



Medtronic

INTERSTIM[®] THERAPY

3093

Model 3093 Lead

3889

Model 3889 Lead

Implant manual

Rx only

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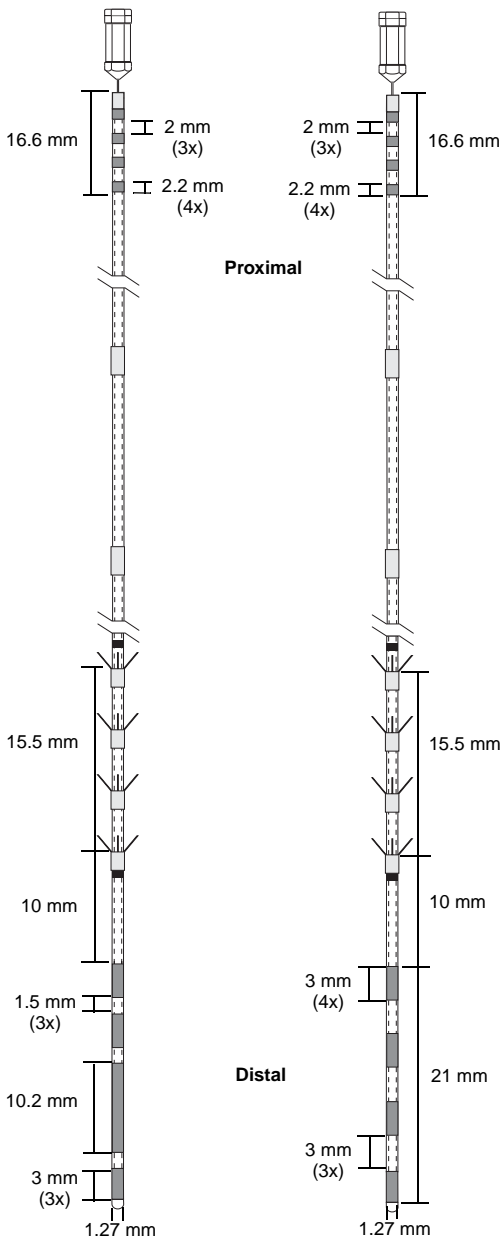
Additional information available for the InterStim Therapy system

Documents packaged with this product:

- For general system information, including contraindications, warnings, precautions, resterilization, component disposal, adverse events, patient counseling, and electromagnetic interference information, refer to the *Information for Prescribers (IFP) Manual*.
- For therapy-specific information, refer to the *Indications Insert*.
- For information regarding device compatibility, refer to the *System Overview and Compatibility Insert*.
- For information on the clinical study results for InterStim Therapy and for a complete summary of adverse events, refer to the *Clinical Summary*.
- For warranty information, refer to the *Limited Warranty and Special Notice Insert*.

Documents packaged with the clinician programmer software application card:

- For neurostimulator selection, battery longevity calculations, and specific neurostimulator specifications refer to the *System Eligibility, Battery Longevity, Specifications Reference Manual*.



Model 3093 Lead

Model 3889 Lead

Available in lengths from 20 - 60 cm (8 - 24 in)

All dimensions are approximate.

Explanation of symbols on product or package labeling

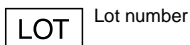
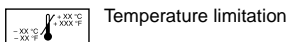
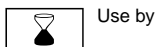
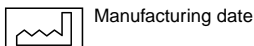
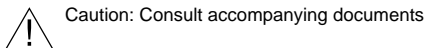
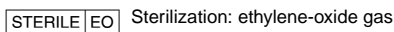
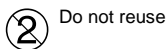
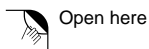


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Introduction

This manual includes information about the Medtronic Model 3093 and Model 3889 tined leads which are used as part of the Medtronic InterStim System. The Model 3093 and Model 3889 leads are designed to be used with a Medtronic neurostimulator.

The Medtronic InterStim II Model 3058 Neurostimulator connects with a lead through which a stimulation program is delivered. The Medtronic InterStim Model 3023 Neurostimulator connects with an extension and the extension connects with a lead through which a stimulation program is delivered.

This manual includes instructions for the Single Stage Implant and the Staged Implant.

Single Stage Implant (Refer to page 12) - If test stimulation with a temporary test stimulation lead is successful, a Single Stage Implant can take place. A Single Stage Implant means that a lead, extension (if applicable), and a neurostimulator are surgically implanted at the same time.

Staged Implant (Refer to page 20) - If test stimulation with a temporary test stimulation lead is inconclusive, a Staged Implant is performed. In a Staged Implant, a lead is surgically implanted at a different time than the extension (if applicable) and neurostimulator. Thus, a Staged Implant occurs in two stages. Stage One means that a lead is surgically implanted and externalized via a percutaneous extension for test stimulation. If Stage One test stimulation is inconclusive, test stimulation may be repeated or the lead may be explanted. If Stage One test stimulation is conclusive, then Stage Two can take place. Stage Two means that an extension (if applicable) and neurostimulator are surgically implanted and attached to the previously implanted lead.

Device Description

The Model 3093 and Model 3889 leads are quadripolar in-line leads designed to be implanted adjacent to the sacral nerve. The Model 3889 lead contains four cylindrical electrodes equal in length and spaced equidistantly. The Model 3093 lead is the same as the Model 3889, except that electrode 1 (the electrode second from the distal end) is an extended (coiled) electrode approximately three times longer than the other three cylindrical electrodes.

