



Medtronic

1X4

74001

2X4

74002

Pocket adaptor kit for spinal cord stimulation

Implant manual

Rx only

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Table of contents

Description 5

Package contents 5

Device specifications 5

Compatible quadripolar extensions 8

Compatible neurostimulators 8

Considerations before implant 9

Instructions for use 10

Positioning the patient 10

Reopening the neurostimulator pocket 10

Retracting the setscrews 10

Disconnecting the extension(s) from the explanted neurostimulator and connecting to the pocket adaptor 11

One extension (4 electrodes) using one 1x4 pocket adaptor 11

One extension (4 electrodes) using one 2x4 pocket adaptor 11

Two extensions or a bifurcated extension (8 combined electrodes) using a 2x4 pocket adaptor 12

Two extensions (4 electrodes each) using two 1x4 pocket adaptors 13

Tightening the pocket adaptor setscrews 16

Connecting the pocket adaptor to the neurostimulator 17

Implanting the pocket adaptor with the neurostimulator 19

Checking system integrity 22

Completing the implant procedure 22

Physician communication to patient if the pocket adaptor is removed 22

At initial programming of the system 22

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.

Description

The Medtronic Models 74001 (1x4) and 74002 (2x4) Pocket Adaptors can be used as a part of a spinal cord stimulation system for pain therapy.

The pocket adaptor is intended to be implanted with the new replacement neurostimulator in the same pocket used for the explanted neurostimulator. Implanting in the same neurostimulator pocket allows for a single-incision procedure.

Package contents

- Pocket adaptor
- Octapolar in-line neurostimulator plug
- Wrench, torque
- Product literature
- Warranty card
- Registration form

Device specifications

The pocket adaptor has connector ports on the distal end for connecting the extension(s) and a 1x8 in-line connector on the proximal end.

The 1x4 pocket adaptor distal end connects to a Medtronic quadripolar extension. The 2x4 pocket adaptor distal end connects to two Medtronic quadripolar extensions or one bifurcated extension. The proximal end connects to a neurostimulator.

See "Compatible quadripolar extensions" and "Compatible neurostimulators" on page 8 for extension and neurostimulator compatibility with the pocket adaptor.

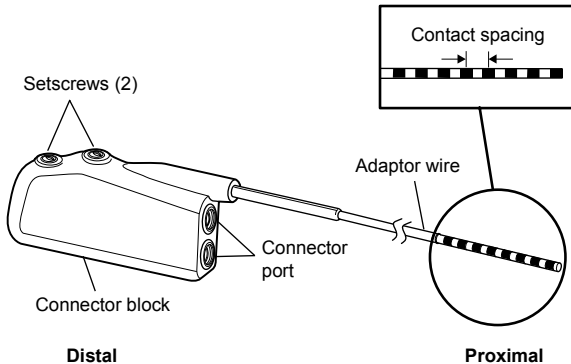


Figure 1. Model 74001 (1x4) pocket adaptor.

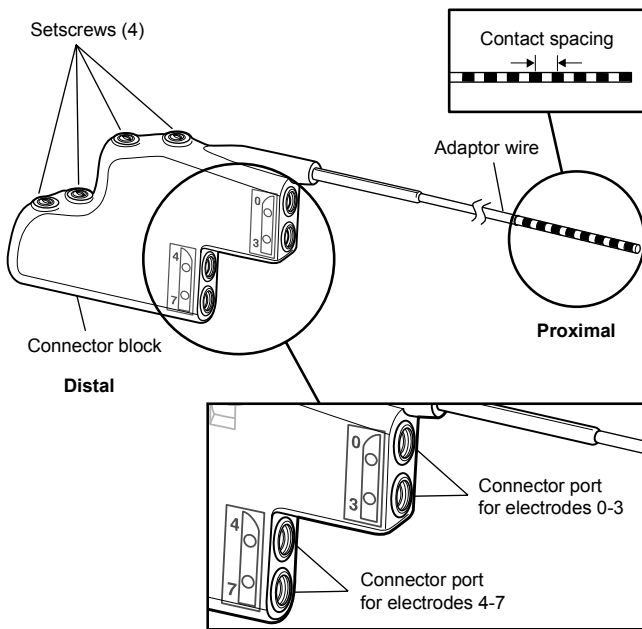


Figure 2. Model 74002 (2x4) pocket adaptor.

