

MT-LA-01 Lead Adapter

Directions For Use

L011-87-01 (Rev B0, 2021-05-20)

Contains directions for the following products:

MT-LA-01

www.fh-co.com



FHC, Inc.
1201 Main Street
Bowdoin, ME 04287 USA
Fax: +1-207-666-8292

EC REP



FHC Europe
(TERMOBIT PROD srl)
42A Barbu Vacarescu Str, 3rd Fl
Bucharest 020281Sector 2
Romania



24 hour technical service:
1-800-326-2905 (US & Can)
+1-207-666-8190

FHC Latin America
Calle 6 Sur Cra 43 A-200
Edificio LUGO Oficina 1406
Medellín-Colombia














Indications for use

The Lead Adapter is intended to assist in functional neurosurgical procedures where recording from and stimulation of brain motor and sensory neurons will aid in the placement of depth electrodes.

Intended use

The Lead Adapter is intended to be used by a neurosurgeon, neurologist or clinical neurophysiologist to accurately position depth electrodes during functional neurosurgical procedures.


Symbol Key


	WARNING / Caution, consult instructions for important cautionary information.		Medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC and Medical Device Regulation (EU) 2017/745.
	Consult the instructions for use.		Telephone number
	In reference to "Rx only" symbol; this applies to USA audiences only.		Authorized Representative in the European Community.
	Caution - Federal law (USA) restricts this device to sale by or on the order of a physician.		European Conformity. This device fully complies with Medical Device Regulation (EU) 2017/745 and legal responsibilities as a manufacturer are with FHC, Inc., 1201 Main Street, Bowdoin, ME 04287 USA.
	Indicates the catalog number so that the medical device can be identified.		Indicates the serial number so that a specific medical device can be identified.
	Instructions for end of life disposal.		Date when the medical device was manufactured.
	Indicates Medical Device		

Product Overview

The Lead Adapter facilitates the connection to the Abbott (formerly St. Jude Medical) Infinity Lead by adapting the micro-HDMI connector of the Multi Lead Trial Cable (MLTC) to eight individual circular 5-pin DIN connectors suitable for connection to the input of a Guideline system. It has no active components.

Warnings and Cautions

 **WARNING:** The Lead Adapter should only be connected to the microTargeting™ Guideline 4000™ or the microTargeting™ Guideline 4000 LP+™ systems.

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

 **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 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 min
- Cable Length: 1.5 meters
- Weight: 350 grams
- MLTC Connector: Shrouded micro-HDMI connector (Pins 17-19 are unused)
- Guideline/LeadPoint system connections: 5 pin circular DIN (240°) male connectors
- Patient Reference connection: 5 pin circular DIN (240°) female connector

Lead #	Contact	MLTC Contact # & micro-HDMI pin #	Lead Adapter Label
1	1	1	1 HDMI-1
1	2A	2	2A HDMI-2
1	2B	4	2B HDMI-4
1	2C	7	2C HDMI-7
1	3A	3	3A HDMI-3
1	3B	6	3B HDMI-6
1	3C	8	3C HDMI-8
1	4	5	4 HDMI-5
-	-	9-19	-

Illustrated Procedure

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. Locate the Lead Adapter just outside the sterile field.
3. Connect the MLTC connector into the Lead Adapter.
4. Using a 66-EL-LC/66-EL-LP Electrode Lead, connect the alligator clip of the cable to a suitable patient reference point such as the insertion tube, the remaining red and black pins should not be connected to anything.
5. Connect the other end of the electrode lead into the Lead Adapter reference cable socket.
6. Connect the Lead Adapter cables to the Guideline system inputs. The cables of the Lead Adapter are labeled to indicate which lead contact they are associated with, unused cables may be left disconnected.
7. Proper connection of the Lead Adapter should be verified by ensuring that:
 - a. The Lead Adapter cable labels associated with the intended lead contacts are plugged into the intended Guideline LP+ channels.
 - b. All Guideline LP+ channels being used have the "Enable LFP for this channel" checkbox checked with a sampling frequency of at least twice the signal bandwidth of interest.
 - c. Unused Lead Adapter cables are safely located and not in contact with the floor
 - d. A patient lead has been connected to the Lead Adapter's reference input cable and to a suitable patient reference point such as the insertion tube.
 - e. The MLTC micro-HDMI plug has been fully inserted into the Lead Adapter.
 - f. The Infinity Lead has been connected to the 1-8 side of the MLTC.
8. Record bio-potentials from, and/or stimulate through, the lead contacts as needed to aid in the verification of lead placement.
 - a. All recordings will be single ended with respect to the patient reference. Within the electrode channel settings dialog, ensure that the "Enable LFP for this channel" check-box has been checked.
 - b. Stimulation may be either mono-polar with respect to the patient reference, or bipolar between two contacts depending on the stimulator return channel selected.
9. When done, disconnect the Lead Adapter from the MLTC, reference cable and the Guideline system.
10. If necessary, clean the Lead Adapter according to the provided cleaning protocol.

