FHC

Neural microTargeting™ Worldwide

Multiple Electrode Carrier

Directions for Use

L011-91 (Rev A0, 2018-08-14)

Contains directions for the following products:
70-AC-05

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EC REP

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FHC Latin America
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Indications for Use

The FHC microTargeting™ STar™ Drive System is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the brain or nervous system.

Intended Use

The Multiple Electrode Carrier is intended for use by neurosurgeons in a standard operating room environment to simultaneously secure up to five single configuration microelectrodes using the microTargeting™ STar™ Drive with single configuration insertion tubes.

Symbol Key

WARNING / Caution, consult instructions for important cautionary information.	Medical device manufacture, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
Indicates the need for the user to consult the 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.	Single configuration
REF Indicates the catalog number so that the medical device can be identified.	LOT Indicates the batch code so that the batch or lot can be identified.

Storage and Handling

Storage: Store the Multiple Electrode Carrier in a clean and dry environment.

Handling and use: Handle the Multiple Electrode Carrier with extreme care. These components may be damaged if excessive force or incorrect handling occurs.

WARNING: All parts are shipped non-sterile and must be sterilized before use. Follow sterilization protocols below.

WARNING: Components should be examined after each sterilization cycle for damage and function. Users should be aware that the effects of unvalidated sterilization protocols could result in damage to the components and affect their function or performance.

Disposal: Dispose of the Multiple Electrode Carrier according to hospital protocol.

Cleaning and Sterilization

The Multiple Electrode Carrier is sterilized in the small parts basket in the STar™ Drive sterilization tray. Refer to the STar™ Drive DFU (L011-1007) or the STar™ Drive Adapter Kit for microTargeting™ Platforms DFU (L011-44) for cleaning and Sterilization.

Maintenance and Repair

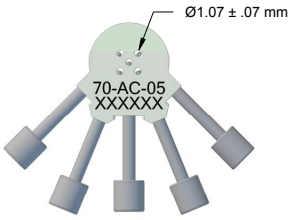
Scheduled maintenance: The Multiple Electrode Carrier should be inspected visually prior to each use for physical damage, or poor fit due to wear or residue buildup. If any component shows wear or damage that could interfere with proper function, please contact FHC for repair or replacement. None of the components require lubrication of any kind.

Repair: 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 for return instructions at 1-800-326-2905 (US & Canada) or +1-207-666-8190.

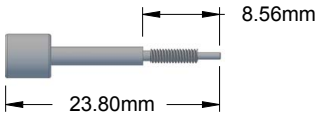
Specifications

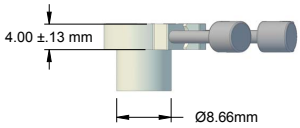
The Multiple Electrode Carrier is used with the FHC STar™ Drive to secure and provide depth control of up to five single configuration microelectrodes simultaneously.

Carrier Body



Carrier Screws (x5)





Material:

- Body Radel
- Screw 17-4PH Stainless Steel

Procedure

1. Place the Multiple Electrode Carrier in the STar™ Drive carriage.
2. Align the Ben-Gun to patient anatomy - make sure the slot in the lower portion of the OD of the carrier is visible through the opening in the front of the carriage.
3. Secure the carrier with the screw on the carriage.
4. Loosen the carrier screws and slide microelectrodes through holes until microelectrode collars are flush with the top of the carrier.
5. Lightly tighten screw - do not overtighten and damage electrode.
6. Assure microelectrodes are secure before advancing STar™ Drive Carriage.