FHC

Neural microTargeting™ Worldwide

mT S/S - Side by Side Electrode

Directions For Use

L011-51-01 (Rev B0, 2021-01-19)

Contains directions for the following products:
mTT (length 100mm-300mm) (Exposure 2mm-50mm)

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mT S/S - Side by Side Electrode Directions For Use

Indications for use

The FHC, Inc. microTargeting™ Electrodes are intended for use in intra-operative recording of single unit neuronal activity or intra-operative stimulation of neural elements in the brain.

Intended use

The FHC microTargeting™ Electrodes are intended to be used by a neurosurgeon for intra-operative recording of single unit neuronal activity or intra-operative stimulation of neural elements in the brain during stereotactic 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, and 98/79/EC.
	Consult instructions for use.		Telephone number
! USA	In reference to "Rx only" symbol; this applies to USA audiences only.	EC REP	Authorized Representative in the European Community.
Rx Only	**Caution**- Federal law (USA) restricts this device to sale by or on the order of a physician.		Array configuration
REF	Indicates the catalog number so that the medical device can be identified.		Single configuration
LOT	Indicates the batch code so that the batch or lot can be identified.		Non-pyrogenic
	Not to be used if package has been damaged or opened.	STERILE EO	Sterilized using ethylene oxide
	Fragile item, can be damaged if not handled carefully.	NON STERILE	Indicates a medical device that has not been subjected to a sterilization process.
	Date after which the medical device is not to be used	2 STERILIZE	Medical device that is not to be resterilized.
	Do Not re-use; intended for one use on a single patient, during a single procedure.	0°C +32°F +40°C +104°F	Indicates the temperature limits to which the medical device can be safely exposed.
		0% 95%	Indicates the range of humidity to which the medical device can be safely exposed.

Sterile Electrodes

WARNINGS:

- 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.

Non Sterile Electrodes

WARNINGS:

- DO NOT attempt to sterilize the electrodes using this package. Remove microTargeting™ Electrodes from the package prior to sterilization. FHC recommends use of the FHC sterilization tray.
- While transferring microTargeting™ Electrodes for sterilization, please maintain a record of the lot number.
- FHC has validated and recommends the following steam sterilization parameters:

  Prevacuum wrapped
  (in 2 layers of 1-ply polypropylene wrap[1])
  Preconditioning pulses: 3
  Exposure time: 4 minutes at +132°C (+270°F)
  Minimum dry time: 30 minutes

  [1] Cycle was validated using Halyard Health H600 wrap

Safety Information

- For single patient use only.
- Do not reuse; reusing single-use medical devices could lead to serious patient injury.
- Not intended for implantation.
- microTargeting™ Electrodes must only be used with a medically approved stereotactic system aligned with a planned trajectory.
- microTargeting™ Electrodes must be used with a medically approved drive system capable of precise depth control.
- microTargeting™ Electrodes must only be inserted through a rigid insertion tube having a maximum inside diameter no more than 100 microns (0.004") larger than the diameter of the electrode.
- microTargeting™ Electrodes must only be used with medically approved (IEC60601 compliant) recording/stimulating devices and patient leads that have been designed for use with high impedance microelectrodes. This equipment must be capable of verifying electrode impedance and controlling the amplitude of stimulation currents delivered through the electrode.

Contraindications

- microTargeting™ Electrodes are not suited for chronic implantation. They have been validated for intracranial placement for 1 hour or less.

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 stimulators equipped with a compliance limit warning indicator.
- microTargeting™ Electrodes are properly installed and can operate correctly and safely if the directions for use are followed.
- Electrode lead cables must have the capability of mating with 0.8±0.04mm diameter microelectrode male pins.

⚠ WARNINGS

- 1 USA **Rx only: Caution-** Federal law (USA) restricts this device to sale by or on the order of a physician.
- Patients with a microTargeting™ Electrode inserted intracranially 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 microTargeting™ Electrode.
- In the event that a patient must be defibrillated via electric shock, the microTargeting™ Electrode should be withdrawn prior to defibrillation.
- To prevent electrical shock hazard DO NOT connect microTargeting™ Electrodes to any line voltage source or any unknown power source.
- Extreme care must be used in handling the microTargeting™ Electrodes. The tips are extremely small and delicate.
- Reusing single-use medical devices could lead to serious patient injury.
- Microelectrode Recording (MER) involves the use of sterile metal probes which are inserted into the brain during surgery. This use may cause a hemorrhage with a known adverse event effect rate of 1-2%.
- Products listed in this DFU must be used by trained personnel.
- Improper cable connections may cause erroneous results including unintended stimulation through metal contacts in the brain.

Procedural Instructions

1. Proper care should be exercised at all times to ensure that the tip of the microTargeting™ Electrode is not damaged.
2. Insert the microTargeting™ Electrode into insertion tube. Lower the electrode to the intended depth. Accurate target positioning cannot be achieved without the use of a suitable stereotactic insertion tube and a drive system capable of precise movements (drive system not provided).
3. Attach the patient leads.
4. If necessary, advance the electrode until the microelectrode tip exits the insertion tube.
5. Measure the electrode impedance to verify the integrity of the microelectrode tip and the proper connection of the patient leads. Note: the impedance measured in vivo should be lower than the nominal tip impedance specified. Discontinue use of the microTargeting electrode if the impedance result is higher or lower than is acceptable.
6. Advance the microTargeting™ Electrode along the planned track. Monitor neural activity encountered to determine the depth of the target. Adjust recording parameters and perform noise reduction procedures to maximize recording quality.
7. After use, the microTargeting™ Electrodes should be placed in an approved sharps disposal container according to hospital protocol.

MTT234(**)(***) (See definitions below)
MTT: microTargeting™ Electrode, Side by Side

2: Base Electrode Material-
W: Tungsten
P: Platinum/Iridium (80%/20%)
S: Stainless Steel

3: Impedance-
Measured at 1000Hz:
A: 500 Kohms (±30%)
B: 1.0 Megohms (±20%)
C: 5.0 Megohms (±20%)
D: 10 Megohms (±20%)
X: Specify between .1 and 10
Z: D.ZAP 1.0 Megohms (±20%)
Measured at 220Hz:
L: D.ZAP 1.0 Megohms (±20%)

4: Packaging-
N: A package of 6 microTargeting™ Electrodes provided non sterile
P: A package of 5 microTargeting™ Electrodes provided sterile

(**)(***): Customer Specific Dimensions-
Electrode Length: 100mm – 300mm
Exposure: 2mm – 50mm