The Model 3093 and Model 3889 leads have tines and marker bands. The tines anchor the lead, and the marker bands indicate lead depth and tine deployment during percutaneous implantation with a Medtronic lead introducer. Marker bands C and D can be seen visually, while marker bands A and B can be seen under fluoroscopy.

The Model 3093 and Model 3889 leads have white marker tips at the proximal end to ensure the lead is fully seated in the Model 3058 Neurostimulator connector block.

Device Description

Figure 1 shows the Model 3093 Lead and Figure 2 shows the Model 3889 Lead.

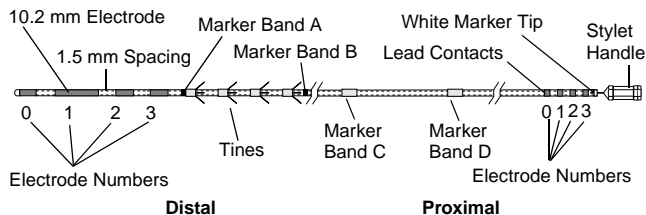


Figure 1. Model 3093 Lead.

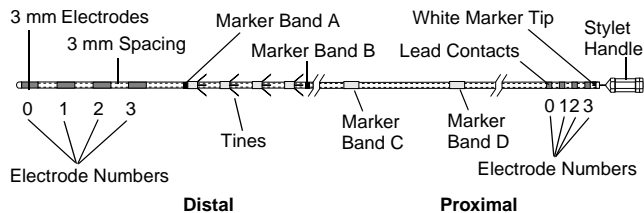


Figure 2. Model 3889 Lead.

Package Contents

The Model 3093 and Model 3889 lead kits contain the following:

- One quadripolar lead (with inserted long stylet)
- One stylet: short (snaps onto lead)
- One stainless-steel tunneling tool, tunneling tip, and tube
- One torque wrench
- One silicone rubber connector boot
- One twist-lock screening cable
- One percutaneous extension (and tunneling tube)

The contents of the inner package are **STERILE**. The lead and all accessories are intended for single use only.

Specifications

Refer to Table 1 for Model 3093 and Model 3889 lead specifications. For detailed descriptions and specifications for other components and accessories, refer to the product literature packaged with those devices.

Table 1. Model 3093 and Model 3889 lead specifications^a

Lead lengths	20 to 60 cm (8 to 24 in)
Lead shape	Straight
Lead diameter	1.27 mm
Connector	In-line
Number of electrodes	4
Electrode shape	Cylindrical/coiled
Electrode Length	
Model 3889	3 mm (4x)
Model 3093	3 mm (3x), 10.2 mm (1x)
Electrode Spacing	
Model 3889	3 mm
Model 3093	1.5 mm
Number of conductor wires	4
Implanted Material in contact with human tissue	
Conductor wires	MP35N
Proximal connector	MP35N
Lead ends	Polyurethane adhesive
Stimulating electrodes	Platinum/Iridium
Tines/Anchor	55 D Polyurethane
Boot	Silicone rubber
Insulation	
Conductor wires	Fluoropolymer
Jacket tubing	55 D Polyurethane
Conductor resistance	28 cm: 125 Ohms (max) 33 cm: 145 Ohms (max) 41 cm: 165 Ohms (max)

^a All dimensions are approximate.

Note: The electrical resistance of leads is proportional to their length. Very long leads have an increased resistance that may limit pulse amplitude at the electrodes.

Single Stage Implant Technique

This section describes the Single Stage Implant technique for buttock placement of the neurostimulator. Refer to “Appendix A: Abdominal Neurostimulator Implantation (Model 3023 Neurostimulator Only)” on page 29 for instructions on abdominal placement of the neurostimulator.

If test stimulation is successful, a Single Stage Implant can take place. A Single Stage Implant means that a lead, extension (if applicable), and a neurostimulator are surgically implanted at the same time.

Note: For information on test stimulation, refer to the product literature packaged with the test stimulation lead kit.

Operating Room Supplies

In addition to standard surgical instruments and supplies selected by the physician, the following should be on hand:

- Medtronic Model 3065U Test Stimulation Lead Kit
- Medtronic Model 3550-18 Lead Introducer Kit
- Medtronic Model 3625 Test Stimulator
- The x-ray from the percutaneous test stimulation as a reference for positioning the lead

Implant Preparation

1. Administer anesthesia to the patient.

Note: Use of muscle relaxants during anesthesia will diminish muscle response to stimulation. Do not use muscle relaxants.

2. Place the patient in a prone position allowing for a 30 degree flexion at the hip and knees.
3. Prepare the patient from the lower back to the perineum for sterile surgery.
4. Drape to allow observation of the pelvic floor for muscle response to test stimulation.
5. Provide visual access to soles of the feet to confirm muscle responses to stimulation.

Acute Test Stimulation

Acute test stimulation is used to properly locate the target nerve with electrical stimulation prior to lead placement.

1. Using bony topography or fluoroscopy as a guide, insert an insulated foramen needle into the selected foramen.



Caution: Limit implant depth and number of needle insertions into the foramen. Cease insertion at the point where the desired response is obtained. The insertion depth is usually 2.5 to 4.0 cm (1.0 to 1.5 in).

