - Subject refusal (8)
- MRI scan not conducted according to protocol (15), with deviations including
    - SAR exceeded 2 W/kg (8)
    - Patient discomfort (4)
    - MRI system malfunction (1)
    - Ventricular threshold exceeded 2V at pre-MRI check (scan completed) (1)
    - Inability to fit the patient into the scanner (head sequences completed) (1)

For each reason for missing or excluding data (other than MRI scans not done), the proportions of excluded data between the MRI and Control groups were comparable. Statistical analyses were also performed to assess the likelihood that missing/excluded data could affect the conclusions from the study. The results from these analyses are consistent with the primary analyses.

Primary Objectives

There were three primary endpoints. Analyses for each primary objective were performed per-protocol which included subjects who met the following criteria:

- Successfully implanted with pacing system and randomized
- Have 9-12 week visit data (pre-MRI/waiting period)
- Met the MR Conditions of Use
- Received an MR scan (if in the MRI group)
- Have 4-month visit data

Published analyses differ slightly from the primary effectiveness tables below. Tables below exclude Control subjects who did not meet the MR Conditions of Use and, had they been in the MRI arm, would not have received an MR scan.[2,3]

MRI-Related Complications Primary Objective - To assess the MRI-related complication-free rate in the month following MRI. The hypothesis is that the MRI-related complication free-rate between the MRI procedure and one month post-MRI is greater than 90%, tested with one-sided type I error, alpha level of 0.025. The result is shown in Table 4.

Table 4: Results of MRI-Related Complications Primary Objective

Success Criteria	Subjects	Complication-Free Rate	One-sided 97.5% Confidence Boundary and P-value	Conclusion
The MRI-related complication-free rate is greater than 90%	211	100%	98.3% $p < 0.001$	Objective Met

Pacing Capture Threshold Primary Objective - To compare the changes in 1) atrial and 2) ventricular voltage thresholds at 0.5 ms before and after an MRI scan between the MRI and Control groups. The hypotheses are that the proportion of subjects who experience an increase greater than 0.5V in atrial and ventricular voltage thresholds are non-inferior across treatment and control, with margin = 10%. The result is shown in Table 5.

Table 5: Results of Capture Threshold Primary Objective

Success Criteria	Comparison	Group	Success/ n	Success Rates	P-value	Conclusion
The proportions of subjects who experienced an increase less than or equal to 0.5 V are non-inferior, defined as within 10%.	Atrial	MRI	165 / 165	100%	Not Applicable*	Objective Met
		Control	157 / 157	100%		
	Ventricular	MRI	190 / 190	100%	Not Applicable*	Objective Met
		Control	177 / 177	100%		

*P-values cannot be calculated since the success rates were 100% for both the MRI and the Control groups.

[2] Wilkoff B, et al. Worldwide randomized clinical trial to evaluate new pacemaker system designed for use during magnetic resonance imaging. Heart Rhythm Society, 2009.
[3] Kanal E, et al. Worldwide randomized clinical trial to evaluate new pacemaker system designed for use during magnetic resonance imaging. Radiological Society of North America, 2009.

Sensed Amplitude Primary Objective: To compare the changes in 1) atrial and 2) ventricular sensed amplitudes before and after MRI between the MRI and Control groups. The hypotheses are that the proportion of subjects who experienced a sensed amplitude decrease not exceeding 50%, and a one-month post-MRI/waiting period sensed amplitude not less than 1.5 mV for atrial measurements and not less than 5.0 mV for ventricular measurements, are non-inferior defined as within 10%. The result is shown in Table 6.

Table 6: Results of Sensed Amplitude Primary Objective

Success Criteria	Comparison		Success/ n	Success Rates	P-value	Conclusion
The proportion of subjects who experienced a sensed amplitude decrease not exceeding 50%, and a one-month post-MRI/waiting period sensed amplitude not less than 1.5 mV for atrial measurements and not less than 5.0 mV for ventricular measurements, are non-inferior, defined as within 10%.	Atrial	MRI Control	124 / 131 123 / 133	94.7% 92.5%	p=0.01	Objective Met
	Ventricular	MRI Control	130 / 134 125 / 131	97.0% 95.4%	p=0.003	Objective Met

Secondary Objectives

Note that prespecified Secondary Objectives #1, #7 and # 6 were prespecified by study protocol to include statistical considerations necessary to allow testing for significance in this order (provided that all primary objectives were met).

Secondary Objective #1 - Characterize all system-related complications. The result is shown in Table 7, and a listing of these events is shown in Table 8.

Table 7: Results of System-Related Complications Secondary Objective

Success Criteria	Subjects	Complication Free Rate	One-sided 95% Confidence Boundary and P-value	Conclusion
The pacing system-related complication-free rate is greater than 80%	447	91.7%	89.3% $p < 0.001$	Objective Met

Table 8: System-Related Adverse Events

Adverse Event	Observations (MRI / Control)	Complications (MRI / Control)	Total AEs (MRI / Control)
Lead dislodgement	0 / 1	12 / 6	12 / 7
Elevated pacing threshold	2 / 1	6 / 3	8 / 4
Failure to capture	0 / 1	0 / 3	0 / 4
Thrombosis	1 / 1	0 / 2	1 / 3
Inappropriate device stimulation of tissue	1 / 1	1 / 0	2 / 1
Pericardial effusion	0 / 0	2 / 1	2 / 1
Atrial fibrillation	1 / 0	0 / 1	1 / 1
Cardiac perforation	0 / 0	2 / 0	2 / 0
Heart rate increased	2 / 0	0 / 0	2 / 0
Implant site infection	0 / 0	1 / 1	1 / 1
Atrial flutter	0 / 1	0 / 0	0 / 1
Cardiac pacemaker revision	0 / 0	1 / 0	1 / 0
Chest pain	0 / 0	0 / 1	0 / 1
Endocarditis	0 / 0	1 / 0	1 / 0
Implant site discharge	0 / 1	0 / 0	0 / 1
Implant site pain	1 / 0	0 / 0	1 / 0
Implant site swelling	1 / 0	0 / 0	1 / 0
Medical device complication	0 / 0	1 / 0	1 / 0
Pain in extremity	0 / 0	0 / 1	0 / 1
Palpitations	1 / 0	0 / 0	1 / 0
Restlessness	1 / 0	0 / 0	1 / 0
Subclavian vein thrombosis	0 / 0	0 / 1	0 / 1
Swelling	1 / 0	0 / 0	1 / 0
Undersensing	0 / 1	0 / 0	0 / 1
Venous insufficiency	0 / 1	0 / 0	0 / 1
Total	12 / 9	27 / 20	39 / 29

Secondary Objective #2 - Confirm that labeling instructions for completing the MRI scans were followed to ensure subject safety. The result is shown in Table 9. There were no defined success criteria for this endpoint.

Table 9: Results of Labeling Instructions Secondary Objective

Success Criteria	Subjects	Subjects with a System-Related Adverse Device Effect that occurred due to Insufficiencies or Incorrect Following of MRI Labeling Instructions
None Defined	211	0

Secondary Objective #3 - Characterize occurrence of sustained ventricular arrhythmias and asystole seen during MR scans. The result is shown in Table 10. There were no defined success criteria for this endpoint. As shown, no arrhythmias were reported during MRI scanning.

Table 10: Results of Occurrence of Arrhythmias Secondary Objective

Success Criteria	Subjects (MRI Group)	Subjects with Sustained Ventricular Arrhythmias and Asystole Attributed to MR Scan
None Defined	211	0

Secondary Objective #4 - Characterize all implant procedure, pacing system- and MRI- procedure-related adverse events. The result is shown in Table 11. There were no defined success criteria for this endpoint.

Table 11: Results of Adverse Events Secondary Objective

Success Criteria	Subjects	System- and Procedure-Related Adverse Event-Free Rate
None Defined	452	78.5%

Secondary Objective #5 - Characterize atrial and ventricular lead impedance through four months post-implant. The result is shown in Table 12. There were no defined success criteria for this endpoint. The findings indicate that lead impedance was stable through the period of MRI exposure.

Table 12: Results of Lead Impedance Secondary Objective

Success Criteria	Comparison	Group	n	Mean ± SD Impedance (Ω)		
				Pre-MRI/Control	One-month post-MRI/Control	Changes from pre-MRI to one-month post-MRI
None Defined	Atrial	MRI	201	516.0 ± 81.4	515.5 ± 78.1	-0.6 ± 61.8
		Control	197	523.6 ± 92.8	530.9 ± 97.7	7.3 ± 50.4
	Ventricular	MRI	201	570.3 ± 109.2	561.3 ± 104.8	-9.0 ± 48.5
		Control	196	571.6 ± 103.0	565.9 ± 105.4	-5.7 ± 51.8

Secondary Objective #6 - Characterize the lead handling of the CapSureFix MRI lead Model 5086MRI in relation to the commercially available lead Model 5076.

This objective characterized the lead handling of the CapSureFix MRI 5086MRI lead in relation to the commercially available Medtronic CapSureFix Model 5076 lead. The comparison group for this evaluation was from a different clinical study - the cohort reported in the clinical study report for PMA-S approval of the Medtronic Model 5076 lead (P930039S/009). This objective was evaluated by analyzing implanting physician responses regarding lead handling, and comparing the responses to the Medtronic Model 5076 lead study cohort. The result is shown in Table 13.

Table 13: Results of Lead Handling Secondary Objective

Success Criteria	Comparison		Mean ± s.d. lead handling score (n)	Difference in Mean Lead Handling Scores	P-Value	Conclusion
Differences in overall lead handling characteristics are non-inferior (Delta=1.5 units on a scale of -3 to +3)	Atrial	5086 MRI	0.53 ± 1.22 (212)	0.15	$p < 0.001$	Objective Met
		5076	0.68 ± 1.16 (117)			
	Ventricular	5086 MRI	0.58 ± 1.17 (211)	0.18	$p < 0.001$	Objective Met
		5076	0.76 ± 1.06 (117)			

Secondary Objective #7 - Characterize four-month pacing thresholds and sensed amplitudes of the MRI group and Control group in relation to the commercially available lead Model 5076.

This objective compared the one-month post-MRI/Control visit (four-months post-implant) pacing thresholds and sensed amplitudes of the CapSureFix MRI 5086MRI leads in both the MRI and Control groups to the three-month post-implant follow-up data from the commercially available Medtronic Model 5076 lead study. The result is shown in Table 14.

Table 14: Results of Lead Performance Secondary Objective

Pacing Capture Thresholds				
Success Criteria	**Comparison**	**Model 5086MRI Mean ± SD (V)**	**P-Value between MRI or Control and 5076**	**Conclusion**
Pacing thresholds are non-inferior (Delta=0.5 V)	Atrial	MRI: 0.78 ± 0.28 Control: 0.77 ± 0.66 5076: 0.61 ± 0.23	p < 0.001 p < 0.001	Objective Met
	Ventricular	MRI: 0.82 ± 0.30 Control: 0.90 ± 0.70 5076: 0.75 ± 0.77	p < 0.001 p < 0.001	Objective Met
Sensed Amplitude				
Sensed amplitudes are non-inferior (Delta=0.9 mV for atrial sensed amplitudes, 2.5 mV for ventricular sensed amplitudes)	**Lead Implant Site**	**Model 5086MRI Mean ± SD (mV)**	**P-Value between MRI or Control and 5076**	**Conclusion**
	Atrial	MRI: 3.0 ± 1.3 Control: 3.1 ± 1.4 5076: 3.2 ± 1.7	p < 0.001 p < 0.001	Objective Met
	Ventricular	MRI: 10.1 ± 5.0 Control: 10.2 ± 5.2 5076: 10.0 ± 4.3	p < 0.001 p < 0.001	Objective Met

Additional Analyses

Additional Analysis #1 - Demonstrate that the EnRhythm MRI SureScan Pacing System (both IPG and leads) can be identified as MRI-Labeled via X-ray. The analysis was based on data collected from 240 cardiology staff and 239 radiologist questionnaires. The questionnaires rated the ease of identifying the pacemaker and lead radiopaque symbols using a scale of -3 (well below expectations) to +3 (well above expectations). The result is shown in Table 15.

Table 15: Results of Identification of Radiopaque Additional Analysis

Radiopaque	Questionnaire	Results (Median Scores)
Pacemaker	Cardiology Staff	1 (Slightly above expectations)
	Radiologists	2 (Moderately above expectations)
Lead	Cardiology Staff	2 (Moderately above expectations)
	Radiologists	2 (Moderately above expectations)

Additional Analysis #2 - Summarize ease of use scores by cardiology users of the SureScan feature, including assessment for any aberrant or undesirable behavior. The analysis was based on data collected from 82 questionnaires completed by cardiology staff. Using a scale of 1 (extremely difficult) to 7 (extremely easy), the cardiology staff were asked to rate the ease of locating the SureScan feature, verifying items on the software application's checklist, selecting the appropriate SureScan pacing mode, and identifying that the SureScan feature was turned on. The result is shown in Table 16.

Table 16: Results of SureScan Feature Performance Additional Analysis

Question	Median Score
Ease of locating the SureScan feature	6 (Easy)
Ease of verifying all of the items on the SureScan software application's check list	6 (Easy)
Ease of selecting the appropriate SureScan pacing feature	6 (Easy)
Ease of identifying that the SureScan feature was turned on	6 (Easy)
Clarity of the device's sensing and diagnostic capabilities when in SureScan feature	6 (Clear)

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Additional Analysis #3 - Summarize ease of safely coordinating and assuring appropriate MRI-related care including whether safeguards and procedures were followed at the time of the MR scans. The data were collected from 82 cardiology staff questionnaires and 84 radiology staff questionnaires. Questions pertained to patient monitoring, equipment availability, and communication between the radiology and cardiac teams. A scale of 1 to 7 was again used for the responses. Some of the key questions and their responses are summarized in Table 17.

