



# microTargeting™ Multi-Oblique Platform

## Incorporating STarFix™ Guidance

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### Directions For Use

L011-77 (Rev G0, 2018-02-20)

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Contains directions for the following products:

MP-KIT-P-ED, MP-KIT-P-EO, MP-KIT-P-ES

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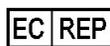
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## Indications for use:

The WayPoint™ Stereotactic 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 systems.

## Intended use:

The microTargeting™ Multi-Oblique Platform is intended for use by neurosurgeons in a standard operating room environment to position compatible tool guides at specific distance for one to twenty or more trajectories.

## Symbol Key

	Warning/ caution, consult instructions for important cautioning information.		Indicates the Authorized Representative in the European Community.		Medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Consult the instructions for use.		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.		Telephone number
	In reference to "Rx only" symbol; this applies to USA audiences only		Indicates the temperature limits to which the medical device can be safely exposed.		Do not re-use; intended for one use on a single patient, during a single procedure.
	<b>Caution-</b> Federal law (USA) restricts this device to sale by or on the order of a physician.		Indicates the range of humidity to which the medical device can be safely exposed.		MR Safe- the item poses NO known hazards in all MR environments
	Indicates the catalogue number so that the medical device can be identified.		Indicates the serial number so that a specific medical device can be identified.		

WayPoint™, microTargeting™ and STar™ are 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 mechanical components of the microTargeting 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 Platform and its accessories with extreme care. These components may be damaged if excessive force or incorrect handling occurs. Do not force engagement during pre-operative assembly or when positioning the implantation tools through microTargeting Platform. Follow the assembly and use instructions carefully.

**Component failures:** While a high degree of reliability is designed into the system, unexpected failure of components is always possible if improper storage or handling occurs.

## Inventory:

**MP-KIT-P-ES: microTargeting Multi-Oblique Single Trajectory Platform**

**MP-KIT-P-ED: microTargeting Multi-Oblique Dual Trajectory Platform**

**MP-KIT-P-EO: microTargeting Multi-Oblique Epilepsy Platform**

A patient-specific platform is designed for each surgical procedure. It is held to a skull-based anchor mount set using standoffs and thumbscrews which pass through the hollow cylindrical platform feet.

**Additional items required for operation, available separately:**

**66-WP-NV(4.4): WayPoint Navigator version 4.4 and above**

or

**66-WP-PL: WayPoint Planner**

FHC microTargeting Platform Planning and Design software is required to plan, verify and submit patient specific microTargeting Multi-Oblique Platform plans for production.

**66-WP-IKS: WayPoint Disposable Anchor Implantation Kit**

Tools and parts needed for the anchor implantation and scanning procedures. See the WayPoint Implant and Surgical Kits Directions For Use (L011-68) for details.

**Various: WayPoint Thumbknobs and Standoffs**

Individual: 20mm Thumbknob and Standoff - Single set (*requires 1 set per leg*)  
**MP-KIT-MD (stainless steel) or MP-KIT-MC (PEEK plastic)**

Bulk: 20mm Thumbknobs - Package of 50 (*requires 1 per leg*)  
**MP-KIT-MD (stainless steel) or MP-KIT-MC (PEEK plastic) and**  
Standoffs - Package of 50 (*Requires 1 per leg*)  
**MP-KIT-MH (stainless steel) or MP-KIT-MJ (PEEK plastic)**

**Various: FHC Multi-Oblique Guides & Accessories**

**Various: Vendor SEEG Depth Electrodes, Accessories and Tools**

Refer to the microTargeting Multi-Oblique Guides & Accessories Directions for Use (L011-84) for information on the tool guides and accessories that are available for the microTargeting Multi-Oblique Platforms to support SEEG, Ablation, and NeuroPace RNS procedures. Contact FHC to determine the specific combination of guides and accessories needed for your application.

**66-WP-HW: WayPoint Hex Wrench**

**66-WP-SW: WayPoint Standoff Wrench**

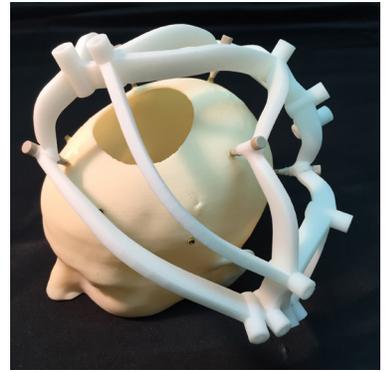
**66-WP-DH: WayPoint Driver Handle**

**66-WP-CD: WayPoint Combination Driver Bit**

Tools from STar™ Drive Platform Adapter Kit (70-FA-SF-01) required to remove platform standoffs and WayPoint anchors. Compatible single use tools are also provided as part of the WayPoint Platform Surgical Kit (66-WP-SKS).

