

MT-LA-02 Lead Adapter

Directions For Use

L011-87-02 (Rev B0, 2021-05-20)

Contains directions for the following products:

MT-LA-02

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EC REP



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






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 sixteen individual 1.5mm touchproof® connectors suitable for connection to the input of a medical grade data acquisition and/or stimulation system. It has no active components.

Warnings and Cautions

 **WARNING:** The Lead Adapter should only be connected to a medical grade, IEC 60601, compliant data acquisition / stimulating system.

 **WARNING:** When using the Lead Adapter, follow all instructions and observe all cautions and warnings provided with the lead and the data acquisition / stimulating 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: 16
- Channel Resistance: 5 Ohms max
- Channel to channel resistance: 50 MOhms min
- Cable Length: 2 meters
- Weight: 0.15 kg
- MLTC Connector: Shrouded micro-HDMI connector (Pins 17-19 are unused)
- Data Acquisition / Stimulation system connectors: 1.5mm touchproof® female connectors

Lead #	Contact	MLTC Contact # & micro-HDMI pin #	Lead Adapter Label
1	1	1	1-1
1	2A	2	2A-2
1	2B	4	2B-4
1	2C	7	2C-7
1	3A	3	3A-3
1	3B	6	3B-6
1	3C	8	3C-8
1	4	5	4-5
2	1	9	1-9
2	2A	10	2A-10
2	2B	12	2B-12
2	2C	15	2C-15
2	3A	11	3A-11
2	3B	14	3B-14
2	3C	16	3C-16
2	4	13	4-13
-	-	17	-
-	-	18	-
-	-	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. Connect the Lead Adapter cables to the data acquisition / stimulation system. The cables of the Lead Adapter are labeled to indicate which lead contact they are associated with.
5. Proper connection of the Lead Adapter should be verified by confirming that the impedance of all channels connected are within the range expected.
6. If single-ended recording or monopolar stimulation is desired, a patient reference connection to the data acquisition / stimulation system must be made independently of the Lead Adapter.
7. Record bio-potentials from, and/or stimulate through, the lead contacts as needed to aid in the verification of lead placement.
8. When done, disconnect the Lead Adapter from the MLTC and the data acquisition / stimulation system.
9. If necessary, clean the Lead Adapter according to the provided cleaning protocol.