Table 17: Results of Analysis of Procedure Additional Analysis

Question	Results (Median Scores)
Cardiology staff's ease of scheduling the appointment with radiology	6 (Easy)*
Radiology staff's ease of scheduling the appointment with cardiology	6 (Easy)*
Radiology staff's level of comfort with monitoring and potentially resuscitating the patient if the staff was Advanced Cardiac Life Support (ACLS) trained	6 (Comfortable)**
Radiology staff's opinion on the clarity of information in the manual if the manual was reviewed	6 (Clear)***

* Numerical range was 1 to 7, extremely difficult to extremely easy

** Numerical range was 1 to 7, extremely uncomfortable to extremely comfortable

*** Numerical range was 1 to 7, extremely unclear to extremely clear

5 Adverse Events Summary

Of the 484 enrolled subjects, there were 283 subjects who experienced a total of 600 adverse events. Sixty percent (60%) of all of the adverse events were clinical observations which required no invasive action. Seventy-eight percent (78%) of the adverse events were not related to the pacing system or to the study procedures, the implant procedure or the MRI procedure. All adverse events were reviewed and classified by the adverse events committee.

Note that pacing system-related and procedure-related adverse events are summarized in secondary objective #4.

While there were no MRI-related complications in the Revo MRI SureScan pacing system clinical study, the adverse events committee classified four events as MRI-procedure related observations: paraesthesia (n=3) and palpitations (n=1). In all cases, the center investigator and adverse events advisory committee classified the events as not related to the pacing system and no actions were taken or required as a result of these events.

Additionally, there were four observations of unknown relatedness to the MRI procedure: chest discomfort (1), dyspnea (1), atrial flutter (1), and atrial fibrillation (1). Two of these four events were atrial arrhythmias which were classified by the center investigator and the Adverse Events Committee as unknown relatedness to the MRI procedure. The subject with atrial flutter had a baseline history of atrial arrhythmias and persistent atrial fibrillation. The subject with atrial fibrillation had a baseline history of paroxysmal atrial fibrillation. In both cases, the arrhythmia resolved the same day as the MRI procedure. Table 18 provides a full listing of all adverse events reported in the clinical study listed by incidence rate, including both observations and complications.

Table 18: All Adverse Events

Adverse Event Key Term	Observations	Complications	Total AEs	Number (%) of Subjects (n = 484)
Atrial fibrillation	32	25	57	49 (10.1%)
Chest pain	13	10	23	23 (4.8%)
Lead dislodgement	1	18	19	19 (3.9%)
Pneumothorax	8	9	17	17 (3.5%)
Dizziness	16	1	17	17 (3.5%)
Palpitations	12	1	13	12 (2.5%)
Elevated pacing threshold	3	9	12	10 (2.1%)
Syncope	7	4	11	10 (2.1%)
Pneumonia	4	6	10	10 (2.1%)
Myocardial infarction	1	7	8	8 (1.7%)
Anaemia	2	6	8	7 (1.4%)
Implant site infection	5	3	8	7 (1.4%)
Urinary tract infection	6	2	8	8 (1.7%)
Atrial flutter	8	0	8	7 (1.4%)

Adverse Event Key Term	Observations	Complications	Total AEs	Number (%) of Subjects (n = 484)
Dyspnea	8	0	8	8 (1.7%)
Cardiac failure	1	6	7	6 (1.2%)
Pleural effusion	1	5	6	4 (0.8%)
Bronchitis	4	2	6	6 (1.2%)
Hypotension	5	1	6	6 (1.2%)
Presyncope	5	1	6	6 (1.2%)
Fatigue	6	0	6	6 (1.2%)
Implant site hematoma	6	0	6	6 (1.2%)
Cataract	0	5	5	4 (0.8%)
Pericardial effusion	1	4	5	5 (1.0%)
Angina pectoris	2	3	5	5 (1.0%)
Atrial tachycardia	3	2	5	5 (1.0%)
Dyspnea exertional	3	2	5	5 (1.0%)
Paraesthesia	5	0	5	5 (1.0%)
Ventricular extrasystoles	5	0	5	5 (1.0%)
Cardiac failure congestive	0	4	4	4 (0.8%)
Coronary artery disease	1	3	4	4 (0.8%)
Failure to capture	1	3	4	4 (0.8%)
Thrombosis	2	2	4	3 (0.6%)
Fall	4	0	4	4 (0.8%)
Insomnia	4	0	4	4 (0.8%)
Diverticulitis	1	2	3	2 (0.4%)
Supraventricular tachycardia	1	2	3	3 (0.6%)
Back pain	2	1	3	3 (0.6%)
Cerebrovascular accident	2	1	3	3 (0.6%)
Chest discomfort	2	1	3	3 (0.6%)
Constipation	2	1	3	3 (0.6%)

Adverse Event Key Term	Observations	Complications	Total AEs	Number (%) of Subjects (n = 484)
Inappropriate device stimulation of tissue	2	1	3	3 (0.6%)
Liver disorder	2	1	3	3 (0.6%)
Pain	2	1	3	3 (0.6%)
Ventricular tachycardia	2	1	3	3 (0.6%)
Chronic obstructive pulmonary disease	3	0	3	3 (0.6%)
Depression	3	0	3	3 (0.6%)
Hypertension	3	0	3	3 (0.6%)
Implant site pain	3	0	3	3 (0.6%)
Influenza	3	0	3	3 (0.6%)
Musculoskeletal pain	3	0	3	3 (0.6%)
Vertigo	3	0	3	3 (0.6%)
Benign prostatic hyperplasia	0	2	2	2 (0.4%)
Cardiac perforation	0	2	2	2 (0.4%)
Endocarditis	0	2	2	2 (0.4%)
Hip fracture	0	2	2	2 (0.4%)
Inguinal hernia	0	2	2	2 (0.4%)
Laceration	0	2	2	2 (0.4%)
Mesenteric artery stenosis	0	2	2	1 (0.2%)
Pulmonary edema	0	2	2	1 (0.2%)
Renal failure chronic	0	2	2	2 (0.4%)
Spinal column stenosis	0	2	2	2 (0.4%)
Urethral stenosis	0	2	2	2 (0.4%)
Acute coronary syndrome	1	1	2	2 (0.4%)
Aortic stenosis	1	1	2	2 (0.4%)
Carpal tunnel syndrome	1	1	2	2 (0.4%)
Headache	1	1	2	2 (0.4%)
Pain in extremity	1	1	2	2 (0.4%)

Adverse Event Key Term	Observations	Complications	Total AEs	Number (%) of Subjects (n = 484)
Pneumonia bacterial	1	1	2	1 (0.2%)
Pulmonary embolism	1	1	2	2 (0.4%)
Pyrexia	1	1	2	2 (0.4%)
Transient ischemic attack	1	1	2	2 (0.4%)
Venous thrombosis	1	1	2	2 (0.4%)
Anxiety	2	0	2	2 (0.4%)
Atrioventricular block second degree	2	0	2	1 (0.2%)
Cough	2	0	2	2 (0.4%)
Electric shock	2	0	2	2 (0.4%)
Haematuria	2	0	2	2 (0.4%)
Heart rate increased	2	0	2	2 (0.4%)
Hypertensive crisis	2	0	2	1 (0.2%)
Hypothyroidism	2	0	2	2 (0.4%)
Infection	2	0	2	2 (0.4%)
Edema peripheral	2	0	2	2 (0.4%)
Sinusitis	2	0	2	2 (0.4%)
Syncope vasovagal	2	0	2	2 (0.4%)
Undersensing	2	0	2	2 (0.4%)
Venous insufficiency	2	0	2	2 (0.4%)
Abscess soft tissue	0	1	1	1 (0.2%)
Acute myocardial infarction	0	1	1	1 (0.2%)
Adenocarcinoma	0	1	1	1 (0.2%)
Angina unstable	0	1	1	1 (0.2%)
Aortic aneurysm	0	1	1	1 (0.2%)
Arteriosclerotic retinopathy	0	1	1	1 (0.2%)
Atrial septal defect	0	1	1	1 (0.2%)
Bacterial pyelonephritis	0	1	1	1 (0.2%)

Adverse Event Key Term	Observations	Complications	Total AEs	Number (%) of Subjects (n = 484)
Basal cell carcinoma	0	1	1	1 (0.2%)
Blood creatinine increased	0	1	1	1 (0.2%)
Bronchial carcinoma	0	1	1	1 (0.2%)
Bronchopneumonia	0	1	1	1 (0.2%)
Bursitis	0	1	1	1 (0.2%)
Cachexia	0	1	1	1 (0.2%)
Cardiac pacemaker revision	0	1	1	1 (0.2%)
Cholecystitis	0	1	1	1 (0.2%)
Cholelithiasis	0	1	1	1 (0.2%)
Colon adenoma	0	1	1	1 (0.2%)
Endometrial disorder	0	1	1	1 (0.2%)
Fecaloma	0	1	1	1 (0.2%)
Fibroadenoma	0	1	1	1 (0.2%)
Fistula	0	1	1	1 (0.2%)
Gastritis erosive	0	1	1	1 (0.2%)
Glioblastoma	0	1	1	1 (0.2%)
Hemangioma	0	1	1	1 (0.2%)
Hematoma	0	1	1	1 (0.2%)
Hemorrhoids	0	1	1	1 (0.2%)
Hypoglycemia	0	1	1	1 (0.2%)
Incontinence	0	1	1	1 (0.2%)
Intestinal perforation	0	1	1	1 (0.2%)
Intracranial aneurysm	0	1	1	1 (0.2%)
Ischemic stroke	0	1	1	1 (0.2%)
Knee arthroplasty	0	1	1	1 (0.2%)
Limb injury	0	1	1	1 (0.2%)
Lumbar spinal stenosis	0	1	1	1 (0.2%)
Lung infection	0	1	1	1 (0.2%)

Adverse Event Key Term	Observations	Complications	Total AEs	Number (%) of Subjects (n = 484)
Medical device complication	0	1	1	1 (0.2%)
Micturition disorder	0	1	1	1 (0.2%)
Multiple myeloma	0	1	1	1 (0.2%)
Osteoarthritis	0	1	1	1 (0.2%)
Peptic ulcer	0	1	1	1 (0.2%)
Postoperative thoracic procedure complication	0	1	1	1 (0.2%)
Postoperative wound infection	0	1	1	1 (0.2%)
Renal cell carcinoma stage unspecified	0	1	1	1 (0.2%)
Renal failure acute	0	1	1	1 (0.2%)
Renal neoplasm	0	1	1	1 (0.2%)
Respiratory failure	0	1	1	1 (0.2%)
Sciatica	0	1	1	1 (0.2%)
Sepsis	0	1	1	1 (0.2%)
Spondylolisthesis	0	1	1	1 (0.2%)
Subclavian vein thrombosis	0	1	1	1 (0.2%)
Urinary retention	0	1	1	1 (0.2%)
Vomiting	0	1	1	1 (0.2%)
Abdominal pain upper	1	0	1	1 (0.2%)
Acute vestibular syndrome	1	0	1	1 (0.2%)
Aneurysm	1	0	1	1 (0.2%)
Arterial occlusive disease	1	0	1	1 (0.2%)
Arthralgia	1	0	1	1 (0.2%)
Asthenia	1	0	1	1 (0.2%)
Atelectasis	1	0	1	1 (0.2%)
Atrial thrombosis	1	0	1	1 (0.2%)
Blood glucose increased	1	0	1	1 (0.2%)
Bradycardia	1	0	1	1 (0.2%)

Adverse Event Key Term	Observations	Complications	Total AEs	Number (%) of Subjects (n = 484)
Brain neoplasm	1	0	1	1 (0.2%)
Brain stem infarction	1	0	1	1 (0.2%)
Calcinosis	1	0	1	1 (0.2%)
Cardiac arrest	1	0	1	1 (0.2%)
Carotid artery stenosis	1	0	1	1 (0.2%)
Cellulitis	1	0	1	1 (0.2%)
Cervicobrachial syndrome	1	0	1	1 (0.2%)
Cholinergic syndrome	1	0	1	1 (0.2%)
Chronic myelomonocytic leukemia	1	0	1	1 (0.2%)
Clavicle fracture	1	0	1	1 (0.2%)
Clostridium difficile colitis	1	0	1	1 (0.2%)
Confusional state	1	0	1	1 (0.2%)
Contusion	1	0	1	1 (0.2%)
Convulsion	1	0	1	1 (0.2%)
Cystitis	1	0	1	1 (0.2%)
Device psychogenic complication	1	0	1	1 (0.2%)
Diarrhea	1	0	1	1 (0.2%)
Diastolic dysfunction	1	0	1	1 (0.2%)
Dyspepsia	1	0	1	1 (0.2%)
Dysphonia	1	0	1	1 (0.2%)
Ear pain	1	0	1	1 (0.2%)
Ejection fraction decreased	1	0	1	1 (0.2%)
Epistaxis	1	0	1	1 (0.2%)
Erythema migrans	1	0	1	1 (0.2%)
Eye hemorrhage	1	0	1	1 (0.2%)
Gastroenteritis	1	0	1	1 (0.2%)
Gout	1	0	1	1 (0.2%)
Gouty arthritis	1	0	1	1 (0.2%)