**Also required:**

- DICOM 3.0+ compatible scanner capability (CT and MR)
- Image transfer facility by removable media or network
- Internet Access



## Specifications:

Hub dimensions:

Inner diameter:  $6.3 \pm 0.05$  mm with 2mm keyway slot

Outer diameter:  $12.7-0+0.5$ mm

Height:  $30.0 -0.05 +.25$ mm

Mounting: WayPoint 20mm Standoff and Thumbknobs (See Inventory for details)

Attachment and registration: WayPoint Fiducial Anchors (See WayPoint anchor/locator DFU, L011-40 for details)

Target accuracy:  $\pm 2.0$ mm from ideal (measured 100mm from top of hub)

Number of trajectories/hubs: 2 or more

Number of legs: 4 or more

Planning/Configuration: WayPoint Navigator 4.4 or above, or WayPoint Planner

## Cleaning and Sterilization:

**WARNING:** The Platform is shipped non-sterile and must be sterilized before use. Follow sterilization protocols below.

**WARNING:** Components should be examined after each sterilization cycle 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.

Platforms 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	<b>Gravity wrapped:</b> (In 2 layers of 1-ply polypropylene wrap <sup>[1]</sup> ) Exposure time: 10 minutes at 132°C (270°F)  [1] Cycle was validated using Halyard Health H600 wrap	<b>Prevacuum wrapped:</b> (In 2 layers of 1-ply polypropylene wrap <sup>[2]</sup> ) 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™	<b>Sterrad™ 100S full cycle</b>	

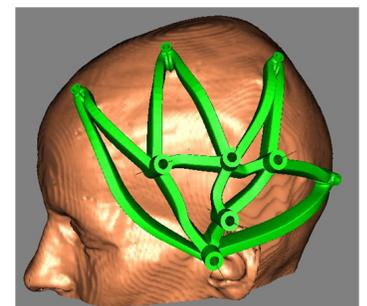
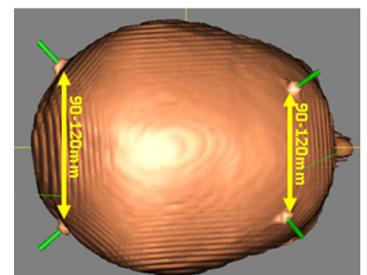
## Procedure:

### Anchor Implantation and Scanning

WayPoint Anchors are implanted under local anesthesia following the detailed instructions in the WayPoint Anchor/Locator DFU, L011-40. A minimum of four anchors should be placed in a configuration providing the widest base for the platform attachment, while avoiding interference with the planned trajectories and anatomical constraints. For large Multi-Oblique Platforms with trajectories in multiple locations, additional anchors are highly recommend to improve stability. While anchors should be implanted as normal as possible to the skull, exact placement and angularity is not critical.

When placing anchors for Multi-Oblique Platform, observe the following additional guidelines:

- 1) Place anchors a minimum of 25mm away from likely trajectories
- 2) Place anchors around planned trajectories on at least three sides
- 3) Avoid excessively cantilevered structures





**WARNING:** Avoid placing anchors in sutures or areas of bone that may not provide sufficient solid bone to hold them in place during the pre-operative wait. Always inspect the anchors for solid implantation both after the scan and just before surgery. Anchors should not be used when bone thickness is less than 4.5 mm or where the possibility of skull penetration above blood vessels is present.

2. Scan the patient. A CT scan is required for accurate microTargeting Platform design, see the WayPoint Anchor/Locator DFU, L011-40 for more details. An MR image set may be fused to the CT, if desired, in the microTargeting Platform Planning and Design Software.
3. Leave the anchors implanted, covering suitably to protect them and prevent infection. The patient is sent home or back to the hospital room. Surgery may be scheduled as much as 28 days after implantation.

