Medtronic

SureScan® MRI Technology

FOR CHRONIC PAIN

Protected with Surescan®

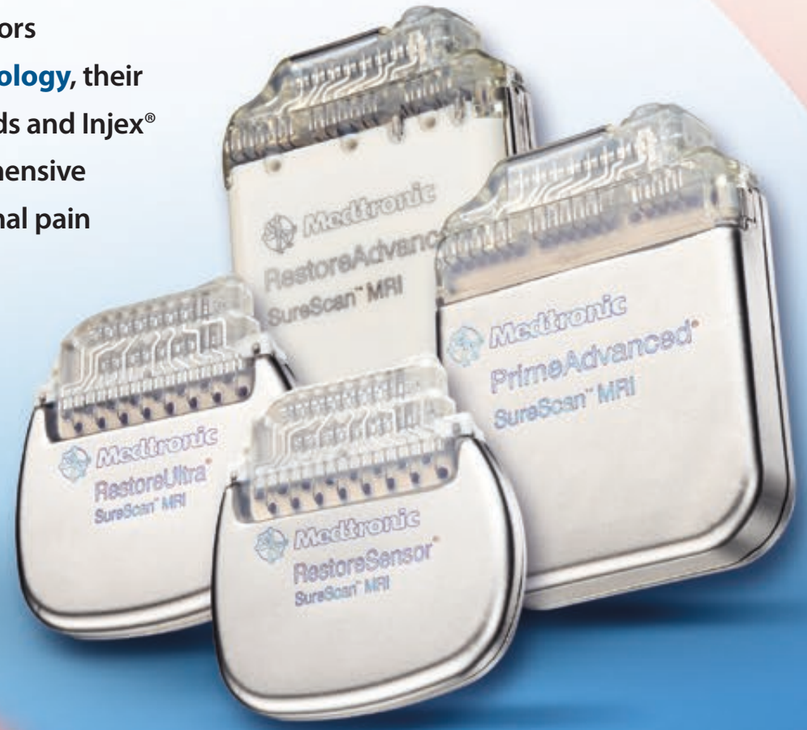
End the guesswork over full-body MRI safety.* With Medtronic SureScan® MRI Technology, be confident that pain stimulation patients can safely receive an MRI scan*

*Under specific conditions and requires SureScan® implantable neurostimulator and Vectris® leads. Refer to approved labeling for full list of conditions.

Innovating for life.

The **First Neurostimulation System** for Full-Body MRI Scans for Pain Patients*

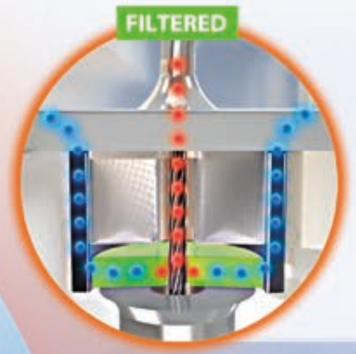
All four pain neurostimulators with SureScan® MRI Technology, their accompanying Vectris® leads and Injex® anchors provide a comprehensive group of 1.5T MR Conditional pain management systems.



Vectris® Lead

Injex® Anchoring System

SureScan® MRI Technology: Protection at the Point of Care



- **Filtered feedthrough technology**
  protects the neurostimulator by preventing radiofrequency (RF) energy from entering the device and damaging internal circuitry and components[1]
- **Shielded Vectris® leads**
  reduce the risk of injury by dispersing RF energy along the entire length of the lead[2]
- **Minimal ferrous material**
  reduces the potential for unwanted movement of the device and leads[1]
- **MRI Mode**
  programming software turns stimulation off prior to an MRI[2,3]

