Intellis™ with AdaptiveStim™ Technology

Intellis™

Rechargeable neurostimulators

Implant manual

Rx only
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
- PIN 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
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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 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.
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Description

The Medtronic Intellis™ with AdaptiveStim™ Technology Model 97715 and Intellis™ Model 97716 Neurostimulators, both with SureScan MRI technology, are 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 14), 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
- Pocket sizer
- Neurostimulator 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 most up-to-date identification card at all times and to bring the card to all MRI appointments.

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 one or more leads. The stimulation settings are stored in programs to target specific effects or 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 four programs can be included in a group, and there can be up to three groups of programs. When a group contains more than one program, the pulses are delivered sequentially—first a pulse from one program, then a pulse from the next program. Pulse width, rate, intensity, cycling, and electrode polarity for each program within a group can have different values. Rate limits, pulse width limits, and intensity limits for each program within a group have the same values.

**Table 1. Operating values for the Intellis with AdaptiveStim™ Technology Model 97715 and Intellis Model 97716 Neurostimulators**

<table>
<thead>
<tr>
<th>Programmable parameter</th>
<th>Operating values and ranges&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of defined groups</td>
<td>1 – 3</td>
</tr>
<tr>
<td>Number of programs</td>
<td>12</td>
</tr>
<tr>
<td>Number of programs per group</td>
<td>1 – 4</td>
</tr>
<tr>
<td>Electrode configuration</td>
<td>2 – 16 electrodes as anode (+), cathode (-), or Off</td>
</tr>
<tr>
<td>Maximum intensity per electrode</td>
<td>0 – 25.5 mA (0.1 mA increment)</td>
</tr>
<tr>
<td>Program intensity</td>
<td>0 – 100 mA</td>
</tr>
<tr>
<td>Intensity – limits</td>
<td>Enabled or disabled at maximum of 25.5 mA per electrode</td>
</tr>
<tr>
<td>Pulse width</td>
<td>60 – 1000 µs (10-µs increment)</td>
</tr>
<tr>
<td>Pulse width – limits&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Enabled or disabled at maximum of 1000 µs</td>
</tr>
<tr>
<td>Rate&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Rate range: 40 – 1200 Hz</td>
</tr>
<tr>
<td></td>
<td>40 – 250 Hz (5 Hz increment)</td>
</tr>
<tr>
<td></td>
<td>250 – 500 Hz (10 Hz increment)</td>
</tr>
<tr>
<td></td>
<td>500 – 1000 Hz (20 Hz increment)</td>
</tr>
<tr>
<td></td>
<td>1000 – 1200 Hz (50 Hz increment)</td>
</tr>
<tr>
<td>Rate ratio</td>
<td>A fraction of the rate (1/1, 1/2, 1/3, 1/4, 1/5, 1/6, 1/7, 1/8, 1/9, 1/10, 1/11, 1/12, 1/13, 1/14, 1/15, 1/16, 1/17, 1/18, 1/19, 1/20)</td>
</tr>
<tr>
<td>Rate limits</td>
<td>Enabled or disabled (at maximum of 1200 Hz)&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>SoftStart/Stop</td>
<td>Off, On: 1, 2, 4, or 8 second ramp duration</td>
</tr>
</tbody>
</table>
Table 1. Operating values for the Intellis with AdaptiveStim™ Technology Model 97715 and Intellis Model 97716 Neurostimulators (continued)

<table>
<thead>
<tr>
<th>Programmable parameter</th>
<th>Operating values and ranges&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycling</td>
<td>Off, On: 0.1 s – 30 min (increments: 0.1 s from 0.1 – 1 s, 1 s from 1 s – 1 min, 1 min from 1 – 30 min)</td>
</tr>
<tr>
<td>AdaptiveStim™ (Model 97715 only)</td>
<td>Off, On: 7 positions</td>
</tr>
</tbody>
</table>

<sup>a</sup> Interlocks will prevent the use of some parameter combinations.
<sup>b</sup> Pulse width limits are not available when AdaptiveStim™ is enabled.
<sup>c</sup> Rate availability depends on how many programs are defined. For example, the maximum rate available in one defined program is 1200 Hz. The maximum rate available if two programs are defined is 600 Hz in each of those two programs.
Table 2. Physical characteristics of the Intellis with AdaptiveStim™ Technology Model 97715 and Intellis Model 97716 Neurostimulators

