FHC
Neural microTargeting™ Worldwide

microTargeting™ DBS Platform

Incorporating STarFix™ Guidance

Directions For Use

L011-42 (Rev G0, 2021-05-18)

Contains directions for the following products:

Platforms: MP-KIT-P-BI, MP-KIT-P-SB, MP-KIT-P-U3, MP-KIT-P-U4
Tool Guide: 66-WP-TG18MM
Mounting hardware: MP-KIT-MA, MP-KIT-MB, MP-KIT-MC, MP-KIT-MD
Accessories: MP-KIT-A-MP, MP-KIT-A-MS, MP-KIT-A-PH

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Indications for use

The microTargeting™ DBS Platform is a component 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 DBS Platform is intended for use by a neurosurgeon in a standard operating room environment to provide pre-configure patient-specific stereotactic guidance platform for use in conjunction with the WayPoint Anchor/Locator System, WayPoint Planner and WayPoint Navigator and compatible positioning and implant devices.

Symbol Key

	WARNING / Caution, consult 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
! USA	In reference to "Rx only" symbol; this applies to USA audiences only.	CE 0413	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.
Rx Only	**Caution**- Federal law (USA) restricts this device to sale by or on the order of a physician.	EC REP	Authorized Representative in the European Community.
REF	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.
SN	Indicates the serial number so that a specific medical device can be identified.	-34°C -29°F +57°C +135°F	The temperature limits to which the medical device can be safely exposed.
LOT	Indicates the batch code so that the batch or lot can be identified.	10% 100%	The range of humidity to which the medical device can be exposed.
MD	Indicates Medical Device	MR	MR Safe - the item poses NO known hazards in all MR environments.
	Date when the medical device was manufactured.		An item that is known to pose hazards in all MRI environments.
	Instructions for end of life disposal.		

WayPoint™, STar™ and microTargeting™ are all trademarks of FHC, Inc.

Warnings and Cautions

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

Handling and Storage

Storage: Store the microTargeting DBS Platform at normal room temperatures between -34°C (-29°F) and 57°C (135°F). Do not expose to temperatures below -34°C (-29°F) or greater than +70°C (158°F), or a relative humidity of less than 10% or more than 100%, including condensation.

Handling and use: Handle the microTargeting DBS Platform with extreme care. These components may be damaged if excessive force or incorrect handling occurs. Do not force alignment with fiducial anchors or apply excessive force to insert compatible positioning devices. Follow the assembly and use instructions carefully.

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.

Cleaning and Sterilization

⚠ **WARNING:** Platforms and hardware are single use devices and should NOT be cleaned prior to sterilization.

⚠ **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:** The microTargeting DBS Platform and mounting hardware are delivered non-sterile and must be sterilized prior to use as described below.

Platform and Tool Guide Sterilization Instructions

(MP-KIT-A-PH, MP-KIT-P-BI, MP-KIT-P-SB, MP-KIT-P-U3, MP-KIT-P-U4, 66-WP-TG18MM)

Platforms and tool guides should be placed in a suitably sized container and sterilized as described below. Platforms and tool guides have been validated for two rounds of steam sterilization. Two rounds of steam sterilization can only be performed if the platform is unused. Re-use is not permitted.

Method	Protocol	
Steam	**Gravity wrapped:** (in 2 layers of 1-ply polypropylene wrap [1]) Exposure time: 10 minutes at 132°C (270°F) [1] Cycle was validated using Halyard Health H600 wrap	**Prevacuum wrapped:** (in 2 layers of 1-ply polypropylene wrap [2]) Preconditioning Pulses: 3 Exposure time: 4 minutes at 132°C (270°F) Minimum Dry Time: 40 minutes [2] Cycle was validated using Halyard Health H200 wrap
Sterrad™	**Sterrad™ 100S full cycle**	

Mounting Hardware Sterilization Instructions

(MP-KIT-A-MP, MP-KIT-MC)

PEEK (plastic) mounting hardware is sterilized with the WayPoint Inserter System in the small tray of the STar™ Steri Suite tray.