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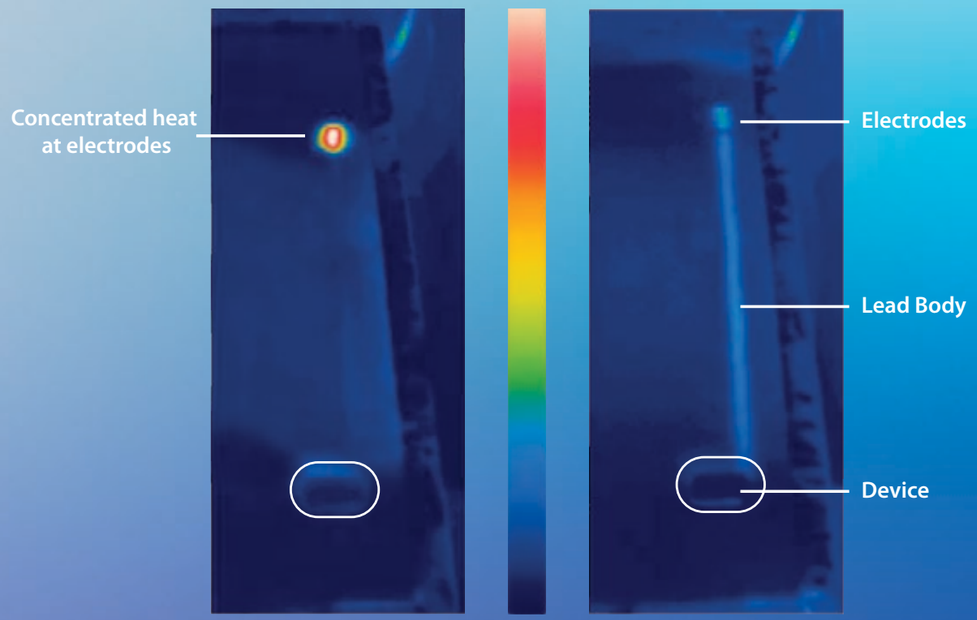
Shielded Vectris® Lead
to Ensure Patient Safety

Shielding dissipates energy along the entire length of the lead

The shielded Vectris® lead

(right) prevents excessive heating of lead electrodes that can occur with a conventional lead (left).[2,3]