**Table 1. Device specifications^a for the Models 74001 and 74002
Pocket Adaptors**

Description	Model 74001	Model 74002
Resistance	Maximum 50.0 Ω	Maximum 50.0 Ω
Length	25.5 cm	27.4 cm
Distal end (adaptor connector block)		
Connector ports	Quadripolar	Quadripolar
Height	16.6 mm	29.7 mm
Length	33.8 mm	45.6 mm
Thickness	7.1 mm	7.1 mm
Volume	2.66 cm ³	4.91 cm ³
Proximal end (adaptor wire, connects to the neurostimulator)		
Connector	Octapolar, in-line	Octapolar, in-line
Contact spacing	2.8 mm	2.8 mm
Diameter	1.3 mm	1.3 mm

^a All measurements are approximate.

Table 2. Material of components in the Models 74001 and 74002 packages

Component	Material	Material contacts human tissue
Pocket adaptor		
Conductor wire	MP35N	No
Distal end (adaptor connector block)		
Overmold	Silicone rubber	Yes
Contacts	MP35N, stainless steel	No
Setscrew connector block	Titanium	Yes
Grommets, seals	Silicone rubber	Yes
Setscrews	Titanium	Yes
Adhesive	Silicone adhesive	Yes
Proximal end (adaptor wire, connects to the neurostimulator)		
Conductor wire insulation	Fluoropolymer	No
Contacts	MP35N	Yes
Insulation	Polyurethane	Yes
Neurostimulator plug	Polyurethane	Yes
Contact	Stainless steel	No
Wrench, torque		
Handle	Polymer	Yes
Shaft	Stainless steel	Yes

Compatible quadripolar extensions

Table 3 shows the compatibility of Medtronic quadripolar extensions with the Models 74001 (1x4) and 74002 (2x4) Pocket Adaptors.

Table 3. Quadripolar extension compatibility with the Models 74001 and 74002 Pocket Adaptors

Quadripolar extension model number	Model 74001 (1x4)	Model 74002 (2x4)
7471 ^a		•
7472 ^a		•
7489	•	•
7495	•	•
7495 LZ	•	•
7496	•	•
7498 ^b	•	•

^a The Models 7471 and 7472 Extensions are bifurcated on the proximal end.

^b The Model 7498 Extension is bifurcated on the distal end.



Warning: Evaluate the suitability of a pocket adaptor for patients with an implanted Model 7498 Extension. This extension is bifurcated on the distal end, connecting two leads in parallel. If one lead should break, an impedance measurement may yield a result in the normal range because of the presence of the second lead. Thus, open circuits may be difficult to detect, which can increase the potential for risks related to MRI.

Compatible neurostimulators

The following are the Medtronic 16-electrode neurostimulators that are compatible with the Models 74001 (1x4) and 74002 (2x4) Pocket Adaptors:

- RestorePRIME Model 37701
- PrimeADVANCED Model 37702
- Restore Model 37711
- RestoreULTRA Model 37712
- RestoreADVANCED Model 37713

Considerations before implant

- The pocket adaptor is intended for neurostimulator revisions only and not for extension or lead revisions, which would require retunneling. The pocket adaptor may not be appropriate if the lead or extension needs to be replaced.

If the implanted neurostimulator is still viable, perform a system integrity check with the neurostimulator before the day of implant surgery to ensure all leads and extensions are still functioning.

- Existing quadripolar extensions should not be replaced with the same or another quadripolar extension model if using the pocket adaptor.
- The pocket adaptor is not compatible or needed if a newer model extension (eg, Model 37083) is used to replace a quadripolar extension.
- Consider using the pocket adaptor when retunneling is not desired.
- Evaluate the patient's overall suitability for a system containing a pocket adaptor. Consideration should be given to cosmesis, erosion, trauma, infection, and patient comfort and risk factors (eg, age, skin thickness, diabetes, chronic steroid use).
- Consider the following when choosing an appropriate pocket adaptor model:
 - number of existing leads and extensions
 - electrode numbering for programming
 - number of components that will be implanted in the pocket
 - future expansion for additional leads
- The 2x4 pocket adaptor has the same electrode numbering as the 4- and 8-electrode neurostimulators and allows for future expansion into the second socket of the new replacement neurostimulator. See "At initial programming of the system" on page 22 for more information on electrode numbering.

Instructions for use

Implanting physicians should be experienced in neurostimulation system implant procedures and should be thoroughly familiar with all product labeling.



Cautions:

- Do not store or transport the kit components or accessories above 57°C (135°F) or below -34°C (-30°F). Temperatures outside this range can damage device components.
- Do not bend, kink, or stretch the extension or adaptor, which may damage the component.
- Do not use any instrument to handle the extension or adaptor. The force may break the wires. Broken wires may create an open circuit, resulting in loss of stimulation or component failure and requiring surgical replacement.

Positioning the patient

1. Locate the neurostimulator pocket and position the patient accordingly.
2. Before opening the adaptor package, verify the model number, use-by date, and connector type.

