



Medtronic

Multi-lead Trialing Cable

355531

Trialing and intraoperative screening cable

Instructions for use

! USA Rx only



2010

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.



Open here



Do not reuse



Sterilized using ethylene oxide



Caution, consult accompanying documents.



Consult instructions for use



Date of manufacture



Manufacturer



Use by



Temperature limitation



Lot number



Conformité Européenne (European Conformity). This symbol means that the device fully complies with MDD 93/42/EEC (NB 0123).



Authorized representative in the European community



For USA audiences only

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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.

Description

The Medtronic Model 355531 Multi-lead Trialing Cable is part of a trialing and intraoperative screening system for neurostimulation therapy.

Package contents

- Multi-lead trialing cable
- Product literature
- Warranty card (USA only)



Warning: This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

Device specifications

The multi-lead trialing cable has a lead housing with a lockable lid on the distal end and a connector plug on the proximal end (Figure 1). The lead housing has channels for up to four quadripolar (4-contact) leads and two octapolar (8-contact) leads. The connector plug inserts into an output jack on an external neurostimulator (ENS).

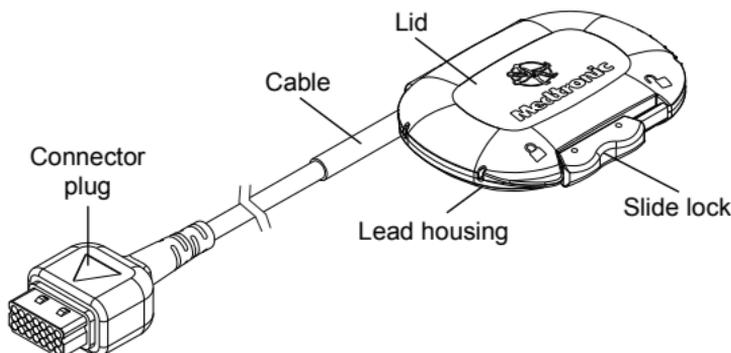


Figure 1. Lead housing, cable, and connector plug.

Table 1. Device specifications for the Multi-lead Trialing Cable Model 355531^a

Description	Value
Capacity	
Leads	4 quadripolar; 2 octapolar
Electrodes	32 electrodes, supporting 16 active
Weight	50 g (1.8 oz)
Width (housing and slide lock)	45 mm (1.8 in)
Length (housing)	57 mm (2.3 in)
Thickness (housing)	10 mm (0.4 in)
Volume (housing)	18 cm ³
Lid	Clear, with lid lift tab
Latch type	Snap lid with slide lock

Table 1. Device specifications for the Multi-lead Trialing Cable Model 355531^a
(continued)

Description	Value
Length (housing, cable, and plug)	152 cm (60 in)
Storage temperature	-34° to +57°C (-30° to +135°F)

^a All measurements are approximate.

Table 2. Material of components in the Multi-lead Trialing Cable Model 355531 package

Component	Material	Material contacts human tissue
Housing		
Base	Polycarbonate	Yes
Lid	Polycarbonate	Yes
Slide lock	Polycarbonate	Yes
Hinge pin	Stainless steel	No
Contacts	Gold- and nickel-plated beryllium copper	No
Cable		
Conductor wires	Copper	No
Jacket	Thermoplastic elastomer (TPE)	Yes
Connector	Thermoplastic elastomer (TPE)	Yes
Connector contacts	Gold-plated bronze	No

Instructions for use

Implanting physicians should be thoroughly familiar with all product labeling.



Caution: To prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation):

- program parameter changes in small increments above the perception threshold (the amplitude value(s) at which the patient first perceives paresthesia).
- decrease the amplitude(s) to 0.0 V before:
 - changing electrode polarities.
 - connecting or disconnecting the cable to the external neurostimulator.
 - replacing the external neurostimulator batteries.
 - turning on the neurostimulator.

Notes:

- The procedure for connecting the multi-lead trialing cable is the same for leads and extensions.
- Lead grooves that share a number are on an interconnected circuit (Figure 2b and Figure 4b).

If connecting a 4-contact lead, go to "Connecting the multi-lead trialing cable to the 4-contact lead(s)" on page 7. If connecting an 8-contact lead, go to

"Connecting the multi-lead trialing cable to the 8-contact lead(s)" on page 8.