2. Connect the mini-hook from the patient cable to the non-insulated section of the foramen needle (black band below hub).
3. Turn the test stimulator output (amplitude) ON.
4. Gradually increase the intensity of stimulation to obtain appropriate paresthesia or muscle response as outlined in the "Acute Stimulation" section of the product literature packaged with the test stimulation lead kit.
5. Turn the test stimulator output (amplitude) OFF when finished.

Lead Implantation

1. Remove foramen needle stylet and replace with directional guide, aligning the bottom of the appropriate depth marker on the directional guide with the top of the needle hub (Figure 3).

Notes:

- Either end of the directional guide is inserted into the foramen needle.
- For a 9.0 cm (3.5 in) foramen needle, align with the most distal depth marker. For a 12.5 cm (5.0 in) foramen needle, align with the second most distal depth marker.

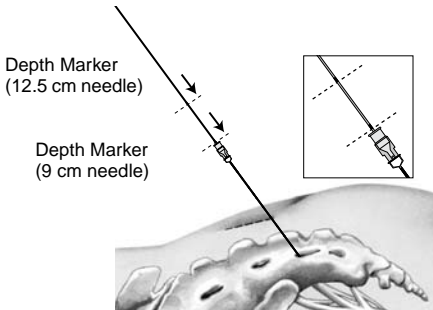


Figure 3. Insert directional guide into foramen needle.

2. Holding the proximal portion of the directional guide in place, gently remove the foramen needle from the patient and from the directional guide (Figure 4).

Single Stage Implant Technique

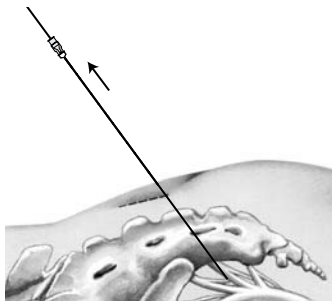


Figure 4. Remove foramen needle.

3. Make a small incision on either side of the directional guide.
4. Holding the directional guide in place near the skin, fit the dilator and introducer sheath over the directional guide and advance into the foramen. Align the bottom of the third most proximal depth marker on the directional guide with the top of the dilator (Figure 5).

Note: To aid advancement, slowly rotate the dilator and introducer sheath during insertion.

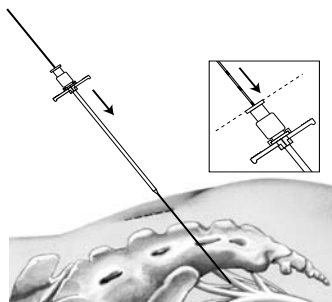


Figure 5. Fit dilator and introducer sheath over directional guide.

5. Unlock the dilator from the introducer sheath (Figure 6). Remove the directional guide and dilator, leaving the introducer sheath in place (Figure 7).

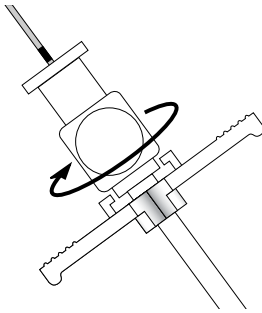


Figure 6. Unlock dilator from introducer sheath.

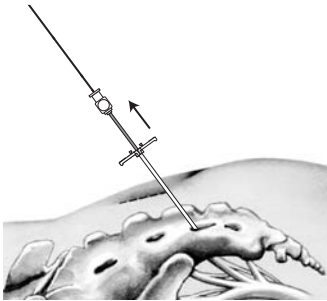


Figure 7. Remove directional guide and dilator.

6. Insert the lead into the introducer sheath and advance the lead until visual marker band C on the lead lines up with the top of the introducer sheath handle. Using fluoroscopy, confirm that electrode 0 of the lead is proximal to the radiopaque marker band at the distal tip of the sheath (Figure 8).

Notes:

- The marker bands on the lead exist to aid in proper lead placement and to notify the physician when the tines are ready to be deployed (refer to Figures 1 and 2 on page 10).
- The stylet supplied inserted into the lead is intended to be approximately 0.64 to 1.27 cm (0.25 to 0.50 in) longer than the lead. The stylet handle does not snap onto the lead.
- If it is difficult to insert the lead into the introducer sheath, sterile water may be used as a lubricant.

Single Stage Implant Technique

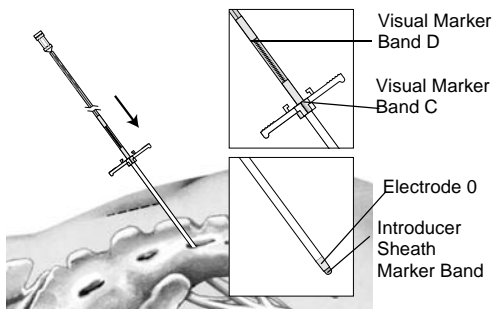


Figure 8. Advance lead through introducer sheath.

7. While holding the lead in place, retract the introducer sheath until visual marker band D on the lead lines up with the introducer sheath handle. Using fluoroscopy, confirm that the radiopaque marker band at the tip of the sheath is proximal to electrode 3 and adjacent to radiopaque marker band A on the lead (Figure 9).

