



Medtronic

EXTENSION

37082

Dual quadripolar extension kit (8-2-4)

Implant manual

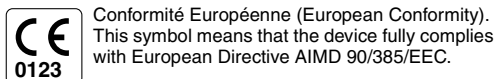
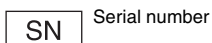
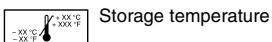
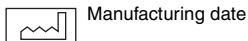
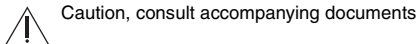
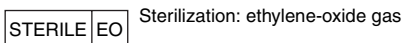
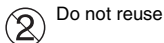
USA Rx only



2006

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.



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Refer to the indications sheet for indications and related information.

Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.

Refer to System Eligibility, Battery Longevity, Specifications reference manual packaged with the software application card for neurostimulator selection, battery longevity calculations and specific neurostimulator specifications.

! USA Refer to the clinical summary booklet packaged with the neurostimulator for information on the clinical study results of the neurostimulation system and individualization of treatment.

Device description

The Medtronic Model 37082 Extension is part of a neurostimulation system for pain therapy.

Package contents

- Extension
- Connector boots, 1 x 4 low-profile (2)
- Octapolar in-line neurostimulator plug
- Setscrews (2)
- Tunneling tools: extension passer, obturator, carrier
- Wrench, torque
- Product literature
- Warranty card (USA only)
- Registration form (USA only)

Device specifications

The extension has eight connectors on the distal end, four connectors on each distal leg, and eight connectors on the proximal end. The in-line distal end is bifurcated to connect to one or two Medtronic quadripolar leads. The proximal end connects to a Medtronic neurostimulator.

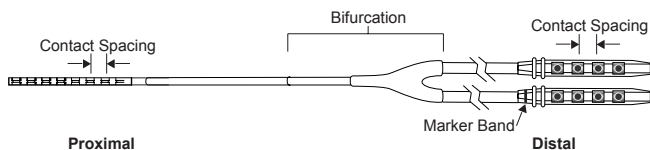


Figure 1. Model 37082 extension.

Note: The marker band is for lead identification. The lead connected to the extension leg with the marker band is for either circuits 0-3 or circuits 8-11.

Table 1. Device specifications^a for the Model 37082 Extension

Description	Model 37082
Resistance ^{b,c}	Maximum 24.0 Ω for all lengths
Length	10 – 110 cm
Distal end (lead)	
Connectors	Quadripolar, in-line (2)
Contact spacing	4.3 mm
Lead entrance diameter	1.5 mm
Connector outer diameter	3.8 mm
Proximal end (neurostimulator)	
Connector	Octapolar, in-line
Contact spacing	2.8 mm
Diameter	1.3 mm

^a All measurements are approximate.

^b Electrical resistance of this device only.

^c Resistance is proportional to length: long lengths have higher resistance that may limit the amplitude.

Table 2. Material of components in the Model 37082 package

Component	Material	Material contacts human tissue
Extension		
Conductor wire	Silver core MP35N	No
Distal end (lead)		
Insulation	Silicone rubber	Yes
Marker band	Platinum-iridium	No
Setscrew connector blocks	Stainless steel	Yes
Proximal end (neurostimulator)		
Conductor wire insulation	Fluoropolymer	No
Contacts	MP35N	Yes
Insulation	Polyurethane	Yes
Connector boots	Silicone rubber	Yes
Neurostimulator plug	Polyurethane	Yes
Setscrews	Titanium	Yes
Tunneling tools		
Carrier	Polypropylene	Yes
Extension passer	Stainless steel and polypropylene	Yes
Obturator	Polypropylene	Yes
Wrench, torque		
Handle	Polymer	Yes
Shaft	Stainless steel	Yes

Instructions for use

Implanting physicians should be experienced in epidural-access procedures and should be thoroughly familiar with all product labeling.

When the patient completes a test stimulation period to determine the effectiveness of stimulation in managing pain, the percutaneous components used to connect the snap-lid connector cable to the lead may be removed at the follow-up visit.

△ Cautions:

- Do not bend, kink, or stretch the lead or extension body, which may damage the component.
- Do not use any instrument to handle the extension. 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. Select a location for the neurostimulator and position the patient accordingly.

△ Caution: Select a location that is:

- a minimum of 20 cm (8 in) away from another neurostimulator to minimize telemetry interference and possible inappropriate therapy.
- on the opposite side of the body from another active implanted device (eg, pacemaker, defibrillator) to minimize possible interaction between the devices.
- away from bony structures (eg, 3 – 4 cm [1.2 – 1.6 in]) to minimize discomfort at the neurostimulator site.
- away from areas of restriction or pressure to minimize the potential for skin erosion and patient discomfort.
- in an area accessible to the patient for proper operation of a patient control device (ie, patient programmer, control magnet, radio-frequency transmitter).

