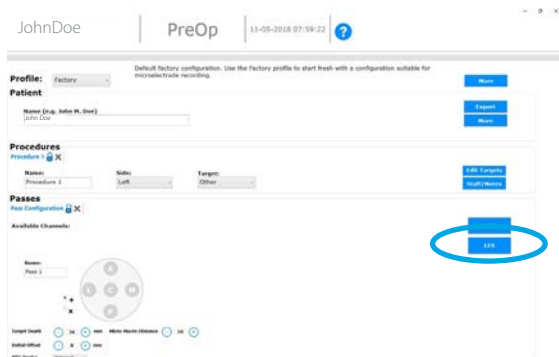
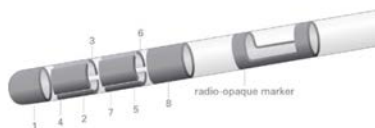


Software Setup

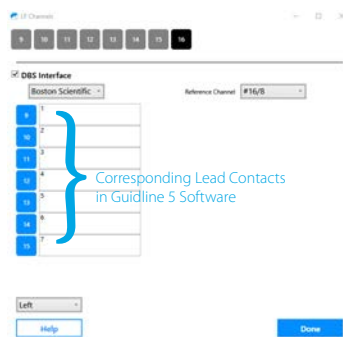
1. In the Pre-OP window of the Guideline 5 software, select the LFS button on the right hand side of the window.



2. Once the LF Window has been opened, check off 'DBS Interface Mode' to start mapping DBS Channels. When checked, a pop-up message will instruct the operator to remove all connections from the front panel of the LF Interface. Select the Boston Scientific DBS Configuration in the drop down menu.
3. To map a channel, select the blue box on the left hand column to turn that channel active for recording/stimulating (see image below). The blue boxes will be numbered 1-9 if the LF Interface is on Port 1, and 9-16 if the interface is on Port 2. The numbers on the right hand side will correspond to the lead contacts on the Boston Scientific DBS Leads as shown below.



Boston Scientific Lead Contacts



4. Once the selected channels have been mapped, select a reference channel for a recording/stimulation return path. The drop down will include the channel number and the DBS contact number. For example, the image above currently has Channel 16 and DBS Contact 8 (#16/8) as the reference channel.




MT-LA-03 Lead Adapter Cable

Directions for Use


L011-87-03 (Rev D0, 2021-05-19)

Contains directions for the following products:
MT-LA-03

www.fh-co.com

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

 FHC Europe
(TERMOBIT PROD srl)
42A Barbu Vacarescu Str, 3rd Fl
Bucharest 020281 Sector 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 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 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 a medical device that has not been subjected to a sterilization process.
	Indicates the batch code so that the batch or lot can be identified.		Indicates Instructions for end of life disposal.
	Date when the medical device was manufactured.		
	Indicates Medical Device		

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

FHC recommends the following manual cleaning protocol: Following use, wipe the Lead Adapter Cable lightly with a dry cloth. If necessary, slightly moisten the cloth with a standard hospital disinfectant and wipe any surfaces suspected of contamination. The Lead Adapter Cable should not be subjected to sterilization.

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

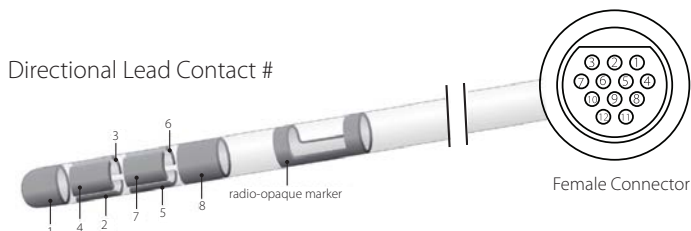
 Return the Lead Adapter Cable to FHC for environmentally conscious end-of-life disposal once it is no longer in use. Please contact an FHC factory authorized representative to arrange a return.

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.



If using an LP+, connect the Lead Adapter cable to the micro-HDMI port on the lead adapter box.



6. When finished, disconnect the Lead Adapter Cable from the O.R. cable and the Guideline 5 LF Interface.
7. If necessary, clean the Lead Adapter Cable according to the provided cleaning protocol.