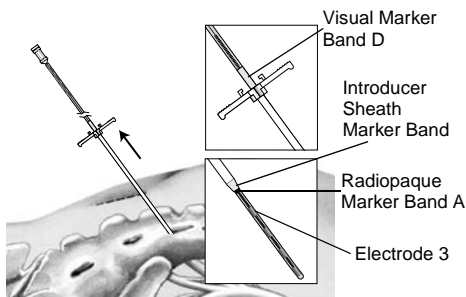


Figure 9. Retract introducer sheath to expose electrode 3.

8. Test stimulate the various electrodes (0, 1, 2, 3) and observe responses. If necessary, reposition the lead within the foramen.

Note: Hold sheath and lead together when adjusting lead position.



Caution: Optimal motor responses should be observed intraoperatively at 1 to 2 volts amplitude during test stimulation of the lead. If strong motor responses are obtained at amplitude levels measured at less than 1 volt intraoperatively, the lead may be placed too close to the intended sacral nerve and should be repositioned farther away.

9. When satisfied with lead position, hold the lead in place and carefully withdraw the introducer sheath and lead stylet (Figure 10).

Note: Withdrawing the introducer sheath deploys the tines, anchoring the lead (Figure 11).



Cautions:

- Use care not to dislodge lead from its position.
- Ensure that the lead is in the correct position before deploying the tines.

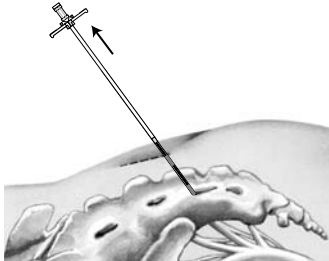


Figure 10. Hold lead and withdraw introducer sheath and lead stylet.

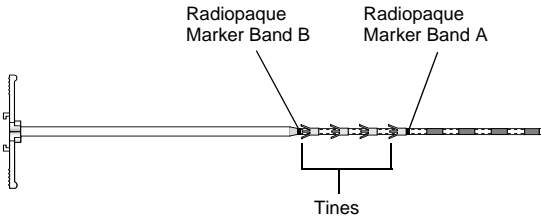


Figure 11. Retraction of sheath deploys tines.

10. Test stimulate the various electrodes (0, 1, 2, 3) to confirm response previously observed.

Notes:

- If you need to advance the lead after the tines have deployed, do so with the lead stylet in place. If you need to retract the lead after the tines have deployed, remove the lead completely using gentle traction and place it again.
- If additional anchors are used to secure the lead, refer to the technical manual packaged with the anchors accessory kit.

Single Stage Implant Technique

Lead Tunneling

For instructions on creating a neurostimulator pocket, refer to the product literature packaged with the neurostimulator.

1. Attach the metal tunneling tip to the tunneling tool (Figure 12) and remove its protective sheath.

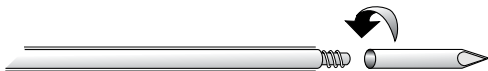


Figure 12. Attach metal tunneling tip.

2. Bend the tunneling tool as necessary to conform to the patient's contour.
3. Tunnel at the subcutaneous level from the lead to the neurostimulator site.

Note: Deep tunneling is not desirable.

4. Remove the tunneling tip and tunneling tool, leaving the tube in place in the tunnel.
5. Gently feed the lead through the tube.
6. Pull the tube out to remove it from the tunnel, leaving the lead in position.
7. Close the lead implant incision and dress the wound appropriately.

If performing Stage One of a Staged Implant procedure, continue with "Percutaneous Extension Tunneling" on page 20.

Making the Lead-Extension Connection (Model 3023 Neurostimulator Only)

1. Push the protective boot over the proximal end of the lead (Figure 13) while stabilizing the lead body.



Figure 13. Push protective boot over lead.

2. Wipe off any remaining body fluids or tissue from the surface of the lead contacts and the extension setscrew connector.
3. Insert the lead fully into the extension setscrew connector. The four metal bands on the lead should be aligned under the four setscrews (Figure 14).

Note: Sterile water may be used as a lubricant to facilitate the insertion of the lead. This may also help to see the lead more clearly through the extension setscrew connector. Do not use saline.

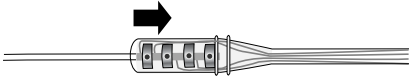


Figure 14. Insert lead into extension setscrew connector.

4. Tighten each of the four setscrews by turning them clockwise with the torque wrench provided before stimulation can be attempted (Figure 15). Tighten the setscrews only until the torque wrench clicks.



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

Note: The setscrews must engage the contacts before stimulation can be attempted.

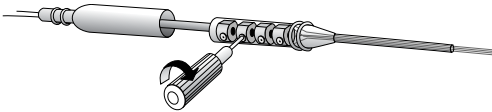


Figure 15. Tighten setscrews.

5. Push the protective boot completely over the lead-extension connection.

Note: Sterile water may be used as a lubricant for ease of placing the boot. Do not use saline.

6. Secure the connection with nonabsorbable sutures around the grooved ends of the boot (Figure 16).



Caution: Do not tie a suture directly to the extension or the lead. If the suture is tied too tightly over other areas of the lead or extension, the suture could cut through the insulation and cause a short.



Figure 16. Suture both ends of connection.

7. Pull any excess extension length toward the neurostimulator pocket. The connection should lie straight in the subcutaneous plane with the lead and extension curving gently away.