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connector type</td>
<td>Octapolar, in-line 2.8-mm (0.110-in) spacing</td>
</tr>
<tr>
<td>Height</td>
<td>57.1 mm (2.2 in)</td>
</tr>
<tr>
<td>Width</td>
<td>47.2 mm (1.9 in)</td>
</tr>
<tr>
<td>Thickness</td>
<td></td>
</tr>
<tr>
<td>Case</td>
<td>6.3 mm (0.2 in)</td>
</tr>
<tr>
<td>Connector</td>
<td>9.1 mm (0.4 in)</td>
</tr>
<tr>
<td>Weight</td>
<td>29.1 g (1.0 oz)</td>
</tr>
<tr>
<td>Volume</td>
<td>13.9 cm³ (0.8 in³)</td>
</tr>
<tr>
<td>Battery life</td>
<td>9 years before ERI</td>
</tr>
<tr>
<td>Power source</td>
<td>Lithium ion rechargeable battery</td>
</tr>
<tr>
<td>Temperature limitation</td>
<td>–35°C to +58°C (–31°F to +136.4°F)</td>
</tr>
<tr>
<td>Serial number model designatorb</td>
<td>NME (Model 97715), NMQ (Model 97716)</td>
</tr>
<tr>
<td>Radiopaque identification (ID) codec</td>
<td>NME</td>
</tr>
<tr>
<td>Transmitter</td>
<td></td>
</tr>
<tr>
<td>Carrier frequency</td>
<td>402 – 405 MHz</td>
</tr>
<tr>
<td>Output power</td>
<td>&lt;25 μW</td>
</tr>
</tbody>
</table>

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; NME 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 Intellis with AdaptiveStim™ Technology Model 97715 and Intellis Model 97716 packages

<table>
<thead>
<tr>
<th>Components</th>
<th>Material</th>
<th>Material contacts human tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurostimulator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case</td>
<td>Titanium</td>
<td>Yes</td>
</tr>
<tr>
<td>Connector block</td>
<td>Titanium, polysulfone, silicone rubber, silicone rubber, silicone medical adhesive</td>
<td>Yes</td>
</tr>
<tr>
<td>Grommets, seals</td>
<td>Silicone rubber</td>
<td>Yes</td>
</tr>
<tr>
<td>Setscrews</td>
<td>Titanium alloy</td>
<td>Yes</td>
</tr>
<tr>
<td>Adhesive</td>
<td>Silicone medical adhesive</td>
<td>Yes</td>
</tr>
<tr>
<td>Pocket sizer</td>
<td>Polypropylene</td>
<td>Yes</td>
</tr>
<tr>
<td>Neurostimulator plug</td>
<td>Polyurethane</td>
<td>Yes</td>
</tr>
<tr>
<td>Contact</td>
<td>Stainless steel</td>
<td>No</td>
</tr>
<tr>
<td>Torque wrench</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handle</td>
<td>Polyetherimide</td>
<td>Yes</td>
</tr>
<tr>
<td>Shaft</td>
<td>Stainless steel</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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. MR scans performed under different conditions can result in patient injury or damage to the implantable device.

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**: 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 recharging instructions, refer to the clinician programming guide. 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 programmer 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 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 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 fully into the neurostimulator.

**Note:** Insert a neurostimulator plug into any unused neurostimulator socket.

4. For each extension, lead, or plug, fully insert the torque wrench (packaged with the rechargeable neurostimulator) 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 is 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

⚠️ 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.

Notes:

- 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 14.)
- Refer to the lead implant manual for instructions on creating the subcutaneous pocket for the neurostimulator. If desired, create the subcutaneous pocket using the pocket sizer. Refer to "Appendix A: Using the pocket sizer" on page 22.

1. Rotate the neurostimulator 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 to coil excess lead or extension length.

Note: Ensure that the leads or extensions first coil around the body of the neurostimulator and not the connector block of the neurostimulator.

2. Insert the neurostimulator and excess lead or extension coils into the subcutaneous pocket. The neurostimulator can be implanted and charged with either side facing outward. For optimal recharging, place the neurostimulator within 1 to 2 cm (0.8 in) of the skin surface. Ensure that the leads or extensions are not twisted or bent sharply.

⚠️ 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 no more than two times around the perimeter of (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 extension or leads around the perimeter of (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

The connections of the extensions and leads to the neurostimulator can be checked using the clinician programmer. Refer to the clinician 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 check connectivity.

2. If the connectivity results are not acceptable, refer to "Connecting the extension or lead to the neurostimulator" on page 16.

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.
Appendix A: Using the pocket sizer

The Medtronic pocket sizer is a single-use acute implant accessory designed to aid in the creation of an implant pocket for Medtronic implantable neurostimulators similar in size and shape to the pocket sizer.

⚠️ Caution: Medtronic has sterilized the package contents according to the process indicated on the package label before shipment. This device is for single use only and is not intended to be resterilized.

