Medtronic

InterStim® Therapy

3058
3023

InterStim® II Model 3058 Neurostimulator
InterStim® Model 3023 Neurostimulator

Implant manual

! USA Rx only

CE 0123
2006 (3058)
1995 (3023)

Explanation of symbols on product or package labeling

Open here

Do not reuse

STERILE EO

Sterilized using ethylene oxide

Use by

SN

Serial number

Do not use if package is damaged

CE 0123

Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123).

Date of Manufacture

Consult instructions for use

Do not resterilize

Temperature limitation

Manufacturer

EC REP

Authorized representative in the Europe2016an community

! USA

For USA audiences only

Table of contents

- Refer to the appropriate Information for Prescribers (IFP) booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.
- Refer to the Indications Insert for indications and related information.
- Refer to the System Overview and Compatibility Insert for information regarding device compatibility.

Note: Some product models described in this manual may not be available in all geographies.

- ! USA Refer to the Clinical Summary for information on the clinical study results for InterStim Therapy and for a complete summary of adverse events.
- ! USA Refer to the Limited Warranty and Special Notice Insert for warranty information.
- Refer to the System Eligibility, Battery Longevity, Specifications reference manual for neurostimulator selection, battery longevity calculations, and specific neurostimulator specifications.

Introduction

This manual includes information about two devices used separately as part of a Medtronic InterStim System. The Medtronic InterStim II Model 3058 Neurostimulator is used with a lead and the Medtronic InterStim Model 3023 Neurostimulator is used with a lead and an extension.

InterStim II Model 3058 Neurostimulator

Device description

The Medtronic InterStim II Model 3058 Neurostimulator is part of a neurostimulation system for InterStim Therapy.

Package contents

- Neurostimulator
- Torque wrench
- Product literature

Patient registration and identification card

The implant registration form registers the device and creates a record of the device in Medtronic's implant data system.

A patient identification card is package 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 implant registration form.

Device specifications

The neurostimulator is a programmable device that accommodates a lead through which a stimulation program is delivered.

Refer to Table 1 for shipping, operating, and power-on-reset values. Refer to Table 2 for physical characteristics. Refer to Table 3 for materials of package components.

Table 1. Shipping, operating, and power-on-reset (POR) values for the Medtronic InterStim II Model 3058 Neurostimulator[a].

Programmable Parameters		Shipping	Operating	POR[b]
Amplitude				
Normal Resolution		0.0 V	100 mV steps	0.0 V
Upper Limit		0.0 V	8.5 V maximum	0.0 V
Lower Limit		0.0 V	0.0 V minimum	0.0 V
Fine Resolution		---	50 mV steps	---
Upper Limit		---	6.35 V maximum	---
Lower Limit		---	0.0 V minimum	---
Rate		14 Hz	49 values (from 2.1 to 130 Hz)	31 Hz
Pulse width		210 µs	Increments of 30 µs steps 450 µs maximum 60 µs minimum	210 µs
Operating Mode		Continuous	Continuous or Cycling	Continuous
Cycle On/Cycle Off time[c]		0.1 sec	0.1 sec to 24 hr	0.1 sec
SoftStart/Stop[d]		Off	1, 2, 4, 8, 15, 30 sec, or Off	Off
Output On/Off		Off	On or Off	Off
Polarity				
	Electrode Number			
	0	–	Off, + or –	–
	1	Off	Off, + or –	Off
	2	Off	Off, + or –	Off
	3	+	Off, + or –	+
	Case[e]	Off	Off or +	Off

[a] All values are approximate.

[b] Power-on-reset (POR) turns OFF stimulation by resetting the amplitude to 0.0 V and all electrodes to OFF. POR can occur 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 reset to a nominal value and must be entered with the clinician programmer.

[c] Cycle On and Cycle Off time must be greater than or equal to the SoftStart/Stop time.

[d] SoftStart/Stop must be less than or equal to the Cycle On and Cycle Off time.

[e] If case electrode is positive, electrodes 0-3 may be programmed to Off or – only.