Connecting the multi-lead trialing cable to the 4-contact lead(s)

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

1. Wipe the lead contacts with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution.
2. Move the slide lock to the unlocked position then push up on the lid lift tab and down on the slide lock to open the multi-lead trialing cable (Figure 2a).
3. Disconnect the long stylet handle from the 4-contact lead and withdraw the long stylet from the 4-contact lead.
4. Insert the short stylet into the 4-contact lead and connect the short stylet handle to the 4-contact lead.
5. Make sure the lead contacts and the electrical contacts inside the lead groove are dry and clean.
6. Align the short stylet and proximal end of the lead against the inside end of a 4-contact lead groove of the connector (Figure 2a).

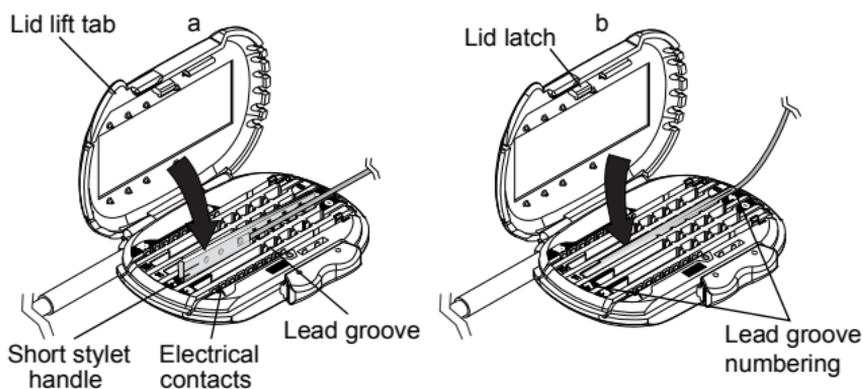


Figure 2. Multi-lead trialing cable with a 4-contact lead.

7. Check that the lead contacts align with the electrical contacts inside the lead groove and that the short stylet handle aligns with the stylet-shaped portion of the lead groove.
Note: The lead and short stylet fit only one way into the multi-lead trialing cable lead housing.
8. Press the lead and short stylet gently into the lead groove (Figure 2b). If an additional 4-contact lead is used, repeat step 1 and steps 3 to 8.
9. Close the lid and move the slide lock into the locked position.
Note: Do not force the lid closed; it should close easily. If it does not, disassemble the components and repeat steps 2 to 9.
10. Confirm correct seating by viewing the lead through the closed and locked lid.
11. After connecting the multi-lead trialing cable to the patient's implanted lead, pass the connector plug out of the sterile field.
12. After verifying that the ENS is turned off, push the connector plug into the output jack of the ENS (Figure 3).

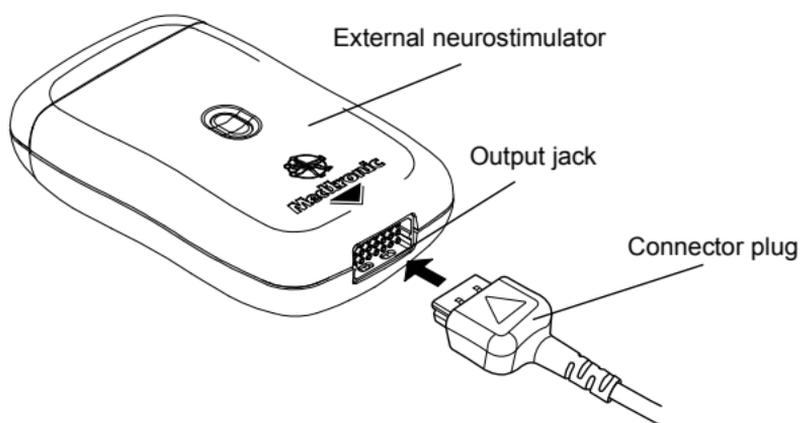


Figure 3. Connecting the Multi-lead trialing cable to the ENS.

Note: Ensure that the arrow on the connector plug points toward the arrow on the ENS and that the keyed slots of the connector plug and output jack match.

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

13. Refer to the appropriate programmer guide, ENS manual, and lead manual to verify proper connection and identify optimal stimulation parameters.

