



Neural microTargeting™ Worldwide

MT-LA-03 Lead Adapter Cable

Directions For Use

L011-87-03 (Rev B1, 2020-07-29)

Contains directions for the following products:

MT-LA-03

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




Indications for use

The Lead Adapter Cable is part of the Guideline 4000™ 5.0 system and Guideline 4000 LP+ system which is intended to record and stimulate electrophysiological activity, as well as aid in the accurate placement of electrodes and other instruments.

Intended use

The Lead Adapter Cable is intended to be used outside the sterile field by a neurosurgeon, neurologist or clinical neuro-physiologist to accurately position depth electrodes during functional neurosurgical procedures.


Symbol Key


	WARNING / Caution, consult instruction for important cautionary information.		Medical device manufacture, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Consult instructions for use.		Telephone number
	Indicates the catalog number so that the medical device can be identified.		Authorized Representative in the European Community
	Indicates the batch code so that the batch or lot can be identified.		In reference to "Rx only" symbol; this applies to USA audiences only
Rx Only	Caution- Federal law (USA) restricts this device to sale by or on the order of a physician.		Indicates a medical device that has not been subjected to a sterilization process.
	Instructions for end of life disposal.		

Product Overview

The MT-LA-03 Lead Adapter Cable facilitates the connection to the Boston Scientific Vercise Cartesia™ Directional Lead and Vercise™ Standard Lead by adapting their specialized connector on the Boston Scientific O.R. Cable (DB-4100) to a connector suitable for the input on Guideline 5 LF Interface and LP+ via the MT-LA-01 Lead Adapter. This cable has no active components.

Warnings and Cautions

 **WARNING:** The Lead Adapter should only be connected to the microTargeting™ Guideline 4000™ LP+ and 5.0 Systems.

 **WARNING:** When using the Lead Adapter Cable, follow all instructions and observe all cautions and warnings provided with the lead and the Guideline system.

 **WARNING:** Do not steam sterilize; the lead adapter cable should be used outside the sterile field.

 **Caution:** FHC has not validated sterilization of this device.

Rx Only Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.


Cleaning

Following use, wipe lightly with a dry cloth. If necessary, slightly moisten the cloth with a standard hospital disinfectant and wipe any surfaces suspected of contamination.

Repair and Warranty

All FHC products are unconditionally guaranteed against defects in workmanship for one year from the date of shipment provided they have been exposed to normal and proper use. Should service or repair be required, please contact FHC at 1-800-326-2905 (US & Canada) or +1-207-666-8190 for instructions.

End-of-Life Disposal

-  Return the Lead Adapter Cable to FHC for environmentally conscious end-of-life disposal once it is no longer in use. Please contact an FHC factory authorized representative to arrange a return.

Specifications

- Channels: 8
- Channel Resistance: <5 Ohms max
- Channel to channel resistance: >50 MOhms
- Cable Length: 14 cm
- Weight: 6.5 grams
- Connectors:
 - Touchproof micro-HDMI connector (Pins 9-19 unused)
 - Omnetics 10 pin circular socket connector

Note: Use Boston Scientific contact numbers for mapping desired channels. See the Guideline 5 LF Interface DFU for full instructions on stimulating and recording using DBS leads.



Illustrated Procedure

Hardware Setup

1. If the lead has been introduced through an insertion tube, ensure that all of the lead contacts are exposed past the bottom of the tube.
2. Ensure the Guideline 5 LF Interface is connected to the Guideline 5 Core module, as instructed in the Guideline 5 DFU. If connecting to an LP+, connect a Lead Adapter box to the LP+ as instructed in the setup instructions in the MT-LA-01 DFU (L011-87-01).
3. Locate the Lead Adapter Cable just outside the sterile field.
4. Connect the Boston Scientific O.R. cable connector to one end of Lead Adapter Cable.



5. If using a Guideline 5, remove LF cover if present and connect the other end of the Lead Adapter Cable to the Guideline 5 LF Interface input.



