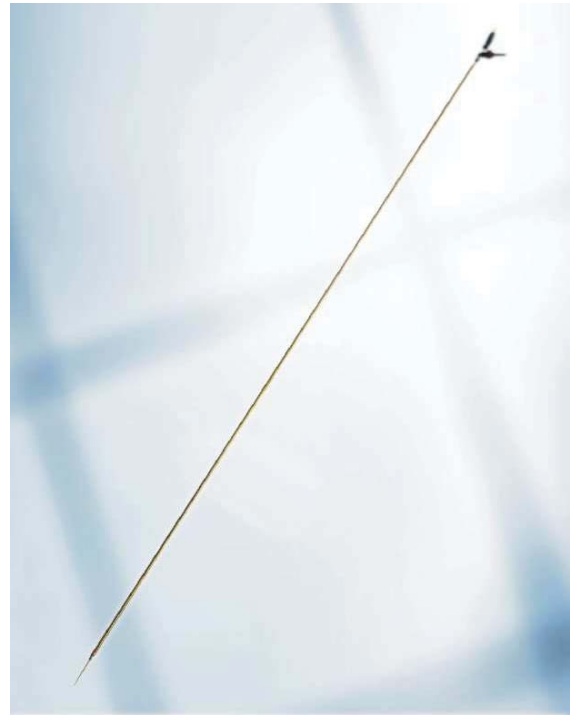


mT S/S - Side by Side Electrode



Directions For Use

L011-51-01 (Rev A0, 2016-04-28)

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

	WARNING / Caution, consult documents		Manufacturer
	Read usage instructions		Telephone number
	Not to be used in case package is damaged		Array configuration
	Re-use is not allowed		Single configuration
	Do not resterilize		Temperature limitation: Storage conditions are between 0°C - 40°C (32°F - 104°F)
	Non-pyrogenic		Humidity limitation: Not to exceed 95%
	Fragile item, handle carefully		Sterilized using ethylene oxide
	Catalog number		Non sterile
	Batch code		
	Use by date		
	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 the order of a physician.		

! WARNINGS

- 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- In the event that a patient must be defibrillated via electric shock, the microTargeting™ Electrode should be withdrawn prior to defibrillation.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%.

Directions For Use

- Proper care should be exercised at all times to ensure that the tip of the microTargeting™ Electrode is not damaged.
- Attach insertion tube/drive system assembly to the stereotactic system.
- Insert the microTargeting™ Electrode into the insertion tube. Accurate target positioning cannot be achieved without the use of a suitable stereotactic insertion tube and a drive system capable of precise movements (stereotactic insertion tube and drive system not provided).
- Attach appropriate cabling.
- Advance the microTargeting™ Electrode according to surgical protocol.
- Adjust recording parameters and perform noise reduction procedures to maximize recording quality.
- After use the microTargeting™ Electrodes should be placed in an approved sharps disposal container according to hospital protocol.
- To prevent Electrostatic Discharge (ESD) damage to the microelectrode, DO NOT allow operating room relative humidity to be less than 20%.

Sterile Electrodes



- 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



- If your microTargeting™ Electrodes were shipped in a standard plastic box, 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)
Preconditioning pulses: 3
Exposure time: 4 minutes at +132°C (+270°F)
Minimum dry time: 20 minutes

The FHC microTargeting™ Electrodes and cables 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; reusing single-use medical devices could lead to serious patient injury
- Not intended for implantation

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.
- microTargeting™ Electrodes are properly installed and can operate correctly and safely if the directions for use are followed.