Infrared image during 1.5T MRI scan

Conventional system with nonshielded lead

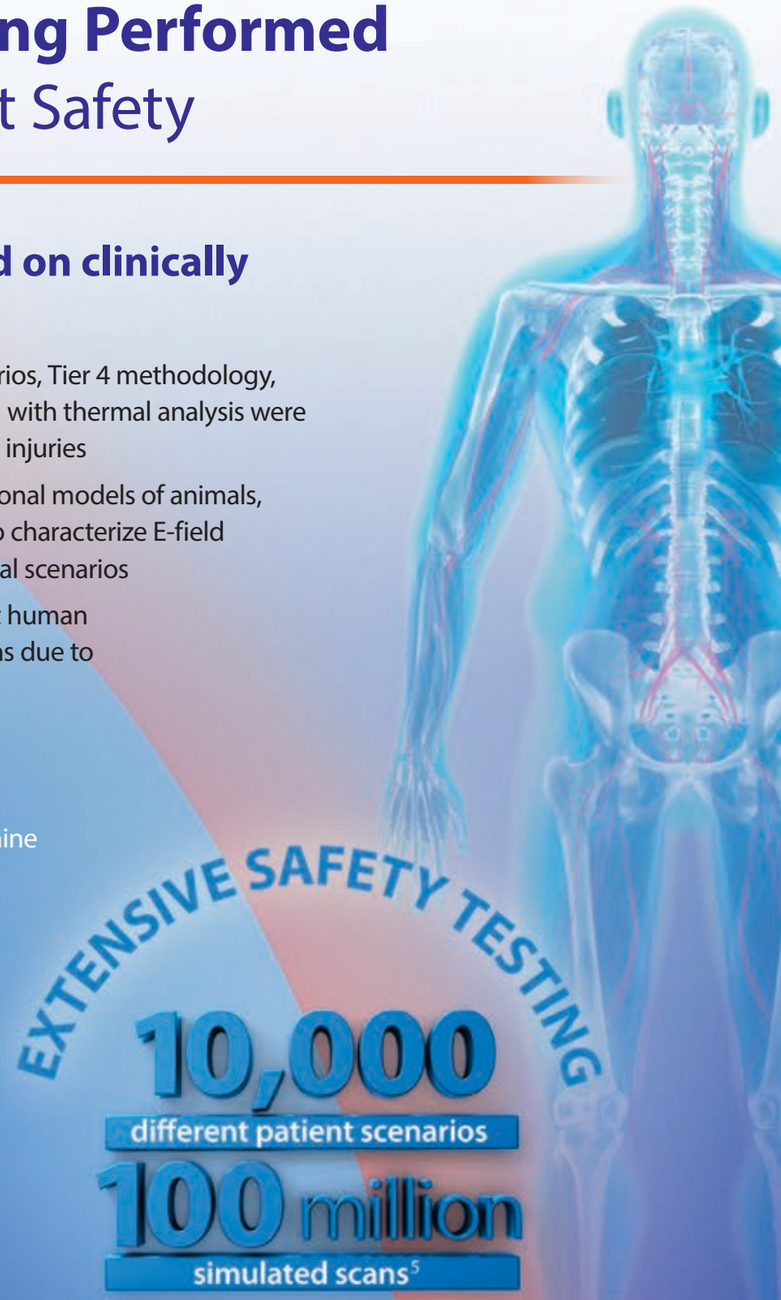
SureScan® MRI System with Vectris® lead

Lead heating is the main concern for patient injury

Extensive Testing Performed
to Ensure Patient Safety

Rigorous criteria based on clinically relevant models[4]

- In millions of clinically relevant scenarios, Tier 4 methodology, as described in ISO/TS10974, coupled with thermal analysis were used to determine expected thermal injuries
- In vivo animal testing and computational models of animals, humans, and phantoms were used to characterize E-field exposures across a full range of clinical scenarios
- Modeling techniques used to predict human temperatures accounted for variations due to
  - Patient size and weight
  - Lead electrode location
  - INS implant location
  - Patient placement in MRI machine
  - RF power level
  - MRI bore size



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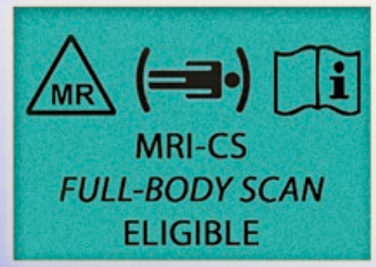
Simplifying MRI Eligibility
With Digital and X-ray Prescreening

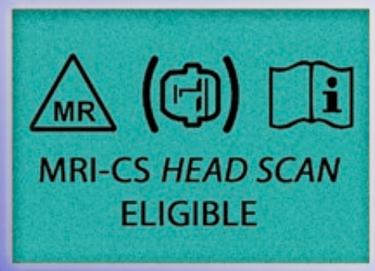
New programmer software reduces uncertainty for greater confidence

The updated MyStim® patient programmer includes screens with three explanatory symbols. The symbols for full-body and head-only scans signify that the criteria for the MRI have been met, and the device is off and ready for scanning.[2,3]



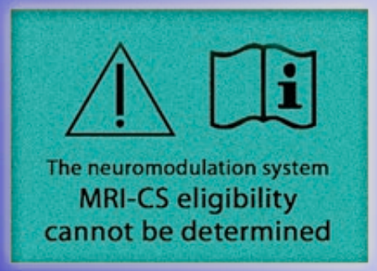
Full-body eligibility*

This patient has:
- A SureScan® device implanted in a tested location
- SureScan® leads with lead tips in tested locations
- No extensions or abandoned leads