(MP-KIT-MA, MP-KIT-MB, MP-KIT-MD, MP-KIT-A-MS)

Stainless steel mounting hardware 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
	Prevacuum wrapped (in 2 layers of 1-ply polypropylene wrap [3]) Preconditioning Pulses: 3 Exposure time: 18 minutes at 134°C (273°F) Minimum Dry Time: 60 minutes [3] Cycle was validated using Halyard Health H300 wrap	

DBS Platform Overview

The microTargeting DBS Platform are available in four different base models. Each model has one or two microTargeting hub mounts with a specific orientation of support legs that are used to mount the platform to the WayPoint fiducial anchors. A model is chosen by the surgeon in the planning software which is then customized to conform to the patient specific anchor and trajectory locations while maintaining the overall shape of the model.

There have been three generations of models that have been available for use. Each generation has had different internal construction techniques and use different combinations of mounting hardware to attach the platform to the Waypoint fiducial anchors. Refer to the specifications section for details.

Platform adaptor hubs are mounted to the platform using index rings. The planning software automatically orients the index ring so that it is aligned with the AC-PC line with "A" facing anterior.

The latest generation of platform models are built with has index microTargeting hub mounting rings integrated directly in the platform. Previous generations require use of a separate metal microTargeting hub mounting indexing ring that is attached to the platform using three screws. The index ring (66-MP-IR), and index ring screws (66-WP-RS) and driver are provided separately or as part of the in the Platform Adapter Kit (70-FA-SF).

Integrated Index Ring

Separate Index Ring

There are two different Bilateral platforms are offered in two different configurations which vary based on the relationship of the anchors to the trajectories:

- 2H2H configuration have two legs on each hub mount
- 2H2B configuration have one leg on each hub mount plus two legs between the hub mounts

2H2H Bilateral

2H2B Bilateral

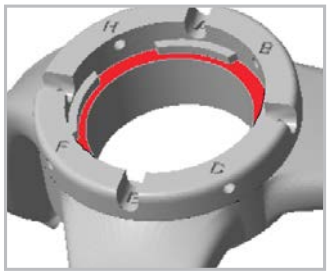
Platform Markings

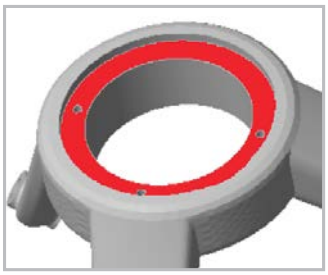
microTargeting DBS platforms are delivered with the following information embossed onto the platform:

MR#, trajectory name(s), Patient code (partial last name e.g. "SM—H" for Smith), and platform height.

For cases using the microTargeting Drive the platform height is shown "T=nn" where "nn" is the drive depth that will position the microelectrode tip at target. For other uses the platform height is shown as "TD=nn" where "nn" is the distance from hub mount floor, shown in red, to target.

If needed, convert using these formulas: TD = T + 90 or T = TD - 90





Anchor Placement Guidelines

Proper placement of the fiducial anchors is important to generate optimal platform geometry. The Fiducial Placement Template DFU (L011-40-05) describes ideal anchor locations for each DBS platform model that can be easily measured using the disposable fiducial placement template.

Planning Software

microTargeting DBS platforms are supported in the following surgical planning software:

- WayPoint Navigator
- WayPoint Planner
- Medtronic FrameLink
- Medtronic Stealth Station® Cranial v3.0

The exact platform models supported in a specific installation will depend on which planning software is used, the version and its configuration.

Specifications

Third Generation Models Available

				Mounting Details
2H2B Bilateral: MP-KIT-P-BI*	2H2H Bilateral: MP-KIT-P-BI*	4-Leg Unilateral: MP-KIT-P-U4	3-leg Unilateral: MP-KIT-P-U3	

* MP-KIT-P-SB contains two identical bilateral platforms for sequential bilateral procedures.

