Medtronic

# ITREL® 3

7425

Neurostimulator

Implant manual

! USA Rx only

CE 0123

1995

## Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

Open here



Do not reuse


Sterilization: ethylene-oxide gas



Attention: See accompanying documentation.

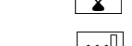
Use by



Manufacturing date


Storage temperature


Serial number




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

The use of this device might be subject to individual country licensing regimes in Europe.




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 System Eligibility, Battery Longevity, Specifications reference manual packaged with the software application card for neurostimulator selection, battery longevity calculations and specific neurostimulator specifications.**

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

## Device description

The Medtronic Model 7425 Itrel 3 Neurostimulator is part of a neurostimulation system for pain therapy.

## Package contents

- Neurostimulator
- Hex wrench
- Product literature
- Warranty card (USA only)
- Registration form
- Patient identification card

## Patient identification card and registration

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 accommodates one extension and delivers one program of stimulation through one or two leads.

A program of stimulation consists of an amplitude, pulse width, and rate delivered to selected electrodes.

*Table 1. Shipping, operating, and power-on-reset (POR) values for the Model 7425 Itrel 3 Neurostimulator[a].*

| Programmable parameter | Shipping | Operating | POR[b] |
|---|---|---|---|
| **Amplitude** | | | |
| **Normal resolution** | 0.0 V | 0.1 V steps | 0.0 V |
| Upper limit | 0.0 V | 10.5 V maximum | 0.0 V |
| Lower limit | 0.0 V | 0.0 V minimum | 0.0 V |
| **Fine resolution** | ----- | 0.05 V steps | ----- |
| Upper limit | ----- | 6.35 V maximum | ----- |
| Lower limit | ----- | 0.0 V minimum | ----- |
| **Rate** | 31 Hz | 49 values (from 2.1 to 130 Hz) | 31 Hz |
| Upper limit | 31 Hz | 130 Hz maximum | 31 Hz |
| Lower limit | 2.1 Hz | 2.1 Hz minimum | 2.1 Hz |
| **Pulse width** | 210 µs | increments of 30 µs | 210 µs |
| Upper limit | 210 µs | 450 µs maximum | 210 µs |
| Lower limit | 60 µs | 60 µs minimum | 60 µs |
| **Operation mode** | Continuous | Continuous or cycling | Continuous |
| **Cycle ON/OFF Time** | | | |
| W/O SoftStart/Stop | 0.1 s | 0.1 s to 24 h | 0.1 s |
| With SoftStart/Stop | ----- | 1 s to 24 h | ----- |
| **SoftStart/Stop** | Off | 1 s, 2 s, 4 s, 8 s, or off | Off |
| **Ramp** | Off | 15, 20, 25, 30 s, or off at start of stimulation | Off |
| **Dose time** | Off | 15, 30, 45, 60, 75 m, or off stimulation periods | Off |
| **Dose lockout time** | 0 h | 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, or 4.0 h | 0 h |
| **Output On/Off[c]** | Off | On or off | Off |
| **Magnet control** | On | On or off | On |

***Table 1. Shipping, operating, and power-on-reset (POR) values for the Model 7425 Itrel 3 Neurostimulator[a]. (continued)***

| Programmable parameter | | Shipping | Operating | POR[b] |
|---|---|---|---|---|
| **Polarity** | **Electrode number** | | | |
| **Program** | 0 | – | OFF, –, or + | – |
| | 1 | OFF | OFF, –, or + | OFF |
| | 2 | OFF | OFF, –, or + | OFF |
| | 3 | + | OFF, –, or + | + |
| | Case | OFF | OFF, or + | OFF |

[a] All measurements are approximate.

[b] Power-on-reset (POR) turns OFF stimulation by resetting the amplitude to 0.0 V and all electrodes to OFF. POR occurs when there is a temporary fluctuation in battery voltage (eg, due to electromagnetic interference during electrocautery or defibrillation) or the battery is depleted. When POR occurs, the serial number is displayed as "????" on the clinician programmer.

[c] Exposure to a strong source of electromagnetic interference (EMI) can cause the output switch to toggle On or Off. However, since the amplitude setting is 0.0 V, there is no neurostimulator output.

*Table 2. Physical characteristics of the Model 7425 Itrel 3 Neurostimulator.*[a]

| Description | Value |
|---|---|
| Height | 55.0 mm (2.2 in) |
| Length | 60.0 mm (2.4 in) |
| Thickness | |
| case | 10.0 mm (0.4 in) |
| connector block | 10.1 mm (0.4 in) |
| Weight | 42.0 g (1.5 oz) |
| Volume | 22.0 $cm^3$ (1.3 $in^3$) |
| Battery | 2.7 Amp hours, 3.7V lithium-thionyl chloride cell |
| Storage temperature | -18° to +52°C<br>-0° to + 125°F |
| Serial Number[b]: | |
| Radiopaque Identification (ID) | NAT |

[a] All measurements are approximate.

