



Medtronic

SPECIFY®

3998

Lead kit

Implant manual

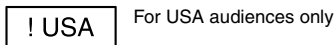
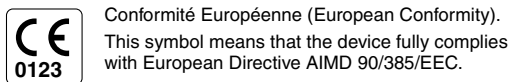
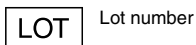
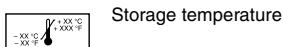
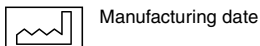
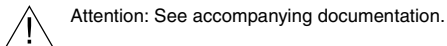
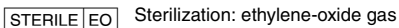
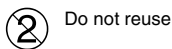
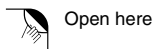
! USA Rx only



1997

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 3998 Specify Lead is a part of a neurostimulation system for pain therapy.

Package contents

- Lead
- Percutaneous extensions
- Anchors
- Connector boots
- Passing elevator
- Lead blank
- Screener cables
- Handles
- Tunneling tools: tunneling rod, tunneling tip, tubes (passing straws)
- Wrench, hex
- Product literature
- Warranty card (USA only)
- Registration form (USA only)

Device specifications

The lead has electrodes on the distal end; the proximal ends fit into two, four-conductor connectors.

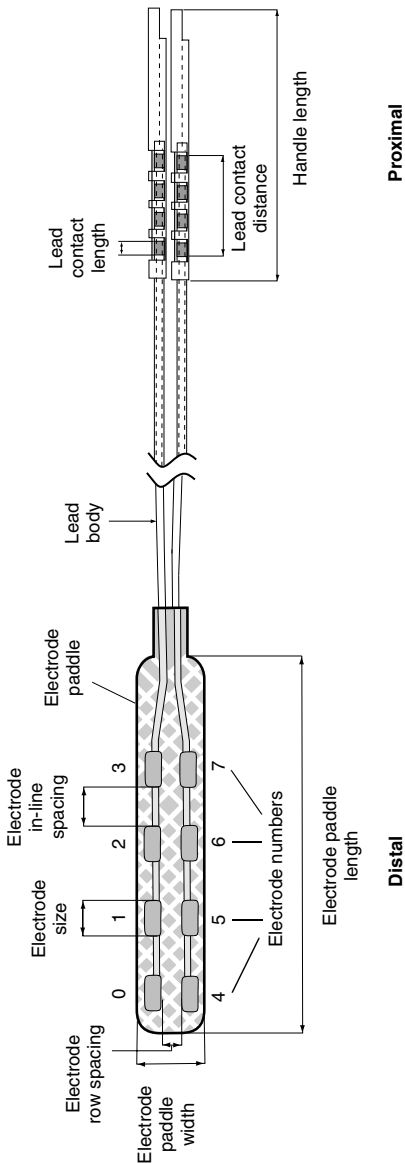


Figure 1. Model 3998 Specify lead.

Table 1. Device specifications^a for lead Model 3998.

Description	Model 3998
Connector	Quadripolar, inline
Shape	Straight
Conductor resistance ^{b,c}	<92 Ω (20 cm)
Length	20 cm
Diameter	1.3 mm
Distal end:	
Number of electrodes	8
Electrode shape	Rectangular
Electrode size	2.0 mm x 3.0 mm
Electrode stimulating area	6.0 mm ²
Electrode spacing (edge to edge)	
in-line spacing	6.0 mm
row spacing	2.0 mm
Electrode paddle length	44.5 mm
Electrode paddle width	7.9 mm
Electrode paddle thickness	1.8 mm
Proximal end	
Lead contact length	2.0 mm
Lead contact distance	16.6 mm
Handle length	40.0 mm

^a All measurements are approximate.

^b Electrical resistance of this device only.

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

Table 2. Material of components in the Model 3998 package.

Component	Material	Material contacts human tissue
Lead		
Conductor wire	MP35N	No
Conductor wire insulation	Fluoropolymer	No
Electrodes	Platinum-iridium	Yes
Electrode paddle	Silicone rubber with polyester paddle mesh	Yes
Insulation	Polyurethane	Yes
Proximal connector	MP35N	Yes
Percutaneous extensions		
Conductor wire	Stainless steel	Yes
Conductor wire insulation	Fluoropolymer	Yes
Handle	Acetal resin	Yes
Insulation	Silicone rubber	Yes
Setscrew connector blocks	Stainless steel	Yes
Setscrews	Titanium	Yes
Anchors		
Twist-lock	Polymer	Yes
Two-wing, three-wing	Silicone rubber	Yes
Connector boots	Silicone rubber	Yes
Passing elevator	Acetal resin	Yes
Lead blank	Silicone rubber	Yes
Screener cables		
Connector	Polycarbonate	Yes
Cable	Rubber	Yes
Handles	Acetal resin	Yes
Wrench, hex		
Handle	Polypropylene	Yes
Shaft	Stainless steel	Yes
Tunneling tools		
Tunneling rod	Stainless steel	Yes
Tunneling tip	Stainless steel	Yes
Tubes (passing straws)	Fluoropolymer	Yes

Instructions for use: spinal cord stimulation

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



Cautions:

- Do not bend, kink, or stretch the lead or extension body, which may damage the component.
- Use only rubber-tipped forceps on the lead body. Do not use sharp-edged instruments (eg, hemostat), which may nick or cut the insulation.
- Do not use saline or other ionic fluids at connections, which could result in a short circuit.