Notes:

- For instructions on connecting the extension to the neurostimulator (Model 3023 Neurostimulator only), refer to the product literature packaged with the neurostimulator.
- For instructions on completing the implant procedure, refer to “Completing Implant Procedure for Single Stage and Staged Procedures” on page 28.

Staged Implant Technique

This section describes the Staged Implant Technique for buttock placement of the neurostimulator.

If percutaneous test stimulation is inconclusive, a Staged Implant can take place. A Staged Implant means that a lead is surgically implanted at a different time than an extension (if applicable) and a neurostimulator. Thus, a Staged Implant occurs in two stages. Stage One means that a lead is surgically implanted and externalized via a percutaneous extension and screening cable for test stimulation. If Stage One test stimulation is inconclusive, test stimulation may be repeated or the lead may be explanted. If Stage One test stimulation is conclusive, then Stage Two can take place. Stage Two means that while a lead remains implanted, an extension (if applicable) and neurostimulator are surgically implanted.

Note: For information on test stimulation, refer to the product literature packaged with the test stimulation lead kit.

Stage One

A lead is surgically implanted and externalized via a percutaneous extension and screening cable for test stimulation.

Note: If Stage One test stimulation is inconclusive, test stimulation may be repeated or the lead and percutaneous extension may be explanted.

Lead Implantation

1. Prepare the patient, perform acute stimulation, and implant the lead using the operating room supplies and instructions in “Single Stage Implant Technique” on page 12.
2. Tunnel the lead to the future neurostimulator pocket site according to “Lead Tunneling” on page 18.

Percutaneous Extension Tunneling

The percutaneous extension is connected to the lead, then subsequently tunneled from the future neurostimulator pocket site to an exit site for connection to the test stimulator with the twist-lock screening cable.

1. Remove the percutaneous extension from the tube and slip the tube over the shaft of the tunneling tool.
2. Attach the metal tunneling tip to the tunneling tool (Figure 17) and remove its protective sheath.



Figure 17. Attach metal tunneling tip.

3. Bend the tunneling tool as necessary to conform to the patient's contour.

4. Make a small stab wound contralateral to the neurostimulator pocket site where the percutaneous extension will exit the skin.
5. Tunnel at the subcutaneous level, from the pocket to the stab wound.

Note: Deep tunneling is not desirable.

6. Remove the tunneling tip and tunneling tool, leaving the tube in place.
7. Gently feed the percutaneous extension through the tube until the setscrew connector junction is partially in the tunnel (Figure 18).

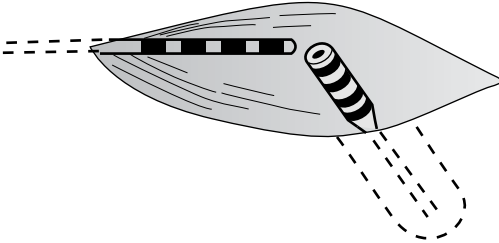


Figure 18. Setscrew connector junction in tunnel.

Connecting the Lead and Percutaneous Extension

1. Push the connector boot over the exposed end of the lead (Figure 19).



Figure 19. Push connector boot over lead.

2. Wipe off any remaining body fluids or tissue from the lead contacts and setscrew connector junction.
3. Insert the exposed lead end fully into the socket of the setscrew connector junction (Figure 20).

Note: Make sure the lead contacts are centered in the connector block under the setscrews. Observing the junction while gently rotating the lead will help to determine whether the lead is properly inserted.

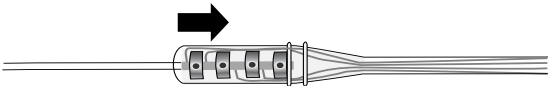



Figure 20. Insert lead fully into setscrew connector junction.

4. Tighten each of the four setscrews by turning them clockwise in the setscrew sockets with the torque wrench provided (Figure 21). Tighten each setscrew only until the torque wrench clicks.

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

Note: The setscrews must engage the contacts before stimulation can be attempted.

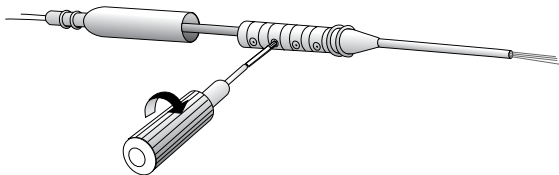



Figure 21. Tighten setscrews.

5. Slide the connector boot into place, completely covering the lead/extension connection.

Note: If it is difficult to position the boot, sterile water may be used as a lubricant. Do not use saline.

6. Secure the boot with one nonabsorbable suture around the wide end of the connection (Figure 22).

-  **Caution:** Do not use a suture to secure the narrow end of the boot because it may damage the lead.

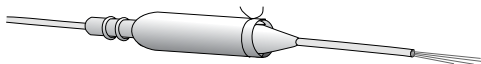


Figure 22. Suture lead/extension connection.

7. Remove the tube from the tunneled pathway.
8. Position the lead and extension to avoid sharp bends or kinks.
Note: Fluoroscopic observation may be necessary.
9. Close the initial incision and stab wound, leaving only the fine percutaneous extension wires and pin connector protruding from the skin.

Connecting the Twist-Lock Screening Cable

1. Insert the pin connector of the percutaneous extension into the cylindrical twist-lock connector on the screening cable and lock it. The pin connector fits into the connector in only one way (Figures 23-26).

