Medtronic

RestoreSensor® SureScan® MRI 97714

Rechargeable neurostimulator

Implant manual

! USA Rx only

CE 0123

2013

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

Open here

Do not use if package is damaged

Do not reuse

Do not resterilize

Sterilized using ethylene oxide

Consult instructions for use

Date of manufacture

Manufacturer

Use by

Temperature limitation

Serial number

Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123).

Authorized Representative in the European Community

For USA audiences only

Table of contents

Refer to the indications sheet for indications and related information.

Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.

Refer to the MRI Guidelines for Medtronic Neurostimulation Systems for Chronic Pain instructions for use manual for the MRI conditions and MRI-specific warnings and precautions for conducting an MRI scan.

Refer to the System Eligibility, Battery Longevity, Specifications reference manual for neurostimulator selection, battery longevity calculations and specific neurostimulator specifications.

! USA **Refer to the clinical summary booklet for information on the clinical study results of the neurostimulation system and individualization of treatment.**

Description

The Medtronic RestoreSensor SureScan MRI Model 97714 Neurostimulator is part of a neurostimulation system for pain therapy.

Neurostimulation systems with SureScan MRI Technology

When a Medtronic neurostimulation system with SureScan MRI Technology is implanted as directed (see "Implant criteria for full-body MRI scan eligibility" on page 12), a patient's full body may be eligible for MRI scans under specific conditions, ie, any part of the patient's anatomy can be scanned when specific conditions are met.

For the MRI conditions and MRI-specific warnings and precautions for conducting an MRI scan, refer to the *MRI guidelines for Medtronic neurostimulation systems for chronic pain instructions for use* manual.

Package contents

- Neurostimulator
- Torque wrench
- Product literature
- Warranty card
- Registration form
- Patient identification card

Patient identification card

A patient identification card is packaged with this device. Advise the patient to carry the most up-to-date identification card at all times and to bring the card to all MRI appointments.

! USA The patient identification card packaged with the device is temporary; a permanent card will be mailed to the patient when Medtronic receives the registration form.

The implant registration form registers the device warranties and creates a record of the device in Medtronic's implant data system.

Device specifications

The neurostimulator is a multi-programmable, rechargeable device that delivers stimulation through 1 or more leads. The stimulation settings are stored in programs. A program is a specific combination of pulse width, rate, and amplitude settings acting on a specific electrode combination (up to 16 electrodes per program). Up to 4 programs can be combined into a group. When using more than 1 program, the pulses are delivered sequentially—first a pulse from one program, then a pulse from the next program.

Pulse width, amplitude, and electrode polarity for each program within the group can have different values. Rate, rate limits, ramping, and cycling for each program within the group have the same values.

Table 1. Operating values for the RestoreSensor SureScan MRI Model 97714 neurostimulator

Programmable parameter	Operating range and resolution[a]
Number of defined groups	1 to 8[b]
Number of programs per group	1 to 4[b]
Electrode configuration	2 to 16 electrodes as anode (+), cathode (-), or Off
Amplitude	0 to 10.5 V with 0.05-V or 0.1-V resolution
Amplitude – upper patient limit	Tracking limit: programmed value +0 to +4 V (0.5-V resolution) Custom limit: programmed value up to 10.5 V (same resolution as amplitude)
Amplitude – lower patient limit	Custom limit: 0 V to the programmed value (same resolution as amplitude)
Pulse width	60 to 1000 µs (10-µs resolution)
Pulse width – upper patient limit[c]	Tracking limit: programmed value +0 to +300 µs (60-µs resolution) Custom limit: programmed value up to 1000 µs (10-µs resolution)
Pulse width – lower patient limit[c]	Custom limit: 60 µs to the programmed value (10-µs resolution)
Rate	2 to 1200 Hz (resolution: 1 Hz from 2 Hz to 10 Hz; 5 Hz from 10 Hz to 250 Hz; 10 Hz from 250 Hz to 500 Hz; 20 Hz from 500 Hz to 1000 Hz; 50 Hz from 1000 Hz to 1200 Hz)[d]
Rate – upper patient limit	Tracking limit: programmed value +0, +10, +20, +50, +100 Hz Custom limit: programmed value to 1200 Hz (same resolution as rate)
Rate – lower patient limit	Custom limit: 2 to the programmed value (same resolution as rate)
SoftStart/Stop	Off, On: 1, 2, 4, or 8 second ramp duration

Table 1. Operating values for the RestoreSensor SureScan MRI Model 97714 neurostimulator (continued)

Programmable parameter	Operating range and resolution[a]
Cycling	Off, On: 0.1 s to 30 min (resolution: 0.1 s from 0.1 s to 1 s; 1 s from 1 s to 1 min; 1 min from 1 min to 30 min)
AdaptiveStim	Off, On: 6 positions

[a] Interlocks will prevent the use of some parameter combinations.

