FHC

Neural microTargeting™ Worldwide

microTargeting™ Electrode Lead Cable

Directions For Use

L011-85-05 (Rev C0, 2019-12-10)

Contains directions for the following products:
Lead Cables: C0230, C0231, C0232

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Indications for use

The microTargeting™ Guideline 4000™ 5.0 is intended to record and stimulate electrophysiological activity, as well as aid in the accurate placement of electrodes and other instruments.

Intended use

The Guideline 5 System 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
- Consult instructions for use
- ! USA — 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 order of a physician
- REF — Indicates catalog number
- LOT — Indicates the batch code
- Indicates the date after which the medical device is not to be used
- Medical device that should not be used if the package has been damaged or opened
- Indicates a medical device that is not to be resterilized
- Do not re-use; intended for one use on a single patient, during a single procedure
- Medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
- Telephone number
- EC REP — Authorized Representative in the European Community
- CE 0413 — European Conformity. This device fully complies with MDD Directive 93/42/EEC and legal responsibilities as a manufacturer are with FHC, Inc., 1201 Main Street, Bowdoin, ME 04287 USA.
- STERILE EO — Indicates a medical device that has been sterilized using ethylene oxide.
- 40°C (104° F) / 0°C (32°F) — Indicates the temperature limits to which the medical device can be safely exposed
- 95% / 0% — Indicates the range of humidity to which the medical device can be safely exposed

Warnings and Cautions

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

WARNING: Sterile Medical Device – Do NOT resterilize.

WARNING: Do not reuse; reusing single-use medical devices could lead to serious patient injury.

WARNING: Do not use the contents if there is any evidence of damage to the package or package seal that could compromise sterility.

WARNING: Remove patient leads if engaging defibrillation

WARNING: Disconnect all patient connections when performing system self-test

WARNING: Do not connect the electrode cables to earth.

WARNING: Electrodes and electrode cables should be connected one at a time. Be careful to assign electrode tracks and electrode contacts correctly. See L011-85-01 for more information regarding track assignments.

WARNING: Route electrode lead cables carefully to avoid a tripping hazard or possible contamination of the sterile field.

Handling and Storage

Storage: Store the microTargeting™ Electrode Lead Cable at normal temperatures between 0°C (32°F) and 40°C (104°F). Do not expose to relative humidity of more than 95%.

Specifications

C0230 – 3m Patient Lead
C0231 – 1.5m Patient Lead
C0232 – 1.5m Patient Lead (Special Use)
Note: C0232 is cleared for use in the US only.

Length: 3 meters (C0230) / 1.5 meters (C0231, C0232)

For Single Use Only, do not re-sterilize

Pre-sterile, sterilization method – EtO

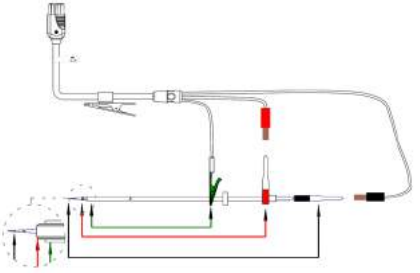
Configuration: Dual, shielded Coaxial, 3.5mm OD

Interface Connector: proprietary, 6-pin

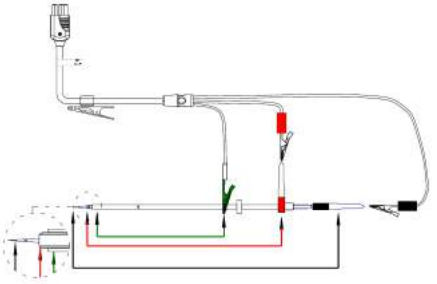
Electrode Connectors:

- Color coded, red - macro, blk - micro
- Gold plated (C0230, C0231)
- Alligator Clips (C0232)
- 0.9mm ID x 3.5mm dp
- Insertion/Extraction force: <500g

Reference Connector: Green, mini-alligator clip
Color Coded Flags: white, blue, green, red, yellow



C0230/C0231 Setup



C0232 Setup*

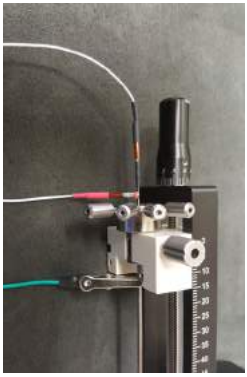
Instructions for Use

The electrode lead cables are designed for use with the microTargeting™ Guideline 4000™ 5.0. For instructions on operating the Guideline system, refer to the Guideline 4000™ 5.0 Directions for Use, L011-85. The procedure below commences once the microelectrodes have been inserted.

Connecting an electrode to the Guideline 5 System is a two-step process: connect the Patient Lead from the electrode to the UE Interface and 'map' that connection in the Guideline application. While these steps may be performed in any order, to avoid the risk of making an error, they should both be completed for every electrode before moving on to the next one.

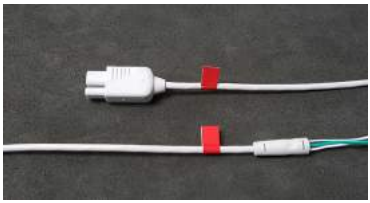
Connecting the Patient Lead: Maintaining sterile protocols, peel open the Patient Lead pouch. Connect the lead contacts to the electrode as shown: black to black for the microelectrode contact, red to gray/red for the macro-electrode contact and connect the patient reference alligator clip to the insertion tube or any other suitable patient reference source. Being careful not to touch the non-sterile UE Interface (or handing off to a non-sterile assistant), plug the opposite end of the lead into the proper channel of the Interface. It will be the one with the green status LED.

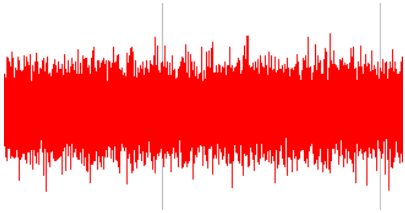
* Setup may vary for Special Use cables depending on electrode. Place the patient leads on the appropriate section of the electrode model being used.



For C0230/C0231 Configuration

Repeat the above procedure for all electrodes that will be used during the recording pass. For an additional level of assurance, colored stickers are provided with the Patient Leads. Selecting a different color for every Patient Lead used, attach a colored sticker near both ends of the lead. These color codes can be matched to the colors used within the Guideline Application to represent that channel.





Associating a color, in this way, with each channel/track/electrode can be very helpful in keeping straight which channel is which throughout the procedure.

When the MER procedure is complete, remove the lead cable from the electrode and Guideline 5 UE Interface.

Dispose of according to hospital protocol.

Recommendations

Do not apply bends in lead cable. Failure to keep lead cable as straight as possible may degrade noise immunity.