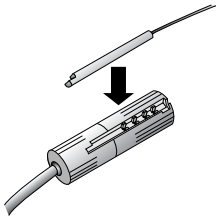


Figure 23. Position pin connector and twist-lock connector.

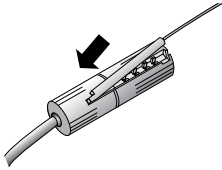


Figure 24. Secure end of pin connector in groove.

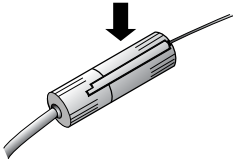


Figure 25. Insert pin connector into groove.

Note: The stylet handle must be completely inserted and level in the twist-lock connector before it can be closed.

2. Lock the stylet handle into the twist-lock connector on the screening cable by twisting connector 1/4 turn until connector stops (Figure 26). If the twist-lock connector does not turn easily, do not force it to turn. Stop, disassemble the components, and repeat step 1 in this section.

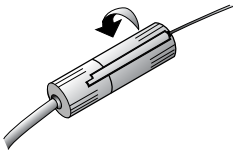


Figure 26. Lock twist-lock connector.

Note: The test stimulator is not sterile and should be operated outside sterile field.

3. Check that the test stimulator output (amplitude) is OFF (refer to product literature packaged with the test stimulator).
4. Push the plug end of the screening cable into the test stimulator output jacks (Figure 27).

Staged Implant Technique

Note: The plug end of the screening cable is designed to fit only into the jacks on the side closest to the Electrode Select switches.



Warning: To prevent possible uncomfortable patient stimulation, always turn the test stimulator amplitude OFF before connecting or disconnecting cables.

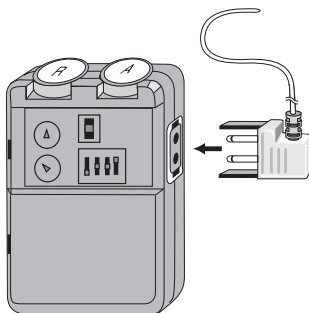


Figure 27. Connect screening cable and test stimulator.

Test Stimulation

The patient's response to the system and the system's efficacy should be evaluated in a clinical setting. An at-home (interoperative) test stimulation period allows you to determine the most effective stimulation for the patient.

1. Check the test stimulator controls as follows (Figure 28):
 - Rate (R) to 15 Hz
 - Amplitude (A) to OFF
 - Rate and Pulse Width Select switch to position A
 - Pulse Width to 210 μ sec
 - Amp Limit to 10 volts
 - Electrode Select switches as shown in Figure 28 (or as appropriate to achieve optimal patient response)

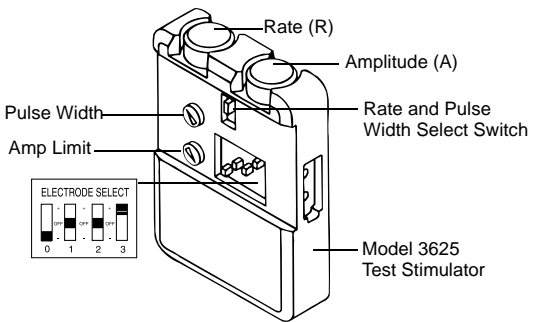


Figure 28. Test stimulator control settings.

2. Swab the area around the exit site of the extension. Tape the pin connector and cable assembly together to secure the connection. Carefully coil and then tape the entire assembly to the patient's skin, allowing for proper strain relief.

Note: Keep the cable taped down to prevent it from getting caught and pulled on. Pulling on the cable will pull on the lead.
3. Cover the entire area with a large transparent dressing.
4. Proceed with the test stimulation.
5. Instruct the patient how and when to use the test stimulator and the level of stimulation to apply.

Notes:

- Because the test stimulator A (Amplitude) dial can be adjusted by the patient, you may want to restrict the maximum amplitude. To do this, set the Amp Limit control (Figure 28) to a lower value appropriate to the patient's stimulation requirements.
 - If the sensation or response is not adequate, carefully check all connections. Make sure the test stimulator is turned on and that the ON light (green) is blinking.
 - Replace the test stimulator's 9-volt battery for each patient. The patient must see the blinking ON light (green) and feel the stimulation in his or her pelvic musculature.
6. You may want to have the patient call your office every day to report his or her status.
 7. Schedule a return evaluation. Test stimulation typically lasts 3-5 days but should not exceed seven (7) days to minimize the risk of infection.
 8. Instruct patients to:
 - Limit physical activities to low or moderate levels.
 - Learn proper use of the test stimulator.
 - Keep the cable taped down to prevent it from getting caught and pulled on. Pulling on the cable will pull on the lead.

Staged Implant Technique

- Consult you if they notice any unusual symptoms or signs, for example swelling or redness at the incision site.
- Inform health care providers that they have an implanted lead.
- Turn the external test stimulator OFF if they drive a motor vehicle or operate potentially dangerous equipment, such as power tools.
- Recognize that when they move, the stimulation they feel may increase or decrease — tell them that some patients experience the increased feeling as uncomfortable (“jolting” or “shocking”)— and explain that the change in feeling is caused by a shift in the lead position relative to the nerve.
- Avoid baths and showers. Take sponge baths, but be careful to keep the area around the lead dry and undisturbed.

Different electrode configurations should be evaluated at various parameter settings (Rate, Amplitude, Pulse Width). Refer to the operator manual packaged with the test stimulator for detailed instructions on using the test stimulator.