Table 2. Physical characteristics of the InterStim II Model 3058 Neurostimulator.[a]

Description	Value	
Height	**44 mm**	**(1.7 in)**
Length	**51 mm**	**(2 in)**
Thickness	**7.7 mm**	**(0.3 in)**
Weight	**22 g**	**(0.77 oz)**
Volume	**14 cm^3**	**(0.85 in^3)**
External shield	**Titanium**	
Power source[b]	**1.3 Amp Hours, 3.2 V Lithium silver vanadium oxide hybrid**	
Storage temperature	**-18 °C to 52 °C (0 °F to 125 °F)**	
Serial Number[c] Radiopaque Identification (ID)	**NJY**	

[a] All measurements are approximate.

[b] The power source is hermetically sealed within the case.

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

X-Ray identification

Radiopaque identification permits the determination of manufacturer and neurostimulator model number (Figure 1). With standard x-ray procedures, the code appears as black characters on white background. The Medtronic symbol identifies Medtronic as the manufacturer. For the Medtronic InterStim II Model 3058 Neurostimulator, the designated characters are NJY.

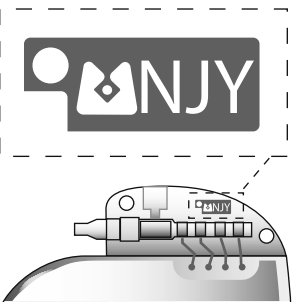

Figure 1. *The InterStim II Model 3058 Neurostimulator radiopaque code block.*

Table 3. Material of components in the Model 3058 package.

Structure	Material	Material Contacts Human Tissue
Case[a]	**Titanium**	**Yes**
Connector	**Urethane**	**Yes**
Grommets, seals, strain relief	**Silicone rubber**	**Yes**
Setscrew and electrical contacts	**Titanium**	**Yes**
Adhesive	**Silicone adhesive**	**Yes**
Torque wrench		
Handle	**Polyetherimide**	**Yes**
Shaft	**Stainless steel**	**Yes**

[a] The electronics and power source are hermetically sealed within the case.

Instructions for use: Model 3058

Cautions:

- When using sharp instruments near the neurostimulator, be careful to avoid nicking or damaging the case 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.

Creating a pocket for the Model 3058 Neurostimulator

1. Create a subcutaneous pocket for the neurostimulator by blunt dissection to the anterior surface of the muscle. The neurostimulator is placed in the upper buttock area.

   Notes:

   - The Model 3058 Neurostimulator should be placed no deeper than 2.5 cm (1 in) below the skin and should be parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, telemetry may be unsuccessful.
   - If the patient has any other neurostimulator, the neurostimulators must be separated by a minimum of 20 cm (8 in).

   Cautions:

   - The neurostimulator is provided sterile. Do not soak the neurostimulator in antibiotic solution. Soaking in antibiotic solution can affect lead connections.
   - To avoid infection, it is recommended that the neurostimulator implant site be irrigated with antibiotic solution, and that IV antibiotics be administered perioperatively. Do not allow the neurostimulator to come into contact with any non-sterile surface. Do not place on skin. If an infection occurs, it may require surgical removal of the implanted system.

2. Place the neurostimulator in the pocket to assure proper fit and then remove it. Keep the neurostimulator sterile and clean.
3. Tunnel from the lead incision site to the neurostimulator pocket. Refer to the product literature packaged with the lead for detailed tunneling and lead implant instructions.

4. Connect the lead to the Model 3058 Neurostimulator according to the steps in "Connecting the lead to the Model 3058 Neurostimulator" in this manual.

Connecting the lead to the Model 3058 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 proximal lead electrode connections with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution, then wipe dry.
2. Make sure the connector block receptacle is dry and clean.
3. Confirm that the lead has four electrodes matching the encapsulated diagram on the neurostimulator (Figure 2).
4. Insert the lead into the neurostimulator connector block until fully seated (Figure 2).

⚠ **Caution:** Do not pull the lead body taut when implanted. The lead is available in different lengths. Select a lead length that allows connection without tension.

Note: To retract the setscrew, insert the torque wrench into the self-sealing grommet and rotate the setscrew counterclockwise; however, do not remove the setscrew from the connector block (Figure 3).

⚠ **Caution:** Do not insert the lead into the connector block if the setscrew is not sufficiently retracted. If the setscrew is not retracted, the lead may damage the setscrew and the lead then will not seat fully into the connector block.