Adverse Event Key Term	Observations	Complications	Total AEs	Number (%) of Subjects (n = 484)
Grand mal convulsion	1	0	1	1 (0.2%)
Groin infection	1	0	1	1 (0.2%)
Head injury	1	0	1	1 (0.2%)
Heat exhaustion	1	0	1	1 (0.2%)
Hypercholesterolemia	1	0	1	1 (0.2%)
Hyperhidrosis	1	0	1	1 (0.2%)
Hyponatremia	1	0	1	1 (0.2%)
Impaired healing	1	0	1	1 (0.2%)
Implant site discharge	1	0	1	1 (0.2%)
Implant site swelling	1	0	1	1 (0.2%)
Inappropriate device therapy	1	0	1	1 (0.2%)
Incision site complication	1	0	1	1 (0.2%)
Incision site erythema	1	0	1	1 (0.2%)
Incision site hemorrhage	1	0	1	1 (0.2%)
Influenza like illness	1	0	1	1 (0.2%)
Loss of consciousness	1	0	1	1 (0.2%)
Lower respiratory tract infection	1	0	1	1 (0.2%)
Lumbar vertebral fracture	1	0	1	1 (0.2%)
Mental status changes	1	0	1	1 (0.2%)
Mouth ulceration	1	0	1	1 (0.2%)
Muscle spasms	1	0	1	1 (0.2%)
Muscle strain	1	0	1	1 (0.2%)
Nasopharyngitis	1	0	1	1 (0.2%)
Neuralgia	1	0	1	1 (0.2%)
Nodal rhythm	1	0	1	1 (0.2%)
Non-cardiac chest pain	1	0	1	1 (0.2%)
Orthostatic hypotension	1	0	1	1 (0.2%)
Panic attack	1	0	1	1 (0.2%)

Adverse Event Key Term	Observations	Complications	Total AEs	Number (%) of Subjects (n = 484)
Parkinson's disease	1	0	1	1 (0.2%)
Pericarditis	1	0	1	1 (0.2%)
Peripheral vascular disorder	1	0	1	1 (0.2%)
Petit mal epilepsy	1	0	1	1 (0.2%)
Plantar fasciitis	1	0	1	1 (0.2%)
Pleuritic pain	1	0	1	1 (0.2%)
Polymyalgia rheumatica	1	0	1	1 (0.2%)
Prostate cancer	1	0	1	1 (0.2%)
Renal failure	1	0	1	1 (0.2%)
Renal tubular acidosis	1	0	1	1 (0.2%)
Respiratory tract infection	1	0	1	1 (0.2%)
Restlessness	1	0	1	1 (0.2%)
Rib fracture	1	0	1	1 (0.2%)
Salivary gland calculus	1	0	1	1 (0.2%)
Sarcoidosis	1	0	1	1 (0.2%)
Sinus arrhythmia	1	0	1	1 (0.2%)
Skin laceration	1	0	1	1 (0.2%)
Stomatitis	1	0	1	1 (0.2%)
Subclavian artery stenosis	1	0	1	1 (0.2%)
Supraventricular extrasystoles	1	0	1	1 (0.2%)
Swelling	1	0	1	1 (0.2%)
Tendonitis	1	0	1	1 (0.2%)
Thrombophlebitis	1	0	1	1 (0.2%)
Thyroid disorder	1	0	1	1 (0.2%)
Traumatic hematoma	1	0	1	1 (0.2%)
Upper respiratory tract infection	1	0	1	1 (0.2%)
Ventricular dysfunction	1	0	1	1 (0.2%)
Viral infection	1	0	1	1 (0.2%)

Adverse Event Key Term	Observations	Complications	Total AEs	Number (%) of Subjects (n = 484)
Vision blurred	1	0	1	1 (0.2%)
Weight decreased	1	0	1	1 (0.2%)
Whiplash injury	1	0	1	1 (0.2%)
Total	359	241	600	283 (58.5%)

6 Death Summary

The AEAC adjudicated that the 11 subject deaths were not related to the pacing system (pacemaker, leads, programmer/software components), not related to the implant procedure, and not-related to the MRI procedure.

Table 19: Study Deaths

Group	Days Post-Implant	Days Post-MRI/Control Visit	Cause of Death	Cardiac or Non-Cardiac*	Sudden or Non-Sudden
Control	226	153	Glioblastoma	Non-Cardiac	Not Applicable
Control	378	308	Myocardial infarction	Cardiac	Sudden
MRI	3	Pre-MRI	Decompensation cardiac	Cardiac	Non-Sudden
MRI	21	Pre-MRI	Pneumonia	Non-Cardiac	Not Applicable
MRI	28	Pre-MRI	Adenocarcinoma	Non-Cardiac	Not Applicable
MRI	79	10	Pulmonary edema	Cardiac	Non-Sudden
MRI	135	51	Sepsis	Non-Cardiac	Not Applicable
MRI	267	183	Myocardial infarction	Cardiac	Sudden
MRI	404	340	Stroke	Non-Cardiac	Not Applicable
MRI	481	403	Acute ischemic stroke	Non-Cardiac	Not Applicable
MRI	544	461	Terminal cardiac failure	Cardiac	Non-Sudden

* Non-cardiac deaths are not classified as sudden or non-sudden.

7 Clinical Study Conclusion

The Revo MRI SureScan pacing system clinical study demonstrated that the Revo MRI SureScan pacing system is safe and effective for use in the MRI environment when used in accordance with its labeling as determined by the following:

- The MRI-related complication-free rate Primary Objective was met and there were no occurrences of sustained ventricular arrhythmias or asystole.
- The proportions of subjects in the MRI-treated group who experienced an increase of 0.5V or less in atrial and ventricular voltage pacing capture thresholds were non-inferior to the Control group subjects (those patients who did not undergo a MRI scan).
- The proportions of subjects in the MRI-treated group who experienced atrial and ventricular sensed amplitude decreases < 50% and whose atrial and ventricular sense amplitudes remained above an acceptable minimum at one-month post MRI/waiting period were non-inferior to the control group subjects.

In summary, all primary safety and effectiveness objectives were met. All secondary objectives were met where performance criteria were predefined. Overall, there were no differences noted in performance between the MRI and the Control groups. In the MRI environment studied, the EnRhythm MRI pacing system performance was commensurate with MR-Conditional labeling requirements.

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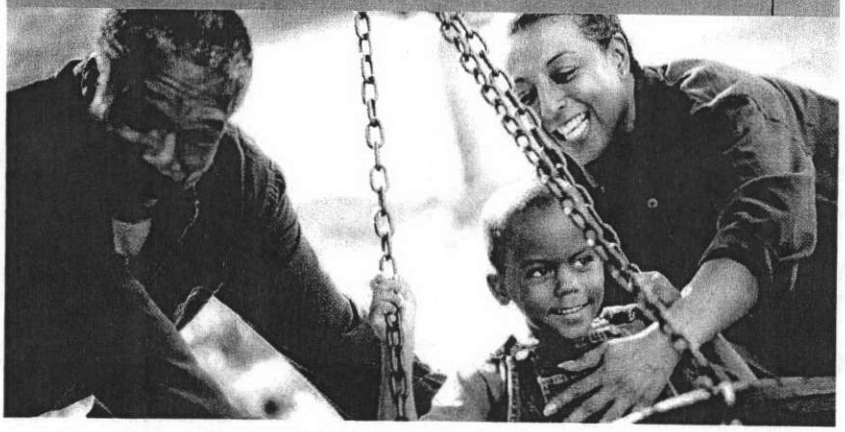
2010-04-08

Medtronic

MRI SureScan™ Pacemaker
Patient Manual



MR Conditional SureScan

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

M938115A001 Revision D
2010-04-12

How to contact Medtronic

Contact us by phone

Our experienced Patient Services group is available to answer any questions or concerns you may have about your pacemaker. To speak directly with a Patient Services Specialist, call 1-800-551-5544. Our staff is available Monday through Friday from 7:00 AM to 6:00 PM (Central Time).

Contact us online

Medtronic is dedicated to providing you with the most up-to-date information available about your Medtronic pacemaker. Website information is available 24 hours a day.

- Medtronic website: www.medtronic.com
- Patient Services website: www.medtronic.com/rhythms

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Contact us by mail or fax

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Mounds View, MN 55112
Fax: (763) 367-5809

Contents

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1 Why read this manual?

Your doctor or doctors should be your first source of information about your heart condition and your general health.

This manual is for people who are about to have or already have a type of **heart device** generally referred to as a **pacemaker**. It's also a good idea to encourage your family and caregivers to review this manual. This manual explains what the pacemaker is, what pacing therapies it provides, how it is implanted, and what you can expect after you have your pacemaker. For answers to questions that new patients frequently ask, including "Why do I need this pacemaker?" and "Is it safe for me to have an MRI scan?", see page 105. If you have questions that are not covered in this manual or you want more information about your pacemaker, contact Medtronic Patient Services at 1-800-551-5544. For your convenience, words that appear in **bold** are defined in the glossary starting on page 117.

Information about you and your pacemaker

Your personal information

Your name _____

Your doctor's name _____ Specialty _____ Phone _____

Your doctor's name _____ Specialty _____ Phone _____

Your medications _____

_____

Your other implanted devices _____

Emergency contact information

Name/address _____ Phone _____

Name/address _____ Phone _____

Information about your pacemaker and leads

Type/Model of pacemaker _____ Serial # _____

Lead 1 model number _____ Serial # _____

Lead 2 model number _____ Serial # _____

Date of implant _____ Hospital where implanted _____

2 About your pacemaker

Your doctor has prescribed a Medtronic pacemaker to relieve your symptoms of heart rhythm disturbances. Although this pacemaker does not prevent or cure your underlying heart rhythm condition, it may improve the quality of your life.

This chapter should answer many of your questions about your pacemaker, including the following questions:

- What is a pacemaker?
- What are the components of a pacing system?
- What is a **pacing therapy** and what does it feel like?

If you have questions that are not answered in this manual, ask your doctor or call Medtronic Patient Services at 1-800-551-5544.

What is a pacemaker?

Pacemakers relieve symptoms of heart rhythm disturbances. They do this by restoring normal heart rates. A normal **heart rate** provides your body with the proper amount of blood circulation. This stops the fatigue, dizziness, and shortness of breath caused by bradycardia. It also improves your breathing comfort during normal activities.

What are the components of a pacing system?

Your pacemaker is part of complete treatment system that includes the following components:

- a pacemaker (also called an implanted heart device)
- two implanted pacing **leads**

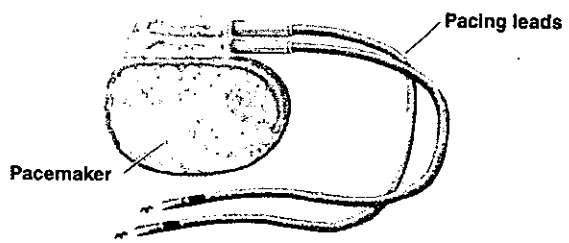

Figure 1: Pacing system

Pacemaker components

Your pacemaker contains a very small computer that is powered by a tiny lithium battery. All electronic components of your pacemaker are sealed inside a metal case made of titanium.

Your pacemaker has an outer case, battery, circuitry, connector block, and two leads, as shown in Figure 2. The leads are inserted into the connector block, which is connected to the metal case.

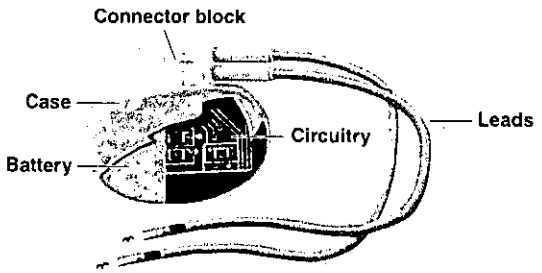

Figure 2: Pacemaker components

- Battery. The pacemaker battery supplies the power for the pacemaker. The battery is a small, sealed, lithium battery.
- Circuitry. The circuitry is a miniature computer inside the pacemaker. The energy from the battery is transformed into tiny electrical pulses. It is the tiny electrical impulses that stimulate the heart to beat. The circuitry controls the timing and intensity of the electrical impulses delivered to the heart.

- Case. The battery and circuitry are sealed inside a metal case (sometimes called a can).
- Connector block. The plastic connector, located on top of the pacemaker's metal case, provides the point of connection between the pacemaker and the leads.

To monitor and adjust the settings of your pacemaker, your doctor uses a **Medtronic CareLink Programmer** (further described in "Medtronic CareLink Programmer" on page 92).

What is a pacing lead?

A **pacing lead** is an insulated wire that connects to a pacemaker. A pacing lead carries the electrical impulse from the pacemaker to the heart. A pacing lead also relays information about the heart's natural activity back to the pacemaker.

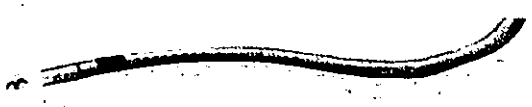

Figure 3: Example of a lead

Leads are extremely flexible and strong. The strength and flexibility allow a lead to withstand the twisting and bending caused by body movement and movement of the beating heart.

How is a pacing lead attached?

One end of the lead is connected to the pacemaker at the connector block. The other end of the lead is attached to the right **ventricle** or the right **atrium**.

A lead can be placed on either the inside or outside wall of the heart. The lead is most often placed inside the heart. This is called an **endocardial lead**. You may also hear it described as a **transvenous lead** because the lead is inserted into a vein that leads to a heart

chamber. The tip of the lead (the electrode) is placed against the inner heart wall.