Connecting the multi-lead trialing cable to the 8-contact lead(s)

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

1. Wipe the lead contacts with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution.
2. Move the slide lock to the unlocked position then push up on the lid lift tab and down on the slide lock to open the multi-lead trialing cable (Figure 4a).
3. Make sure the lead contacts and the electrical contacts inside the lead grooves are dry and clean.
4. While holding the 8-contact lead, disconnect the stylet handle from the lead (proximal end), and partially withdraw the stylet.
5. Align the proximal end of the lead against the inside end of an 8-contact lead groove of the connector (Figure 4a).

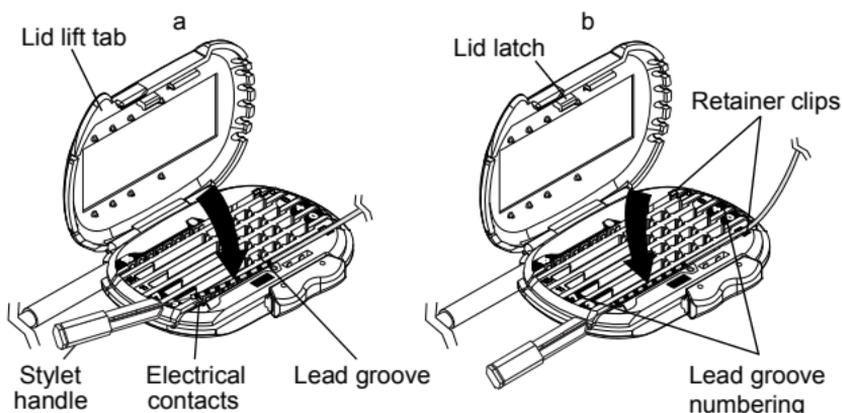


Figure 4. Multi-lead trialing cable with an 8-contact lead.

6. Check that the lead contacts align with the electrical contacts inside the lead groove.
Note: The lead fits only one way into the multi-lead trialing cable lead housing.
7. Press the lead gently into the lead groove and the retainer clip (Figure 4b). If an additional 8-contact lead is used, repeat step 1 and steps 3 to 7.
8. Close the lid and move the slide lock into the locked position.
Note: Do not force the lid closed; it should close easily. If it does not, disassemble the components and repeat steps 2 to 8.
9. Confirm correct seating by viewing the lead through the closed and locked lid.
10. After connecting the multi-lead trialing cable to the patient's implanted lead, pass the connector plug out of the sterile field.
11. After verifying that the ENS is turned off, push the connector plug into the output jack of the ENS (Figure 5).

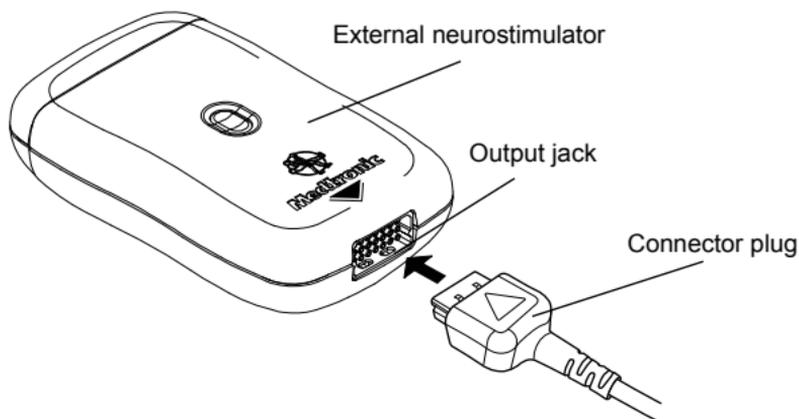


Figure 5. Connecting the Multi-lead trialing cable to the ENS.

Note: Ensure that the arrow on the connector plug points toward the arrow on the ENS and that the keyed slots of the connector plug and output jack match.

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

12. Refer to the appropriate programmer guide, ENS manual, and lead manual to verify proper connection and identify optimal stimulation parameters.

Preparing the multi-lead trialing cable for trial screening

1. Place a gauze bandage on the skin where the lead and multi-lead trialing cable will be placed on the patient.
2. Tape the lead and multi-lead trialing cable together to secure the connection.
3. Tape the entire assembly to the patient's skin, allowing for strain relief.
4. Proceed with the trial evaluation.

Removing the multi-lead trialing cable after trial screening

1. After verifying that the ENS is turned off, pull the connector plug from the output jack of the ENS.
2. Remove all tape from the lead and multi-lead trialing cable.
3. Move the slide lock to the unlocked position then push up on the lid lift tab and down on the slide lock to open the multi-lead trialing cable.
4. Gently lift the lead from the electrical contacts in the lead groove.