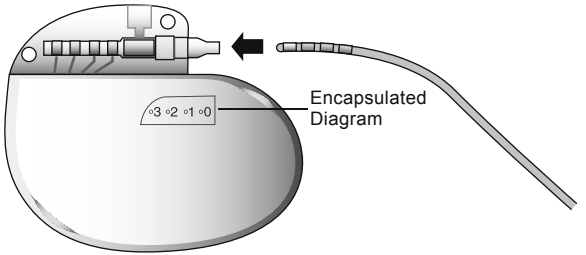

Figure 2. *Insert lead fully into Model 3058 Neurostimulator connector block.*

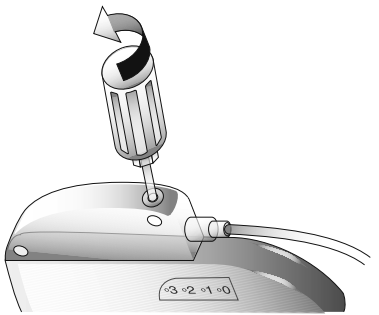

Figure 3. *To back out the setscrew from the Model 3058 Neurostimulator, use the torque wrench and turn setscrew counterclockwise.*

Note: The torque wrench must be oriented to the same angle as the setscrew (Figure 3).

5. Fully insert the torque wrench into the self-sealing grommet of the connector block and tighten the setscrew by turning clockwise until the torque wrench clicks (Figure 4).

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 setscrew, ensure that the lead is inserted into the connector block to prevent damaging the connector block.
- Verify that 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.
- Discard the torque wrench after making the connection. The torque wrench is single-use-only. Its operation cannot be assured if it is used for multiple surgeries.

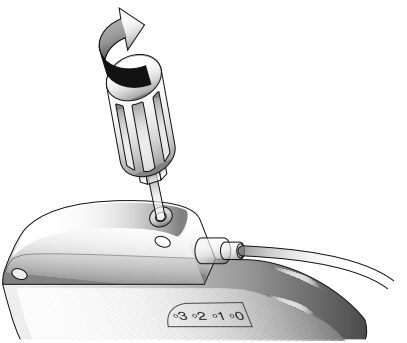

Figure 4. *Tighten the setscrew in the self-sealing grommet by turning clockwise until the torque wrench clicks.*

Note: The torque wrench must be oriented to the same angle as the setscrew (Figure 4).

Implanting the Model 3058 Neurostimulator

1. Place the neurostimulator into the subcutaneous pocket with the etched identification side placed outward, away from muscle tissue, and ensure that the lead is not bent sharply.

   Note: The Model 3058 Neurostimulator should be placed no deeper than 2.5 cm (1 in) below the skin and should be parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, telemetry may be unsuccessful.

   Caution: Do not coil excess length in front of the etched identification side of the neurostimulator. Wrap excess length around the perimeter of the neurostimulator (Figure 5) to avoid increasing subcutaneous pocket depth, help minimize potential damage during neurostimulator replacement surgery, help minimize potential kinking, and minimize interference with telemetry during programming.

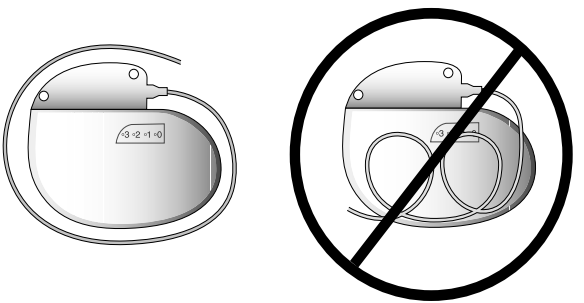

Figure 5. *Wrap excess length around perimeter of the Model 3058 Neurostimulator.*

2. Check the system integrity before securing the neurostimulator in place.
   a. Use the clinician programmer and the product literature packaged with it 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 to ensure proper readings.
   b. Program the stimulation parameters you have selected for your patient according to the product literature packaged with the programmer.
   c. Check the battery status; if applicable, check the electrode impedances to rule out a short or open circuit.

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

Completing the implant procedure

1. Close and dress all incisions.
2. Ensure that a patient programmer and a patient ID card are given to the patient.

   Caution: Because the patient programmer is the patient's only means to adjust or turn the neurostimulator on or off, the patient must carry a programmer at all times.