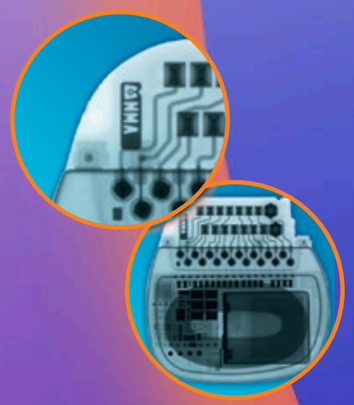


Head-scan-only eligibility*

This patient has:
- A Medtronic neurostimulation system
- Leads that are not in the head or neck (ie, not within the RF head coil)
- No abandoned leads



Undetermined eligibility*
- Review the labeling or contact Medtronic to discuss MRI safety based on the patient's system configuration



Neurostimulators with SureScan® and Vectris® leads are identifiable via X-ray.[3]

*Refer to approved labeling for complete list of conditions.

Medtronic: Expanding MRI Safety†
for Pain Stimulation Patients

A legacy of devices with MR Conditional safe labeling

Head Scan Only

2005
Restore®

2006
RestorePrime®
PrimeAdvanced®
RestoreAdvanced®

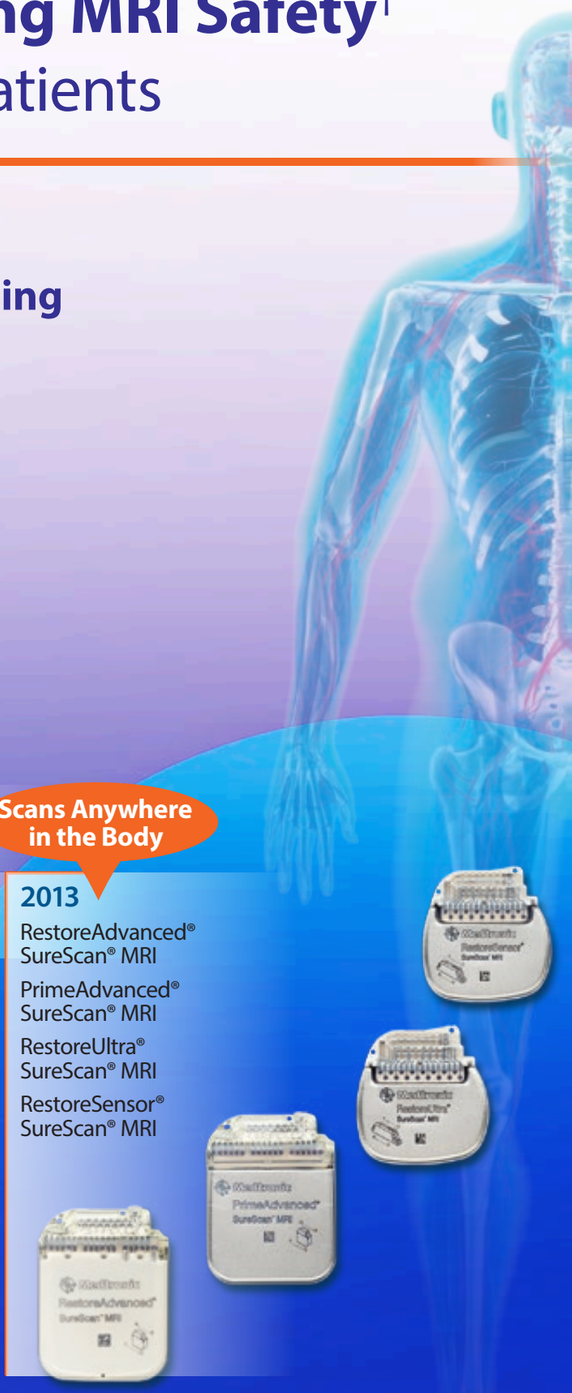
2007
RestoreUltra®

2010
RestoreSensor®

2012
Itrel® 4

Scans Anywhere in the Body

2013
RestoreAdvanced® SureScan® MRI
PrimeAdvanced® SureScan® MRI
RestoreUltra® SureScan® MRI
RestoreSensor® SureScan® MRI



Where to find specific instructions and labeling information

- Visit **mrisurescan.com** for educational tools and training information
- Visit **medtronic.com/mri** for labeling and technical support

†Under specific conditions and requires SureScan® implantable neurostimulator and Vectris® leads. Refer to approved labeling for full list of conditions.