Sometimes, a lead is attached to the outside wall of the heart. This is called an **epicardial lead**. With this type of lead, an incision is made in the chest. Then the lead is attached to the outer wall of the heart.

What is a pacing therapy and what does it feel like?

If your heart's rhythm becomes too slow, your pacemaker delivers a steady pattern of small electrical pulses to your heart to encourage a regular heartbeat. This is called **pacing** your heart. Pacing therapy was one of the very first treatments available from a heart device commonly known as a pacemaker. The pacing therapy provided by your pacemaker ensures that your heart maintains a heart rhythm that supports your body's needs.

Most people do not feel pacing therapies when they are delivered. The few that report feeling this type of therapy describe it as painless.

How does a pacing system work?

A pacing system performs two vital functions, pacing and **sensing**.

- Pacing means that a pacemaker sends an electrical impulse to your heart through a pacing lead. This pacing pulse starts a heartbeat. The pacemaker paces the heart when the heart's own rhythm is interrupted, irregular, or too slow.
- A pacemaker will also sense (monitor) the heart's natural electrical activity. When the pacemaker senses a natural heartbeat, it will not deliver a pacing pulse.

A pacemaker relieves the symptoms for most patients. However, a pacemaker is not a cure but rather a treatment for underlying heart rhythm disorders. (Pacemakers will not prevent or cure heart disease, or prevent **heart attacks**.)

What are the different types of pacing systems?

Depending on your heart condition, your doctor will prescribe the number of chambers that need to be "paced". Pacemakers are

designed for either **single chamber** or dual chamber pacing. Your pacemaker is designed to provide dual chamber pacing.

Dual chamber pacing

For **dual chamber pacing**, both the right atrium and right ventricles of the heart are paced. This typically requires two pacing leads. One lead is placed in the right atrium. Another lead is placed in the right ventricle.

For dual chamber pacing, the pacemaker senses (monitors) electrical activity in both the atrium and the ventricle. The pacemaker determines whether or not pacing is needed. The pacemaker also ensures that the contraction of the atria is followed closely by a contraction in the ventricles. **Dual chamber pacemakers** help the upper and lower chambers of your heart to beat in their natural sequence. Therefore, a paced heart mimics a naturally beating heart. A dual chamber pacemaker, with leads positioned in both the right atrium and right ventricle, is shown in Figure 4 on page 22.

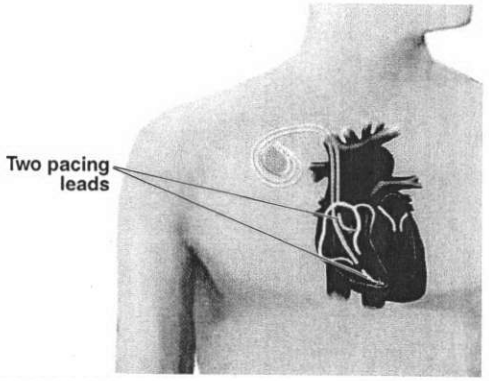

Figure 4: Dual chamber pacing often uses two pacing leads.

What type of therapies can my pacemaker provide?

Your pacemaker can provide more than one therapy to treat irregular heart rhythms. Your doctor has set up your pacemaker to

deliver the most effective types of therapy for your specific heart rhythm condition. There are two kinds of therapies that your pacemaker can provide:

- **Rate-responsive pacing**
- **Antitachycardia pacing**

Rate-responsive pacing

Your normal heart rhythm slows down or speeds up many times during the day. The heart beats slower while you are resting or sleeping; it beats faster in response to exercise and excitement. Your heart rate changes to supply the blood your body needs during your changing levels of activity.

Rate-responsive pacing is needed when your heart cannot adjust its rate to meet the needs of your body. This type of pacing varies its rate depending on your level of activity. Rate-responsive pacing can be part of single chamber or dual chamber pacing.

When your heart cannot adjust its rate, a **rate-responsive pacemaker** uses one or more special sensors. These sensors monitor changes in

your body. The pacemaker uses this information to increase or decrease your heart rate.

Variations in pacing rate allow you to perform your everyday activities with ease. If you are walking, exercising, or gardening, the pacemaker automatically adjusts your heart rate to match your level of activity. When you slow down, rest, or sleep, the rate decreases. The way your heart rate changes is based on the values (programmed settings) chosen by your doctor.

You do not need to engage in strenuous activity to benefit from a rate-responsive pacemaker. The simple act of walking may require a rate of more than 100 beats per minute, as shown in Figure 5 on page 25.

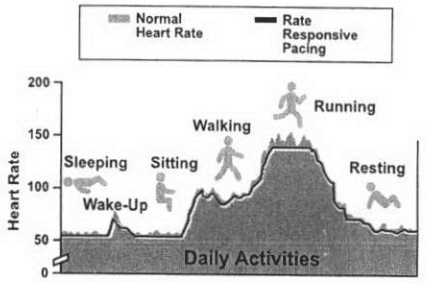

Figure 5: Rate-responsive pacing adjusts the pacing rate according to the needs of your body.

Patients who have rate-responsive pacing report feelings of well-being and the ability to resume active and satisfying lifestyles.

Antitachycardia pacing

Antitachycardia pacing (ATP) is a type of therapy your pacemaker uses to treat a fast or uneven heart rhythm.

During antitachycardia pacing therapy, your pacemaker releases several short bursts of pacing pulses; then it pauses to check for a normal heart beat. If the heart rhythm is still irregular, the next ATP therapy is initiated.

3 Your heart has a natural rhythm

To help you understand how your pacemaker works, it is helpful to understand how the heart functions and how abnormal heart rhythms can affect the heart. This chapter describes the anatomy of the heart and some of the most common types of abnormal heart rhythm conditions.

For details about your health and individual heart condition, always talk to your doctor.

The anatomy of the heart

The heart is a fist-sized organ that acts as a pump to circulate blood through the body. Arteries are the blood vessels that carry blood with oxygen and nutrients to all parts of the body. Veins are the blood vessels that carry blood depleted of oxygen and nutrients back to the heart and lungs.

The heart is actually a large hollow muscle divided into four chambers. The two upper chambers are referred to as the right **atrium** and the left atrium. The term **atria**, the plural of atrium, refers to both the right and the left atrium.

The lower chambers of the heart are called the **ventricles** and are referred to as the right ventricle and the left ventricle. The muscled wall dividing the right and left sides of your heart is called the **septum**.

The right atrium draws blood in from your body and pumps it into the right ventricle. The right ventricle then pumps the blood into the lungs to be **reoxygenated**. The left atrium draws oxygen-rich blood in from the lungs and pumps it into the left ventricle. The left ventricle then pumps the blood out to the rest of your body.

Each chamber of the heart contracts by squeezing its muscles together. Each contraction pushes blood from one chamber to the next chamber or out into the body. Heart valves regulate the flow of blood between each chamber and keep the blood flowing in only

one direction. It is the actual opening and closing of the valves that creates what we hear as our heartbeat.

After each chamber contracts completely, pushing out most of the blood, it relaxes and fills with more blood again. In a healthy heart, each chamber contracts in a coordinated effort with the other chambers of the heart.

The atria contract first, filling the ventricles with blood. When the ventricles are filled, they both contract at the same time, moving the blood into the lungs and the rest of the body, as illustrated in Figure 6 on page 30.

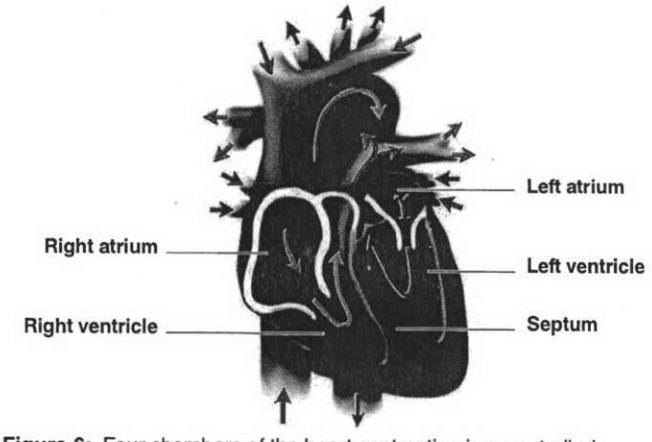

Figure 6: Four chambers of the heart contracting in a controlled sequence to circulate blood throughout the body

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Electrical conduction in the heart

The muscle cells of the heart, just like all the muscle cells throughout your body, contract and relax in response to electrical impulses.

The electrical impulses that cause your heart muscle to contract are generated by the heart's natural pacemaker, called the **sinoatrial node** (or **SA node**). The SA node is located on the upper inside wall of the right atrium. These natural electrical impulses move through the muscle of your heart in tiny thread-like paths, from the top of the atria to the bottom of the ventricles, then up the ventricles' outer walls.

After the SA node releases an electrical impulse, the impulse travels across the top of the right atrium and the left atrium. The impulse then travels down through both atria. As the atria are stimulated, they contract from the top down, pushing blood into the ventricles. When the electrical impulse reaches the lower wall of the atria, the **atrioventricular node** (or **AV node**) is stimulated. The AV node delays the impulses just long enough for the atria to finish pushing

blood into the ventricles, then it passes the impulse along organized pathways into the ventricles.

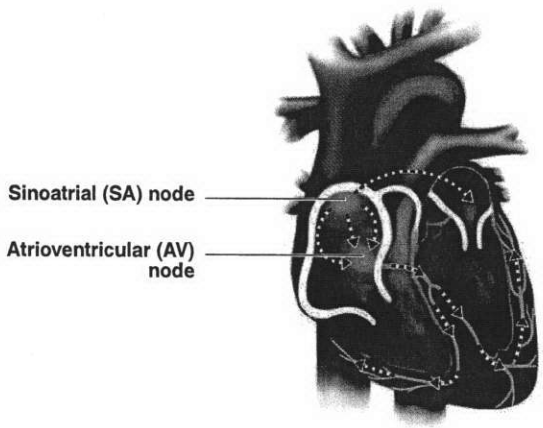

Figure 7: The electrical impulses that cause the heart to contract start at the SA node and move through the atria to the AV node. The AV node controls when the impulse is released to travel through the ventricles.

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The AV node controls how quickly the impulse travels through the rest of the heart. This controlled impulse release helps coordinate when each chamber contracts. Without this control, the heart would not pump blood very productively. The coordination between the contracting chambers of the heart is very important for maintaining adequate blood flow between your heart and the rest of your body.

The electrical impulse passes down to the bottom of the ventricles. From here, the pulse sweeps across the surface of the right and left ventricles from the bottom up, causing the ventricles to contract in the same bottom-up direction. This action pushes the blood out of the valves at the top of the ventricles to the lungs (from the right ventricle) and to the rest of the body (from the left ventricle).

The heart is very sensitive to the body's needs

The rate at which the chambers of the heart contract is controlled by your brain and your **autonomic nervous system**.

If, for example, you start to jog instead of walk, your body's demand for blood increases. Your heart automatically contracts faster when

you are active in order to increase the amount of blood supplied to your body.

How abnormal heart rhythms affect the heart

There are many reasons why a heart might not beat "normally". Whether due to disease, defect, or injury, the heart's conduction system can become unreliable. The areas of the heart that control the heart rhythm can malfunction, causing slow, fast, erratic, or uncoordinated heart rhythms. Any of these abnormal heart rhythms can affect the amount of blood supplied to the body.

The effects of abnormal heart rhythms can range from severe fatigue to **sudden cardiac arrest (SCA)**.

If the heart is not beating normally because of a problem with its conduction system, then the problem may be one of two common abnormal heart rhythm conditions.

Here are the two common heart rhythm conditions:

- **Tachyarrhythmia** – when the heart beats too fast
- **Bradycardia** – when the heart beats too slowly

These conditions can be treated with medications or by implanting a pacemaker. Sometimes they are treated with both methods. Your pacemaker is capable of treating bradycardia.

Bradycardia – When the heart beats too slowly

Bradycardia is a slow or irregular heart rhythm, usually less than 60 beats per minute. When the heart rate is this slow, not enough oxygen-rich blood is pumped to the body. With this extremely slow heart rate, the heart cannot pump enough blood to the body to support daily activities or mild exercise.

Here are some symptoms of bradycardia:

- dizziness
- shortness of breath
- extreme fatigue
- fainting spells

Here are some causes of bradycardia:

- hereditary defects
- certain illnesses
- some cardiac drugs
- the aging process
- a heart attack
- an unknown cause

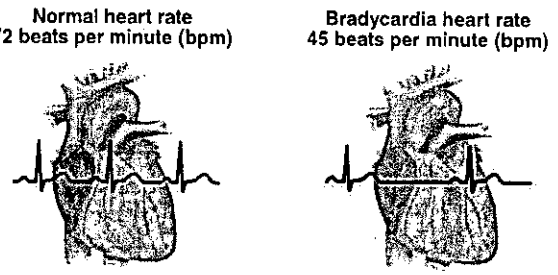

Figure 8: A normal heart rate compared to a bradycardia rate

Bradycardia can be caused by the delayed release of electrical impulses from the SA node (the heart rate determining mechanism) or when the normal pathway for electrical impulses in the heart is interrupted (**heart block**).

Sinoatrial (SA) node disease

Rhythm disorders of the SA node are described as "**sick sinus syndrome**." Sometimes the SA node, your heart's natural pacemaker, cannot begin a heartbeat or cannot increase the heart rate. When this happens, other tissues in the heart often take over the job of the SA node.