Caution: Do not pull on the cable. Pulling on the cable may break a wire or dislodge the lead. A broken wire or dislodged lead may result in loss of stimulation and may require surgery to replace the lead.

5. Dispose of the multi-lead trialing cable according to environmental regulations.

Contacts:**Asia:**

Medtronic International Ltd.
Tel. 02891-4068
Fax 02591-0313
Medtronic Asia Ltd.
Tel. (02)-548-1148
Fax (02)-518-4786

Australia:

Medtronic Australasia Pty. Ltd.
97 Waterloo Road
North Ryde, NSW 2113
Australia
Tel. +61-2-9857-9000
Fax +61-2-9878-5100
Toll free 1-800-668-6700

Austria:

Medtronic Österreich GmbH
Tel. 01-240440
Fax 01-24044-100

Belgium:

Medtronic Belgium S.A.
Tel. 02-456-0900
Fax 02-460-2667

Canada:

Medtronic of Canada Ltd.
Tel. (1-905)-460-3800
Fax (1905)-826-6620

Czech Republic:

Medtronic Czechia s.r.o.
Tel. 2-965-795-80
Fax 2-965-795-89

Denmark:

Medtronic Danmark A/S
Tel. 45-32-48-18-00
Fax 45-32-48-18-01

Finland:

Medtronic Finland Oy/LTD
Tel. (09)-755-2500
Fax (09)-755-25018

France:

Medtronic France S.A.S.
Tel. 01-5538-1700
Fax 01-5538-1800

Germany:

Medtronic GmbH
Tel. (02159)-81490
Fax (02159)-8149100

Greece:

Medtronic Hellas S.A.
Tel. 210-67-79-099
Fax 210-67-79-399

Hungary:

Medtronic Hungária Kft.
Tel. 1-889-06-00
Fax 1-889-06-99

Ireland:

Medtronic Ireland Ltd.
Tel. (01)-890-6522
Fax (01)-890-7220

Italy:

Medtronic Italia SpA
Tel. 02-241371
Fax 02-241381
Tel. 06-328141
Fax 06-3215812

Japan:

Medtronic Japan
Tel. 3-6430-2016
Fax 3-6430-7110

Latin America:

Medtronic, Inc.
Tel. (1305)-500-9328
Fax (1786)-709-4244

Norway:

Medtronic Norge AS
Tel. 067-10-32-00
Fax 067-10-32-10

Poland:

Medtronic Poland Sp. z.o.o.
Tel. (022)-465-69-00
Fax (022)-465-69-17

Portugal:

Medtronic Portugal, Lda.
Tel. 21-724-5100
Fax 21-724-5199

Russia:

Medtronic Russia
Tel. (8495) 580-7377
Fax (8495) 580-7378

Slovakia

Medtronic Slovakia, o.z.
Tel. 0268 206 911
Fax 0268 206 999

Spain:

Medtronic Ibérica, S.A.
Tel. 91-625-0400
Fax 91-650-7410

Sweden:

Medtronic AB
Tel. 08-568-585-00
Fax 08-568-585-01

Switzerland:

Medtronic (Schweiz) AG
Tel. 031-868-0100
Fax 031-868-0199

The Netherlands:

Medtronic B.V.
Tel. (045)-566-8000
Fax (045)-566-8668

U.K.:

Medtronic U.K. Ltd.
Tel. 01923-212213
Fax 01923-241004

USA:

Medtronic, Inc.
Tel. (1763)-505-5000
Fax (1763)-505-1000
Toll-free: (1-800)-328-0810



Medtronic

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Manufacturer

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
www.medtronic.com
Tel. 1-763-505-5000
Fax 1-763-505-1000

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Authorized Representative in the European Community

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel. 31-45-566-8000
Fax 31-45-566-8668

Europe/Africa/Middle East Headquarters

Medtronic Europe Sàrl
Route du Molliau 31
Case Postale 84
CH-1131 Tolochenaz
Switzerland
www.medtronic.eu
Tel. 41-21-802-7000
Fax 41-21-802-7900

Asia-Pacific

Medtronic International Ltd.
Suite 1602 16/F, Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel. 852-2891-4068
Fax 852-2591-0313

Contacts for specific countries are listed inside this cover.



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