Material		Duraform PA medical grade nylon
MR safety		MR MR-Safe
Dimensions		Varies - patient specific
Hub indexing ring(s)		Integrated
Mounting hardware[1]	**Individual**:	20mm Thumbknob and Standoff - single set (***requires 1 set per leg***) **MP-KIT-MD** (***stainless steel***) or **MP-KIT-MC** (*PEEK plastic*) 20mm Indexing Ring Thumbknob (***requires 2 per hub***) **MP-KIT-A-MS** (***stainless steel***) or **MP-KIT-A-MP** (*PEEK plastic*)
	Bulk: (See L011-88)	20mm Thumbknobs - package of 50 (***requires 1 per leg + 2 per hub***) **MP-KIT-ME** (***stainless steel***) or **MP-KIT-MG** (*PEEK plastic*) Standoffs - package of 50 (***requires 1 per leg***) **MP-KIT-MH** (***stainless steel***) or **MP-KIT-MJ** (*PEEK plastic*)
Supported software		WayPoint Navigator, WayPoint Planner[2], Medtronic Stealth Station® Cranial v3.0

[1]Four sets of 20mm PEEK thumbknobs and standoffs are provided in the waypoint single-use surgical kit (66-WP-SKS)
[2]Support in WayPoint Planner requires model configuration update

Integrated Ring Thumbknobs

Integrated ring DBS platforms require two additional thumbknobs, mounted 90 degrees apart, to hold a microTargeting hub into each hub mounting ring. Four PEEK thumbknobs are provided in the waypoint surgical kit (66-WP-SKS). If the surgical kit is not used the appropriate number of stainless steel thumbknobs (MP-KIT-A-MS) or PEEK (MP-KIT-A-MP) thumbknobs are provided.

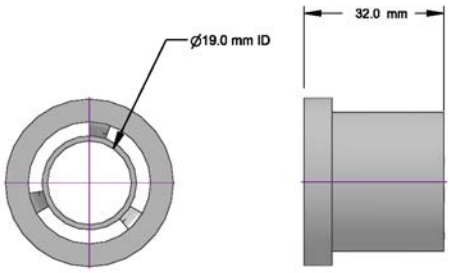
Optional Phantom

Third generation bilateral platforms can be ordered with an optional phantom (blue) that has physical pointers at the actual patient target locations. Once the matching platform (gray) is mounted on the phantom the actual devices and tools that will be used can be attached to verify they are positioned at the proper location relative to the target prior to use.

Material	Duraform PA medical grade nylon
MR safety	MR MR-Safe
Dimensions	Varies - patient specific
Mounting hardware	20mm thumbknobs (from Platform)

Optional Tool Guide

Material	Duraform PA medical grade nylon
MR safety	MR MR-Safe
Dimensions	ø19.0 mm ID x 32.0 mm



Second Generation Previous Models Available

Information about previous generation models is included for users of old planning software. These models should only be used if the 3rd generation models are not supported in your planning software.

2H2B Bilateral: MP-KIT-P-BI*

3-leg Unilateral: MP-KIT-P-U3

Mounting Details

* MP-KIT-P-SB contains two identical bilateral platforms for sequential bilateral procedures.

Material		Duraform PA medical grade nylon
MR safety		MR MR-Safe
Dimensions		Varies - patient specific
Hub indexing ring(s)		Separate
Mounting hardware	Individual:	13mm Thumbknob and standoff - singlr set (***requires 1 set per leg***) **MP-KIT-MB** (***stainless steel***) and 20mm indexing ring thumbknob (***requires 2 per hub***) **MP-KIT-MS** (***stainless steel***)
	Bulk: (See L011-88)	13mm thumbknobs - package of 50 (***requires 1 per leg + 2 per hub***) **MP-KIT-MF** (***stainless steel***) Standoffs - package of 50 (***requires 1 per leg***) **MP-KIT-MH** (***stainless steel***)
Supported software		WayPoint Navigator, WayPoint Planner

First Generation Previous Models Available

Information about previous generation models is included for users of old planning software. These models should only be used if the 3rd generation models are not supported in your planning software.