However, the other tissue often cannot maintain a consistent heart rate. Or, the other tissue may create a rate that is too slow or too fast for normal activities. A pacemaker can solve this problem by taking over the job of the SA node.

Heart block

The electrical signal from the SA node must pass through the AV node. The signal then continues through the conduction pathways

of the ventricles. At or below the AV node, the electrical signal may become slow or irregular. The signal may even stop. This is called heart block because the electrical impulse is blocked from moving from the atria to the ventricles. Heart block is described as first, second, or third degree. How slow the heart rate becomes depends on the degree of heart block. A pacemaker can take over for an impaired AV node and restore normal heart functioning. For an illustration of how heart block interrupts the electrical signals to the ventricles, refer to Figure 9 on page 40.

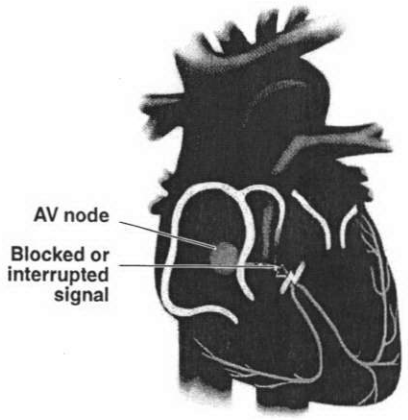

Figure 9: Electrical signal to the ventricles is blocked or interrupted.

4 Your implant procedure and recovery

Being told you need a pacemaker can be upsetting, but knowing what to expect about your implant procedure can help reduce your concern. The implant procedure does not require open heart surgery. You will be given medication to make you sleepy and comfortable, but the surgery is typically performed using local anesthesia.

You will usually stay in the hospital overnight and go home the next day with instructions on caring for your incision. For a short time after surgery, your doctor may want you to limit how much you move the arm that is closest to your implant site.

This chapter has important information about the following topics:

- The implant procedure
- Potential risks after the implant procedure

- Recovering after your surgery and keeping follow-up appointments

The implant procedure

The implant procedure includes these general steps:

1. Making the incision and inserting the leads.
2. Testing the leads.
3. Implanting the pacemaker and closing the incision.

Making the incision and inserting a lead

Your doctor will make a small incision, just below your collarbone, on the left or right side of your chest. The doctor inserts the lead into a vein, threading the lead through the vein into your heart. The tip of a lead is positioned so that it touches the inside wall of your heart. This type of lead is called a transvenous lead. (Note: In a child or small adult, a pacemaker is sometimes implanted in the abdominal area.)

Sometimes a lead needs to be placed on the outside of the heart. This type of lead is called an epicardial lead. If this type of lead is needed, your doctor inserts it by making a small incision between your ribs just over your heart.

In general, a lead is referred to by its location in your heart:

- An atrial lead is placed in the right atrium.
- A right ventricular lead is placed inside the right ventricle.

Testing a lead

After a lead is placed in your heart, it is tested to make sure that it will operate effectively. Your doctor tests the lead to make sure that it can accurately monitor your heart rate and deliver heart rhythm therapies.

Implanting the pacemaker and closing the incision

After testing, the lead is attached to your pacemaker. The pacemaker is then implanted under the skin and your doctor closes the incision.

Potential risks after the implant procedure

Your doctor and Medtronic have attempted to minimize the risks associated with implanting a pacemaker. However, as with any kind of surgery, there are potential risks.

The following potential risks are associated with implanting a pacemaker:

- pain, swelling, or bruising around the implant site
- bleeding
- infection
- blood clots
- punctures of the heart muscle, vein, or lung space caused while implanting a lead
- heart attack
- stroke

Your doctor should discuss these and other potential risks of this surgical procedure with you.

After the implant procedure is finished, there is a potential risk of additional hospitalization or surgery to modify or adjust your pacemaker. Additional hospitalization may be required under some conditions, such as these:

- movement of the pacemaker from its original location or wearing away of the skin over the pacemaker
- changes in your heart rhythms that require adjustment or changes to the lead system
- changes in the lead system that prevent the pacemaker from detecting the heart rhythm or delivering therapies
- stimulation of muscles other than the heart muscle by the pacemaker

Recovering after your implant surgery

Some time after your pacemaker is implanted, your doctor may order some tests such as an electrocardiogram (ECG), blood tests, or x-rays to confirm that your lead is in the proper position inside your heart. The operating settings for your pacemaker may also be

checked again to make sure that your pacemaker is providing the best treatment for your heart condition.

As you recover, follow your doctor's suggestions about resuming normal activities. Expect a gradual recovery. It is normal to see a slight bulge under your skin where the pacemaker is located.

Here are general recommendations for the first few weeks after your surgery:

- Call your doctor immediately if any swelling, warmth, or drainage appears around your incision or if you develop a fever.
- Use care when exercising and bathing, according to your doctor's directions.
- Avoid tight clothing that may irritate your incision.
- Limit arm movements as directed by your doctor.
- Avoid lifting more than 10 to 15 pounds (5 to 7 kilograms).
- Avoid excessive twisting of your torso.
- Avoid pushing or pulling heavy objects.

- When you are driving or riding in a vehicle, the shoulder seat belt strap may feel uncomfortable. You can place a soft towel between the shoulder seat belt strap and your implant site to cushion the area during the first few weeks after surgery. In any case, seat belts should be worn at all times.

Tell your other doctors and your dentist that you have a pacemaker. They may choose to prescribe antibiotics for you to take before and after surgery or dental work to prevent infection.

Follow-up appointments

Your doctor or nurse will work with you to schedule follow-up care appointments. For more information about these appointments, read the chapter on "Follow-up care" on page 89.

5 Living life with your pacemaker

Many people resume their normal daily activities after full recovery from surgery (see "Your implant procedure and recovery" on page 41). However, there may be certain situations that your doctor will ask you to avoid. Your doctor will provide the most important guidance for your particular condition.

This chapter has important information about the following topics:

- food and medications (see page 50)
- your physical activity now that you have a pacemaker (see page 50)
- information and instructions about any electrical equipment that may cause interference with your pacemaker (see page 52)
- precautions about certain types of medical procedures (see page 77)

Food and medications

Your doctor may instruct you to eat or avoid eating certain foods. For information about food, talk with your doctor.

Your doctor may prescribe medications that will treat your heart condition. Please talk with your doctor about medications.

Recommendations about your physical activity

Upon the advice of your doctor, you can gradually return to your normal lifestyle and to activities such as these:

- pursuing hobbies or recreational activities
- returning to your job
- resuming strenuous activity
- resuming sexual activity
- traveling

Your doctor might ask you to avoid situations where a few seconds of unconsciousness could be dangerous to you or others. Such

situations might include driving, swimming or boating alone, or climbing a ladder.

Recreation and activities

Avoid rough physical contact that could cause you to fall or to hit your implant site. Your pacemaker can be damaged or your leads could become detached from the pacemaker during rough contact.

- If you use a rifle or shotgun, rest the butt on the shoulder of the side opposite from your pacemaker.
- In activities that use a shoulder harness, protect your pacemaker and leads from jolts or rough rubbing.
- If you plan to scuba dive, discuss your medical condition with your doctor. General recommendations about scuba diving vary depending on many factors.

If you have additional questions about any recreational activities you normally pursue, contact Medtronic Patient Services at 1-800-551-5544.

Driving a car

Discuss with your doctor whether you can safely drive a car or other vehicle. You may be able to resume driving, depending on local laws and insurance regulations and on your medical condition. Your doctor will decide what is best for your safety and the safety of others.

Seat belts are a very important safety device and should always be worn while driving or riding in a vehicle. While you are driving or riding in a vehicle, the shoulder seat belt strap may feel uncomfortable during the first few weeks after surgery. You can place a soft towel between the seat belt strap and your implant site to cushion the area.

What you need to know about electromagnetic compatibility (EMC)

Everything that uses electricity produces an **electromagnetic energy field**. This energy field surrounds the electrical item while it is connected to a source of electricity (even a battery source). The

energy field is strongest near the item and weakens with distance from the item.

The relationship between these energy fields and your pacemaker is called **electromagnetic compatibility (EMC)**. Most electromagnetic energy fields are small and weak and do not affect your pacemaker. Electrical items that generate strong electromagnetic energy fields may not be compatible with your pacemaker.

Because your pacemaker is designed to sense the electrical activity of your heart, it is possible that it may sense a strong electromagnetic energy field outside your body and deliver a therapy that is not needed or withhold a therapy that is needed.

Several safeguards are built into your pacemaker to shield it from strong electromagnetic energy fields. For example, the metal case of your pacemaker acts as a shield against electromagnetic energy fields. There are also electronic filters built into your pacemaker that help your pacemaker distinguish between external electromagnetic energy fields and the internal electrical pulses of your natural heartbeat.

You can avoid potential EMC problems by keeping your pacemaker a minimum distance away from the electrical item. See the following pages for more information, including the recommended safe distances for certain types of electrical items.

? How could electromagnetic energy fields affect my pacemaker?

High electromagnetic energy fields could affect how your pacemaker senses your heart rhythm. Because your pacemaker is designed to sense the electrical activity of your heart, it may also sense a strong electromagnetic energy field outside your body.

If your pacemaker is exposed to a strong electromagnetic energy field, it may not detect an abnormal heart rhythm or it may deliver a pacing therapy when your heart does not need it. Any effects of electromagnetic energy fields on your pacemaker are temporary and will stop when you move away from the source of the electromagnetic energy field.

? What do I do if I think that an electrical item is affecting my pacemaker?

If you feel dizzy or feel rapid or irregular heartbeats, release whatever you are touching or move away from the item. Your pacemaker should immediately return to its normal operation. If your symptoms do not improve when you move away from the item, you should contact your doctor.

? What about static electricity or shocks from household outlets?

Static electricity shocks will not damage your pacemaker. A "momentary" shock from an electrical outlet (110/220 volts) is unlikely to damage your pacemaker, depending on how long you stay in contact with the outlet.

? What items are safe and what kind of precautions do I need to take?

Most electrical items are safe for you to use. However, you should keep some items that produce a stronger electrical field a minimum distance away from your pacemaker. This minimum distance can range from 6 to 12 inches (15 to 30 centimeters) or more, depending on the type of item. Refer to the tables starting on page 61 for recommended safe distances.

General rules for safe use of electrical items

The following pages provide tips on how to avoid any possible effects of electromagnetic energy fields on your pacemaker. If you have questions about EMC or the safe use of a specific item that is not listed, please call Medtronic Patient Services at 1-800-551-5544.

Your home and workplace contain a variety of electrical items. Most are safe to use, and some should be kept a minimum distance from your pacemaker.

Proper grounding of electrical items

To protect yourself from electrical current that may leak from improperly grounded electrical items and pass through your body, follow these suggestions:

- Make sure that all electrical items are properly wired and grounded.
- Make sure that electrical supply lines for swimming pools and hot tubs are properly installed and grounded according to local and national electrical code requirements.

Wireless communication devices

Follow these guidelines when using wireless communication items:

- **Handheld cellular, mobile, or cordless telephones (wireless phones)**

  Your pacemaker has been tested with many types of wireless telephone technologies to ensure that it will operate correctly while you are using a wireless phone. Keep the antenna of a handheld

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wireless phone at least 6 inches (15 centimeters) away from your pacemaker. This is easily done by holding the phone to the ear farthest away from your implant. Don't carry the phone in a pocket over your pacemaker or in a shoulder bag near your pacemaker.

- **Two-way pagers, PDAs, or mobile mailboxes**

  Handheld devices that let you send text or data messages use the same type of transmitter as a handheld wireless phone, so follow the same guidelines just described for wireless phones.

- **Wi-Fi enabled laptop computers and Bluetooth devices**

  Wi-Fi enabled laptop computers and Bluetooth devices contain small transmitters. Keep them at least 6 inches (15 centimeters) away from your pacemaker.

Kitchen appliances

One kitchen appliance that could possibly affect your pacemaker is an induction cooktop. An induction cooktop uses an alternating magnetic field to generate heat. You should keep your pacemaker at

least 24 inches (60 centimeters) away from the heating zone when the induction cooktop is turned on.

Most glass-topped or ceramic-topped ranges use conventional heating elements beneath their flat cooking surfaces. If you can use aluminum or glass cookware on your range and the cooking area stays hot after the burner has been turned off, your stove has conventional heating elements. This type of cooktop will not affect your pacemaker. Call Medtronic Patient Services at 1-800-551-5544 for the latest information about kitchen appliances.

Items that contain magnets

Caution: Avoid holding magnets, or items that use magnets, close to your pacemaker. Magnets produce magnetic fields, which can interfere with the normal operation of your pacemaker.

For example, avoid using magnetic mattress pads or pillows because they cannot easily be kept away from your pacemaker.

The following list provides examples of items containing magnets that can be used as long as they are kept at least 6 inches (15 centimeters) away from your pacemaker:

- **Large magnets** such as a bingo wand and a mechanic's extractor wand.
- **Stereo speakers.** Do not carry or hold speakers close to your pacemaker. Stereo speakers have magnets inside them. Even if the power for the speakers is disconnected, you should keep speakers at least 6 inches (15 centimeters) away from your pacemaker.

EMC with household and hobby items

Caution: Household and hobby items that have motors, have magnets, or are capable of generating electromagnetic energy fields could interfere with your pacemaker. You should move away from the interference source or turn off the source if you experience any dizziness or heart palpitations.

On the following pages, Table 1 and Table 2 provide the recommended minimum distances for electrical household and hobby items.