3. Complete the device tracking and patient registration paperwork and return the documents to Medtronic.

   Note: See the Information for Prescribers booklet packaged with this device for clinician instructions to patients and for information regarding the return of product documentation.
4. Schedule regular patient follow-up appointments to monitor the condition of the neurostimulator and to confirm that the programmed parameter values are appropriate.

Replacing the Model 3058 Neurostimulator

If replacing a Model 3023 Neurostimulator, refer to page 24 of this manual.

1. Open the implant site using normal surgical procedure and carefully remove the neurostimulator from the subcutaneous pocket.
2. Clean the neurostimulator connector block and lead with sterile water; wipe dry with sterile gauze.
3. Insert a torque wrench through the prepierced hole in the rubber sealing grommet and loosen the setscrew by turning it counterclockwise.
4. Gently retract the lead from the neurostimulator connector block.

   Caution: Replace any device that shows signs of damage, pitting, or corrosion.

5. Clean and dry the connector block and lead — which must be free of fluids or tissue.
6. Set aside the explanted components for return to Medtronic.
7. Connect the lead and replacement neurostimulator according to the product literature packaged with those devices.

   Note: Increased pocket size may be necessary if replacement neurostimulator uses an extension.
8. Return explanted devices to Medtronic according to product literature packaged with those devices.

InterStim Model 3023 Neurostimulator

Device description

The Medtronic InterStim Model 3023 Neurostimulator is part of a neurostimulation system for InterStim Therapy.

Package contents

- Neurostimulator
- Torque wrench
- Product literature

Patient registration and identification card

The implant registration form registers the device and creates a record of the device in Medtronic's implant data system.

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 implant registration form.

Device specifications

The neurostimulator is a programmable device that accommodates an extension by which a stimulation program is delivered through a lead.

Refer to Table 4 for shipping, operating, and power-on-reset values. Refer to Table 5 for physical characteristics. Refer to Table 6 for materials of package components.

Table 4. Shipping, operating, and power-on-reset (POR) values for the Medtronic InterStim Model 3023 Neurostimulator[a].

Programmable Parameters		Shipping	Operating	POR[b]
Amplitude				
Normal Resolution		**0.0 V**	**100 mV 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		**---**	**50 mV steps**	**---**
Upper Limit		**---**	**6.35 V maximum**	**---**
Lower Limit		**---**	**0.0 V minimum**	**---**
Rate		**14 Hz**	**49 values (from 2.1 to 130 Hz)**	**31 Hz**
Pulse Width		**210 µs**	**Increments of 30 µs steps 450 µs maximum 60 µs minimum**	**210 µs**
Operating Mode		**Continuous**	**Continuous or Cycling**	**Continuous**
Cycle On/Cycle Off time[c]		**0.1 sec**	**0.1 sec to 24 hr**	**0.1 sec**
SoftStart/Stop[d]		**Off**	**1, 2, 4, 8, 15, 30 sec, or Off**	**Off**
Magnet Control		**Disabled**	**Enabled/Disabled**	**Enabled**
Output On/Off		**Off**	**On or Off**	**Off**
Polarity				
	Electrode Number	**Polarity**		
	0	**–**	**Off, + or –**	**–**
	1	**Off**	**Off, + or –**	**Off**
	2	**Off**	**Off, + or –**	**Off**
	3	**+**	**Off, + or –**	**+**
	Case[e]	**Off**	**Off or +**	**Off**

[a] All values are approximate.

[b] Power-on-reset (POR) turns OFF stimulation by resetting the amplitude to 0.0 V and all electrodes to OFF. POR can occur 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 reset to a nominal value and must be entered with the clinician programmer.

[c] Cycle On and Cycle Off time must be greater than or equal to the SoftStart/Stop time.

[d] SoftStart/Stop must be less than or equal to the Cycle On and Cycle Off time.

[e] If case electrode is positive, electrodes 0-3 may be programmed to Off or – only.

Table 5. Physical characteristics of the InterStim Model 3023 Neurostimulator[a].