Reopening the neurostimulator pocket



Caution: When using sharp instruments near the implanted neurostimulator, be extremely careful to avoid nicking or damaging the extension. Damaging the extension may require surgical replacement.

1. Make an incision to access the neurostimulator.
2. Remove the neurostimulator from the pocket, taking care not to pull excessively on the extension, which could cause lead dislodgement.
3. Perform a system integrity check:

Notes:

- To ensure the implanted leads and extensions are functional, use the currently implanted neurostimulator for the system integrity check before disconnecting any extensions. The pocket adaptor may not be appropriate if an extension needs to be replaced.
 - If the neurostimulator battery is depleted, wait to perform the system integrity check until the "Disconnecting the extension(s) from the explanted neurostimulator and connecting to the pocket adaptor" procedure on page 11, when the extension is connected to the adaptor. At that point, use a Medtronic Model 37021 or Model 37022 External Neurostimulator along with a Model 3550-31 snap-lid screening cable attached to the proximal end of the pocket adaptor to perform the electrode impedance check.
 - Do not use the patient programmer to perform system integrity checks. Only use the clinician programmer.
4. Reduce or expand the size of the pocket to accommodate the pocket adaptor and the new neurostimulator. However, do not make the pocket any larger than what is needed. Too large of a pocket may cause patient twiddling, component migration, or flipping of the neurostimulator.

Note: Refer to the neurostimulator implant manual for the proper subcutaneous pocket depth placement of the neurostimulator below the skin. To allow for successful telemetry and/or recharge operation, ensure that the subcutaneous pocket does not allow the neurostimulator to fall below the required measurement beneath the skin.

Retracting the setscrews

1. Using the torque wrench, retract the setscrews within the explanted neurostimulator connector block (Figure 3).

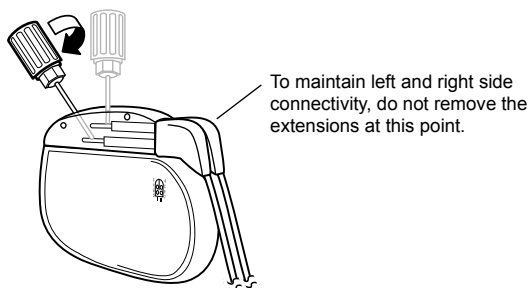


Figure 3. Retract the setscrews within the explanted neurostimulator using the torque wrench.

2. Check the pocket adaptor connector block and determine if any setscrews obstruct the connector ports. If needed, partially retract the setscrews.
 - a. To partially retract a setscrew, use the torque wrench and turn the setscrew counterclockwise only until the connector port is unobstructed.

Disconnecting the extension(s) from the explanted neurostimulator and connecting to the pocket adaptor

Use the appropriate procedure in this section specific to the extension and pocket adaptor configuration.



Cautions:

- Do not use saline or other ionic fluids at connections, which could result in a short circuit.
- 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.
- Do not pull the extensions taut. Pulling the extensions taut may result in a short or open circuit or migration of implanted components.

One extension (4 electrodes) using one 1x4 pocket adaptor

1. Remove the extension connector from the neurostimulator socket.
2. Wipe the extension connector pins with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution.
3. Ensure the connector pins and the adaptor connector ports are dry and clean.
4. Insert the extension connector pins into the 1x4 pocket adaptor connector port until fully seated.
5. Proceed to "Tightening the pocket adaptor setscrews" on page 16.

One extension (4 electrodes) using one 2x4 pocket adaptor

1. Remove the extension connector from the neurostimulator socket.
2. Wipe the extension connector pins with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution.
3. Ensure the connector pins and the adaptor connector ports are dry and clean.
4. Insert the extension connector pins into Connector Port 1 (top port) of the 2x4 pocket adaptor until fully seated.
5. Insert the two-pronged plug from the Model 3550-09 accessory kit into Connector Port 2 of the adaptor.
6. Proceed to "Tightening the pocket adaptor setscrews" on page 16.

Two extensions or a bifurcated extension (8 combined electrodes) using a 2x4 pocket adaptor

△ Cautions:

- Use only a 2x4 pocket adaptor for systems using the Model 7471 or the Model 7472 bifurcated extension. Using two 1x4 pocket adaptors with these bifurcated extensions will cause electrode numbering mismatches when programming and cause some neurostimulator features to be inoperable.
- Maintain left and right side connectivity for a two-extension or a bifurcated-extension system when disconnecting the extensions from the explanted neurostimulator and connecting to the 2x4 pocket adaptor. If left and right side connectivity is not maintained, the current electrode configuration will not be maintained in the new neurostimulator.
- Do not tie ligatures around the extension or adaptor wire to distinguish left or right side. Ligatures can damage the insulation.

