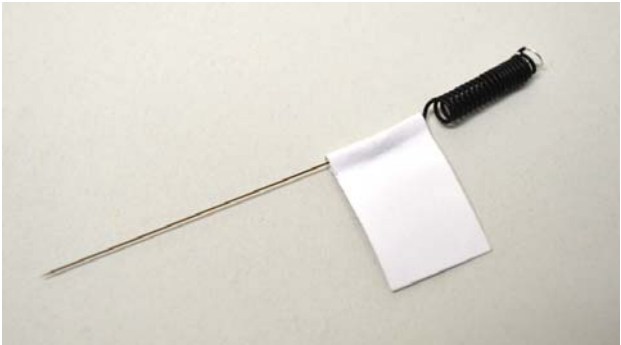


μEN

Microelectrode Neurography Needles

Directions For Use

L011-66 (Rev A0, April 2013)



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Microelectrode Neurography Needles

! USA Rx only. **Caution-** Federal law (USA) restricts this device to sale by or on the order of a physician.

microTargeting™ is a trademark of FHC, Inc.

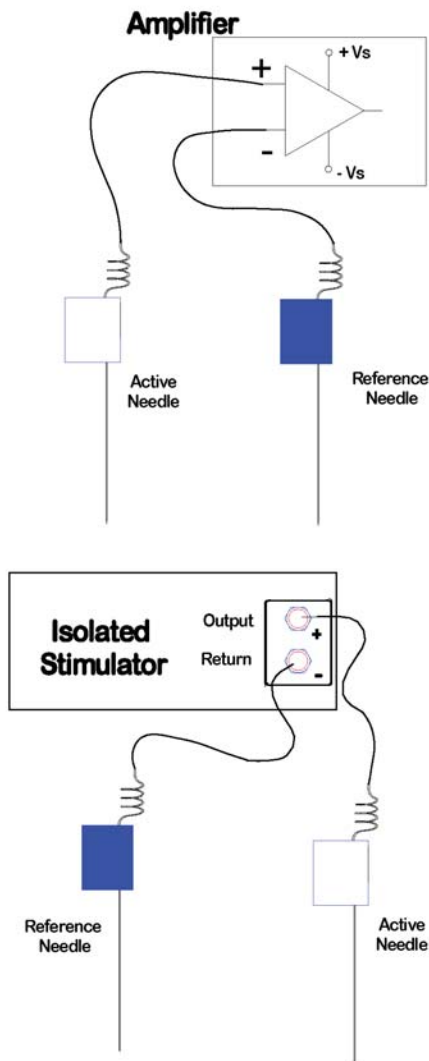
 User must examine unit prior to use to ensure it has no shipping damage.

 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
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STERILE EO Sterilized by ethylene oxide

PYROGEN Non-pyrogenic

- ◇ Sterile Medical Device - Do NOT resterilize
- ◇ Do not use the contents if there is any evidence of damage to the package or package seal that could compromise sterility.



Indications For Use

Microelectrode Neurography Needles are intended for use in intra-operative recording of single unit neuronal activity or intra-operative stimulation of neural elements in the brain.






Safety Information

- ◇ For single patient use only
- ◇ Do not reuse
- ◇ Not intended for implantation

Contraindications

Microelectrode Neurography Needles are not suited for chronic implantation. They have been validated for subcutaneous placement for 1 hour or less.

Warnings

-  **WARNING: Patients with a Microelectrode Neurography Needle inserted subcutaneously should not be exposed to the electromagnetic fields produced by magnetic resonance imaging (MRI). Use of intraoperative MRI may cause heating, movement, or induced voltages in the Microelectrode Neurography Needle.**
-  **WARNING: In the event that a patient must be defibrillated via electric shock, the Microelectrode Neurography Needle should be withdrawn or disconnected from any instrumentation prior to defibrillation.**
-  **WARNING: When using the needles for stimulation, excessive stimulus current may result in tissue damage.**
-  **WARNING: When using the needles for stimulation, the stimulator's reference point MUST be isolated from earth and/or patient ground or unintended current paths may result.**
-  **WARNING: To prevent electrical shock hazard, DO NOT connect Microelectrode Neurography Needles to any line voltage source or any unknown power source.**

Cautions

CAUTION: Extreme care must be used in handling the Microelectrode Neurography Needles. The tips are extremely small and delicate.

Notes

We recommend the use of a high impedance, low leakage current amplifier specially designed for use with microelectrodes.

We recommend the use of isolated, constant current stimulators equipped with a compliance limit warning indicator

Procedure

1. Proper care should be exercised at all times to ensure that the tip of the Microelectrode Neurography Needle is not damaged.
2. No preconditioning of the Microelectrode Neurography Needle is necessary or recommended.
3. Attach cable from the recording or stimulating system to the connector of the needles.
4. Insert the reference needle 1-2 cm away from the targeted nerve area, then insert an Active needle through the skin and into the nerve. Proceed with recording. Adjust recording parameters and perform noise reduction procedures to maximize recording quality.
5. If stimulating: stimulation should only be performed using an electrically isolated stimulator. Connect per attached diagram. Stimulate with internal electrical stimulation until a superficial muscle twitch is elicited. Stop stimulation, and proceed with recordings.
6. After use Microelectrode Neurography Needles should be placed in an approved sharps disposal container according to hospital protocol.