Note: Also take into account:

- possible future cardiac needs (eg, pacemaker, defibrillator). Implanting a neurostimulator on the patient's right side allows for possible future placement of cardiac devices on the patient's left side.
 - the cosmetic needs of the patient.
2. Before opening the extension package, verify the model number, use-by date, extension length, and connector type.
 3. Identify the neurostimulator pocket site and mark the intended extension route from the lead-incision site to the neurostimulator pocket.

Removing the remaining segment of the in-line percutaneous extension

1. After finding and exposing the percutaneous extension connector, make an incision large enough to grasp the lead body and maintain lead position.

Notes:

- Blunt dissection may be needed to expose the lead-extension connection.
- If the percutaneous components were not removed, locate the wire inside the incision and cut the wire. Pull the outside percutaneous components and discard the cable and wires.

△ **Caution:** When severing the percutaneous extension, use minimal traction on the extension because strong force may dislodge the lead.

2. While maintaining lead position, carefully remove the lead-extension connection from the incision.
3. Disconnect the lead from the percutaneous extension:
 - a. Remove the ligature, then slip the connector boot off the connection.

△ **Caution:** Do not use sharp instruments near the lead. Nicking or cutting the insulation may cause loss of stimulation or component failure requiring surgical replacement.

- b. Loosen each setscrew by turning the wrench counterclockwise.
- c. Gently separate the extension setscrew connector from the lead.

△ **Caution:** If resistance is felt while removing the lead from the extension connector, first, loosen (but do not remove) the setscrews to ensure the lead contacts are not engaged. Next, inspect the lead connector for damage (eg, flattening of the lead contacts, stretching of the lead), which may result in intermittent or loss of stimulation.

- d. Remove and discard the connector boot; if necessary, carefully slit the boot along the extension setscrews.
4. Discard the remaining segment of the percutaneous extension.
5. For a second percutaneous extension, repeat steps 1– 4.

Creating a subcutaneous pocket for the neurostimulator

1. Make an incision equal to the length of the neurostimulator.
2. Use blunt dissection to create a subcutaneous pocket.

Note: Refer to the neurostimulator implant manual for the proper subcutaneous pocket depth.

Tunneling the extension

1. Identify the tunneling route between the lead incision and the neurostimulator pocket.

△ Cautions:

- When routing the extension, avoid sharp bends or kinks, which may break the wires. Broken wires may create an open circuit, resulting in loss of stimulation or component failure and requiring surgical replacement.
- When multiple leads are implanted, route the lead-extensions so the area between them is minimized (Figure 2). If the lead-extensions are routed in a loop and the patient is exposed to some sources of electromagnetic interference (eg, theft detectors), the patient may perceive a momentary increase in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation).

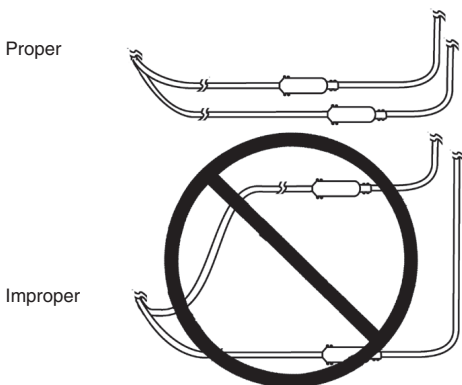


Figure 2. Routing for multiple lead-extensions.

2. Assemble the tunneling tool and bend it as necessary. Next, tunnel subcutaneously from the lead site to the neurostimulator site until the tip of the obturator is exposed at the neurostimulator pocket.

△ Cautions:

- Do not bend the extension passer at an angle greater than 90° at any one bend. An angle greater than 90° may damage the passer and prevent the extension from advancing, or damage the extension, resulting in intermittent or loss of stimulation.
- Proceed slowly when the tunneling tool approaches the neurostimulator pocket. If excess force is used, the patient could experience additional trauma when resistance to tunneling suddenly ceases.

Notes:

- Deep tunneling is not desirable.
 - Avoid the thoracic ribs.
 - If the tunneling tool does not extend to the neurostimulator pocket, make an intermediate incision.
3. Remove the obturator from the tunneling tool.
 4. Insert the carrier into the extension passer.

5. Insert the extension setscrew connector junctions into the carrier grooves. Insert the first extension into the carrier groove, then gently pull the proximal end of the carrier further through the extension passer handle and snap in place. Gently place the second extension in the other carrier groove.

