



MR Lead Insertion Tube Handling Instructions

Directions For Use

L011-62 (Rev A0, 2016-07-29)

Contains directions for the following products:

66-IT-MR1



www.fh-co.com



FHC, Inc.
1201 Main Street
Bowdoin, ME 04287
Fax: 207-666-8292



FHC Europe
(TERMOBIT PROD srl)
42A Barbu Vacarescu Str, 3rd Fl
Bucharest 020281 Sector 2
Romania



24 hour technical service:
1-800-326-2905 (US & Can)
+1 207-666-8190

FHC Latin America
Calle 6 Sur Cra 43 A-200
Edificio Lugo Oficina 1406
Medellín, Colombia

MR Lead Insertion Tube Handling Instructions

Indications for use: The WayPoint™ 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: For use by neurosurgeons in stereotactic procedures in an “MR Environment.”

Symbol Key

	WARNING / Caution, consult documents		Manufacturer
	Read usage instructions		Telephone number
	Catalog number		Authorized Representative in the European Community
	Batch code		Re-use is not allowed
	Serial number		Do not re-sterilize
	For use with microTargeting™ Platform		Non sterile
	Fragile item, handle carefully		Temperature limitation: Storage conditions are between 0°C - 40°C (32°F - 104°F)
	In reference to “Rx only” symbol; this applies to USA audiences only		Humidity limitation: Not to exceed 95%
			MR Safe - the item poses NO known hazards in all MR environments

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

Sterilization

Method	Protocol
Steam	<p><u>Gravity Steam Sterilization:</u></p> <p>Minimum Temperature, Wrapped: 132°C Exposure Time: 10 minutes</p> <p><u>Prevacuum Steam Sterilization:</u></p> <p>Preconditioning Pulses: 3 Minimum Temperature, Wrapped: 132°C Full Cycle Time: 4 minutes Minimum Dry Time: 20 minutes</p>



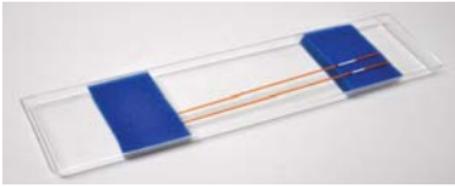
WARNING: DO NOT attempt to sterilize the insertion tubes using the package they were shipped in. Remove insertion tubes from the package prior to sterilization. FHC recommends use of the FHC sterilization tray.

Specifications

Lead Electrode IT and stylet:

Dimensions/material: 1.8 mm OD, 1.6 mm ID/ Polyimide, ceramic coated with epoxy

Required Components



66-IT-MR1



67-00-1

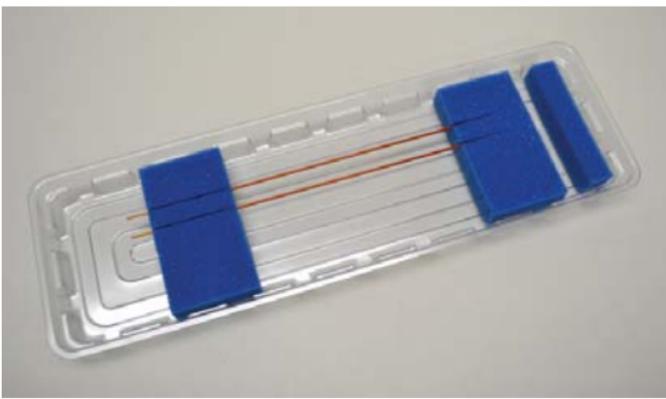
Handling Instructions for the 66-IT-MR1



WARNING: Stylet should not be subjected to forces that cause it to bend more than 1mm.