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

*Table 3. Material of components in the Model 7425 package.*

| Component | Material | Material contacts human tissue |
|---|---|---|
| Neurostimulator | | |
| Case | Titanium | Yes |
| Connector block | Polyurethane | Yes |
| Grommets, seals | Silicone rubber | Yes |
| Setscrews | Titanium | Yes |
| Insulation coating | Fluoropolymer | Yes |
| Adhesive | Silicone adhesive | Yes |
| Hex wrench | | |
| Handle | Acetal resin | 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.

△ **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, use the clinician programmer to interrogate the neurostimulator and verify neurostimulator battery status and current settings.

**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).

   **Note:** To retract the setscrews, insert the hex 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 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.

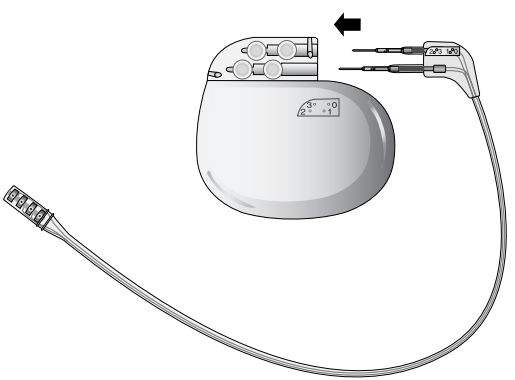


***Figure 1.*** *Insert the extension connector pins fully into the neurostimulator.*

4. Fully insert the hex wrench (packaged with the neurostimulator) into the self-sealing grommet of the connector block and tighten each setscrew.

**Cautions:**

- To avoid undertightening, do not use a torque wrench. Undertightening the neurostimulator setscrews may result in insufficient electrical contact within the connector block, resulting in intermittent or loss of stimulation.
- Be sure the hex wrench is fully inserted into the self-sealing grommet. If the hex wrench is not fully inserted, the setscrew may be damaged, resulting in intermittent or loss of stimulation.
- Before tightening setscrews, ensure that the extension connector pins are inserted into the connector block to prevent damaging the connector block.
- When using the hex wrench, do not overtighten the setscrews. Overtightening may damage the setscrews and prevent setscrew removal.
- Verify that each leaf of the self-sealing grommet is closed after the hex 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.

**Note:** The hex wrench must be oriented to the same angle as the setscrew (Figure 2).

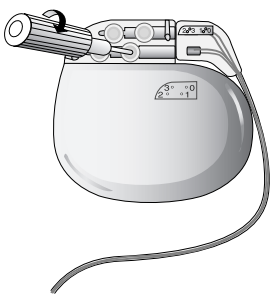


***Figure 2.*** *Tightening the setscrews in the self-sealing grommet.*

## Implanting the neurostimulator

1. Place the neurostimulator into the subcutaneous pocket with the etched identification side placed 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 place the etched identification side of the neurostimulator facing inward. Placing the etched side inward could increase the possibility of skeletomuscular stimulation, which the patient may perceive as twitching or burning.
   - Do not coil excess extension in front of the etched identification side of the neurostimulator. Wrap excess extension around the perimeter of the neurostimulator (Figure 3) to avoid increasing subcutaneous pocket depth, help minimize potential damage during neurostimulator replacement surgery, help minimize potential kinking of the extension, and minimize interference with telemetry during programming.

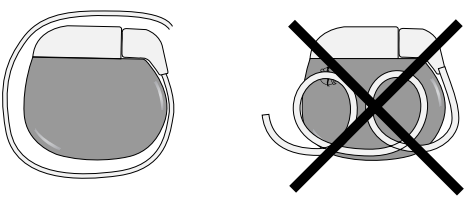


***Figure 3.*** *Wrap excess extension around the perimeter of the neurostimulator.*

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

## Checking system integrity

1. Use the clinician programmer to confirm the integrity of the connected system.

   △ **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.

2. Program the basic stimulation parameters and check the battery status; if applicable, check the electrode impedances to rule out a short or open circuit.
3. Complete the stimulation assessment form.