This procedure disconnects and connects one extension at a time to the adaptor, which helps to maintain the left and right side connectivity.

1. Remove Extension 2 from Socket II (back socket) of the explanted neurostimulator (Figure 4).

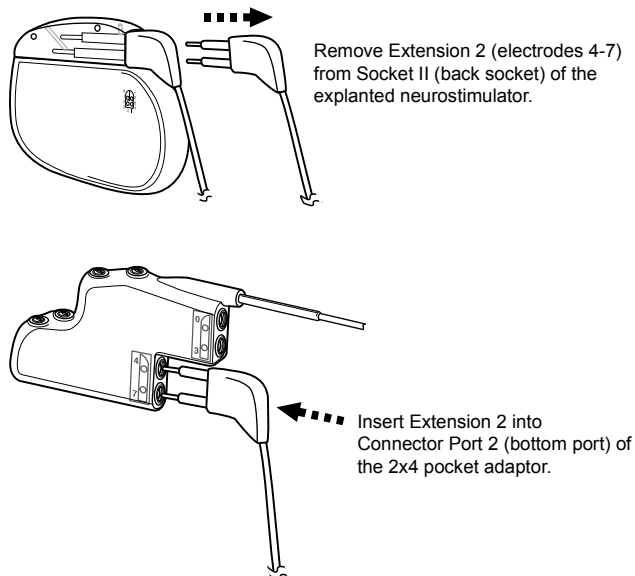


Figure 4. Remove Extension 2 from Socket II of the explanted neurostimulator and insert into Connector Port 2 of the 2x4 pocket adaptor.

2. Wipe the extension connector pins with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution.
3. Ensure the connector pins and the adaptor connector ports are dry and clean.
4. Insert the connector pins of Extension 2 into Connector Port 2 (bottom port) of the 2x4 pocket adaptor until fully seated (Figure 4).

5. Remove Extension 1 from Socket I (front socket) of the explanted neurostimulator (Figure 5).

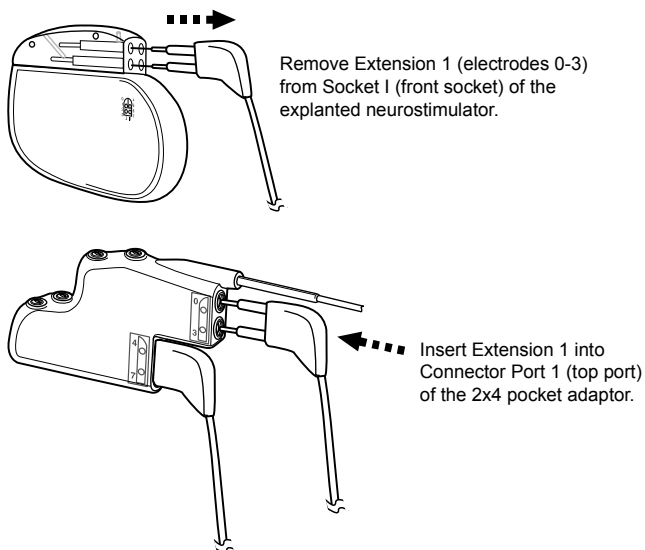


Figure 5. Remove Extension 1 from Socket I of the explanted neurostimulator and insert into Connector Port 1 of the 2x4 pocket adaptor.

6. Wipe the extension connector pins with sterile gauze. If necessary, use sterile USP water or a nonionic antibiotic solution.
7. Ensure the connector pins and the adaptor connector ports are dry and clean.
8. Insert the connector pins of Extension 1 into Connector Port 1 (top port) of the 2x4 pocket adaptor until fully seated (Figure 5).
9. Proceed to "Tightening the pocket adaptor setscrews" on page 16.

Two extensions (4 electrodes each) using two 1x4 pocket adaptors



Cautions:

- Use only a 2x4 pocket adaptor for systems using the Model 7471 or the Model 7472 bifurcated extension. Using two 1x4 pocket adaptors with these bifurcated extensions will cause electrode numbering mismatches when programming and cause some neurostimulator features to be inoperable.
- Maintain left and right side connectivity for a two-extension system when disconnecting the extensions from the explanted neurostimulator, connecting to the 1x4 pocket adaptors, and then connecting the adaptors to the new neurostimulator. If left and right side connectivity is not maintained throughout all connections, the current electrode configuration will not be maintained in the new neurostimulator.
- Do not tie ligatures around the extension or adaptor wire to distinguish left or right side. Ligatures can damage the insulation.

