

microTargeting™ Platform Mounting Hardware

Directions for Use

L011-88 (Rev A1, 2018-03-12)

Contains directions for the following products:

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

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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, simulating 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 and 98/79/EC.
	Consult the instructions for use.		Indicates the date when the medical device was manufactured.
	In reference to "RX only" symbol: this applies to USA audiences only		Telephone number
	Caution-Federal Law (USA) restricts this device to sale by or on the order of a physician.		Do not re-use; intended for one use on a single patient, during a single procedure.
	Indicates the catalog number		Indicates a medical device that has not been subjected to a sterilization process.
	Authorized Representative in the European Community		An item that is known to pose hazards in all MRI environments.
	European Conformity. This device fully complies with MDD Directive 93/42/EEC and legal responsibilities as a manufacturer are with FHC, Inc., 1201 Main Street, Bowdoin, ME 04287 USA.		MR safe- the item poses NO known hazards in all MR environments

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

Warnings and Cautions:

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

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

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:

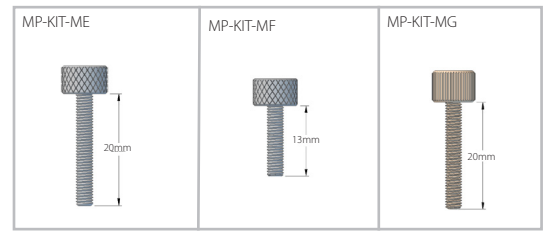
-PEEK (Plastic) mounting hardware (MP-KIT-MG, MP-KIT-MJ) is sterilized with the WayPoint inserter system in the small tray of the STar Steri Suite tray.




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

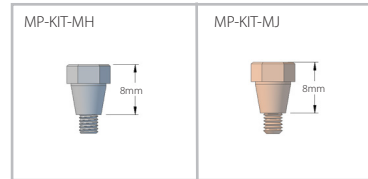
Specifications:



Thumbknob



	MP-KIT-ME	MP-KIT-MF	MP-KIT-MG
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



	MP-KIT-MH	MP-KIT-MJ
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

- Expose previously implanted WayPoint fiducial anchors.
- 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.
- For microTargeting Platform models that do not use standoffs
 - Place microTargeting platform over anchors and lightly tighten thumbknob into each anchor.
- For DBS microTargeting platforms with integrated rings
 - Use two thumbknobs positioned 90 degrees apart to secure microTargeting hub (provided separately) into platform.