Description	Value
Height	**55 mm (2.2 in)**
Length	**60 mm (2.4 in)**
Thickness	**10 mm (0.4 in)**
Weight	**42 g (1.5 oz)**
Volume	**25 cm^3 (1.5 in^3)**
External shield	**Titanium**
Power source[b]	**2.7 Amp hours, 3.7 V Lithium-thionyl chloride cell**
Storage temperature	**-18 °C to 52 °C (-0 °F to 125 °F)**
Serial Number[c] Radiopaque Identification (ID)	**NBV**

[a] All measurements are approximate.

[b] The power source is hermetically sealed within the case.

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

X-Ray identification

Radiopaque identification permits the determination of manufacturer and neurostimulator model number (Figure 6). With standard x-ray procedures, the code appears as black characters on white background. The Medtronic symbol identifies Medtronic as the manufacturer. For the InterStim Model 3023 Neurostimulator, the designated characters are NBV.

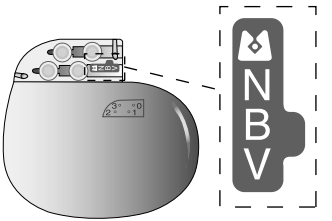

Figure 6. *The InterStim Model 3023 Neurostimulator radiopaque code block.*

Table 6. Material of components in the Model 3023 package.

Structure	Material	Material Contacts Human Tissue
Case[a]	**Titanium**	**Yes**
Connector	**Urethane**	**Yes**
Grommets, seals	**Silicone rubber**	**Yes**
Setscrews	**Titanium**	**Yes**
Insulation coating[b]	**Polymeric insulating film**	**Yes**
Adhesive	**Silicone adhesive**	**Yes**
Torque wrench		
Handle	**Polyetherimide**	**Yes**
Shaft	**Stainless steel**	**Yes**

[a] The electronics and power source are hermetically sealed within the case.

[b] The etched side of the Model 3023 case is uninsulated and can be programmed as an indifferent electrode.

Instructions for use: Model 3023

Cautions:

- When using sharp instruments near the neurostimulator, be 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.

Creating a pocket for the Model 3023 Neurostimulator

1. Create a subcutaneous pocket for the neurostimulator by blunt dissection to the anterior surface of the muscle. The neurostimulator is typically placed in the upper buttock area.

   Notes:

   - Abdominal placement is an option with the Model 3023 Neurostimulator. Abdominal implant instructions are included in the product literature packaged with the leads.
   - The Model 3023 Neurostimulator should be placed no deeper than 4 cm (1.5 in) below the skin and should be parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, telemetry may be unsuccessful.
   - The uncoated, etched side of the 3023 case can be programmed as an indifferent electrode. The etched side of the neurostimulator must face away from muscle to prevent uncomfortable stimulation.
   - If the patient has any other neurostimulator, the neurostimulators must be separated by a minimum 20 cm (8 in).
   - The Model 3023 Neurostimulator requires the use of an extension.

Cautions:

- The neurostimulator is provided sterile. Do not soak the neurostimulator in antibiotic solution. Soaking in antibiotic solution can affect lead connections.
- To avoid infection, it is recommended that the neurostimulator implant site be irrigated with antibiotic solution, and that IV antibiotics be administered perioperatively. Do not allow the neurostimulator to come into contact with any non-sterile surface. Do not place on skin. If an infection occurs, it may require surgical removal of the implanted system.

2. Place the neurostimulator in the pocket to assure proper fit and then remove it. Keep the neurostimulator sterile and clean.
3. Tunnel from the lead incision site to the neurostimulator pocket. Refer to the product literature packaged with the lead for detailed tunneling and lead implant instructions.
4. Wipe the proximal end of the lead with sterile gauze and make sure the extension is dry and clean.
5. Connect and implant the lead and extension according to product literature packaged with those devices.
6. Connect the extension to the Model 3023 Neurostimulator according to the steps in “Connecting the extension to the Model 3023 Neurostimulator” in this manual.

Connecting the extension to the Model 3023 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, then wipe dry.
2. Make sure the connector block receptacles are dry and clean.
3. Confirm that the encapsulated diagram on the extension has four electrodes matching the encapsulated diagram on the neurostimulator (Figure 7).
4. Insert the extension connector pins into the neurostimulator until they are fully seated within the connector block (Figure 7).