Warning: Safety and effectiveness of this lead has not been established for use with more than one neurostimulator. If this lead is connected to more than one neurostimulator, damage to nerve tissue may result.

Preparing for surgery

Before opening the lead package, verify the model number, use-by date, lead-length, and connector type.

Placing a surgical lead

Consider the following suggestions when performing the laminotomy:

- Perform a laminotomy 1-2 vertebral spaces inferior to the desired final location of the surgical lead paddle.
- Use electrocautery to dissect the site.
- Avoid subperiosteal stripping to maintain a clear operative field.
- Inject additional local anesthesia just prior to stripping the paraspinal muscles from the spine.
- Additional anesthesia should be liberally administered on patient demand.
- Make the laminotomy width consistent with the lead paddle's width.



Caution: Ensure that the laminotomy is wide enough to accommodate the surgical lead paddle. Failure to do so may result in forcing the lead into the epidural space, which may damage the lead.

- If the interlaminar space is narrow, use instruments to reflect the ligamentum flavum and remove enough bone for the lead blank insertion. (A rongeur may be required during this exposure.)
- Use bipolar forceps to grasp and coagulate the epidural fat so that the fat can be stripped away, exposing the dura mater.


Note: A hemilaminotomy is preferred over a laminotomy because surgical leads are designed to fit in the epidural space under the vertebral body.

1. Carefully introduce the epidural passing elevator.
 - a. Hold the curved portion of the passing elevator with your fingertips.
 - b. Slowly and with minimal force introduce the passing elevator into the epidural space along the midline, guiding the entry so that the approach angle is as shallow as possible.




Warning: Introduce the passing elevator at a shallow angle. Using an angle that is too deep could cause contusion to the spinal cord.

2. Carefully introduce the lead blank:
 - a. Introduce the lead blank into the epidural space to ensure proper size and location of the lead site.
 - b. Remove and discard the lead blank.

 **Caution:** Use bone wax or instrumentation to ensure that the bony edge of the laminotomy is smooth. Sharp edges may damage the lead, resulting in intermittent or loss of stimulation.

3. Position the surgical lead:
 - a. Using a rubber-tipped forceps to handle the lead paddle, carefully position the proximal segments of the lead paddle in the epidural space.
Note: Make sure the stimulating electrodes face the dura mater.
 - b. Advance the lead paddle cephalad until the entire paddle is in the epidural space.
 - c. For bilateral pain, place the lead close to the midline.
4. Verify the lead position under fluoroscopy (AP and lateral views).
5. Record the location of the center bipolar electrodes.
 - If good paresthesia coverage is not attained, change electrode settings before repositioning the lead to confirm the direction of lead movement.
 - Leave the twist-lock end of the screening cable in the sterile field so stimulation parameters can be tested again before closing.

Testing stimulation intraoperatively


 **Caution:** To prevent an abrupt change in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation):

- Program parameter changes in small increments above the perception threshold (the amplitude value at which the patient first perceives paresthesia).
- Decrease the amplitude to 0.0 V before:
 - changing electrode polarities.
 - connecting the screener cable to the screener.
 - turning ON the neurostimulator or screener.

1. Attach the handles to the proximal end of each lead body.
2. After connecting the screener cables to the patient's implanted lead handles, pass the plug ends out of the sterile field.


Notes:

- The lead body corresponding to electrodes 0-3 has a white mark.
 - On the screener, use channel 1 for electrodes 0-3 and channel 2 for electrodes 4-7.
3. After verifying that the screener is turned OFF, connect the screener cable plug to the appropriate receptacle of the screener.


 **Warning:** Maintain adequate slack in the screener cable. If there is not enough slack and the cable is pulled, the percutaneous components may be dislodged.

4. Identify optimal stimulation parameters, beginning at a pulse width of 210 – 240 μ s and a rate of 30 Hz.
Note: Ensure that the patient can provide immediate feedback.
5. Increase the amplitude beginning from 0.0 V while asking the patient close-ended questions to identify the perception threshold (the amplitude at which the patient first perceives paresthesia), the discomfort threshold (the amplitude at which paresthesia is beyond the patient's tolerance), and the paresthesia coverage.
Note: If good paresthesia coverage is not attained, change electrode settings before repositioning the lead to confirm the direction of lead movement.
6. In the patient's chart, document the lead position that provided appropriate stimulation coverage (ie, record the settings and patient responses and include a fluoroscopic image of the final lead position).

7. Disconnect the screener cable from the lead. Leave the screener cable in the sterile field for additional parameter testing before closing.

 **Caution:** Do not pull directly on the cable to disconnect the connector because this may lead to wire breakage and inadequate or discontinuous stimulation.

