



Medtronic

RestoreULTRA™

Multi-program rechargeable neurostimulator

37712

Implant manual

USA Rx only



2007

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.



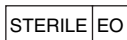
The use of this device might be subject to individual country licensing regimes in Europe.



Open here



Do not reuse



Sterilization: ethylene-oxide gas



Caution: consult accompanying documents



Use by



Manufacturing date



Serial number



Storage temperature



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 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.

Device description

The Medtronic Model 37712 RestoreULTRA Neurostimulator is part of a neurostimulation system for pain therapy.

Package contents

- Neurostimulator
- Torque 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 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 four programs can be combined into a group. When using more than one 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 Model 37712 RestoreULTRA 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 ^c
Amplitude – upper patient limit	Tracking limit: programmed value +0 to +4 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 1000 μ s (10- μ s resolution)
Pulse width – upper patient limit	Tracking limit: programmed value +0 to +300 μ s (60- μ s resolution) Custom limit: programmed value to 1000 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 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
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)
Scheduled therapy	OFF, ON: 1 to 8 events per 24-h period

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

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

^c Only 0.1 V resolution possible from 10.0 V to 10.5 V amplitude.

^d Rate limited to 600 Hz when two programs/group are active, 400 Hz when three programs/group are active and 300 Hz when four programs/group are active.

Table 2. Physical characteristics of the Model 37712 RestoreULTRA 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
Battery life	9 years
Power source	Lithium ion rechargeable battery
Storage temperature	-18° to +52°C (0° to +126°F)
Serial number model designator ^b	NKF
Radiopaque Identification (ID) code	NKD

^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 Model 37712 RestoreULTRA 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	Ultem	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 recharger, antenna, and belt are 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

If desired, 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 connections 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.

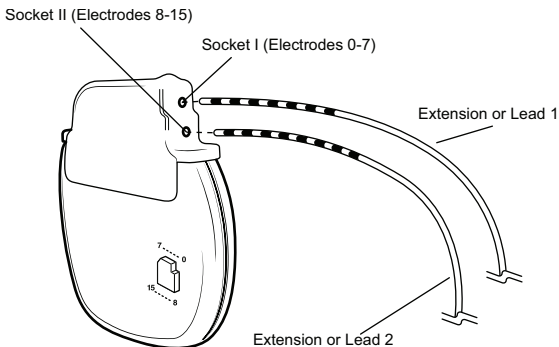


Figure 1. Insert the extension or lead connector pins fully into the neurostimulator.

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

- 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.

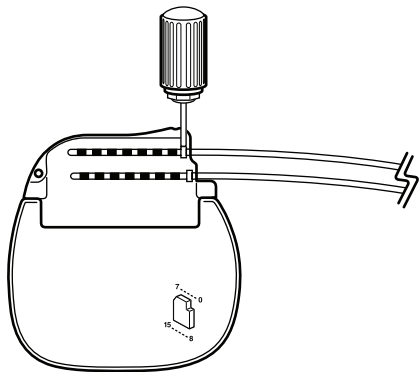


Figure 2. Tightening the setscrews in the self-sealing grommet.

Implanting the neurostimulator

- Place the neurostimulator into the subcutaneous pocket with the Medtronic logo facing outward, away from muscle tissue, and ensure that the extension or lead is not 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 cannot be charged.
- Do not coil excess extensions or leads in front of the neurostimulator. Wrap excess extensions 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.

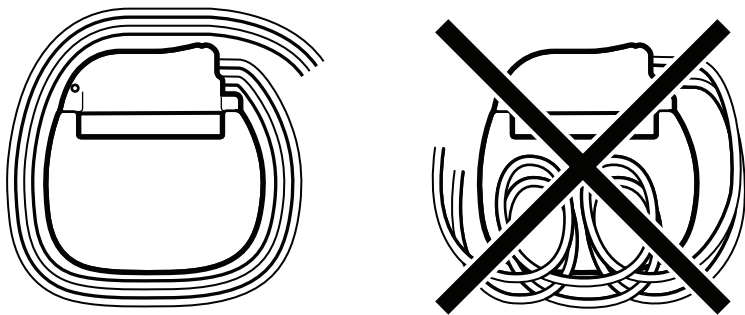


Figure 3. Wrap excess extensions or leads around the perimeter (or behind) the neurostimulator.

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

Checking system integrity

△ **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 10.
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.

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Medtronic

Alleviating Pain · Restoring Health · Extending Life

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inside this cover.



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