[b] No more than 16 programs may be defined within the 8 groups.

[c] Pulse width limit and rate limit are not available for groups with AdaptiveStim enabled.

[d] Rate limited to 600 Hz when 2 programs per group are active, 400 Hz when 3 programs per group are active, and 300 Hz when 4 programs per group are active.

Table 2. Physical characteristics of the RestoreSensor SureScan MRI Model 97714 neurostimulator[a]

Description	Value
Connector type	Octapolar, in-line 2.8-mm (0.110-in) spacing
Height	54.0 mm (2.1 in)
Length	54.0 mm (2.1 in)
Thickness	
case	9.0 mm (0.4 in)
connector	11.0 mm (0.4 in)
Weight	45.0 g (1.6 oz)
Volume	22.0 cm^3 (1.34 in^3)
Battery life	9 years
Power source	Lithium ion rechargeable battery
Temperature limitation	–18 °C to +52 °C (0 °F to +126 °F)
Serial number model designator[b]	NMD
Radiopaque identification (ID) code[c]	NMA

[a] All measurements are approximate.

[b] The serial number is the model designator followed by a number. The clinician programmer displays the entire serial number beginning with the model designator.

[c] The radiopaque ID code is located in the connector block; NMA indicates that the neurostimulator has SureScan MRI Technology. This radiopaque ID code is for confirming, if needed, that a SureScan MRI neurostimulator is implanted and is not to be used for concluding that the entire neurostimulation system is full-body MRI scan eligible.

Table 3. Material of components in the RestoreSensor SureScan MRI Model 97714 package

Components	Material	Material contacts human tissue
Neurostimulator		
Case	Titanium	Yes
Connector block	Polysulfone, silicone rubber, silicone medical adhesive	Yes
Grommets, seals	Silicone rubber	Yes
Setscrews	Titanium alloy	Yes
Adhesive	Silicone medical adhesive	Yes
Torque wrench		
Handle	Polyetherimide	Yes
Shaft	Stainless steel	Yes

Declaration of conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 90/385/EEC on Active Implantable Medical Devices.

For additional information, contact the appropriate Medtronic representative listed on the inside back cover of this manual.

Implanted components and MRI scans

Implant criteria for full-body MRI scan eligibility

Caution: To allow a patient full-body MRI scan eligibility under specific conditions, implant a Medtronic neurostimulation system with SureScan MRI Technology as follows:

- Use only SureScan MRI neurostimulation system components (eg, leads and neurostimulators).

  Note: Extension model numbers in the 3708 series (eg, 37081, 37082, 37083) are not full-body MRI scan eligible.
- Implant the neurostimulator in the buttocks, abdomen, or flank (ie, the lateral and posterior region between the ribs and pelvis).
- Place the lead tip(s) in the spinal epidural space.
- Explant any previously abandoned pain leads or extensions that may be in the patient (ie, leads or extensions, or portions of, that are not connected to a neurostimulator).

  Note: Confirm MRI compatibility of any other implanted medical devices. Other implanted medical devices may limit or restrict MRI scans.
- Enter all component model number and implant location information using the clinician programmer.

If the above implant criteria are not met, the patient will not have a neurostimulation system with full-body MRI scan eligibility. MRI scan eligibility will be restricted.

For the MRI conditions and MRI-specific warnings and precautions for conducting an MRI scan, refer to the *MRI guidelines for Medtronic neurostimulation systems for chronic pain instructions for use* manual.

When changing components

Warning: Before explanting and replacing an existing neurostimulator, print a report from the existing neurostimulator that shows implanted and any abandoned component information. When adding, changing, or removing neurostimulators, leads, extensions, and accessories, always program up-to-date component model numbers, implant locations, and any abandoned component information to re-establish MRI-scan eligibility.

If this information is not updated or is entered incorrectly, MRI scan-type eligibility data will be inaccurate, and the patient is at risk for one of the following:

- The patient is allowed to have an MRI scan inappropriate for the implanted components, which could cause tissue heating, resulting in tissue damage or serious patient injury.
- The patient is unnecessarily restricted from having an MRI scan.

When explanting components

Caution: If permanently explanting a neurostimulator, be sure to also explant all leads, extensions, and accessories. Abandoned components may prevent the patient from being allowed MRI scans in the future due to concerns of lead electrode heating that can result in tissue damage.

Instructions for use

Implanting physicians should be experienced in epidural-access procedures and should be thoroughly familiar with all product labeling.