Table 1: Examples of EMC with household items

Low risk	Keep pacemaker at least 6 inches (15 centimeters) away	Special considerations
Kitchen items: Microwave oven; electric, gas, or convection oven; toaster; blender; electric can opener; food processor; cordless electric knife.	**Kitchen items:** Handheld appliances such as an electric mixer.	**Kitchen items:** Induction cooktop — keep your pacemaker at least 24 inches (60 centimeters) away from the heat source when cooktop is on. For more information, see "Kitchen appliances" on page 58.

Table 1: Examples of EMC with household items (continued)

Low risk	Keep pacemaker at least 6 inches (15 centimeters) away	Special considerations
Personal care items: Salon hair dryer; cordless shaver; electric blanket; heating pad; tanning bed.	**Personal care items:** Corded handheld hair dryer; corded electric shaver; electric or ultrasonic toothbrush (base charger); back massager; magnetic chair pad; magnetic bracelet or magnetic clasp.	**Personal care items:** Electronic body fat scale — not recommended because it passes electricity through the body.

Table 1: Examples of EMC with household items (continued)

Low risk	Keep pacemaker at least 6 inches (15 centimeters) away	Special considerations
Communication devices: Corded home or public telephone.	**Wireless communication devices:** Wireless phones (home cordless telephone, cellular phone, or mobile phone); two-way pager; mobile mailbox.	**Wireless communication devices:** For details, see page 57.

Table 1: Examples of EMC with household items (continued)

Low risk	Keep pacemaker at least 6 inches (15 centimeters) away	Special considerations
Home office items: Desktop or laptop computer; home-use copier, printer, fax, and scanner.	**Home office items:** Personal digital assistant (PDA); modem; Bluetooth devices; Wi-Fi enabled laptop computers and devices.	

Table 1: Examples of EMC with household items (continued)

Low risk	Keep pacemaker at least 6 inches (15 centimeters) away	Special considerations
Home electronics items: AM and FM radio; cassette tape recorder; CD player; camcorder; video recorder (VCR); MP3 player; television; video game system; stereo; DVD player; remote control for entertainment system.	**Home electronics items:** Stereo speakers.	**Home electronics items:** UPS (uninterruptable power source) up to 200 Amps — keep at least 12 inches (30 centimeters) away; if operating by battery source, keep at least 18 inches (45 centimeters) away.

Table 1: Examples of EMC with household items (continued)

Low risk	Keep pacemaker at least 6 inches (15 centimeters) away	Special considerations
Miscellaneous items: Laundry and cleaning items: Clothes iron; vacuum cleaner; electric broom. Pager that only receives messages; remote control for garage door; portable space heater.	**Miscellaneous items:** Sewing machine and serger (motor).	**Miscellaneous items:** Electronic pet fences/invisible fences — keep at least 12 inches (30 centimeters) away from the buried wire and the indoor antenna.

Table 2: Examples of EMC with hobby items

Keep pacemaker at least 6 inches (15 centimeters) away	Special considerations
Mechanic's extractor wands (uses a magnet to pick up metal items).	Home-use electric kilns — keep at least 24 inches (60 centimeters) away.
Bingo wands.	Citizen Band (CB) radio antennas, HAM radios, amateur radios, and other radio transmitters — for distance information, see "EMC and radio transmitters" on page 73.
Radio-controlled toys (antenna).	"Beach comber" metal detectors — keep the detector end at least 24 inches (60 centimeters) away.
Two-way walkie-talkies (less than 3 watts).	

Table 2: Examples of EMC with hobby items (continued)

Keep pacemaker at least 6 inches (15 centimeters) away	Special considerations
	Boat motors (electrical trolling motors and gas powered motors) and portable generators (up to 20 kilowatts) — keep at least 12 inches (30 centimeters) away.

EMC with home power tools

Most home power tools should not affect your pacemaker. Follow these common-sense guidelines:

- Keep all equipment in good working order to avoid electrical shock.
- Be certain that plug-in tools are properly grounded (or double insulated).

- If you use power machinery often, a ground-fault-interrupt outlet is a good safety measure. This inexpensive device prevents a sustained electrical shock.

The items and activities in the following list could affect pacemaker operation. Follow these guidelines to reduce any possibility of interference:

- **Gas-powered tools and gas-powered yard equipment,** such as lawn mowers/tractors, snowblowers, leaf blowers, and weed eaters. Turn off the motor before making adjustments. Keep components of the ignition system at least 12 inches (30 centimeters) away from your pacemaker when operating the machinery.
- **Car engine repair.** Turn off the engine before making any adjustments. When the engine is running, keep components of the ignition system at least 12 inches (30 centimeters) away from your pacemaker.

- **Chainsaws.** Avoid using a chainsaw.
  - You could be seriously injured if you become dizzy or lose consciousness.
  - You should keep the ignition system of the chainsaw at least 12 inches (30 centimeters) away from your pacemaker. For most chainsaws, it is difficult to maintain this distance between the ignition system and your pacemaker while operating the saw.
  - The ignition system, specifically the spark plug, on some chainsaws is actually inside the hand grip area. If the insulation covering the spark plug is faulty, electrical current could pass through your body and affect your pacemaker.
  - The vibration of a chainsaw can affect the rate of pacing you receive from your pacemaker.
- **Soldering guns and demagnetizers.** Keep these tools at least 12 inches (30 centimeters) away from your pacemaker.

- **Small power tools.** Keep handheld motorized tools, such as battery-operated cordless screw drivers, at least 6 inches (15 centimeters) away from your pacemaker.
- **Electric yard tools.** Keep these tools at least 6 inches (15 centimeters) away from your pacemaker.

EMC with industrial equipment

After recovering from surgery, most pacemaker patients can return to work or school. However, if you use or work near high-voltage equipment or sources of high electrical current, consult with your doctor. Using or working near high-voltage equipment, sources of high electrical current, or magnetic fields may affect pacemaker operation. Refer to Table 3 on page 72 for examples of industrial equipment that you may not be able to use or work near. Contact Medtronic Patient Services at 1-800-551-5544 if you have any questions or concerns about industrial equipment.

Table 3: Examples of industrial equipment in the workplace you may need to avoid

Electric furnaces used in the manufacturing of steel.
Induction heating equipment and induction furnaces, such as kilns.
Industrial magnets or large magnets such as those used in surface grinding and electromagnetic cranes.
Dielectric heaters used in industry to heat plastic and dry glue in furniture manufacturing.
Electric arc and resistance welding equipment. For detailed information about electric arc and resistance welding, call Medtronic Patient Services at 1-800-551-5544.
Broadcasting antennas of AM, FM, shortwave radio, and TV stations.

Table 3: Examples of industrial equipment in the workplace you may need to avoid (continued)

Microwave transmitters. Note that microwave ovens are unlikely to affect your pacemaker.
Power plants, large generators, and transmission lines. Note that lower voltage distribution lines for homes and businesses are unlikely to affect your pacemaker.

EMC and radio transmitters

Determining a safe distance between the antenna of a radio transmitter and your pacemaker depends on many factors such as transmitter power, frequency, and the antenna type. If the transmitter power is very high, or if the antenna cannot be specifically directed away from you, you may need to stay further away from the antenna. Refer to Table 4 on page 74 for a list of safe distances from various radio transmitters.

Table 4: Safe distances from radio transmitters

Two-way radio transmitter (less than 3 watts): Keep at least 6 inches (15 centimeters) between the antenna and your pacemaker.
Portable transmitter (3-15 watts): Keep at least 12 inches (30 centimeters) between the antenna and your pacemaker.
Commercial and government vehicle-mounted transmitters (15-30 watts): Keep at least 24 inches (60 centimeters) between the antenna and your pacemaker.
HAM transmitter (125-250 watts): Keep at least 9 feet (2.75 meters) between the antenna and your pacemaker. (Note that HAM transmitters are not used or available in all countries.)
For transmission power levels higher than 250 watts, consult with Medtronic Patient Services at 1-800-551-5544.

EMC and security systems

Most people with implanted pacemakers can travel without taking special precautions. However, when you pass through metal detectors (such as in an airport, courthouse, or jail), you must follow certain instructions and take certain precautions.

- **Identification (ID) card.** Always carry your pacemaker ID card. This card is helpful should your pacemaker set off a metal detector or security system.
- **Electronic antitheft systems** (such as in a store or library). Electronic antitheft systems should not affect your pacemaker. Do not linger near or lean against antitheft systems, such as those found in retail stores and libraries. Simply walk through these systems at a normal pace. If you are near an antitheft system and you feel symptoms, promptly move away from the equipment. Your pacemaker will resume its previous state of operation when you move away from the equipment.
- **Home security systems.** It is unlikely that your pacemaker will be affected by home security systems.

- **Airport, courthouse, and jail security systems.** It is unlikely that a walk-through security system will affect your pacemaker. However, the metal case of your pacemaker could set off a metal detector. Before entering the metal detector archway, follow these steps:
  1. Identify yourself as having an implanted pacemaker.
  2. Show your pacemaker ID card.
  3. Do not linger near or lean against metal detector archways such as those found in airports, courthouses, and jails. Simply walk through these archways at a normal pace.
  4. If a handheld screening wand (metal detector) is used, ask the security operator not to hold it over your pacemaker and not to wave the wand back and forth over your pacemaker. Alternatively, you can request a hand search.

Precautions about medical procedures

Caution: Before you undergo any medical procedure, tell the doctor, dentist, or technician that you have an implanted pacemaker.

- The doctor, dentist, or technician may need to speak with your heart doctor before performing the procedure. Showing them your pacemaker ID card may be helpful.
- Some procedures may potentially affect the function of your pacemaker, and such procedures may require precautionary measures to prevent or minimize impact on your pacemaker.

Talk with your doctor to weigh any potential risk against the benefits of the medical procedure. See the following pages for more information.

Medical procedures that are not recommended

Some medical procedures should not be performed on anyone with an implanted pacemaker. Talk to your doctors about finding alternatives to these procedures. Your doctor may decide to contact your heart doctor or Medtronic Technical Services for more information.

Refer to Table 5 for procedures that are not recommended.

Table 5: Medical procedures that are not recommended

Warning: People with metal implants such as an implanted pacemaker and accompanying leads should not receive the following medical procedures. Such treatments can result in serious injury and damage to your pacemaker.

Catheter microwave ablation

Diathermy treatment (high frequency, short wave, or microwave)

Transurethral needle ablation (TUNA)

Medical procedures that require some precautions

Some medical procedures can be safely performed, if certain precautions are taken by your doctor to avoid potential pacemaker function problems or interference.

If you or your doctor have any concerns about these necessary precautions, your doctor should contact a Medtronic representative or Medtronic Technical Services.

The doctor should make sure that your pacemaker is operating correctly after completing the procedure.

Refer to Table 6 for procedures that require some precautions.

Table 6: Medical procedures that require some precautions

Computerized axial tomography (CT or CAT) scan
Diagnostic ultrasound
Electrocautery
Electrolysis

Table 6: Medical procedures that require some precautions (continued)

External defibrillation and **elective cardioversion**
High-energy radiation therapy
Hyperbaric Oxygen Therapy (HBOT)
Lithotripsy
MRI (magnetic resonance imaging) scans **Note:** For more information, see "Is it safe for me to have an MRI scan?" on page 107. **Caution:** If your doctor provided you with a Patient Assistant (handheld recorder), do not take the Patient Assistant into the MRI controlled room (magnet room).
Radiofrequency ablation
Therapeutic ultrasound
Transcutaneous Electrical Nerve Stimulation (TENS)
Transmitting loop for digital hearing aid

Acceptable medical procedures

Many medical procedures will not affect your pacemaker. However, the equipment used for the procedure must be used correctly and must be properly maintained.

Tell your doctors and dentist you have an implanted pacemaker before beginning any medical or dental procedure.

Refer to Table 7 for some of the acceptable medical procedures.

Table 7: Acceptable medical procedures

Dental procedures Procedures that use dental drills or ultrasonic probes to clean teeth are acceptable. Dental x-rays are also acceptable.
Diagnostic x-rays, such as chest x-rays and mammograms, are acceptable.

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6 Registering your pacemaker

Registering your pacemaker is important. Registration ensures that medical information related to your pacemaker is on file and that Medtronic can notify your doctor with any relevant device information if necessary.

The Food and Drug Administration (FDA) requires that medical device companies keep track of their devices implanted in the United States. The registration information must be accurate and current. This information is always kept confidential.

This chapter has important information about the following topics:

- pacemaker registration form
- pacemaker identification (ID) card
- pacemaker travel card

Pacemaker registration form

In the United States and its territories, the pacemaker registration form is completed by your doctor, nurse, or Medtronic representative at the time of your implant. This form is then sent to Medtronic.

The form includes this information:

- your name and contact information
- pacemaker model and serial number
- date of implant
- your follow-up care doctor's name and phone number

This same information is included on your temporary and permanent pacemaker ID cards.

Note: Your U.S. Social Security number is a key piece of information that helps either Medtronic or your doctor locate your address if you move. If you live outside the United States, check with your doctor for the regulations in your country.

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Your pacemaker ID card

While in the hospital, you will receive a temporary pacemaker ID card. Your permanent card will be mailed to you within 6 weeks of your implant. If you have not received your card within 6 weeks of your implant surgery, contact Medtronic Patient Registration Services at 1-800-551-5544.

Carry your pacemaker ID card with you at all times

Your pacemaker ID card is especially helpful during your follow-up appointments, when seeing other doctors or your dentist, and when traveling. It could be essential in case of a medical emergency. You should carry your pacemaker ID card with you at all times.