## Pre-Operative Planning

**The microTargeting Multi-Oblique Platform is supported in the following surgical planning software:**

WayPoint Navigator 4.4 and above

WayPoint Planner 3.0 with Multi-Oblique Extensions

### Overview of steps to plan a microTargeting™ Multi-Oblique Platform:

1. Load patient CT scan with anchors
2. Automatically locate, then confirm anchor locations
3. Load and co-register MR scan(s)
4. Add/edit all trajectories
5. Set platform parameters
6. Create microTargeting™ Multi-Oblique Platform model
7. Edit connections and re-create platform as needed
8. Submit production file

Specific instructions for planning a microTargeting™ Multi-Oblique Platform with WayPoint™ Navigator 4.4 are provided in the WayPoint™ Navigator 4.4 Directions for Use (L011-58).

Specific instructions for planning a microTargeting™ Multi-Oblique Platform with WayPoint™ Planner 3.x are provided in Appendix A. General instructions for operating WayPoint™ Planner 3.x are provided in the WayPoint™ Planner Directions for Use (L011-43).

## Surgery

### Pre-Use Checkout

1. Inspect platform to assure that there are no breaks between hubs or anchor mounts.
2. Assure availability of at least one sterile standoff and thumbknob for each platform leg.
3. Assure that trajectory depth table shipped with platform is present during surgery and serial number listed on table matches the serial number of the platform.

### Platform Attachment

1. Place the patient on the table in a comfortable position. A noninvasive restraint system or tape should be used to prevent sudden or uncontrolled movements of the head. Drape the sterile field appropriately.
2. Apply local anesthetic, expose the anchors.
3. Use the provided standoffs and thumbscrews, attach the platform to the anchors.
4. Do not use the Multi-Oblique Platform to support the patient as that may cause incorrect targeting.

## Depth Electrode Implantation

1. The planning software will output a table that lists the distance from the top of each platform hub to its target. Each hub will have a single letter ID embossed near the hub that allows each hub to be matched to the corresponding trajectory.
2. Insert Tool Guide and rotate clockwise to lock.
3. Refer to microTargeting™ Multi-Oblique Accessories Directions For Use (L011-84) for specific instructions on use of tool guides and accessories. This will provide detailed instructions on how the platform height is used with to implant the depth electrode to the target depth for each trajectory.



**WARNING:** Targeting accuracy can only be assured when platform is used with an FHC Multi-Oblique tool. Please contact FHC for information on currently supported options.

4. Rotate counter clockwise until pin stops, then lift up to remove.
5. Repeat step 2 for all trajectories.

## Platform Removal

1. Assure all implant tools have been removed from microTargeting™ Multi-Oblique Platform.
2. While supporting platform, unscrew thumbknobs holding platform to standoffs. Set platform aside.
3. Remove standoffs from anchors using standoff wrench.
4. The WayPoint™ Anchors may be left in the patient for post-operative scanning and may remain in place for up to 28 days if attachment of another platform for inserting additional electrodes or positioning laser ablation probes is necessary.
  - If anchors remain - cover anchors suitably to protect them and prevent infection.
  - To remove anchors - use anchor wrench and combo driver to remove anchors from skull then close scalp incision.

## Additional Information

**Removal of Components:** When the depth electrode 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, re-attachment of the platform. Remove the anchors from the skull using the WayPoint™ Hex Wrench tool and combination drill bit installed in the driver handle. WayPoint™ Anchors, platform and standoffs are single use items.

**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. If the WayPoint™ Anchors are left in the patient (for up to 28 days) for future cases, a new platform must be created since each platform is a single use device.

**Reusable components:** The only reusable components of the system are the driver and hex wrench for the bone anchor implant and removal. The microTargeting™ Multi-Oblique 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.

## Appendix A:

This appendix provides instructions for creating the microTargeting™ Multi-Oblique Platforms using WayPoint™ Planner 3.0 with Multi-Oblique Extensions. Please be aware of the following differences from planning with WayPoint™ Navigator 4.4:

- In Planner 3.0 the distance from the hub to the skull is not constant for all trajectories. The height of the hub is based on a user-scalable sphere which approximates the shape of the skull. When planning with WayPoint™ Navigator the height of the hub is automatically set to a user specified distance above the skull.
- Editing of the platform bridge configuration is not integrated into Planner 3.0 and is done in a separate window using separate user interface.
- In Planner 3.0 the user must save intermediate file (PPR) to specific location and name before building and editing a platform.

