Medtronic

RESTOREPRIME™ 37701

Multi-program neurostimulator

Implant manual

Rx 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.

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 37701 RestorePRIME Neurostimulator is part of a neurostimulation system for pain therapy.

Package contents

- Neurostimulator
- Torque wrench
- Product literature
- Warranty card
- 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.

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 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 myStim 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 37701 RestorePRIME neurostimulator[a]

Programmable parameter	Operating range and resolution
Number of defined myStim groups	1 to 26[b]
Number of programs per myStim group	1 to 4[b]
Electrode configuration	2 to 16 electrodes defined 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 with 0.5 V resolution Custom limit: programmed value up to 10.5 V with same resolution as amplitude
Amplitude – lower patient limit	Custom limit: 0 V to the programmed value with same resolution as amplitude
Pulse width	60 to 450 µs with 10 µs resolution
Pulse width – upper patient limit	Tracking limit: programmed value +0 to +150 µs with 30 µs resolution Custom limit: programmed value up to 450 µs with 10 µs resolution
Pulse width – lower patient limit	Custom limit: 60 µs to the programmed value with 10 µs resolution
Rate	2 to 130 Hz with 1 Hz resolution to 10 Hz, 5 Hz resolution from 10 Hz to 130 Hz
Rate – upper patient limit	Tracking limit: programmed value +0 to +50 Hz with 10 Hz resolution[d]
Rate – lower patient limit	Custom limit: 2 to the programmed value with 1 Hz resolution to 10 Hz, 5 Hz resolution from 10 Hz to 130 Hz[d]
SoftStart/Stop	OFF, ON: 1, 2, 4, or 8 sec ramp duration
Cycling	OFF, ON: 0.1 sec to 30 min with 0.1 sec resolution from 0.1 sec to 1 sec, 1 sec resolution from 1 sec to 1 min, 1 min resolution from 1 min to 30 min
Scheduled therapy	OFF, ON: 1 to 8 events per 24 h period

[a] All values are approximate.

[b] No more than 32 programs may be defined within the 26 myStim groups.

[c] Only 100 mV resolution possible from 10.0 V to 10.5 V amplitude.

[d] The rate is limited to 85 Hz when three programs are active in a group and to 65 Hz when four programs are active in a group.

Table 2. Physical characteristics of the Model 37701 RestorePRIME neurostimulator.[a]

Description	Value
Connector Type	Octapolar, in-line 2.8 mm (0.110") spacing
Height	65 mm (2.6 in)
Length	49.0 mm (1.9 in)
Thickness	
case	15.0 mm (0.6 in)
connector block	15.0 mm (0.6 in)
Weight	67 g (2.4 oz)
Volume	39 cm^3
Power source	6.3 Amp hours, 3.2 V HCSVO[c] cell
Storage temperature	-18° to +52°C (0° to +126°F)
Serial Number[b]:	
Radiopaque Identification (ID) code	NKD

[a] All measurements are approximate.

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

[c] Hybrid combined silver vanadium oxide.

Table 3. Material of components in the Model 37701 RestorePRIME package.

Component	Material	Material contacts human tissue
Neurostimulator		
Case	Titanium	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	Ultem	Yes
Shaft	Stainless steel	Yes

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, 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") 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. Unretracted setscrews may damage the extension or lead and prevent the extension or lead from fully seating into the connector block.

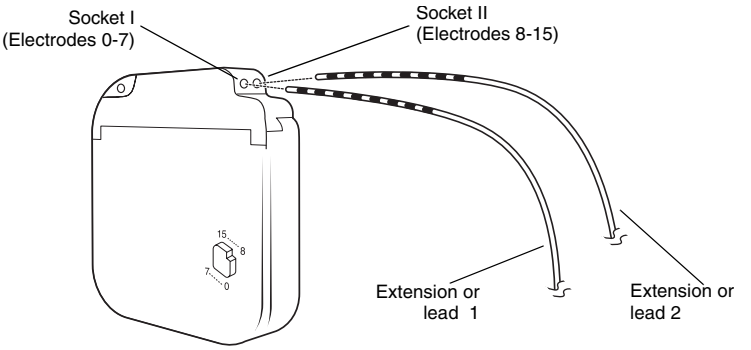

Figure 1. *Insert the extension or lead connector pins fully into the neurostimulator.*

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

4. For each extension, lead, or plug, fully insert the torque wrench (packaged with the 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 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, intermittent stimulation, or loss of stimulation.

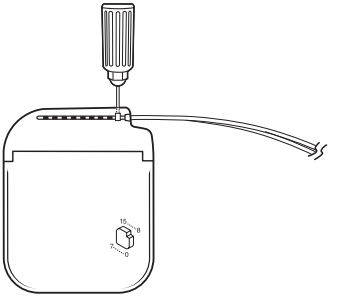

Figure 2. *Tightening the setscrews in the self-sealing grommet.*

Implanting the neurostimulator

1. Place the neurostimulator into the subcutaneous pocket 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 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 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/lead, and minimize interference with telemetry.

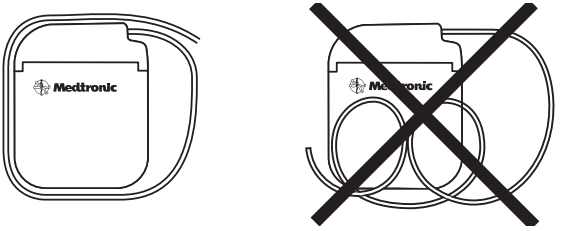

Figure 3. *Wrap excess extensions or leads around the perimeter (or behind) the neurostimulator.*

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

Checking system integrity

1. To ensure that you have properly connected each extension or lead to the neurostimulator, 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.

   If the system integrity test results are not acceptable, refer to “Connecting the extension or lead to the neurostimulator” on page 8.
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.

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