Proceed as follows:

1. Remove Extension 2 from Socket II (back socket) of the explanted neurostimulator (Figure 6a on page 14).

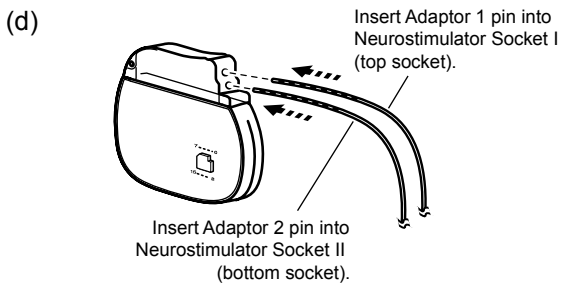
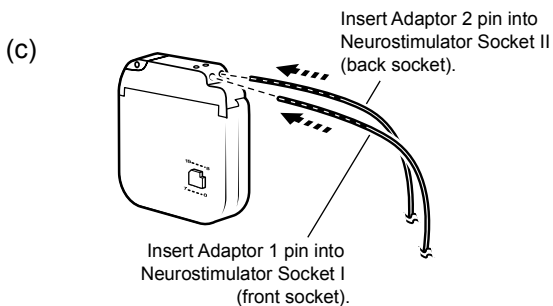
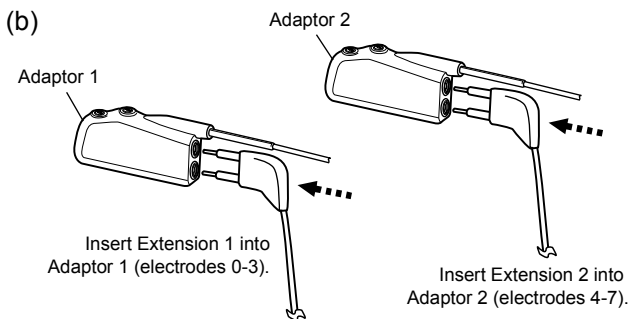
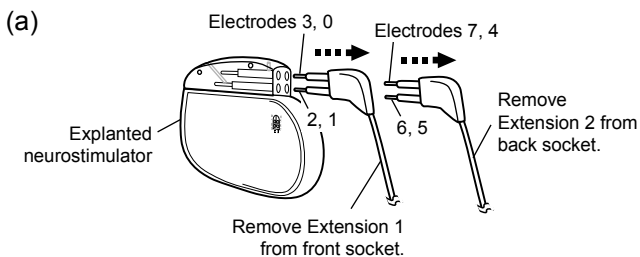


Figure 6. Connecting two extensions to two 1x4 pocket adaptors.

2. Wipe the extension connector pins with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution.
3. Ensure the connector pins and the adaptor connector ports are dry and clean.
4. Insert the connector pins of Extension 2 into the connector port of a 1x4 pocket adaptor until fully seated (Adaptor 2 in Figure 6b on page 14).
5. On the proximal end of the adaptor, wipe the adaptor connector pins with sterile gauze. If necessary, use sterile USP water or a nonionic antibiotic solution.
6. Ensure the adaptor connector pin and the neurostimulator connector block receptacle are dry and clean.
7. Slowly advance the proximal end of Adaptor 2 into Socket II (back socket or bottom socket) of the replacement neurostimulator until fully seated within the connector block (Figure 6c or d on page 14). Take care not to bend or kink the adaptor wire.

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.
8. Remove Extension 1 from Socket I (front socket) of the explanted neurostimulator (Figure 6a on page 14).
 9. Wipe the extension connector pins with sterile gauze. If necessary, use sterile USP water or a nonionic antibiotic solution.
 10. Ensure the connector pins and the adaptor connector ports are dry and clean.
 11. Insert the connector pins of Extension 1 into the connector port of the other 1x4 pocket adaptor until fully seated (Adaptor 1 in Figure 6b on page 14).
 12. On the proximal end of the adaptor, wipe the adaptor connector pins with sterile gauze. If necessary, use sterile USP water or a nonionic antibiotic solution.
 13. Ensure the adaptor connector pin and the neurostimulator connector block receptacle are dry and clean.
 14. Slowly advance the proximal end of Adaptor 1 into Socket I (front socket or top socket) of the replacement neurostimulator until fully seated within the connector block (Figure 6c or d on page 14). Take care not to bend or kink the adaptor wire.
 15. Tighten the setscrews on both 1x4 adaptors (two setscrews each):
 - a. Ensure all extension connector pins are fully seated in each pocket adaptor connector port.
 - b. Insert the torque wrench through the rubber grommet to engage the setscrew.