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Now with CE Mark for full-body MRI scans*

Protected With SureScan®

- Shielded leads, filtered feedthrough, and minimal ferrous material reduce the potential for patient injury and device damage during an MRI scan[1,2]
- Extensive safety testing through 10,000 different patient scenarios in 100 million simulated scans[5]
- Simplified digital prescreening validates MRI eligibility and readiness[2,3]

Medtronic provides you with a confident, safe,* and responsible solution for pain stimulation patients who need an MRI scan on any part of the body.

†Under specific conditions and requires SureScan® implantable neurostimulator and Vectris® leads. Refer to approved labeling for full list of conditions.

References: 1. Neuromodulation MRI Standard Letter, Spinal Cord Stimulation Systems, 2011. **2.** Risk Management Report for SureScan (MRI compatible) Implantable Neurostimulation System and 1x8 Vectris Percutaneous Leads. NDHF1173—126742. **3.** MRI Guidelines. **4.** Data compiled from Medtronic, NRP1041-34805, 2012; and ISO, Technical Specification 10974, Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device, 2012. **5.** Medtronic data on file, NRP1041-34805, 2012.

NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY
Brief Summary: Product manuals must be reviewed prior to use for detailed disclosure.
Indication Neurostimulation for Spinal Cord Stimulation (SCS) – Medtronic SCS neurostimulation system is indicated for SCS as an aid in the management of chronic, intractable pain of the trunk and/or limbs, peripheral vascular disease, or intractable angina pectoris. Neurostimulation for Peripheral Nerve Stimulation (PNS) using percutaneous leads - A Medtronic PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the posterior trunk. Neurostimulation for Peripheral Nerve Stimulation (PNS) using surgical leads – A Medtronic PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the trunk and/or limbs. **Contraindications** Diathermy - Do not use shortwave diathermy, microwave or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the locations of the implanted electrodes, resulting in severe injury or death. **Warnings** Sources of strong electromagnetic interference (eg, defibrillation, diathermy, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the neurostimulation system, resulting in serious patient injury or death. These and other sources of EMI can also result in system damage, operational changes to the neurostimulator or unexpected changes in stimulation. Rupture or piercing of the neurostimulator can result in severe burns. An implanted cardiac device (eg, pacemaker, defibrillator) may damage a neurostimulator, and the electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device. Patients treated for intractable angina pectoris should be educated on the signs and symptoms of myocardial infarction and should seek medical attention immediately if signs and symptoms develop. **Precautions** The safety and effectiveness of this therapy has not been established for pediatric use (patients under the age of 18), pregnancy, unborn fetus, or delivery. Patients should be detoxified from narcotics prior to lead placement. Clinicians and patients should follow programming guidelines and precautions provided in product manuals. Patients should avoid activities that may put undue stress on the implanted neurostimulation system components. Patients should not scuba dive below 10 meters of water or enter hyperbaric chambers above 2.0 atmosphere absolute (ATA). Electromagnetic interference, postural changes, and other activities may cause shocking or jolting. Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging. **Adverse Events** Adverse events may include: undesirable change in stimulation described by some patients as uncomfortable, jolting or shocking; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, and surgical risks.

www.medtronic.eu

Europe
Medtronic International Trading Sàrl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
www.medtronic.eu
Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

United Kingdom/Ireland
Medtronic UK Ltd.
Building 9
Croxley Green Business Park, Watford
Hertfordshire WD18 8WW, UK
www.medtronic.co.uk
Tel: +44 (0)1923 212213
Fax: +44 (0)1923 241004

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