Caution: Do not pull the extension or lead body taut when implanted. The extension and lead are available in different lengths. Select a length that allows connection without tension.

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 (Figure 8).

Caution: Do not insert the extension connector pins 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.

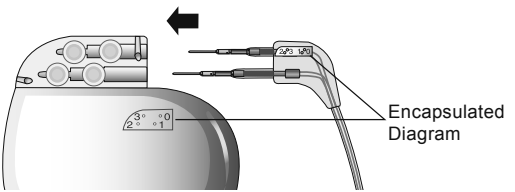

Figure 7. *Insert extension connector pins fully into Model 3023 Neurostimulator connector block.*

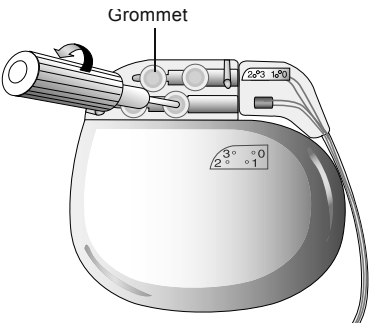

Figure 8. *To back out a setscrew from the Model 3023 Neurostimulator, use the torque wrench and turn the setscrew counterclockwise.*

Note: The torque wrench must be oriented to the same angle as the setscrew (Figure 8).

5. Fully insert the torque wrench into the self-sealing grommet of the connector block and tighten each setscrew by turning clockwise until the torque wrench clicks (Figure 9).

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 connector pins are inserted into the connector block to prevent damaging the connector block.
- Verify that each 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.
- Discard the torque wrench after making all of the connections. The torque wrench is single-use-only. Its operation cannot be assured if it is used for multiple surgeries.

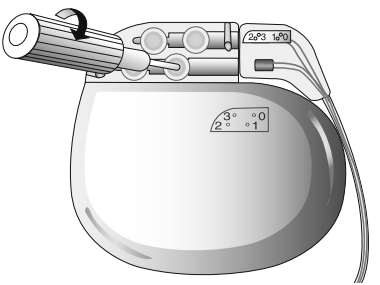

Figure 9. *Tighten the setscrews in the self-sealing grommet by turning clockwise until the torque wrench clicks.*

Note: The torque wrench must be oriented to the same angle as the setscrew (Figure 9).

Implanting the Model 3023 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.

   Note: The Model 3023 Neurostimulator should be placed no deeper than 4 cm (1.5 in) below the skin and should be parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, telemetry may be unsuccessful.

   Cautions:

   - 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 length in front of the etched identification side of the neurostimulator. Wrap excess length around the perimeter of the neurostimulator (Figure 10) to avoid increasing subcutaneous pocket depth, help minimize potential damage during neurostimulator replacement surgery, help minimize potential kinking, and minimize interference with telemetry during programming.

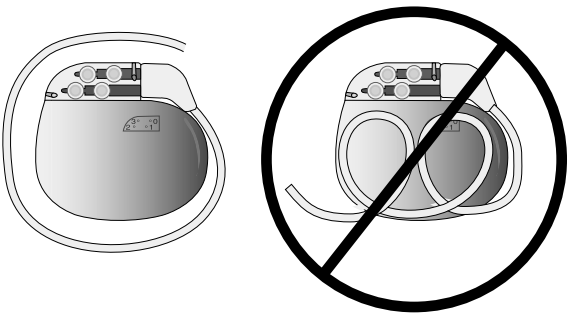

Figure 10. *Wrap excess extension around the perimeter of the Model 3023 Neurostimulator.*

2. Check the system integrity before securing the neurostimulator in place.
   a. Use the clinician programmer and the product literature packaged with it 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 to ensure proper readings.

b. Program the stimulation parameters you have selected for your patient according to product literature packaged with the programmer.

c. Check the battery status; if applicable, check the electrode impedances to rule out a short or open circuit.

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

Completing the implant procedure

1. Close and dress all incisions.
2. Ensure that a patient programmer and a patient ID card are given to the patient.

Caution: Because the patient programmer is used to adjust or turn the neurostimulator on or off, the patient must carry a programmer at all times. Patients implanted with a Model 3023 Neurostimulator may also receive the optional Model 7452 Control Magnet that is used to turn the neurostimulator on or off. In order for the control magnet to turn the neurostimulator on or off, the clinician must enable Magnet Control on the Model 3023 Neurostimulator using the clinician programmer. Magnet Control can not be enabled or disabled using the patient programmer.