Caution: 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.

- c. Tighten the setscrew by turning the torque wrench clockwise until resistance is felt.
- d. Continue tightening until you hear clicking from the torque wrench. The setscrews must touch the extension connector pins for a proper electrical connection
- e. Repeat steps b-d for the remaining adaptor setscrews (total of two setscrews for each 1x4 pocket adaptor).



Cautions:

- Ensure all adaptor setscrews are fully tightened. Undertightening may result in insufficient electrical contact

within the connector block, which may cause intermittent stimulation.

- Verify that each leaf of the self-sealing grommet is closed after the torque wrench is withdrawn. If fluid leaks through a grommet seal that is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant location, or intermittent stimulation, or loss of stimulation.
16. Fully insert the torque wrench (packaged with the neurostimulator) into each self-sealing grommet of the neurostimulator connector block and tighten each setscrew until you hear clicking from the torque wrench.



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.
 - Ensure all neurostimulator setscrews are fully tightened. Undertightening may result in insufficient electrical contact within the connector block, which may cause intermittent stimulation.
 - Verify that each leaf of the self-sealing grommet is closed after the torque wrench is withdrawn. If fluid leaks through a grommet seal that is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant location, or intermittent stimulation, or loss of stimulation.
17. Proceed to "Implanting the pocket adaptor with the neurostimulator" on page 19.

Tightening the pocket adaptor setscrews

1. Ensure all extension connector pins are fully seated in the adaptor connector ports (Figure 7).

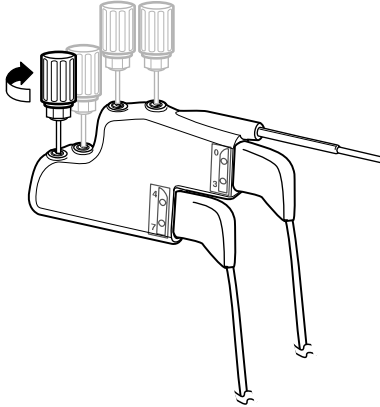


Figure 7. Ensure all extension connector pins are fully seated in the adaptor and tighten all adaptor setscrews (total of two setscrews for the 1x4 pocket adaptor; total of four setscrews for the 2x4 pocket adaptor).

2. Insert the torque wrench through the rubber grommet to engage the setscrew.



Caution: 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.

3. Tighten the setscrew by turning the torque wrench clockwise until resistance is felt.
4. Continue tightening until you hear clicking from the torque wrench. The setscrews must touch the extension connector pins for a proper electrical connection.
5. Repeat steps 2-4 for the remaining adaptor setscrews (total of two setscrews for the 1x4 pocket adaptor; total of four setscrews for the 2x4 pocket adaptor).



Cautions:

- Ensure all adaptor setscrews are fully tightened. Undertightening may result in insufficient electrical contact within the connector block, which may cause intermittent stimulation.
- Verify that each leaf of the self-sealing grommet is closed after the torque wrench is withdrawn. If fluid leaks through a grommet seal that is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant location, or intermittent stimulation, or loss of stimulation.

Connecting the pocket adaptor to the neurostimulator

Use this procedure when there is only one 1x4 pocket adaptor or one 2x4 pocket adaptor being implanted.

If two 1x4 pocket adaptors are used, the instructions to connect to the neurostimulator are in the "Two extensions (4 electrodes each) using two 1x4 pocket adaptors" procedure on page 13.



Caution: Before connecting components, wipe off any body fluids and dry all connections. Fluids in the connections may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.

1. Wipe the adaptor connector pin with sterile gauze. If necessary, use sterile USP water or a nonionic antibiotic solution.
2. Ensure the adaptor connector pin and the neurostimulator connector block receptacles are dry and clean.
3. Slowly advance the adaptor connector pin into Socket I (front socket or top socket) of the neurostimulator until seated fully within the connector block (Figure 8a or b, depending on the model of the replacement neurostimulator). Take care not to bend or kink the adaptor wire.

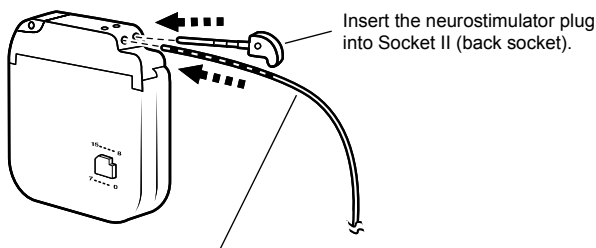


Caution: Do not insert the adaptor connector pin into the neurostimulator connector block if the setscrews are not sufficiently retracted. If the setscrews are not retracted, the setscrews may damage the adaptor and the adaptor will not be seated fully into the connector block.