Anchoring the lead

 **Caution:** Do not tie ligatures around the lead or extension body, which may damage the insulation.

1. Prepare the anchor site by making a 5 – 7 cm (2.0 – 2.8 in) longitudinal incision around the needle shaft, dissecting down to the supraspinous ligament, and establishing hemostasis.
2. Disconnect the handles from the leads.
3. Slide the anchor onto the proximal end of the lead and continue sliding the anchor down as close as possible to where the lead emerges from the vertebral column. Use care to maintain the lead position.


Notes:

- Each lead body should be anchored separately.
 - The anchor can be lubricated with sterile water.
 - For a twist-lock anchor, ensure that the anchor is unlocked before sliding the anchor onto the lead. (An unlocked anchor is twisted so the two parts are at a 90° angle to each other.)
4. Use 2-0 nonabsorbable suture (such as silk or some types of braided polyester mesh) to secure the anchor.

Cautions:

- Do not use polypropylene suture material on silicone components. Polypropylene may damage the component, resulting in component failure.
- Do not overtighten ligatures on the anchor or connector boot. Ligatures that are too tight may damage the component.

For the twist-lock anchor: Suture the unlocked anchor to the supraspinous ligament or deep fascia. Gently push and turn the unsutured part so the parts are closed and parallel. When the two parts are closed, the anchor is locked and the lead is secured in position.

 **Caution:** Ensure the anchor is locked. An unlocked anchor will not stabilize the lead and may result in lead migration.

Note: If minor repositioning is necessary, unlock the anchor, reposition the lead, then relock the anchor.

For the winged anchor: Tie ligatures around the grooves in the middle of the anchor to secure the anchor to the lead. Next, suture the anchor to the supraspinous ligament or deep fascia.

Note: Laboratory testing has shown that injecting silicone medical adhesive between the anchor and lead after tying the ligatures increases the anchor-to-lead holding force.

5. Verify test stimulation parameters to ensure that the lead has not moved: connect the handles to each lead, connect the screener cables to the lead handles, and then connect the screener cable plugs to the screener. If the lead has moved, reposition it.

Tunneling the percutaneous extensions

1. After simulating the tunneling route, mark the two routes for each of the lead bodies on the patient's skin at the lead-extension connection sites and at the percutaneous extension exit sites (exit sites). The exit sites should be on the side opposite that intended for the neurostimulator and at least 10 cm (4 in) lateral. (The neurostimulator should be placed on the opposite side of the body from another active implanted device and should be placed preferably on the right side of the body to allow for future placement of cardiac devices on the patient's left side.)



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 two 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).

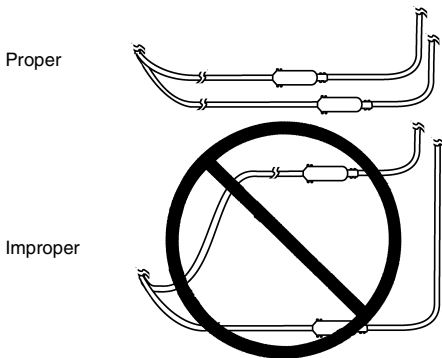


Figure 2. Routing for two lead extensions.

2. After assembling the tunneling tools, make an incision at the exit sites.
3. Begin at each exit site and tunnel subcutaneously to the lead incision.

Notes:

- Deep tunneling is not desirable.
 - Avoid the lower thoracic ribs.
 - If the tunneling tool does not extend to the lead-extension connection site, make an intermediate incision.
4. Use blunt dissection to form a tunnel to each lead-extension connection site.
 5. After tying a ligature to the handle of each percutaneous extension, gently pull each extension through the passing straws to each exit site.

Connecting the percutaneous extensions to the lead



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

1. After disconnecting the handle from each lead, slip a connector boot onto each lead body with the open end of the connector boot facing outward, exposing the lead contacts.

Note: Irrigate the connector boot with a nonionic antibiotic solution. Dry the interior of the boot.

2. Wipe the lead body and 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 connector fully into the extension setscrew connector junction.

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

4. Tighten the setscrews to complete the electrical circuit with the lead contacts.

△ **Caution:** Do not overtighten the extension setscrews. Overtightening the extension setscrews may damage the lead contacts and cause an open or short circuit, resulting in intermittent or loss of stimulation.

5. Confirm the integrity of the connection by rechecking the stimulation pattern.
6. After sliding the connector boot over each lead-extension connection, tie a ligature around the wide end of the connection.

Note: Do not suture the narrow end of the connector boot.

7. Carefully pull each lead-extension connection through the tunnel to the lead-extension connection sites.

△ **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 3). A circular loop decreases the possibility of electromagnetic interference and its effects and prevents kinking or damaging the lead body.

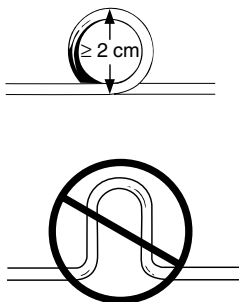


Figure 3. Coiling excess lead.

8. After carefully removing the passing straw from the tunnel, verify that the location of the lead and the pattern of stimulation have not changed.
9. Close the lead incision and the percutaneous extension exit site, leaving the percutaneous extension wires looped under a dressing with the handle exiting the bandage.
10. Connect the screener cable to the percutaneous extension so that the screener cable is available for trial evaluation.

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