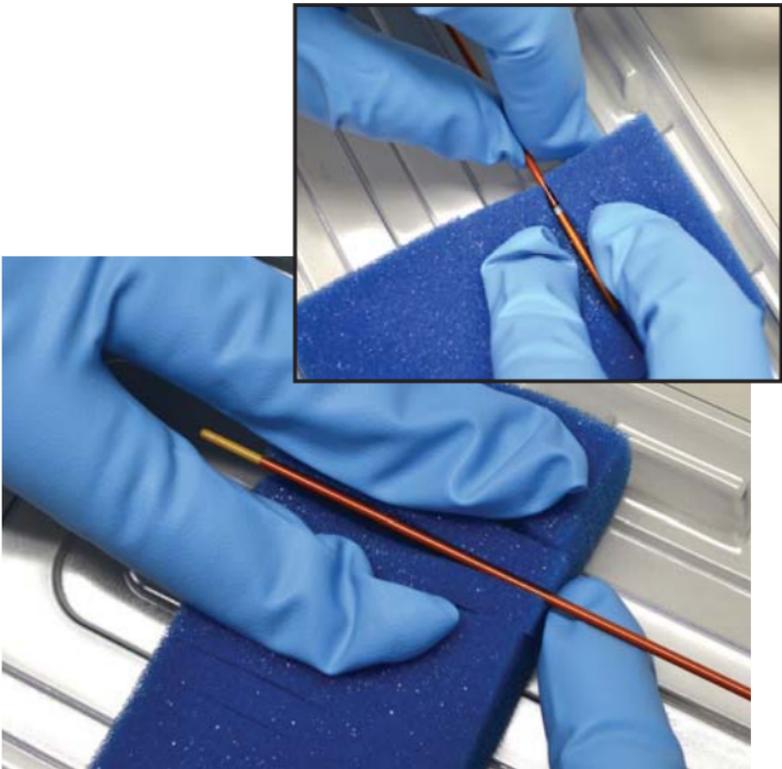


WARNING: Do not subject tube to excessive downward force relative to the collar.

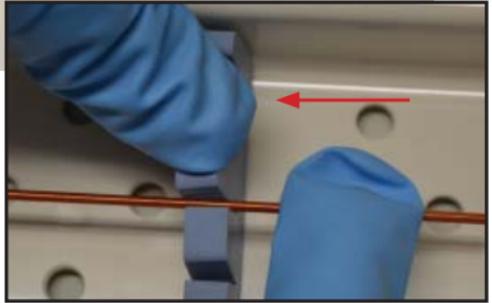
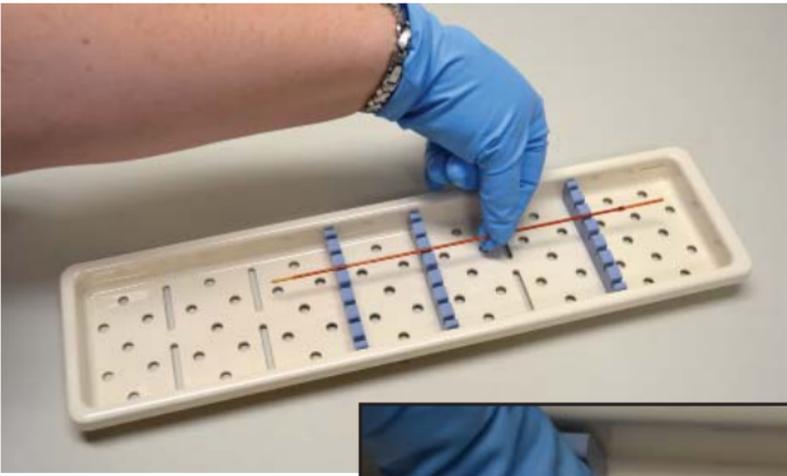


Insertion Tube and Stylet shown in shipping package

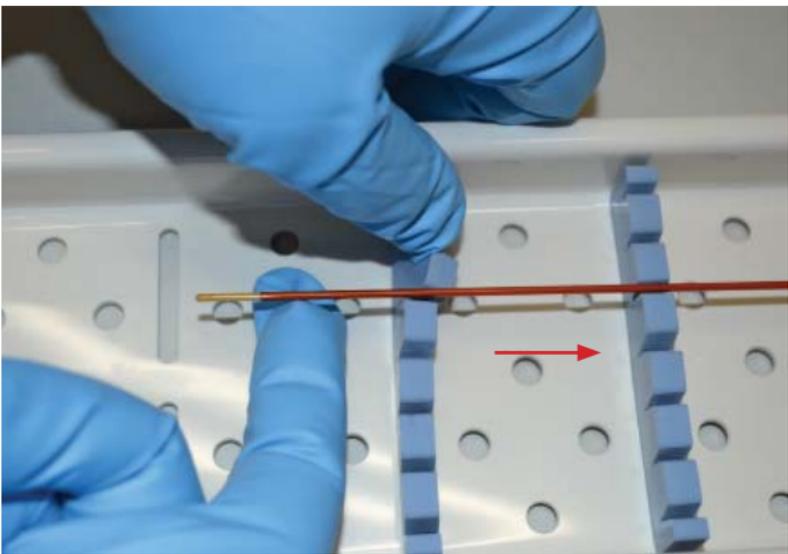
1. Keep stylet in insertion tube during all handling operations.



2. Remove insertion tube and stylet from the shipping package prior to sterilization by first spreading the blue foam with first and middle fingers and lifting the assembly to the foam surface. Then repeat at the other end.



3. Place insertion tube/stylet into the support slots of the sterilization tray, as shown. To secure, apply enough pressure on the side of the silicone support to deflect about 1cm and gently push the tube down 1mm. Release the silicone which will secure the tube in the slot. Repeat at the silicone support at the other end.
4. Secure the lid to the base using the 2 latches.
5. Sterilize following recommended sterilization parameters.



6. To remove the tube/stylet for use, apply enough pressure on the side of the silicone support to deflect about 1cm and gently lift the tube about 1mm to free it from the slot. Repeat at the silicone support at the other end.