Stage Two

If Stage One test stimulation is conclusive, Stage Two can take place. For Stage Two, a lead remains implanted and an extension (if applicable) and neurostimulator are surgically implanted.

Note: If Stage One test stimulation is inconclusive or if not proceeding with implantation of the neurostimulation system, test stimulation may be repeated, or the lead and percutaneous extension may be explanted.

Disconnecting the Twist-Lock Screening Cable

Remove the percutaneous extension according to the following procedures.

1. Turn the test stimulator output (amplitude) OFF.
2. Unlock the cylindrical twist connector (Figure 29).

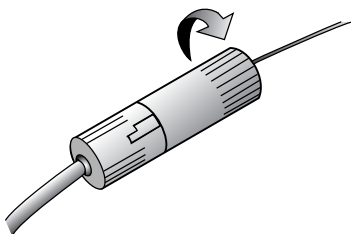


Figure 29. *Unlock twist-lock connector.*

3. Disconnect the percutaneous extension from the twist-lock screening cable.

Removing the Percutaneous Extension

1. Carefully open the percutaneous extension-lead connector site.
2. Cut the suture and slide the connector boot back over the setscrews to expose the setscrews.



Caution: Do not cut near the lead when removing sutures from the percutaneous extension. Cutting the lead's insulation can result in loss of stimulation and lead failure.

3. Using the torque wrench, loosen each of the four setscrews in the setscrew connector by turning the wrench counterclockwise (approximately one turn).
4. Gently remove the lead from the setscrew connector.



Caution: If resistance is felt when removing the lead from the percutaneous extension, loosen the setscrews slightly to ensure that they clear the lead contacts. Avoid disengaging the setscrews. Inspect the lead contacts for damage (flattening or stretching of lead) if resistance was felt prior to removal.

5. Remove the boot from the lead and discard the boot.
6. Cut the percutaneous extension behind the setscrews below the protective plastic sheath. Discard the severed segment, making sure not to leave any of the plastic sheath in the wound.
7. Use sterile forceps to withdraw the remainder of the percutaneous extension through the contralateral exit site and discard it.



Caution: Use a surgical tool or reglove after removal of the percutaneous extension to maintain a sterile field and minimize the risk of infection.

8. Close the exit site.

Notes:

- For instructions on connecting the lead to the Model 3058 Neurostimulator, refer to product literature packaged with that device.
- For instructions on connecting the lead to the extension, refer to “Making the Lead-Extension Connection (Model 3023 Neurostimulator Only)” on page 18.
- For instructions on removing the lead, refer to “Post Surgery Lead Removal” on page 28.

Completing Implant Procedure for Single Stage and Staged Procedures

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 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.

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 parameters values are appropriate.

Post Surgery Treatment

Administer antibiotics prophylactically for 24 hours.

Post Surgery Lead Removal

If you need to remove the implanted tined lead, the most effective removal technique is to use gentle traction and pull the lead in a straight, not oblique, line from the lead tines (for example, pull from the lead introducer insertion site).

Make a small incision and use gentle traction to completely remove the entire lead.



Caution: Do not use more than gentle traction to remove the tined lead. Use only gentle traction. More than gentle traction may result in lead breakage.

If resistance occurs during lead removal, gentle traction should be stopped to reduce the risk of lead breakage. Additional dissection may be needed to release the lead tines and to remove the entire lead.

Appendix A: Abdominal Neurostimulator Implantation (Model 3023 Neurostimulator Only)

This section describes implantation of the Model 3023 Neurostimulator in the abdomen.

Lead Tunneling

1. Hold the lead over the patient's skin to simulate its subcutaneous path to the extension-lead connection site. Mark the location of the connection site on the patient's skin.

Note: Routing the lead to follow the pelvic girdle, below the iliac crest, may help to minimize torsional forces on the lead postoperatively.

2. Check that the tube is on the shaft of the tunneling tool.
3. Attach the metal tunneling tip to the tunneling tool (Figure 30) and remove its protective sheath.



Figure 30. Attach metal tunneling tip.

4. Bend the tunneling tool as necessary to conform to the patient's contour.
5. Make a small stab wound at the extension-lead connection site.
6. Tunnel at the subcutaneous level from the sacral foramen to the connection site.

Note: Deep tunneling is not desirable.

7. Remove the tunneling tip and tunneling tool, leaving the tube in place in the tunnel.
8. Attach the enclosed short stylet to the proximal end of the lead.
(Figure 31).
 - a. Insert the short stylet completely into the lead.
 - b. Secure the lead in the stylet handle.

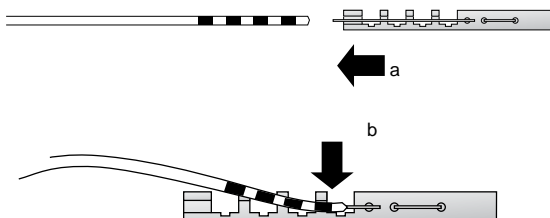


Figure 31. Attach short stylet to lead.

Appendix A: Abdominal Neurostimulator Implantation (Model 3023 Neurostimulator Only)

9. Attach a suitably stiff suture to the short stylet and pass it through the hole provided, leaving a long enough tail to pass through the tube (Figure 32).