△ **Caution:** Use care when inserting the extension body into the carrier groove. Rough handling may damage the extension insulation.

6. Using minimal force, pull the carrier-extension assembly through the tunnel to where the lead is anchored.

Note: Ensure that the bifurcation portion of the extension remains in the neurostimulator pocket when the extension is tunneled.

7. Remove the extension setscrew connector junctions from the carrier grooves.
8. Discard the tunneling tool.

Creating a pocket for the lead-extension connection

Use blunt dissection to form a subcutaneous lead-extension connector pocket. The pocket should be:

- lateral to the lead incision.
- deep enough to minimize the potential for skin erosion or irritation.
- large enough to accommodate the lead-extension connection(s).

△ **Caution:** Do not place the lead-extension connection on the paraspinal muscles or the spinous processes. The connection may erode through the skin, resulting in infection and requiring removal of the neurostimulation system.

Connecting the lead to the extension

△ **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.
1. Slip the connector boot onto the lead body with the open end facing out, exposing the lead contacts.

Notes:

- Irrigate the connector boot with a nonionic antibiotic solution. Dry the interior of the connector boot.
 - A clear and white radiopaque boot are provided for use in dual-lead systems.
2. Wipe the lead body and the extension setscrew connector junction with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution. Dry all connections.
 3. Insert the lead fully into the extension setscrew connector.

Note: Each lead contact must be aligned under each setscrew.

4. Use the torque wrench to tighten each setscrew to complete the electrical circuit. Hold the extension firmly on the sides of each connector block while tightening the setscrew (Figure 3).

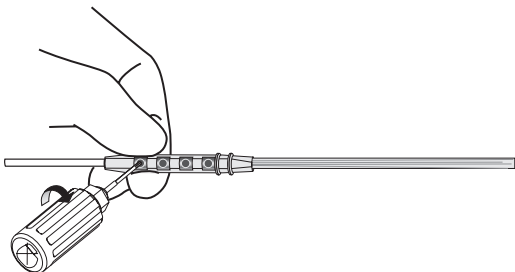


Figure 3. Tighten the setscrews holding the extension firmly on the sides of each connector block.

△ **Cautions:**

- To avoid overtightening, use only the torque wrench included in the extension package to tighten the extension setscrews. The torque wrench included in the extension package is marked with an icon to indicate it is not for use with the neurostimulator. Overtightening the extension setscrews may damage the lead contacts and cause an open or short circuit, resulting in intermittent or loss of stimulation.
 - Discard the torque wrench after making all connections. Reusing a torque wrench may result in undertightening or overtightening and subsequently, intermittent or loss of stimulation.
5. Using minimal force, pull on the connection to ensure that it is secure.
 6. Slide the connector boot over the lead-extension connection and tie a ligature (using nonabsorbable silk) between the pairs of rings at either end. Suture the ends of the connector boot.

△ **Cautions:**

- Do not tie ligatures around the lead or extension body, which may damage the insulation.
 - Do not overtighten ligatures on the anchor or connector boot. Ligatures that are too tight may damage the component.
 - Ensure that the end of the connector boot is secure to prevent fluid in the lead-extension connection, which may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.
7. For a second lead, repeat steps 2 – 6.

Note: If only one lead will be connected to the extension, cover the unused connector with a 1 x 4 low-profile closed connector boot from an accessory kit, and suture.

Note: When using one or two leads, use the marker band on the leg of the extension as a reference for lead identification.

8. Using minimal force, pull the extension at the neurostimulator pocket and feed the lead-extension connections into the lead-extension connector pocket.

△ **Cautions:**

- Do not pull the lead or extension taut. Allow enough slack in the lead or extension to accommodate patient movement. Pulling the lead or extension taut may result in a short or open circuit or migration of implanted components.

- Coil the excess lead body into a circular loop greater than 2 cm (0.8 in) in diameter. Do not use a U-shaped loop or bend (Figure 4). A circular loop decreases the possibility of electromagnetic interference and its effects and prevents kinking or damaging the lead body.

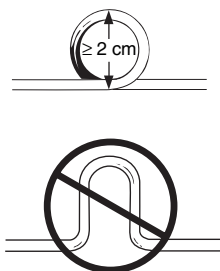


Figure 4. Coiling excess lead.

9. Insert the coiled lead body into the pocket, under the connections, leaving as much slack as possible in the lead body between the anchor and the lead-extension connections.
10. If desired, use the external neurostimulator to verify that the location of the lead and the pattern of stimulation have not changed.

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