

# microTargeting™ Platform Mounting Hardware

Directions for Use

L011-88 (Rev B0, 2021-05-13)

Contains directions for the following products:

MP-KIT-ME, MP-KIT-MF, MP-KIT-MG  
MP-KIT-MH, MP-KIT-MJ

[www.fh-co.com](http://www.fh-co.com)



FHC, Inc.  
1201 Main Street  
Bowdoin, ME 04287 USA  
Fax: +1-207-666-8292



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

















## Indications for Use

The microTargeting™ platform mounting hardware components are part of the WayPoint™ Stereotactic system which 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 systems.

## Intended Use






The microTargeting platform mounting hardware components are intended for use by a neurosurgeon in standard operation room environment to attach patient-specific microTargeting Platforms to previously implanted WayPoint anchors to provide stereotactic guidance for compatible positioning and implant devices.

## Symbol Key

	WARNING / Caution, consult documents instructions for important cautionary information.		Medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC and Medical Device Regulation (EU) 2017/745.
	Consult the instructions for use.		Telephone number
	<b>Caution</b> -Federal Law (USA) restricts this device to sale by or on the order of a physician.		Authorized Representative in the European Community
	In reference to "RX only" symbol: this applies to USA audiences only.		European Conformity. This device fully complies with Medical Device Regulation (EU) 2017/745 and legal responsibilities as a manufacturer are with FHC, Inc., 1201 Main Street, Bowdoin, ME 04287 USA.
	Indicates the catalog number so that the medical device can be identified.		Do not re-use; intended for one use on a single patient, during a single procedure.
	Indicates the date when the medical device was manufactured.		Indicates a medical device that has not been subjected to a sterilization process.
	Indicates Medical Device		An item that is known to pose hazards in all MRI environments.
	Instructions for end of life disposal.		MR safe- the item poses NO known hazards in all MR environments

WayPoint™, microTargeting™, and STarFix™ are trademarks of FHC, Inc.

## Warnings and Cautions

-  **WARNING:** Reusing single-use medical devices could lead to patient infection.
-  **WARNING:** All parts are shipped non-sterile and must be sterilized before use.
-  **WARNING:** Components should be examined after sterilization 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 functioning or performance.
-  **WARNING:** DO NOT sterilize the hardware in the clear plastic storage box. Remove hardware from the package prior to sterilization.
-  **WARNING:** The risk of surface finish degradation may occur after multiple sterilizations.

Rx Only **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a Physician.

## Handling and use

Components should align properly and easily screw together. Do not force with fiducial anchors or apply excessive force when attaching microTargeting platform.

 **Disposal:** Dispose of hardware according to Hospital protocol.

## Sterilization

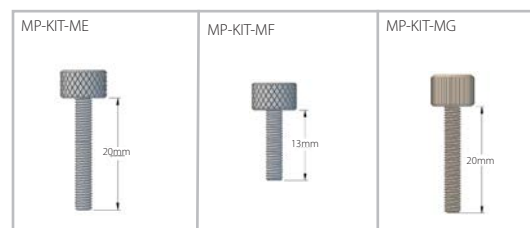
-PEEK (Plastic) mounting hardware (MP-KIT-MG, MP-KIT-MJ) is sterilized with the WayPoint inserter system in the small tray of the STar Steri Suite tray.

-Stainless steel mounting hardware (MP-KIT-ME, MP-KIT-MF, MP-KIT-MH) is sterilized with the microTargeting STar Drive in the small tray of the STar Steri Suite tray.

Method	Protocol	
Steam	<b>Gravity wrapped</b> (in 2 layers of 1-ply polypropylene wrap <sup>[3]</sup> ) <b>Exposure Time:</b> 30 minutes at 132°C (270°F) <b>Minimum Dry Time:</b> 60 minutes [3] Cycle was validated using Halyard Health H300 wrap	<b>Prevacuum wrapped</b> (in 2 layers of 1-ply polypropylene wrap <sup>[4]</sup> ) <b>Preconditioning Pulses:</b> 3 <b>Exposure Time:</b> 4 minutes at 132°C (270°F) <b>Minimum Dry Time:</b> 60 minutes [4] Cycle was validated using Halyard Health H400 wrap

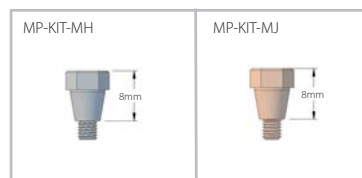
## Specifications



### Thumbknob



Material:	316 Stainless Steel	316 Stainless Steel	PEEK plastic
MR safety:	MR-Unsafe 	MR-Unsafe 	MR-Safe 
Dimension:	20mm M3x0.5	13mm M3x0.5	20mm M3x0.5

### Standoff



Material:	316 Stainless Steel	PEEK plastic
MR safety:	MR-Unsafe 	MR-safe 
Dimension:	8mm M3x0.5	8mm M3x0.5

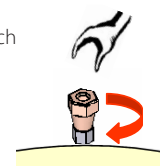
## Operation

**Note:** the Specific combination of mounting hardware required to attach a microTargeting Platform to the WayPoint Anchors depends on the platform model. Please refer to the appropriate microTargeting platform DFU to Determine the exact type and quantity of mounting hardware required for your specific platform.

## Platform Attachment

1. Expose previously implanted WayPoint fiducial anchors.
2. For microTargeting platform models that use standoffs.

- Screw and lightly hand tighten one standoff into each fiducial anchor.
- Place microTargeting platform over standoffs and screw and lightly hand tighten a thumbknob into each standoff.



3. For microTargeting Platform models that do not use standoffs

- Place microTargeting platform over anchors and lightly tighten thumbknob into each anchor.

4. For DBS microTargeting platforms with integrated rings.

- Use two thumbknobs positioned 90 degrees apart to secure microTargeting hub (provided separately) into platform.

