Medtronic

Intellis™ 97715

Rechargeable neurostimulator

Implant manual

! USA Rx only

CE 0123 2012

M946871A001

2012-06

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.

Warning

Consult instructions for use

Do not reuse

Do not resterilize

Date of manufacture

Manufacturer

Open here

Use by

Serial number

Sterilized using ethylene oxide

Authorized Representative in the European Community

For USA audiences only

Temperature limitation

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 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 Intellis Model 97715 Neurostimulator is part of a neurostimulation system for pain therapy.

Package contents

- Neurostimulator
- Torque wrench
- Pocket sizer
- Bore plugs (2)
- Product literature
- Registration form
- Patient identification card
- Warranty card

Patient identification card

A patient identification card is packaged with this device. Advise the patient to carry the identification card at all times.

! 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 to target pain areas. A program is a specific combination of pulse width, rate, and intensity settings acting on a specific electrode combination (up to 16 electrodes per program). Up to 4 pain areas can be targeted by programs. When stimulating more than one pain area, the pulses are delivered sequentially—first a pulse from one program, then a pulse from the next program.

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

Table 1. Operating values for the Intellis Model 97715 Neurostimulator

Programmable parameter	Operating values and ranges[a]
Number of defined groups	1-3 (optional)
Number of programs per pain area	1-3
Number of programs	12
Number of pain areas	1-4
Electrode configuration	2-16 electrodes as anode, cathode, or Off
Maximum intensity per electrode	0-25.5 mA (0.1 mA increment)
Program intensity	0-100 mA
Intensity – limits	Enabled or disabled at maximum of 25.5 mA per electrode
Pulse width	60-1000 µs (10-µs increment)
Pulse width – limits[b]	Enabled or disabled at maximum of 1000 Hz
Master rate[a]	10-1200 Hz (increment: 1 Hz from 10-30 Hz, 5 Hz from 30-250 Hz, 10 Hz from 250-500 Hz, 20 Hz from 500-1000 Hz, 50 Hz from 1000-1200 Hz)
Rate ratio	A fraction of the master rate (1/1, 1/2, 1/3, 1/4, 1/5)
Rate limits	Enabled or disabled (at maximum of 1200)[a]
SoftStart/Stop	Off, On: 1, 2, 4, or 8 second ramp duration
Cycling[c]	Off, On: 0.1 s-30 min (resolution: 0.1 s from 0.1-1 s, 1 s from 1 s-1 min, 1 min from 1-30 min)
AdaptiveStim	Off, On: 7 positions

[a] Rate availability depends on how many pain areas are defined. For example, the maximum rate available in one defined pain area is 1200 Hz. The maximum rate available if two pain areas are defined is 600 Hz in each of those two pain areas.

[b] Pulse width limits are not available when AdaptiveStim is enabled.

[c] Cycling is not available for pain areas with AdaptiveStim enabled.

Table 2. Physical characteristics of the Intellis Model 97715 Neurostimulator[a]

Description	Value
Connector type	Octapolar, in-line 2.8-mm (0.110-in) spacing
Height	57.0 mm (2.1 in)
Width	47.3 mm (1.9 in)
Thickness	
case	6.3 mm (0.2 in)
connector	8.9 mm (0.4 in)
Weight	29.9 g (1.1 oz)
Volume	13.7 cm^3
Battery life	9 years before ERI
Power source	Lithium ion rechargeable battery
Storage temperature	–18 °C to +52 °C (0 °F to +126 °F)
Serial number model designator[b]	NME
Radiopaque identification (ID) code	NME

[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.

Table 3. Material of components in the Intellis Model 97715 package

Components	Material	Material contacts human tissue
Neurostimulator		
Case	Titanium	Yes
Connector block	Titanium, polysulfone, silicone rubber, silicone medical adhesive	Yes
Grommets, seals	Silicone rubber	Yes
Setscrews	Titanium alloy	Yes
Adhesive	Silicone medical adhesive	Yes
Pocket sizer	Polypropylene	Yes
Bore plug	Silicone rubber; stainless steel	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 1999/5/EC on Radio and Telecommunications Terminal Equipment and 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.