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.

(a)



Insert the adaptor connector pin into Socket I (front socket):

Electrodes 0-3 for the 1x4 adaptor
Electrodes 0-7 for the 2x4 adaptor

(b)

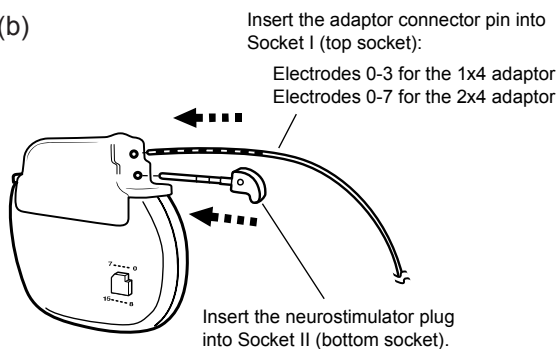


Figure 8. Insert the adaptor connector pin fully into neurostimulator Socket I. Insert the neurostimulator plug into Socket II.

4. Insert the neurostimulator plug into Socket II (back socket or bottom socket) of the neurostimulator (Figure 8a or b, depending on the model of the replacement neurostimulator).
5. Fully insert the torque wrench (packaged with the neurostimulator) into each self-sealing grommet of the neurostimulator connector block and tighten each setscrew until you hear clicking from the torque wrench (Figure 9a or b, depending on the model of the replacement neurostimulator).



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.
- Ensure all neurostimulator setscrews are fully tightened. Undertightening may result in insufficient electrical contact

within the connector block, which may cause intermittent stimulation.

- Verify that each leaf of the self-sealing grommet is closed after the torque wrench is withdrawn. If fluid leaks through a grommet seal that is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant location, or intermittent stimulation, or loss of stimulation.

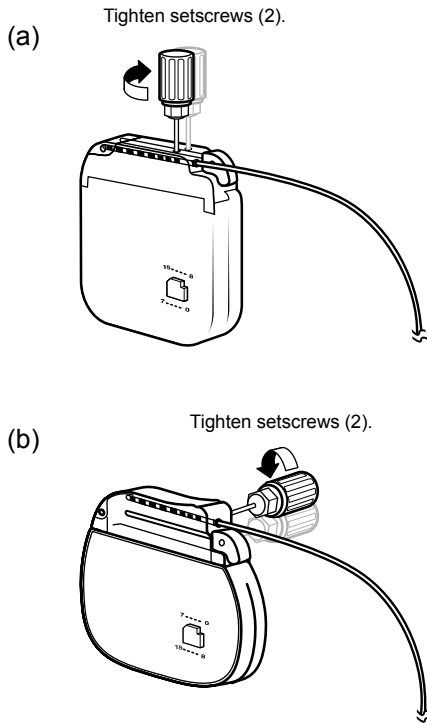


Figure 9. Tighten the neurostimulator setscrews in the self-sealing grommets.

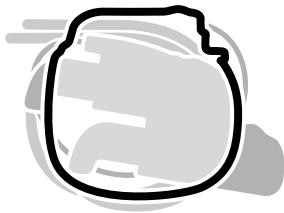
Implanting the pocket adaptor with the neurostimulator

Notes:

- Ensure all setscrews are tightened on the adaptor connector block and on the neurostimulator.
- Refer to the neurostimulator implant manual for the proper subcutaneous pocket depth placement of the neurostimulator below the skin.
- Implant the adaptor behind the neurostimulator so the neurostimulator is nearest the skin.

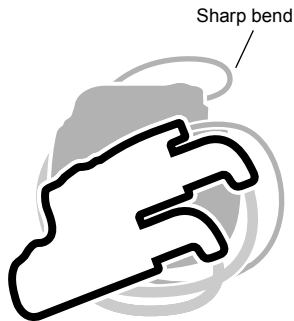
Proceed as follows:

1. Place the pocket adaptor behind the neurostimulator. Coil the adaptor wire and the excess extension wire behind the adaptor, ensuring there are no sharp bends in any of the wires (Figure 10).



There should be no sharp bends for the adaptor and extension wires.


YES



The adaptor and extension wires should not sharply bend.

NO

Figure 10. Ensure there are no sharp bends in any of the wires.

 **Warning:** Do not place any extension and adaptor wire between the neurostimulator and the adaptor. Placement of the wires between the two devices can damage the wire insulation and result in loss of stimulation.

2. Place the neurostimulator, adaptor, and coiled wires (placed behind the adaptor) into the subcutaneous pocket. The Medtronic logo on the neurostimulator should face outward, away from muscle tissue.