3. Complete the device tracking and patient registration paperwork and return the documents to Medtronic.

   Note: See the Information for Prescribers booklet packaged with this device for clinician instructions to patients and for information regarding the return of product documentation.
4. Schedule regular patient follow-up appointments to monitor the condition of the neurostimulator and to confirm that the programmed parameter values are appropriate.

Replacing the Model 3023 Neurostimulator

If replacing a Model 3058 Neurostimulator, refer to page 14 of this manual.

1. Open the implant site using normal surgical procedure and carefully remove the neurostimulator from the subcutaneous pocket.
2. Clean the neurostimulator connector block and extension connector with sterile water; wipe lead dry with surgical sponges.

3. Insert a torque wrench through each prepierced hole in the rubber sealing grommet and loosen the setscrews by turning them counterclockwise.
4. Gently retract the extension connector pins from the neurostimulator connector block.

Caution: Replace any device that shows signs of damage, pitting, or corrosion.

5. Clean and dry the connector block and extension connector pins which must be free of fluids or tissue.

   Note: If the replacement neurostimulator does not require the existing extension, disconnect the extension from the lead. Clean and dry the proximal end of the lead. Take care not to move the lead when extension is disconnected.
6. Set aside the explanted components for return to Medtronic.
7. Connect the replacement neurostimulator according to the product literature packaged with that device.
8. Return explanted devices to Medtronic according to product literature packaged with those devices.

Declaration of conformity

Medtronic declares that the Model 3058 and Model 3023 Neurostimulators are in conformity with the essential requirements of Directive 90/385/EEC on Active Implantable Medical Devices.

For additional information, contact the appropriate Medtronic office listed on the inside back cover of this manual.

Control magnet

The Medtronic Model 7452 Control Magnet allows your patient to turn the Model 3023 Neurostimulator on or off. The control magnet is not used with the Model 3058 Neurostimulator.

When the control magnet on/off control circuit is enabled, applying the flat, rectangular edge of the control magnet over the implant site for 1 to 2 seconds (Figure 11) and then removing it turns the neurostimulator on or off.

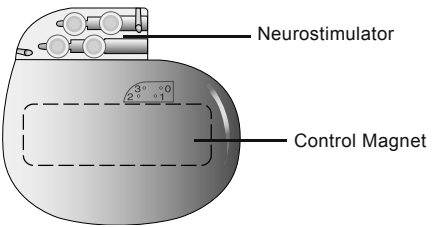

Figure 11. *Control magnet properly positioned over the Model 3023 Neurostimulator.*

If SoftStart/Stop is in use, turning the Model 3023 Neurostimulator on causes the amplitude to ramp up from zero to the selected output amplitude. Turning the neurostimulator off causes the amplitude to ramp down to zero again. The ramp time is set by the SoftStart/Stop parameters.

The control magnet on/off control circuit does not affect programmed parameters; when the output is turned on with the control magnet, the output resumes its previously programmed waveform and stimulation mode.

For patients who live or work in electrically noisy environments, random on or off switching may be a problem. If on or off switching occurs, you can disable the magnet control circuitry with a command to the neurostimulator from the clinician programmer. Detailed instructions on disabling this feature are provided in the product literature packaged with the programmer software.

Note: The patient with a Model 3023 Neurostimulator may carry the optional control magnet to turn the neurostimulator on or off.

The patient programmer will still operate the neurostimulator because it uses a different circuit than the control magnet to turn the neurostimulator on or off. The magnet control circuit can be enabled again with another command from the clinician programmer, if desired.

Caution: Because the patient programmer is used to adjust or turn on or off the neurostimulator, the patient must carry a programmer at all times. Patients implanted with a Model 3023 Neurostimulator may also receive the optional Model 7452 Control Magnet that is used to turn the neurostimulator on or off. In order for the control magnet to turn the neurostimulator on or off, the clinician must enable Magnet Control on the Model 3023 Neurostimulator using the clinician programmer. Magnet Control can not be enabled or disabled using the patient programmer.

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Contacts for specific countries are listed inside this cover.

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