2H2B Bilateral: MP-KIT-P-BI*

2H2H Bilateral: MP-KIT-P-BI*

3-leg Unilateral: MP-KIT-P-U3

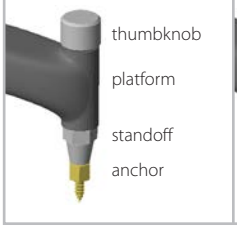
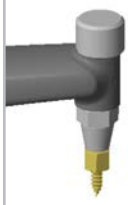
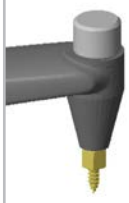
Mounting Details

* MP-KIT-P-SB contains two identical bilateral platforms for sequential bilateral procedures.

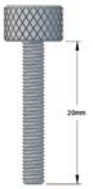
Material		Duraform PA medical grade nylon
MR safety		MR MR-Safe
Dimensions		Varies - patient specific
Hub indexing ring(s)		Separate
Mounting hardware	Individual:	20mm thumbknob (***requires 1 per leg***) **MP-KIT-MA** (***stainless steel***) and 20mm indexing ring thumbknob (***requires 2 per hub***) **MP-KIT-A-MS** (***stainless steel***)
	Bulk: (See L011-88)	20mm thumbknobs - Package of 50 (***requires 1 per leg + 2 per hub***) **MP-KIT-ME** (***stainless steel***)
Supported software		WayPoint Navigator, WayPoint Planner, Medtronic FrameLink

Mounting Hardware

The specific mounting hardware needed to attach a microTargeting DBS Platform to the fiducial anchor depends on the platform model used in the planning software. Refer to platform specifications to determine mounting hardware options.

	MP-KIT-MD	MP-KIT-MC*	MP-KIT-MB	MP-KIT-MA
				
Material:	316 Stainless Steel	PEEK plastic	316 Stainless Steel	316 Stainless Steel
MR safety:	MR-Unsafe	MR-Safe	MR-Unsafe	MR-Unsafe
Thumbknob:	20mm M3x0.5	20mm M3x0.5	13mm M3x0.5	20mm M3x0.5
Standoff:	8mm M3x0.5	8mm M3x0.5	8mm M3x0.5	None

*Four sets of 20mm PEEK thumbknobs and standoffs are also provided in the waypoint single-use surgical kit (66-WP-SKS)

	MP-KIT-A-MS MP-KIT-ME	MP-KIT-MF	MP-KIT-A-MP MP-KIT-MG	MP-KIT-MH	MP-KIT-MJ
					
Material:	316 Stainless Steel	316 Stainless Steel	PEEK plastic	316 Stainless Steel	PEEK plastic
MR safety:	MR-Unsafe	MR-Unsafe	MR-Safe	MR-Unsafe	MR-Safe
Dimension:	20mm M3x0.5	13mm M3x0.5	20mm M3x0.5	8mm M3x0.5	8mm M3x0.5

Removal of Components

When the lead implantation procedure has been completed, the platform can then be removed from the anchor standoffs by removing the thumbscrews securing it. WayPoint™ Anchors may remain in the skull for up to 28 days for post operative scanning or to allow additional surgical procedure(s). Remove the anchors from the skull using the WayPoint™ Hex Wrench tool and combination bit installed in the driver handle.

System Disposal

The single use items of the microTargeting™ Platform kit, including the patient and procedure customized platform itself, contain no hazardous materials requiring special handling, and may be disposed of using normal precautions for biohazardous materials.

Reusable components: The only reusable components of the system are the driver and hex wrench for the bone anchor implant and removal. The microTargeting™ DBS Platform is a single use device and is not reusable.

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