



Medtronic

Itrel 4

37703

Programmable neurostimulator

Implant manual

USA Rx only



2012

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.



Open here



Do not reuse



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) and R&TTE Directive 1999/5/EC.



Authorized Representative in the European Community



For USA audiences only

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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.**

Description

The Medtronic Itriel 4 Model 37703 Neurostimulator is part of a neurostimulation system for pain therapy.

Package contents

- Neurostimulator
- Torque wrench
- Product literature
- [USA] 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 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 programmable device that delivers stimulation through 1 lead. The stimulation settings are stored as a program. A program is a specific combination of pulse width, rate, and amplitude settings acting on a specific electrode combination (up to 4 electrodes).

Table 1. Operating values for the Itrel 4 Model 37703 neurostimulator

Programmable parameter	Operating range and resolution^a
Number of programs	1
Electrode configuration	1 to 4 electrodes as anode (+), cathode (-), or Off; case as anode 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 +4.0 V (0.5 V resolution) Custom limit: Programmed value 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 450 μ s (10 μ s resolution)
Pulse width – upper patient limit	Tracking limit: Programmed value +0 to +150 μ s (30 μ s resolution) Custom limit: Programmed value to 450 μ s (10 μ s resolution)
Pulse width – lower patient limit	Custom limit: 60 μ s to the programmed value (10 μ s resolution)
Rate	2 to 130 Hz (resolution: 1 Hz from 2 Hz to 10 Hz, 5 Hz from 10 Hz to 130 Hz)
Rate – upper patient limit	Tracking limit: Programmed value +0 to +50 Hz (10 Hz resolution) Custom limit: Programmed value to 130 Hz (same resolution as rate)
Rate – lower patient limit	Custom limit: 2 Hz to the programmed value (same resolution as rate)
SoftStart/Stop	Off, On: 1-, 2-, 4-, or 8-second ramp duration
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)

^a Interlocks will prevent the use of some parameter combinations.

Table 2. Physical characteristics of the Itrel 4 Model 37703 neurostimulator^a

Description	Value
Connector type	Quadrapolar, two bore ^b
Height	55 mm (2.2 in)
Length	60 mm (2.4 in)
Thickness	11 mm (0.4 in)
Weight	45 g (1.6 oz)
Volume	28 cm ³
Power source	4.5 Amp hours, 3.2 V HCSVO ^c cell
Temperature limitation	-18 °C to +52 °C (0 °F to +126 °F)
Serial number model designator ^d	NMX
Radiopaque identification (ID) code	NMX

^a All measurements are approximate.

^b Compatible with two-pronged extension.

^c Hybrid combined silver vanadium oxide.

^d 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 Itrel 4 Model 37703 package

Components	Material	Material contacts human tissue
Neurostimulator		
Case	Titanium, parylene	Yes
Connector block	Polyurethane, 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 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, as well as thoroughly familiar with all product labeling.



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.

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 service life. (Refer to the software manual for instructions on how to read the battery service life.)



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 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 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 connector pins into the appropriate neurostimulator socket until they are seated fully within the connector block (Figure 1). If resistance is felt while inserting the connector pins, use the torque wrench (packaged with the neurostimulator) to retract the setscrews.

Note: 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.



Cautions:

- Do not insert the extension connector into the connector block if the setscrews are not sufficiently retracted. If the setscrews are not retracted, the extension

connector pins may damage the setscrews and the extension connector pins will not be seated fully into the connector block.

- Limit counter-clockwise rotations of the neurostimulator setscrews when retracting them. Too many counter-clockwise rotations may disengage the setscrew from the connector block.

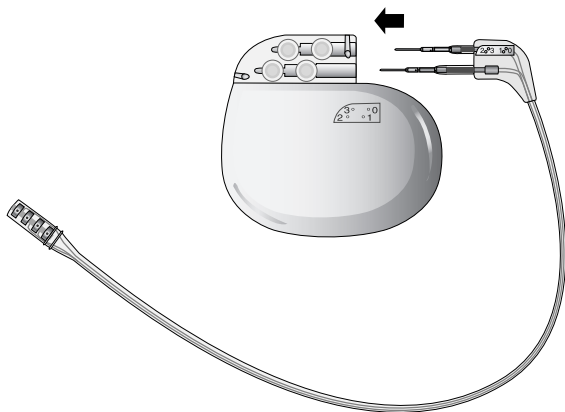


Figure 1. Insert the extension connector pins fully into the neurostimulator.

4. Fully insert the torque wrench into each self-sealing grommet of the connector block and tighten each setscrew (Figure 2).

Note: The torque wrench must be oriented to the same angle as the 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 the setscrews, ensure that the extension connector pins are inserted into the connector block to prevent damaging the connector block.
- 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 may occur.

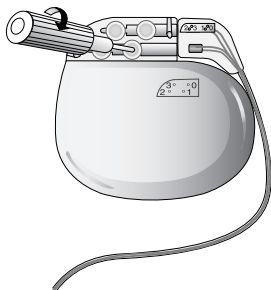


Figure 2. Tightening the setscrews in the self-sealing grommet.

Implanting the neurostimulator

1. Place the neurostimulator into the subcutaneous pocket with the Medtronic logo facing outward, away from muscle tissue, and ensure that the extension is not bent sharply.



Cautions:

- Ensure that the neurostimulator is placed no deeper than 4 cm (1.5 in) below the skin and is parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, telemetry may be unsuccessful.
- Do not coil excess extension in front of the neurostimulator. Wrap excess extension around the perimeter (Figure 3) of the neurostimulator to minimize subcutaneous pocket depth, help minimize potential damage during neurostimulator replacement surgery, help minimize potential kinking of the extension, and minimize interference with telemetry. Excess extension should not exceed two wraps around the perimeter of the neurostimulator. Extension lengths requiring more than two wraps can interfere with telemetry.

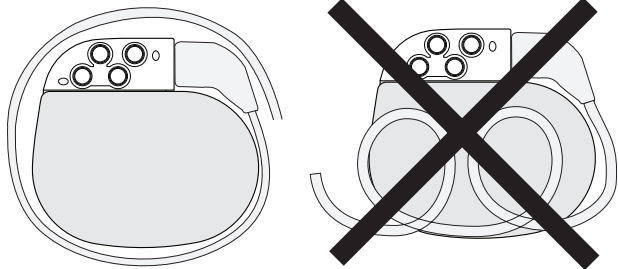


Figure 3. Wrap excess extension around the perimeter of the neurostimulator.

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

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 the extension to the neurostimulator, use the clinician programmer to program the lead configuration and 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 to the neurostimulator" on page 9.

Completing the implant procedure

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

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