Warning: DO NOT use the recharger on an unhealed wound. The recharging system is not sterile, and contact with the wound can cause an infection.

Caution: Advise patients to charge the neurostimulator when a **Low battery** () screen is displayed on the patient programmer or recharger; this prevents the battery from overdischarging. If the neurostimulator battery is allowed to overdischarge, the patient cannot charge the neurostimulator; however, the clinician may be able to restore the battery function using the Physician Recharge Mode on the recharger (refer to the troubleshooting section of the software manual).

Allowing the neurostimulator battery to overdischarge will permanently affect the neurostimulator in one of the following ways:

- Battery function is restored; however, charging sessions may be more frequent because battery capacity has been reduced.
- Battery function is not restored and the neurostimulator must be surgically replaced. Battery function is not restored when:
  - the neurostimulator battery is permanently damaged.
  - the neurostimulator battery has been overdischarged and restored twice before. The third time the battery is overdischarged, the neurostimulator will reach end of service. Surgery is required to replace the neurostimulator.

Cautions:

- When using sharp instruments near the neurostimulator, be extremely careful to avoid nicking or damaging the case, the insulation, or the connector block. Damaging the neurostimulator may require surgical replacement.
- Do not use saline or other ionic fluids at connections, which could result in a short circuit.

Charging the neurostimulator battery

Charge the neurostimulator battery before opening the package. For charging instructions, refer to the charging system user manual.

Verifying neurostimulator operation

Before opening the sterile neurostimulator package, verify that the neurostimulator is operable by using the clinician programmer to interrogate the neurostimulator and read the neurostimulator battery charge level. (Refer to the software manual for instructions on how to read the battery charge level.)

⚠ **Caution:** Do not implant a neurostimulator if it was dropped onto a hard surface from a height of 30 cm (12 in) or more, because the neurostimulator may be damaged and fail to operate properly.

Note: The neurostimulator pocket may be flushed with an antibiotic solution; do not submerge the neurostimulator in fluid.

Connecting the extension or lead to the neurostimulator

⚠ **Caution:** Before connecting components, wipe off any body fluids and dry all connections. Fluids in the connection may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.

1. Wipe the extension or lead connector pins with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution.
2. Make sure the connector block receptacles are dry and clean.
3. Insert the appropriate extension or lead connector pins into the appropriate neurostimulator socket until they are seated fully within the connector block (Figure 1).

   Notes:

   - During insertion, some resistance is typical.
   - To retract the setscrews, insert the torque wrench into the self-sealing grommet and rotate the setscrews counterclockwise; however, do not remove the setscrews from the connector block.

     ⚠ **Caution:** Do not insert the extension or lead connector into the connector block if the setscrews are not sufficiently retracted. Unretracted setscrews may damage the extension or lead and prevent the extension or lead from fully seating into the connector block.

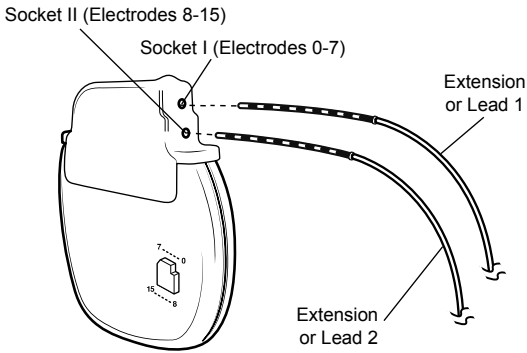

Figure 1. *Insert the extension or lead connector pins fully into the neurostimulator.*

Note: Insert a connector plug (from an accessory kit) into any unused neurostimulator socket.

4. For each extension, lead, or plug, fully insert the torque wrench into each self-sealing grommet of the connector block and tighten each setscrew (Figure 2).

   Cautions:

   - Be sure the torque wrench is fully inserted into the self-sealing grommet. If the torque wrench is not fully inserted, the setscrew may be damaged, resulting in intermittent or loss of stimulation.
   - Before tightening setscrews, ensure that the extension or lead connector pins are inserted into the connector block to prevent damaging the lead or extension.
   - Verify that each leaf of the self-sealing grommet is closed after the torque wrench is withdrawn. If fluid leaks through a grommet seal that is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant location, or intermittent stimulation, or loss of stimulation.

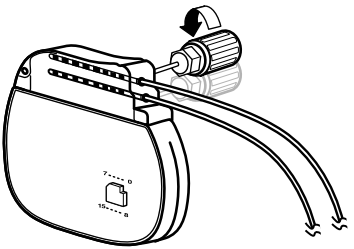

Figure 2. *Tightening the setscrews in the self-sealing grommet.*

Implanting the neurostimulator

⚠ **Warning**: Do not enclose a neurostimulator with SureScan MRI Technology in a cover, such as those used to mitigate a titanium allergy. A neurostimulator cover may cause significant heating of the lead electrodes during an MRI scan, placing the patient at risk for tissue heating, resulting in tissue damage or serious patient injury.