### Pre-operative Planning with WayPoint™ Planner

1. Load the patient scan data into the microTargeting™ Platform Planning workstation.
2. Following the procedures in the software guide, process the scans to create one or more data sets. A CT dataset is required as the primary dataset.
3. Perform any desired preliminary functions such as image co-registration, segmentations, or threshold adjustments.
4. Locate and verify the anchor points in the scanned images.
5. Set patient anatomy by identifying the anterior commissure (AC) and posterior commissure (PC). The orientation of the mid-sagittal plane will be given by AC, PC and a third point typically selected on the superior region of the mid-sagittal plane, near the sagittal suture.

 **WARNING:** WayPoint™ Multi-Oblique Guides and Accessories may not function with less than 30mm of clearance between bottom of hub and scalp. Refer to Multi-Oblique Guides and Accessories DFU (L011-84) for details.

6. Create as many oblique trajectories as needed, by selecting the target and entry points.
7. Verify the points and inspect the planned trajectories. A surgeon's eye view display mode and multiple trajectories view options may be used in the inspection of the planned trajectories.
8. After the points are verified and the trajectory inspected, select the anchor set, select the "WP Epilepsy Multi-Hub" platform model and use the default platform scale of 100.
9. Export the plan in .ppr format by clicking on "8. Save File..." then picking "Export PPR...". Locate the "plans" subdirectory in the Navigator or Planner program directory (see below) and always export as "platform.ppr" overwriting any existing file.

#### Normal Planner/Navigator Program directory locations:

WayPoint Navigator on 32-bit Windows	C:\Program Files\FHC\WayPoint Navigator
WayPoint Navigator on 64-bit Windows	C:\Program Files (x86)\FHC\WayPoint Navigator
WayPoint Planner on 32-bit Windows	C:\Program Files\FHC\WayPoint Planner
WayPoint Planner on 64-bit Windows	C:\Program Files (x86)\FHC\WayPoint Planner

10. After the " " file has been exported, create the platform by clicking "7. Design Platform" then selecting "Create Platform..."

11. The Virtual Platform will appear in the 2D and 3D images, in place, on the anchors

- a. An automated algorithm will generate an initial set of connections between hubs and anchors.
- b. If user answers yes to “would you like to manually edit connections” prompt, the new platform will be displayed in a separate window (see example at right). The model can be moved/scaled/rotated using the tool bar at the top of the window.

A separate two column connection table (lower right) allows connections to be added, edited or removed. Trajectory hubs are labeled with numbers starting at 1 and anchor feet are labeled with numbers starting at 100.

**To edit connections:** Edit one or both values in the table. For instance, if hub 2 needs to be connected to hub 4 instead of hub 5, edit line 2 [2, 5] to change hub foot 2 from 4 to 5.

**To remove a connection:** Enter zero for both values in table

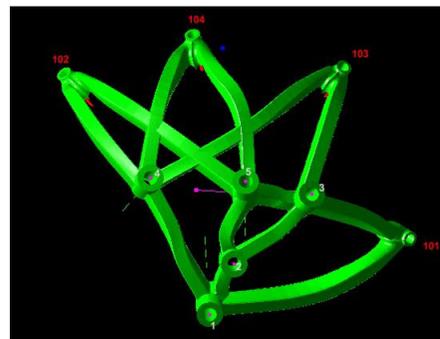
**To add a connection:** edit one of the empty (0, 0) lines at the bottom with the new hub/foot values.

No more than 5 connections to each hub

No more than 2 connections to each foot

**To rebuild the platform based on the modified connection list:** press rebuild. On each rebuild, two lines containing zeros will be added to the end of the connection table.

**To close the windows and return to the main application window:** press “Done” button.



	Hub/Foot 1	Hub/Foot 2
1	1	2
2	2	5
3	2	101
4	2	102
5	2	104
6	3	5
7	3	101
8	3	103
9	4	5
10	4	102
11	4	104
12	5	103
13	0	0
14	0	0

12. Inspect the position and shape of the displayed platform by selecting each individual trajectory with the “trajectory” display orientation. Check for trajectory issues relative to the entry or target point locations and adjust as needed. Special care should be taken **to assure that a minimum of 30mm exists between the scalp and the bottom of ALL trajectory hubs. If the platform is too close, rebuild it using a higher scale value.**

13. Return to step 9 to regenerate a new platform after any trajectory or scale edits.

14. Save/export the microTargeting™ Platform Model Files and transmit them to FHC’s fabrication facility by direct internet connection. A delivery confirmation will be sent back immediately.

15. A validated microTargeting™ Platform will be sent by expedited carrier within 24-72 hours.