 **Warnings:**

- Do not place the pocket adaptor connector block or the adaptor wire between the skin and the neurostimulator (Figure 11). Implanting the adaptor in this location can cause failures in telemetry and/or recharge (for rechargeable neurostimulators). Furthermore, placing the adaptor and wire in this location nearest the skin may lead to damage to the adaptor and severing of the adaptor wire in a future neurostimulator revision procedure.



Place the adaptor behind the neurostimulator. The neurostimulator should be nearest the skin.

YES



Never place the adaptor between the skin and the neurostimulator.

NO

Figure 11. Never place the adaptor between the skin and the neurostimulator. Place the adaptor behind the neurostimulator.

- Do not place the pocket adaptor connector block in a medial, lateral, superior, or inferior positions relative to the neurostimulator. Placing the pocket adaptor connector block in any one of these positions may cause skin erosion.



Cautions:

- Position the neurostimulator with the Medtronic logo facing outward. If implanted with the Medtronic logo facing inward, rechargeable neurostimulators cannot be charged.
- Do not wrap or coil the extension or the adaptor wire around the perimeter or in front of the neurostimulator (Figure 12). Wrapping around the perimeter of the neurostimulator increases the potential for the wires to slip between the neurostimulator and the adaptor. Placing wires in front of the neurostimulator increases the potential for kinking of the extension and adaptor wires, for interference with telemetry and/or recharge operation, and for damage during future neurostimulator replacement surgery.

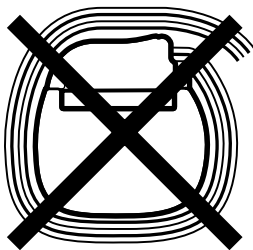


Figure 12. Do not wrap or coil the extension or adaptor wire around the perimeter or in front of the neurostimulator.

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

Checking system integrity

Refer to the neurostimulator manual for instructions. Use only the clinician programmer to perform system integrity checks.

In addition, refer to the *Model 8840/8870 N'Vision Clinician Programmer Guide* for detailed information to perform the following tasks to check the system integrity for the system that now contains the pocket adaptor:

1. Interrogate the neurostimulator.
2. Program lead configuration. If needed, renumber the electrodes according to Table 4 on page 22 of this manual.
3. Check electrode impedance.

Completing the implant procedure

1. Visually inspect that all implanted components are not nicked, cut, or damaged in any way.
2. Close and dress all incisions.
3. Ensure that a patient control device is given to the patient.
4. Complete the device tracking and patient registration paperwork included in the pocket adaptor package and return the documents to Medtronic.

Physician communication to patient if the pocket adaptor is removed

If the pocket adaptor is ever explanted, communicate to the patient at that time that the pocket adaptor was intentionally removed.

At initial programming of the system

- Indicate the use of the pocket adaptor in the Notes field on the Patient Data screen of the Model 8840 N'Vision Clinician Programmer.
- There may be differences between the explanted neurostimulator and the replacement neurostimulator. These include lead-electrode numbering (see Table 4), amplitude settings, and impedance measurements.
- Different impedances and an enhanced neurostimulator impedance measurement system can cause different impedance measurements from the explanted neurostimulator.
- See Table 4 for neurostimulator socket and electrode numbering. If electrodes require renumbering, use the Lead Configuration screen of the clinician programmer.

Table 4. Neurostimulator sockets and electrode numbering

Pocket adaptor	Neurostimulator socket and corresponding electrodes	Lead Configuration ^{a,b}
One 2x4	<ul style="list-style-type: none">▪ If Socket I is used, the default electrode numbering is as follows and requires no renumbering:<ul style="list-style-type: none">— Lead I: 0-3— Lead II: 4-7▪ If Socket II is used, the electrodes require renumbering to the following:<ul style="list-style-type: none">— Lead I: 8-11— Lead II: 12-15	2x4
One 1x4	<ul style="list-style-type: none">▪ If Socket I is used, the default electrode numbering is 0-3 and requires no renumbering.▪ If Socket II is used, the electrodes require renumbering to 8-11.	1x4

Table 4. Neurostimulator sockets and electrode numbering (continued)

Pocket adaptor	Neurostimulator socket and corresponding electrodes	Lead Configuration^{a,b}
Two 1x4s	<ul style="list-style-type: none">▪ Socket I default electrode numbering for Lead I is 0-3 and requires no renumbering.▪ Socket II electrodes for Lead II require renumbering to 8-11.	2x4

^a This is the configuration to select in the Lead Configuration screen of the clinician programmer.

^b If additional leads are added to the system, the lead configuration will be different from what is given in this column.



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