⚠ **Warning**: Do not tie ligatures directly around the lead body. Ligatures around the lead body can damage the lead body or conductor wires, resulting in a loss of therapy. During an MRI scan, the patient could be at risk of tissue heating, resulting in tissue damage or serious patient injury.

△ **Caution**: To prevent device inversion, do not make the neurostimulator pocket any larger than necessary to fit the neurostimulator and excess lead or extension. Device inversion may result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site, requiring repeat surgery to restore therapy.

Note: For full-body MRI scan eligibility, confirm that the subcutaneous pocket for the neurostimulator has been created in the buttocks, abdomen, or flank. (See the caution in "Implant criteria for full-body MRI scan eligibility" on page 12.)

1. With the Medtronic logo facing outward, away from muscle tissue, rotate the neurostimulator counterclockwise to coil the excess lead or extension (Figure 3).

   △ **Caution**: Do not twist or kink the lead or extension bodies when rotating the neurostimulator and coiling the excess lead or extension. Twisting or kinking of the components creates a torsional load that may increase the risk of unwanted movement or damage to the neurostimulation system components.

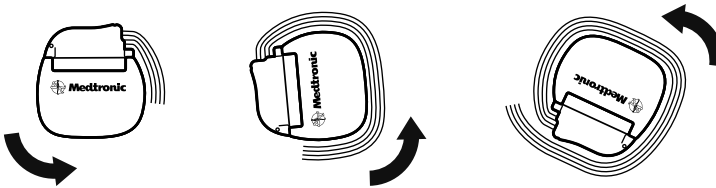

Figure 3. *Rotate counterclockwise to coil excess lead or extension length.*

2. Insert the neurostimulator and excess lead or extension coils into the subcutaneous pocket with the Medtronic logo facing outward, away from muscle tissue. Ensure that the leads or extensions are not twisted or bent sharply.

Cautions:

- Ensure that the neurostimulator is placed no deeper than 1 cm (0.4 in) below the skin and is parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, recharge may be inefficient or unsuccessful.
- Position the neurostimulator with the Medtronic logo facing outward. If implanted with the Medtronic logo facing inward, the neurostimulator will be difficult to charge.
- Do not coil excess extensions or leads in front of the neurostimulator. Wrap excess extensions or leads around the perimeter (Figure 4) or behind the neurostimulator to help minimize potential damage during neurostimulator replacement surgery, help minimize potential kinking of the extension or lead, and minimize interference with telemetry and recharge operation.

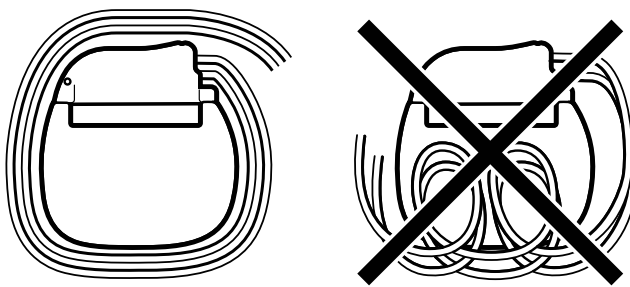

Figure 4. *Wrap excess extensions or leads around the perimeter (or behind) the neurostimulator.*

3. Use the suture holes in the connector block to secure the neurostimulator to the muscle fascia with nonabsorbable silk.

   Notes:

   - Secure the neurostimulator in the pocket to minimize movement or migration of the neurostimulator.
   - Suturing the neurostimulator also may prevent movement of the neurostimulator from torque and other forces during an MRI scan.

Checking system integrity

⚠ **Caution:** To use the nonsterile clinician programmer in a sterile field, place a sterile barrier between the patient and the programming head to prevent infection. Do not sterilize any part of the clinician programmer. Sterilization may damage the programmer.

Note: The neurostimulator should be in the pocket during system interrogation for integrity to ensure proper readings.

1. To ensure proper connection of each extension or lead to the neurostimulator, use the clinician programmer to program the basic stimulation parameters, check the battery status, and check the electrode impedances to rule out a short or open circuit.
2. If the system integrity test results are not acceptable, refer to "Connecting the extension or lead to the neurostimulator" on page 14.
3. Complete the stimulation assessment form.

Completing the implant procedure

1. Close and dress all incisions.
2. Ensure that a patient control device and a completed patient identification card are given to the patient.
3. Complete the device tracking and patient registration paperwork and return the documents to Medtronic.

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