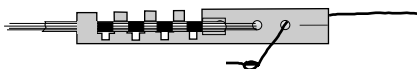


Figure 32. Attach suture to short stylet.

Note: To help pass the suture through the tube, apply suction at the tube exit or use the tunneling tool and tie the suture to its threaded tip.

10. Pull on the suture to draw the lead through the tube.
11. Test stimulate the various electrodes (0, 1, 2, 3) to confirm response previously observed.
12. Carefully disconnect and remove the short stylet from the lead.
13. Pull the tube out to remove it from the tunnel, leaving the lead in position.
14. Attach a silk tie with 5-cm tags to the end of the lead to identify its location after patient rotation.
15. Irrigate and close both incisions, the final closure of the sacral incision and the temporary closure of the lead-extension connection site, to accommodate patient rotation.

Tunneling to the Implant Site

1. Reposition the patient to the lateral decubitus position.
2. Prepare the patient's lower quadrant and connection site.
3. Drape to allow access to the lead connection site and the neurostimulator implant site.
4. Reopen the lead connection site and expose the proximal end of the lead. Test stimulate to confirm proper response.
 - a. Connect the patient cable mini-hook to the lead contact.
 - b. Turn the test stimulation output (amplitude) ON.
 - c. Gradually increase the intensity of stimulation to obtain appropriate paresthesia or muscle response as outlined in the "Acute Stimulation" section of the product literature packaged with the test stimulation lead kit.



Caution: Optimal motor responses should be observed intraoperatively at 1 to 2 volts amplitude during test stimulation of the lead. If strong motor responses are obtained at amplitude levels measured at less than 1 volt intraoperatively, the lead may be placed too close to the intended sacral nerve, and should be repositioned farther away. If motor responses are only observed intraoperatively at > 5 volts, the lead may be too far from the intended sacral nerve and should be repositioned closer to the nerve.

- d. Turn the test stimulator output (amplitude) OFF when the patient's response has been confirmed.
 - e. Disconnect the patient cable from the lead.
 - f. Disconnect the test stimulation cable from the ground pad and then the test stimulator.
5. Carefully remove the silk tags from the proximal end of the lead.
 6. Create a subcutaneous pocket for the neurostimulator by blunt dissection to the anterior surface of the muscle. The neurostimulator is typically placed in the lower right or left quadrant.

Notes:

- The Model 3023 Neurostimulator should be placed no deeper than 3.8 cm (1.5 in) below the skin and should be parallel to the skin. If the neurostimulator is too deep, or if it is not parallel to the skin, telemetry may not be successful. The etched side of the neurostimulator must face away from muscle to prevent uncomfortable stimulation.
- If the patient has other neurostimulators, the neurostimulators must be separated by a minimum of 20 cm (8.0 in).



Cautions:

- The neurostimulator is provided sterile. Do not soak the neurostimulator in antibiotic solution. Soaking in antibiotic solution can possibly 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.

-
7. Place the neurostimulator in the pocket to assure a proper fit and then remove it.
 8. Provide a tunnel for the extension.
 - a. Attach the wedge tip to the tunneling tool (Figure 33).



Figure 33. Attach wedge tip.

Note: A tunneling tool extender is provided in the extension kit for situations where the tunneling tool is not long enough. Remove the wedge tip and attach the extender using the extender wrench (Figure 34). Then attach the wedge tip.

Appendix A: Abdominal Neurostimulator Implantation
(Model 3023 Neurostimulator Only)

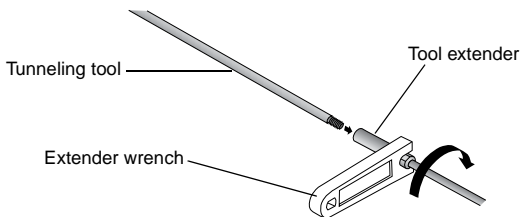


Figure 34. Attach tunneling tool extender.

- b. Bend the tunneling tool as necessary to conform to the patient's body contour.
- c. Tunnel from the lead-extension connection site to the neurostimulator pocket. Use caution when approaching the neurostimulator pocket to avoid additional trauma to the patient as resistance to tunneling suddenly ceases.

Note: An intermediate incision may be necessary if the tunneling tool does not extend the entire distance.

9. With the tunneling tool in place, remove the wedge tip and attach the carrier tip (Figure 35).
10. Insert the extension setscrew connector into the groove in the carrier tip (Figure 35). Carefully draw the assembly through the tunnel to where the lead lies exposed.

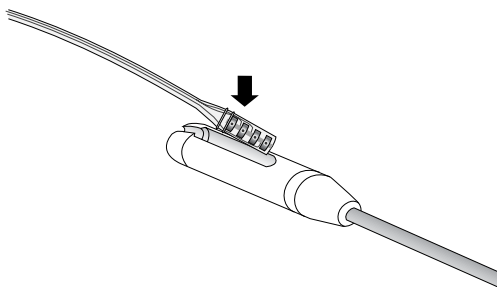


Figure 35. Insert extension setscrew connector into carrier tip.

11. Remove the extension setscrew connector from the carrier tip. To aid in removing the connector, push the connector forward in the groove, then lift the connector to remove.

Note: For instructions on connecting the lead to the extension, refer to "Making the Lead-Extension Connection (Model 3023 Neurostimulator Only)" on page 18.



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A12232001
March 2005