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:** If the neurostimulator is not being used for an extended period of time, recommend that your patient charge the neurostimulator at least once per year. If the battery is discharged, stimulation will stop and the neurostimulator may not communicate with the controller.

⚠ **Caution:** Advise patients to charge the neurostimulator when a low battery message is displayed on the controller in order to maintain uninterrupted therapy from the neurostimulator. If the battery is discharged, stimulation will stop and the neurostimulator may not communicate with the controller.

Note: The patient will be able to use the controller and recharger to charge a discharged battery without causing damage to the battery or 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

Check the battery level of the neurostimulator before opening the package, and recharge the neurostimulator if the battery is low. For charging instructions, refer to the recharging system user manual. If the patient will be sent home with stimulation on, charge the neurostimulator in the package before implant.

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 programming guide 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. If the setscrews are not retracted, the setscrews may damage the extension or lead and the extension or lead will not be seated fully into the connector block.

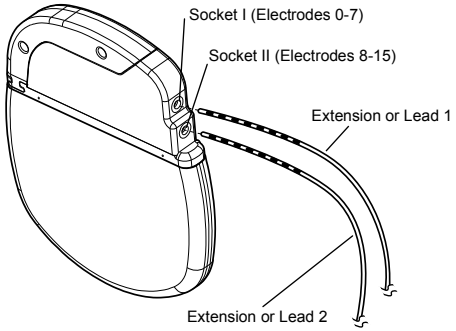

Figure 1. *Insert the extension or lead connector pins fully into the neurostimulator.*

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 (packaged with the rechargeable neurostimulation system) 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.

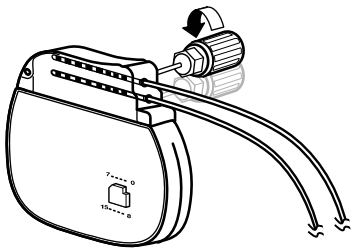

Figure 2. *Tightening the setscrews in the self-sealing grommet.*

Implanting the neurostimulator

1. Place the neurostimulator into the subcutaneous pocket using the pocket sizer if desired and ensure that the extension or lead is not bent sharply. The neurostimulator can be implanted and charged with either side facing outward. for optimal recharging, place the neurostimulator within 1-2 cm (0.8 in.) of the skin surface.

   Cautions:

   - Ensure that the neurostimulator is placed no deeper than 3 cm (1.2 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.

- Do not coil excess extension in front of the neurostimulator. Wrap excess extension or leads around the perimeter (Figure 3) 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.

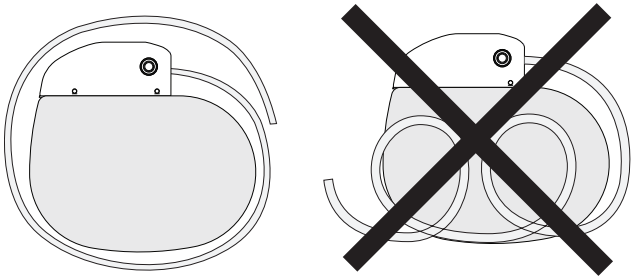

Figure 3. *Wrap excess extension around the perimeter of the neurostimulator.*

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

   Note: Secure the neurostimulator in the pocket to minimize movement or migration of the neurostimulator.

Checking system integrity

The connections of the extensions and leads to the neurostimulator can be checked using the clinician programmer. Refer to the programming guide for detailed programming instructions.

⚠ **Warning:** To use the nonsterile programmer system components in a sterile field, place a sterile barrier between the patient and system components to prevent infection. Do not sterilize any components of the programmer system. Sterilization may damage the components.

1. To ensure proper connection of each extension or lead to the neurostimulator, use the clinician programmer to perform the lead insertion check.
2. If the lead insertion check results are not acceptable, refer to "Connecting the extension or lead to the neurostimulator".

Completing the implant procedure

1. Close and dress all incisions.
2. Turn off stimulation before sending your patient home.
3. Ensure that a patient control device is given to the patient.

4. Complete the device tracking and patient registration paperwork and return the documents to Medtronic.

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Alleviating Pain · Restoring Health · Extending Life

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