



MR Lead Insertion Tube Handling Instructions

Directions For Use

L011-62 (Rev B0, 2019-08-07)

Contains directions for the following products:
66-IT-MR1, 66-IT-MR3

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







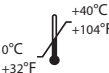




Indications for use

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 instructions for important cautionary information.		Medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Consult the instructions for use.		Telephone number
	Indicates the catalog number so that the medical device can be identified.		Authorized Representative in the European Community.
	Indicates the batch code so that the batch or lot can be identified.		Do not re-use; intended for one use on a single patient, during a single procedure.
	Serial number Indicates the serial number so that a specific medical device can be identified.		Medical device that is not to be re-sterilized.
	For use with microTargeting™ Platform.		Medical device that has not been subject to sterilization process.
	Fragile item, can be damaged if not handled carefully.		Indicates the temperature limits to which the medical device can be safely exposed.
	In reference to “Rx only” symbol; this applies to USA audiences only.		Indicates the range of humidity to which the medical device can be safely exposed.
	Caution- Federal law (USA) restricts this device to sale by or on the order of a physician.		MR Safe - the item poses NO known hazards in all MR environments.

Sterilization

Method	Protocol
Steam	Gravity Steam Sterilization: Temperature: 132°C Wrapped in 2 layers of 1-ply polypropylene wrap ^[1] Exposure Time: 10 minutes
	Prevacuum Steam Sterilization: Preconditioning Pulses: 3 Temperature: 132°C Wrapped in 2 layers of 1-ply polypropylene wrap ^[1] Exposure time: 4 minutes Minimum Dry Time: 30 minutes [1] Cycle was validated using Halyard Health H600 wrap

 **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

Materials:

- Polyimide
- ceramic coated with epoxy

Dimensions:

66-IT-MR1

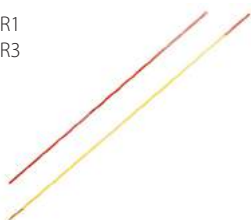
Outer Diameter - 1.8mm
Inner Diameter - 1.6mm
Insertion Tube Length - 202.5mm
Stylet Length - 215.5mm

66-IT-MR3

Outer Diameter - 1.8mm
Inner Diameter - 1.6mm
Insertion Tube Length - 215.5mm
Stylet Length - 216.5mm

Required Components

66-IT-MR1
66-IT-MR3



67-00-1



Handling Instructions

⚠ 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.

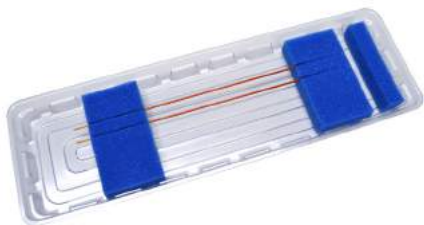
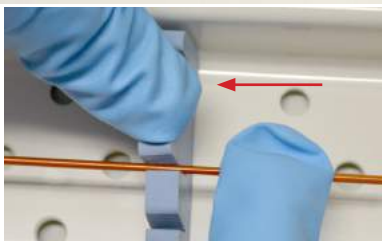
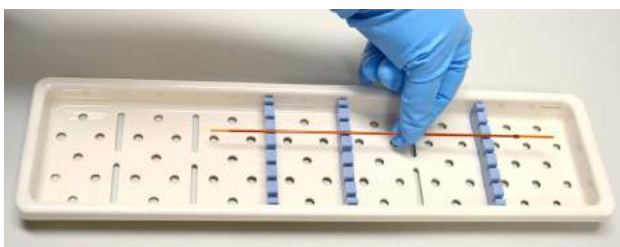


Image: Insertion Tube and Stylet shown in shipping package

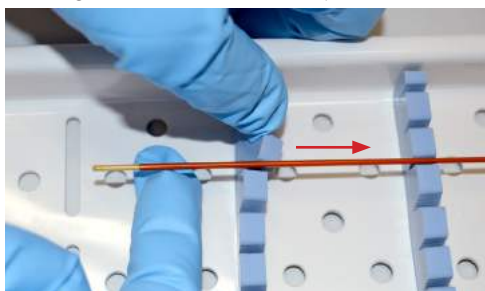
1. Keep stylet in insertion tube during all handling operations.



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.

Note: For further instructions on use please refer to the WayPoint™ Inserter System Directions for Use (L011-61).