## 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.

**Contacts:**

**Asia:** Medtronic International Ltd.
Suite 1602 16/F, Manulife Plaza,
The Lee Gardens, 33 Hysan Avenue,
Causeway Bay, Hong Kong
Tel. 852-2891-4068 Fax 852-2591-0313

Medtronic Asia Ltd.
3 Floor Peter Building,
570-6 Shinsa-Dong Kangnam-ku,
Seoul 135-120, South Korea
Tel. 82-2-548-1148 Fax 82-2-518-4786

**Australia:** Medtronic Australasia Pty. Ltd.
Unit 4/446 Victoria Road, Gladesville NSW 2111
Tel. 02-9879-5999 Fax 02-9879-5100

**Austria:** Medtronic Österreich GmbH
Millennium Tower, Handelskai 94-96, 1200 Vienna
Tel. 01-24044 Fax 01-24044-100

**Belgium:** Medtronic Belgium S.A.
Boechoutlaan 55, 1853 Strombeek-Bever
Tel. 02-456-0900 Fax 02-460-2667

**Canada:** Medtronic of Canada Ltd.
6733 Kitimat Road, Mississauga,
Ontario L5N 1W3
Tel. 905-826-6020 Fax 905-826-6620

**Denmark:** Medtronic-ViCare A/S
Birkerød Kongevej 150B, DK-3460 Birkerød
Tel. 45-823366 Fax 45-823365

**Finland:** Medtronic Finland OY/LTD
Sahaajankatu 24, P.O. Box 230,
FIN-00810 Helsinki
Tel. 9-755-2500 Fax 9-755-25018

**France:** Medtronic France S.A.S.
122, avenue du Général Leclerc,
92514 Boulogne-Billancourt Cedex
Tel. 01-5538-1700 Fax 01-5538-1800

**Germany:** Medtronic GmbH
Emanuel-Leutze-Straße 20, 40547 Düsseldorf,
P.O. Box 110738
Tel. 0211-52930 Fax 0211-5293100

**Greece:** Medtronic Hellas S.A.
Agias Varvaras 5, 15231 Halandri, Athens
Tel. +30 2 10-677 90 99 Fax 30 2 10-677 93 99

**Italy:** Medtronic Italia SpA,
P.zza Indro Montanelli 30,
20099 Sesto San Giovanni (MI).
Tel. 02-241371. Fax 02-241381.

Via Lucrezio Caro, 63, 00193 Roma
Tel. 06-328141 Fax 06-3215812

**Japan:** Medtronic Japan
Solid Square West Tower 6F,
580 Horikawa-cho, Saiwai-ku,
Kawasaki, Kanagawa 210-0913
Tel. 044-540-6112 Fax 044-540-6200

**Latin America Headquarters:** Medtronic, Inc.
710 Medtronic Parkway,
Minneapolis, MN 55432-5604
USA
Tel. 763-514-4000 Fax 763-514-4879

**The Netherlands:** Medtronic B.V.
Earl Bakkenstraat 10, P.O. Box 2542,
6401 DA Heerlen
Tel. 045-5668000 Fax 045-5668668

**Norway:** Medtronic Vingmed AS
Fjordveien 1, Postboks 366, 1323 Høvik
Tel. 67 58 06 80 Fax 67 10 12 12

**Portugal:** Medical Implant Portugal, Lda.
Rua Tomás da Fonseca,
Torre E 8, andar A,B, 1600 - 209 Lisboa
Tel. 21-724-5100 Fax 21-724-5199

**Spain:** Medtronic Ibérica, S.A.
Centro Empresarial Miniparc III, Edificio K,
Calle Caléndula, 93, El Soto de la Moraleja,
28109 Alcobendas – Madrid
Tel. 91-625-0400 Fax 91-650-7410

**Sweden:** Medtronic AB
Dackevägen 33, Box 265, S-177 25 Järfälla
Tel. 08-5222-0000 Fax 08-5222-0050

**Switzerland:** Medtronic (Schweiz) AG
Route du Molliau 31
Case Postale 84
CH-1131 Tolochenaz
Tel. 021-803-8000 Fax 021-803-8099

**U.K. and Ireland:** Medtronic U.K. Ltd.
Suite 1, Sherbourne House,
Croxley Business Center, Watford,
Herts WD1 8YE, United Kingdom
Tel. 1923-212213 Fax 1923-241004

**USA:** Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel. 1-763-505-5000
Toll-free: 1-800-328-0810
Fax 1-763-505-1000

**Medtronic**

*When Life Depends on Medical Technology*

**Manufacturer**
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Internet: www.medtronic.com
Tel. 1-763-505-5000
Fax 1-763-505-1000

**Medtronic E.C. Authorized Representative/Distributed by**
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel. 31-45-566-8000
Fax 31-45-566-8668

**Europe/Africa/Middle East Headquarters**
Medtronic Europe Sàrl
Route du Molliau 31
Case Postale
CH-1131 Tolochenaz
Switzerland
Internet: www.medtronic.co.uk
Tel. 41-21-802-7000
Fax 41-21-802-7900

**Asia-Pacific**
Medtronic International Ltd.
Suite 1602 16/F, Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel. 852-2891-4068
Fax 852-2591-0313

Contacts for specific countries are listed inside this cover.



221656001