If you do not have your pacemaker ID card with you during a medical situation, your doctor or nurse can call Medtronic (or the medical records department of the hospital where your pacemaker was implanted) to request information about your pacemaker.

The card helps remind you that unlike most pacemakers, your pacemaker is "**MR Conditional**", which means you can undergo an

MRI scan as long as certain criteria are met and your doctor follows the precautions provided by Medtronic (for more information, see "Is it safe for me to have an MRI scan?" on page 107). If any of your doctors (including non-cardiologists) are considering you for an MRI scan, show your ID card to that doctor. This card will advise the doctor to contact your attending heart doctor. If needed, your doctor can seek more information from a Medtronic representative or from the website www.mrisurescan.com.

Requesting a new ID card or updating personal information

If you lose your pacemaker ID card or need to update your personal information, such as your address, ZIP code, or heart doctor, contact Medtronic Patient Registration Services at 1-800-551-5544.

Our staff is available at the following times:

Monday through Friday, 7:00 AM to 7:00 PM (Central Time)

You can also update your information online. On the Internet, go to www.medtronic.com/idcard.

If you change your doctor

If you change your heart doctor, always notify Medtronic Patient Registration Services by calling 1-800-551-5544 or by updating your ID card information online at www.medtronic.com/idcard. Also, notify Medtronic if you no longer reside in the United States.

Medtronic pacemaker travel card

A special Medtronic pacemaker travel card is also available from Medtronic. This multilanguage card identifies you as having an implanted pacemaker and provides instructions for security personnel on how to properly scan your pacemaker with a handheld scanner.

You can use this card, along with your pacemaker ID card, when you pass through security gates at airports and other secured buildings such as some libraries and government buildings. The card is especially useful when traveling internationally.

You can request the Medtronic pacemaker travel card by calling Medtronic Patient Registration Services at 1-800-551-5544 or at website www.medtronic.com/rhythms.

7 Follow-up care

Before you leave the hospital, your doctor will tell you when you need to schedule a follow-up appointment.

Follow-up appointments are important to ensure that your pacemaker settings are working well for you. No surgery is required, and the procedure is painless. The appointment usually takes the same amount of time as a regular doctor's appointment.

Follow-up appointments can be done at a clinic or in your doctor's office. Another option is **remote monitoring**. Remote monitoring offers a convenient way to send your pacemaker information to your clinic without leaving your home. For more information about monitoring capabilities available with your pacemaker, see "Remote monitoring" on page 91.

Follow-up information

The purpose of follow-up appointments is to check or monitor the following types of information:

- Assess your general medical condition.
- Check the operation of your pacemaker. This includes checking the battery power and the status of your implanted leads.
- Review the information saved by your pacemaker.
- Adjust your pacemaker settings, if necessary, to provide the best treatment for your heart condition.

Your doctor or nurse will review your current medications with you and can answer any questions you have during the visit.

Your doctor will tell you how often your pacemaker should be checked. Your first follow-up appointment is usually scheduled for 1 month after your pacemaker is implanted.

Depending on your doctor's normal practice and your medical condition, additional follow-up appointments are scheduled every

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3 to 6 months. More frequent appointments are usually scheduled as your pacemaker nears its expected replacement time.

Remote monitoring

In addition to the monitoring you receive from your doctor at clinic visits, remote monitoring offers a convenient way to send your pacemaker information to your clinic using a telephone instead of visiting in person. The information you send over a standard telephone line is available for your doctor's review within minutes.

Remote monitoring over a telephone is convenient and provides peace of mind. With **telephone monitoring**, you will not have to leave your home for most follow-up appointments. Note that transmitting data over a mobile phone is not currently supported.

If your doctor chooses to have you use telephone monitoring, you will receive special equipment to use with your telephone to transmit an ECG. The equipment is simple for you, your family, or your care provider to use. The transmitter relays your ECG to a

receiver and it is recorded. A technician analyzes your ECG. Then the technician sends the information to your doctor.

Your doctor will prescribe how often you need telephone monitoring. Be sure to follow the schedule your doctor has set for you. Generally, you will be called for your ECG transmission. The time and day of the week can be arranged for your convenience.

If the pacemaker information that is sent to your doctor indicates that you should be seen in person, your doctor or clinic will contact you to set up an appointment. The doctor may need to adjust your pacemaker settings or adjust your medications. Your pacemaker settings cannot be adjusted unless you see the doctor in person.

Medtronic CareLink Programmer

The Medtronic CareLink Programmer is a specialized computer designed to work specifically with your Medtronic pacemaker.

Your doctor or nurse uses the programmer during the implant procedure to initially set up and change the pacemaker settings.

Using radio waves to "read" your pacemaker, the programmer displays information that is collected and stored in your pacemaker.

Your doctor or nurse uses the Medtronic CareLink Programmer during every follow-up appointment to make sure that your pacemaker is operating correctly and to check for any changes in your heart rhythm condition.

Reviewing information saved by your pacemaker

During a follow-up appointment in the clinic or hospital, your doctor or nurse will use the Medtronic CareLink Programmer to read data collected by your pacemaker or to change the operating settings of your pacemaker. Your pacemaker collects and saves the following information:

- ECG recordings of any unusual heart rhythms
- a list of any therapies you have received
- the status of the pacemaker battery
- the status of your implanted lead

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Based on this information and a review of your medications, your doctor may adjust the settings of your pacemaker to fit your individual needs.

When to call your doctor

Contact your doctor or nurse if you experience any of the following situations:

- You notice any swelling, warmth, or drainage around your incision or if you develop a fever while your incision is healing.
- You notice new, unexplained heart symptoms or if you experience the same heart symptoms you had before receiving your pacemaker.
- You have heart rhythm symptoms that last longer than 3 minutes (or any length of time specified by your doctor). These symptoms can include extreme fatigue, racing heart, pounding heart, or feeling faint or dizzy.

Pacemaker replacement

Your pacemaker is powered by a lithium battery. This battery is sealed inside the titanium case of your pacemaker. Eventually, when the battery power is low, your pacemaker will need to be replaced. The average pacemaker battery lasts 7 to 12 years. How long your battery lasts depends on several factors. Some of these factors include the type of pacemaker you have and the nature of your heart condition.

Replacing your pacemaker is typically easier and quicker than your first implant procedure. Your doctor makes an incision, removes your current pacemaker, and checks the lead.

Your implanted lead may be used with your new pacemaker if it is still in good working condition. If not, your doctor will implant a new lead. At the time of pacemaker replacement, you should discuss lead replacement with your doctor or nurse.

The lead is connected to your new pacemaker, and the pacemaker is tested and usually implanted in the same place as your first

pacemaker. Then the doctor closes the incision and sets the features of your new pacemaker.

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8 Caring for yourself

Caring for yourself is one of the most important parts of your follow-up care. Talk with your family and caregivers about how you are feeling, and share the information in this manual with them so that they can help you return to your normal activities.

Give yourself and your family a few months to adjust to living with your pacemaker. Most people report that they have a wide range of emotions after receiving a pacemaker. It is natural and normal to feel a little cautious and nervous about how your pacemaker will affect your life.

With time, your confidence will return as you get back to your normal activities and family life. Addressing your concerns and having a positive attitude toward your pacemaker and the therapies it provides can enhance the quality of your life over the long term (for guidance on developing a positive attitude, see page 100).

Dealing with anxiety and getting the support you need

After receiving a pacemaker, many people report a positive change with feelings of relief, comfort, and well-being. Yet, experiencing feelings of anger, fear, and guilt are also natural and expected. You may want to talk with your doctor or nurse about anything that is causing you to worry.

? What is one common source of stress for pacemaker patients and families?

A common worry pertains to the pacemaker performance. Medtronic medical pacemakers are extremely reliable, and most patients feel that their quality of life improves after the implant because the pacemaker can effectively relieve the troubling symptoms. Yet, at times, you may worry about whether the pacemaker will work when needed. Follow-up appointments help monitor the performance of your pacemaker and provide you with

an opportunity to ask questions. With that comes comfort and reassurance, thus reducing the anxiety.

? What are some other ways to relieve stress and get answers to my questions?

It often helps to talk with other people who have a pacemaker and ask them how they have adjusted to it. Ask your doctor or nurse if there is a support group for pacemaker patients at your clinic or a nearby hospital.

In addition, Medtronic websites provide information you may find helpful:

- *Rhythms of Life* newsletter offers information for patients about their pacemakers, including patient stories and other resources. Past newsletters and additional information are available at www.medtronic.com/rhythms.
- For in-depth information on heart conditions and various pacemakers used to treat heart conditions, such as pacemakers and defibrillators, see www.medtronic.com.

Shaping a positive attitude about life with your heart device

Remind yourself of the benefits – Remind yourself that your heart device protects you from the serious consequences of irregular heartbeats.

Block negative thinking – Catch yourself if you are imagining the worst-case scenarios. Remind yourself that most patients feel overwhelmingly positive about having their heart device.

Discuss concerns – Make a list and discuss any worries you might have about your condition or heart device with your doctor and with your loved ones. Develop a plan about how to cope with your concerns.

Explore the unknown – Learn about your medical condition and your heart device from your doctor, nurse, library, device manufacturer, and Internet websites. Often learning about your heart device helps reduce anxiety.

Plan your quality of life – The goal of your ongoing care is to achieve the best quality of life possible. Take an inventory of the activities that are most important to you and discuss plans to return to those activities with your doctor.

Provided by: Dr. Sam Sears of East Carolina University and Dr. Wayne Sotile of Wake Forest University. Both health psychologists are experts who work extensively with heart device patients and provide educational information on www.medtronic.com.

Medical care

- Follow your doctor's instructions about diet, medications, and physical activity.
- Attend all pacemaker follow-up appointments and other general health checkups.
- Remote monitoring may be prescribed instead of an office visit. Following your remote transmission schedule is as important as an office visit for your medical care. If necessary, you can reschedule your transmission appointment by contacting your doctor's office. For more information about remote monitoring, see "Remote monitoring" on page 91.
- Tell any new doctor, dentist, or other health professional that you have a pacemaker.

Planning for an emergency

Because you have a pacemaker, it is important to be prepared in case of any emergency. Talk to your doctor or nurse about planning for

emergencies. They may suggest that you develop a plan with your family and friends that includes the following points:

- Carry your pacemaker ID card in an easy-to-find place such as a wallet.
- Carry a list of medications and dosages.
- Keep emergency phone numbers in an easy-to-find place.
- Inform significant coworkers, traveling companions, and so on, that you have a pacemaker.
- When traveling by air, inform airline security personnel that you have a pacemaker.

You may also want to post information that you want to have readily available near your phone.

What your family and friends should know

Your family and friends can be a big support for you during your hospital stay and after you get home. Encourage them to learn about your pacemaker and about how they can continue to support you.

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If your family or caregivers have any questions or concerns, have them call your doctor or nurse.

Some friends and family members may want to receive training in **cardiopulmonary resuscitation** (CPR). They may also want to attend support group meetings with you.

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9 Frequently asked questions

New patients often have the same initial concerns about their pacemakers. Here are some of the questions new patients frequently ask.

? Why do I need this pacemaker?

A pacemaker is an implanted medical device that stimulates the heart muscle with timed pulses of electricity (called **pacing therapy**, or simply "therapy"). These very small amounts of electricity cause the heart to contract, mimicking a naturally occurring heart rhythm.

The most common medical condition needing a pacemaker is called "bradycardia," meaning an abnormally low **heart rate** that is less than 60 beats per minute during normal daily living activities. People who have low heart rates that cause symptoms often need a

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pacemaker. A pacemaker stimulates or increases the heart rate to a level that meets the demands of everyday living.

Needing a pacemaker is very common. Since the late 1950s when pacemakers were first successfully placed inside a body, millions of people have been helped by this remarkable invention.

Although this pacemaker does not prevent or cure your underlying heart rhythm condition, it should improve your quality of life and help you get back to doing things that you haven't been able to do for a while.

Heart medications and surgical procedures may be prescribed instead of, or in addition to, a pacemaker. Based on your individual health condition, your doctor has determined that the treatment provided by a pacemaker may help to improve your symptoms.

Although your pacemaker is not a cure, it does help to protect you from heart rhythms that can weaken or even endanger your health. Many patients say that this pacemaker gives them and their families a sense of security. See "Caring for yourself" on page 97 for guidance on dealing with anxiety and other concerns.

? Is it safe for me to have an MRI scan?

A magnetic resonance imaging (MRI) scan is a type of medical imaging that uses magnetic fields to create an internal view of the body, which doctors use for diagnostic purposes. You can undergo an MRI scan as long as you meet the patient eligibility requirements that Medtronic provides to your heart doctor. For example, your pacing system must consist only of a Medtronic SureScan model pacemaker and SureScan compatible leads. Your pacemaker ID card specifies your implanted device and lead models.

Unlike previous generations of pacemakers, your SureScan pacemaker was designed, tested and approved to be used safely with MRI scanners. The electromagnetic fields present during MRI scans have the potential to cause hazardous effects on pacemakers, which can result in cardiac tissue heating, inappropriate pacing, and dangerous arrhythmias. Due to the unique design of the SureScan pacing system, these risks are reduced to a very low level so that under specified conditions, patients may safely undergo MRI scans.

Prior to receiving an MRI scan, your doctor will verify that you meet the patient eligibility requirements, verify that your SureScan pacing system is functioning properly, and ensure that the SureScan feature is programmed to "On".

During the MRI procedure, you are monitored continuously to ensure your safety.

If you have questions about your eligibility to receive an MRI scan, contact Medtronic Patient Services at 1-800-551-5544. If any of your doctors have questions, they should contact a Medtronic representative or Medtronic Technical Services.