Notes:

- For instructions on creating the subcutaneous pocket for the neurostimulator, refer to the lead implant manual.
- For instructions on implanting the neurostimulator, including the location and depth of the pocket, refer to "Implanting the neurostimulator" on page 18.

Inserting and removing the pocket sizer

1. Insert the pocket sizer into the implant area.
2. Mark the incision site based on the pocket sizer size and shape.
Contacts:

Asia:
Medtronic International Ltd.
Tel. 02919-1300
Fax 02891-6830
Medtronic Asia Ltd.
Tel. (02)-548-1148
Fax (02)-518-4786

Australia:
Medtronic Australasia P/L
5 Alma Road
Macquarie Park NSW 2113
Australia
Tel. +61-2-9857-9000
Fax +61-2-9878-5100
Toll-free 1-800-668-670

Austria:
Medtronic Österreich GmbH
Tel. 01-240440
Fax 01-24044-100

Belgium:
Medtronic Belgium S.A.
Tel. 02-456-0900
Fax 02-460-2667

Canada:
Medtronic of Canada Ltd.
Tel. (1-905)-460-3800
Fax (1905)-826-6620

Czech Republic:
Medtronic Czechia s.r.o.
Tel. 2-965-795-80
Fax 2-965-795-89

Denmark:
Medtronic Danmark A/S
Tel. 45-32-48-18-00
Fax 45-32-48-18-01

Finland:
Medtronic Finland Oy/LTD
Tel. (09)-755-2500
Fax (09)-755-25018

France:
Medtronic France S.A.S.
Tel. 01-5538-1700
Fax 01-5538-1800

Germany:
Medtronic GmbH
Tel. (02159)-81490
Fax (02159)-8149100

Greece:
Medtronic Hellas S.A.
Tel. 210-67-79-099
Fax 210-67-79-399

Hungary:
Medtronic Hungária Kft.
Tel. 1-889-06-00
Fax 1-889-06-99

Ireland:
Medtronic Ireland Ltd.
Tel. (01)-890-6522
Fax (01)-890-7220

Italy:
Medtronic Italia SpA
Tel. 02-241371
Fax 02-241381
Tel. 06-328141
Fax 06-3215812

Japan:
Medtronic Japan
Tel. 03-6776-0017
Fax 03-6774-4645

Latin America:
Medtronic, Inc.
Tel. (1305)-500-9328
Fax (1786)-709-4244

Norway:
Medtronic Norge AS
Tel. 67-10-32-00
Fax 67-10-32-10

Poland:
Medtronic Poland Sp. z.o.o.
Tel. (022)-465-69-00
Fax (022)-465-69-17

Portugal:
Medtronic Portugal, Lda.
Tel. 21-724-5100
Fax 21-724-5199

Russia:
Medtronic Russia
Tel. (8495) 580-7377
Fax (8495) 580-7378

Slovakia:
Medtronic Slovak, o.z.
Tel. 0268 206 911
Fax 0268 206 999

Spain:
Medtronic Ibérica, S.A.
Tel. 91-625-0400
Fax 91-650-7410

Sweden:
Medtronic AB
Tel. 08-568-585-00
Fax 08-568-585-01
Switzerland:  
Medtronic (Schweiz) AG  
Tel. 031-868-0100  
Fax 031-868-0199

The Netherlands:  
Medtronic B.V.  
Tel. (045)-566-8000  
Fax (045)-566-8668

Turkey:  
Medtronic Turkey  
Tel. +90 216 636 1000  
Fax +90 216 636 1008

U.K.:  
Medtronic U.K. Ltd.  
Tel. 01923-212213  
Fax 01923-241004

USA:  
Medtronic, Inc.  
Tel. (1-763)-505-5000  
Fax (1-763)-505-1000  
Toll-free: (1-800)-328-0810
Manufacturer
Medtronic, Inc.
710 Medtronic Parkway,
Minneapolis, MN 55432-5604,
USA
www.medtronic.com
Tel. +1-763-505-5000
Fax +1-763-505-1000

Authorized Representative
in the European Community
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 International Trading Sàrl
Route du Molliau 31,
Case Postale 84
CH - 1131 Tolochenaz,
Switzerland
www.medtronic.eu
Tel. +41-21-802-7000
Fax +41-21-802-7900

Asia-Pacific
Medtronic International Ltd.
Suite 1106-11, 11/F, Tower 1, The Gateway,
25 Canton Road, Tsimshatsui,
Kowloon,
Hong Kong
Tel. +852-2919-1300
Fax +852-2891-6830

Contacts for specific countries are listed inside this cover.