? Will I be able to drive?

Whether you will be able to drive or not depends on your individual heart condition. Many people with a pacemaker are able to resume driving if their doctor approves and if allowed by the laws and insurance regulations in their state. For more information, see "Driving a car" on page 52. If you have concerns, talk with your doctor.

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Will I be able to travel?

Most people who have a pacemaker can travel without taking special precautions if they follow their doctor's instructions.

Wherever you travel, your pacemaker will monitor your heart and provide therapy whenever it is needed. You can travel knowing that resources for your pacemaker are available in 120 countries (see the back cover of this manual for information on contacting Medtronic headquarters located worldwide).

It is unlikely that your pacemaker will trigger the security gates at airports or other secure buildings. If it does, present your pacemaker ID card. If a handheld screening wand is used, ask the security operator not to hold it over your pacemaker and not to wave the wand back and forth over your pacemaker. See "EMC and security systems" on page 75 for more information.

A multilanguage pacemaker travel card is available that provides instructions in several languages for safe security scanning; the card is especially useful for international travel. See page 87 for more

information about the multilanguage pacemaker travel card. Contact Medtronic Patient Registration Services at 1-800-551-5544 if you would like to request a multilanguage pacemaker travel card.

If you have any other travel-related questions, contact Medtronic Patient Services or consult the Medtronic travel website at www.medtronic.com/traveling.

Can I walk through antitheft systems found in public places?

Yes, simply walk through the antitheft system at a normal pace. Under some circumstances, the systems located in stores, libraries, and other places may temporarily interfere with your pacemaker if you stop or linger near this equipment. The interference stops when you move away from the equipment.

Can I use a mobile phone?

Yes, you can use mobile phones (including cellular phones and other wireless phones). However, mobile phones may cause electrical interference with your pacemaker when the phone is turned on and

held too close to your pacemaker. Any effect is temporary, and simply moving the phone away will return the pacemaker to its previous state of operation.

To avoid any possible interference between mobile phones and your pacemaker, keep all mobile phones at least 6 inches (15 centimeters) away from your pacemaker. When using a mobile phone, hold it to the ear that is farthest away from your pacemaker. Also, do not carry a mobile phone close to your pacemaker, such as in a shirt pocket (or in a pants pocket if your pacemaker is implanted in your abdomen). For more information about using mobile phones and other wireless communication devices, see "General rules for safe use of electrical items" on page 56.

Can I use a microwave oven and other electrical items?

Yes, you can use a microwave oven as well as major appliances, electric blankets, and heating pads. See "Living life with your pacemaker" on page 49 for information about electrical items and any restrictions or cautions you should know about.

? Will my pacemaker need to be replaced?

Yes. Because your pacemaker operates using a battery sealed inside the pacemaker, the entire pacemaker will need to be replaced when battery power falls to a low level. The average pacemaker battery lasts 7 to 12 years. How long your battery lasts depends on several factors. Some of these factors include the type of pacemaker you have and the nature of your heart condition.

The battery power is checked at each pacemaker follow-up appointment. Your doctor or nurse will let you know when you need to have your pacemaker replaced.

? How often will my doctor need to check my pacemaker?

When you go home after your implant surgery, your doctor will periodically check your pacemaker. These follow-up appointments can be performed at your clinic, or if your doctor instructs you to use remote monitoring, you can send your pacemaker information directly to your doctor or clinic over your home telephone line. For

more information about follow-up services, see "Follow-up care" on page 89.

? How do I know if my pacemaker battery is still working?

The strength of your pacemaker battery is checked during your follow-up appointments, either in the clinic or through your monitor. Because the battery is sealed inside your pacemaker and cannot be recharged, your pacemaker will need to be replaced when the battery power is low. For more information about pacemaker replacement, see "Pacemaker replacement" on page 95.

? Can I have sexual relations?

Most people resume sexual activity, based on their doctor's instructions. You and your partner should be able to enjoy all the benefits of intimacy.

If you have additional questions

If you have questions that are not covered in this manual or you want more information about your pacemaker, contact:

Medtronic Patient Services
Monday through Friday, 7:00 AM to 6:00 PM (Central Time)
1-800-551-5544
www.medtronic.com/rhythms

If you have questions about your Medtronic pacemaker ID card or to update your address or other contact information, contact:

Medtronic Patient Registration Services
Monday through Friday, 7:00 AM to 7:00 PM (Central Time)
1-800-551-5544
www.medtronic.com/idcard

Medtronic Warranty

For complete warranty information, call Medtronic Patient Services at 1-800-551-5544. Our staff is available Monday through Friday from 7:00 AM to 6:00 PM (Central Time).

Glossary

The words that appear in this section are found in **bold** throughout this manual. It may be helpful to familiarize yourself with them.

antitachycardia pacing (ATP) – Small, rapid pacing pulses delivered by a pacemaker to treat an abnormally fast heart beat.

atrioventricular node (AV node) – An area of cardiac muscle fibers located in the middle of the heart. Electrical signals from the sinoatrial (SA) node travel through the AV node before moving to the rest of the heart. The AV node helps keep the upper and lower heart chambers beating in a balanced rhythm.

atrium (plural = atria) – The two upper chambers of the heart are referred to as the right atrium and the left atrium. The term "atria" is the plural of "atrium," and refers to both the right and the left atrium.

autonomic nervous system – The autonomic nervous system regulates internal body processes that require no conscious effort, such as heart rate and blood pressure. This system is made up of the sympathetic and parasympathetic systems. These systems work together; for example, the sympathetic division increases pulse, blood pressure, and breathing rates, and the parasympathetic system decreases each of them.

AV node – See **atrioventricular node.**

bradycardia – A type of heart condition in which the heart beats less than 60 beats a minute.

cardiopulmonary resuscitation (CPR) – A life saving procedure that includes the timed external compression of the chest wall (to stimulate blood flow), alternating with mouth-to-mouth breathing to provide oxygen.

cardioversion – A therapy provided by an implanted defibrillator to treat an extremely fast but regular heart rate. Cardioversion therapy

catheter microwave ablation – A surgical technique where microwaves are used to destroy cells by creating heat.

computerized axial tomography (CT or CAT) scan – A computerized process in which two-dimensional x-ray images are used to create a three-dimensional x-ray image.

diagnostic ultrasound – An imaging technique used to visualize muscles and internal organs, their size, structures, and any pathological lesions.

diathermy treatment – A treatment involving the heating of various areas of the body.

dual chamber pacemaker – A type of pacemaker that typically requires two pacing leads to provide pacing therapy to two chambers of the heart. One lead is placed in the right atrium. The other lead is placed in the right ventricle.

dual chamber pacing – A type of therapy in which both atrial and ventricular activity in the heart (natural heartbeats) are sensed by the pacemaker. When this sensing (or monitoring) determines that pacing therapy is needed, the implanted pacemaker delivers an electrical pulse into the atrium (an "atrial pace"), which is followed closely by an electrical pulse to the ventricle (a "ventricular pace"). The timing of the paces mimics the heart's natural activity.

ECG or EKG – ECG (EKG) is an abbreviation for "electrocardiogram." An electrocardiogram is a test that measures the electrical activity of a person's heart.

electrocardiogram – See **ECG.**

electrocautery – A process in which an electric probe is used to remove unwanted tissue and to control bleeding.

electrolysis – The permanent removal of hair using an electrified needle inserted into the hair follicle.

electromagnetic compatibility (EMC) – Fields of energy around certain types of equipment that use electricity and magnets may interfere with the normal operation of other electronic devices, such as an implanted pacemaker. These energy fields created around electrical items can be strong or weak. The closer to the item you are, the stronger the energy field. Electromagnetic compatibility means that the electrical energy field generated by an electrical item is compatible with other electrically sensitive items such as an implanted pacemaker.

electromagnetic energy field – A force that certain types of equipment that use electricity and magnets exert on objects in their vicinity.

EMC – See **electromagnetic compatibility.**

endocardial lead – A pacing lead threaded through a vein and placed inside the heart. Also called a transvenous lead. See also **lead.**

epicardial lead – A pacing lead attached to the outside surface (epicardium) of the heart. May also be called a myocardial lead. See also **lead.**

external defibrillator – Emergency personnel use either manual external defibrillator equipment or a handheld automated external defibrillator (AED) to deliver defibrillation therapy shocks to treat.

external defibrillation – Use of an **external defibrillator.**

heart attack (myocardial infarction) – When some of the heart's blood supply is reduced or cut off, causing the heart muscle (myocardium) to die because it is deprived of its oxygen supply.

heart block – A type of heart problem where the electrical impulses traveling from the upper chambers to the lower chambers of the heart are slowed (first degree heart block), irregular (second degree heart block), or blocked (third degree heart block).

heart device – An active, implantable, medical device that treats abnormal heart rhythms (arrhythmias). Types of arrhythmias that can be treated include bradycardia, when the heart beats too slowly, or tachycardia, when the heart beats too fast. See also **arrhythmia** and **pacemaker.**

heart rate – The number of contractions of the cardiac ventricles per unit of time (such as beats per minute).

high-energy radiation therapy – A cancer treatment that uses radiation to control cell growth.

hyperbaric oxygen therapy (HBOT) – The medical use of oxygen at a higher than atmospheric pressure.

lead, lead system – A flexible wire surrounded by insulation material (urethane or silicone) that delivers the electrical pulse or therapy to the heart from an implanted pacemaker. A lead also senses the electrical activity of the heart and carries this information back to the pacemaker for every heartbeat. See also **endocardial lead, epicardial lead, transvenous lead.**

lithotripsy – A medical technique that uses electrically produced shock waves to break up kidney and gallbladder stones.

magnetic resonance imaging (MRI) – See **MRI.**

Medtronic CareLink Programmer – A small laptop-style computer used by your doctor, nurse, or trained technician to check your pacemaker settings, retrieve information stored by your pacemaker, and adjust your pacemaker settings if necessary.

MR Conditional – The designation "MR Conditional" means your implanted pacemaker has been shown to pose no known hazards in a specified MR environment with specified conditions of use. If you are being considered for an MRI scan, your heart doctor will have information about the environment and conditions.

MRI (magnetic resonance imaging) – A type of medical imaging that uses magnetic fields to create an internal view of the body.

pacemaker – An implanted medical device that restores your heart rate to a more normal rhythm by stimulating the heart with precisely timed pulses of electricity. These very small amounts of electricity cause the heart to contract (push blood out), mimicking a naturally occurring heart rate.

pacing, pacing therapy – A type of therapy provided by an implanted pacemaker (pacemaker or defibrillator) to treat a slow heart rate. Pacing consists of small electrical pulses delivered to the heart to speed up a person's heart rate.

pacing lead – An insulated wire that connects to a pacemaker, carries the electrical impulse from the pacemaker to the heart, and relays information about the heart's natural activity back to the pacemaker.

radiofrequency ablation – A nonsurgical procedure used with heart patients, in which painless radio waves are used to destroy cells by creating heat, thereby stopping the extra electrical pulses that caused the abnormal heartbeats.

rate-responsive pacemaker – A type of pacemaker with one or more special sensors. These sensors recognize changes in the body, such as movement of the body or respiration rate (breathing) and change the rate of electrical pulses generated by the pacemaker to achieve a faster heart rhythm for that period of time.

rate-responsive pacing – A type of pacing in which the pacing rate varies to meet the body's changing needs.

remote monitoring – See **telephone monitoring.**

reoxygenated – To add oxygen back into the blood cells.

SA node – See **sinoatrial node.**

SA node disease – See **sick sinus syndrome.**

sensing – The ability of a pacemaker to detect an electrically conducted signal produced by the heart. Using a lead system, the pacemaker determines (or senses) whether the heart is beating normally, and if it is not, the pacemaker can deliver the required pacing therapy.

septum – The muscled wall dividing the right and left sides of the heart.

sick sinus syndrome – A problem with the SA node where it does not generate a heart rate that is regular or fast enough for the needs of the body. A pacing lead in the atrium treats this irregular or slow heart rate.

single chamber pacemaker – A type of pacemaker in which one lead is connected to either the right atrium or the right ventricle, depending on the condition being treated.

single chamber pacing – A type of pacing in which only one heart chamber is paced. Most often, the right ventricle is paced.

sinoatrial node (SA node) – The heart's natural pacemaker located in the right atrium. Electrical impulses originate here and travel through the heart, causing it to beat. Also called the sinus node. See also **atrium.**

sudden cardiac arrest (SCA) – Also called "cardiac arrest." Failure of the heart to pump blood through the body. If left untreated, it will lead to death within minutes.

tachyarrhythmia – A fast or irregular heart rhythm, usually more than 100 beats per minute and as many as 400 beats per minute. See also **tachycardia.**

tachycardia – An abnormally fast heart rhythm, usually between 100 to 250 beats per minute. See also **tachyarrhythmia.**

telephone monitoring – A kind of pacemaker follow-up method. An ECG of your heart rhythm is sent to another location using a special telephone transmitter.

therapeutic ultrasound – The use of ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body.

transcutaneous electrical nerve stimulation (TENS) – A pain control technique that uses electrical impulses passed through the skin to stimulate nerves.

transurethral needle ablation (TUNA) – A surgical technique in which precisely focused radio frequency energy is used to destroy prostate tissue.

transvenous lead – A pacing lead threaded through a vein and placed inside the heart. See also **lead.**

ultrasound – A medical imaging technique that uses sound waves to create an internal image of the body.

ventricles – The two lower chambers of the heart. These are called the left and the right ventricle.

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