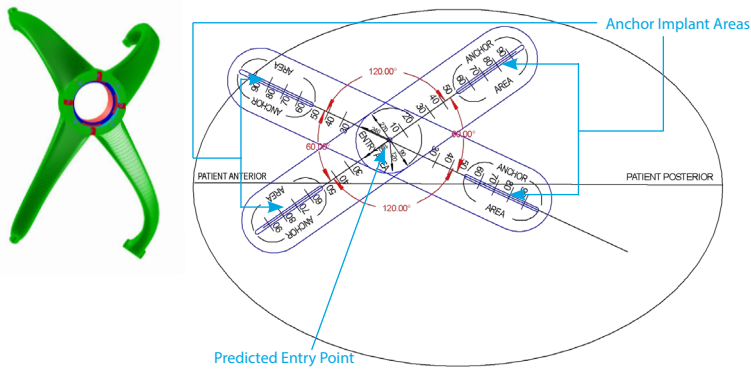
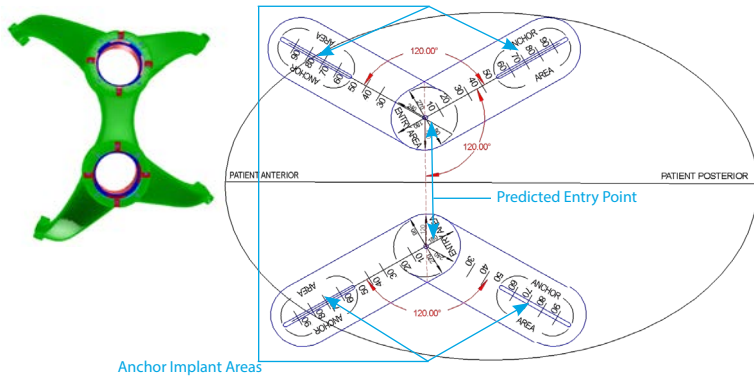


Basic 4 legged unilateral microTargeting Platform:



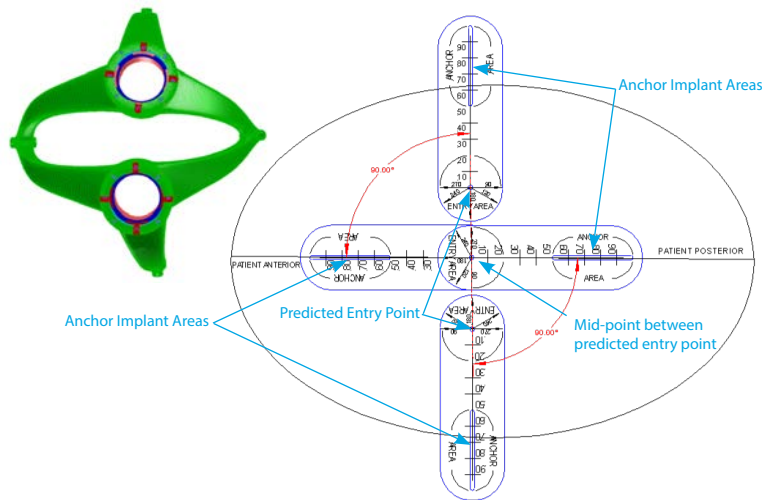
Bilateral microTargeting Platform 2H2H type, 2 legs on each hub:

The best formed and supported 2H2H platforms will be generated using the templates in the orientation shown. This configuration is useful for bilateral entries very medial or very lateral where a 2H2B platform will not work. The anchors should be placed in the indicated areas. If the location of the entry point is uncertain, placing the implants at the outer boundaries of the areas at least 70 mm from the predicted entry will give the greatest latitude for moving it during planning. Additional anchors for mounting set combinations may also be implanted to allow further flexibility.



Bilateral microTargeting Platform 2H2B type, 3 legs on each hub, 4 anchors:

The best formed and supported 2H2B platforms will be generated using the templates in the orientation shown. This configuration is useful for bilateral entries 70 to 100 mm apart. Longer distances tend to make thin lateral legs and shorter ones do not allow room on the bridge for the medial legs. The anchors should be placed in the indicated areas. If the location of the entry point is uncertain, placing the implants at the outer boundaries of the areas at least 70 mm from the predicted entry will give the greatest latitude for moving it during planning. Additional anchors for mounting set combinations may also be implanted to allow further flexibility.




Fiducial Placement Template

Directions for Use


L011-40-05 (Rev C0, 2021-05-17)

Contains directions for the following products:
66-DA-FT-02 and 66-DA-FT-03

www.fh-co.com

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

 FHC Europe
(TERMOBIT PROD srl)
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FHC Latin America
Calle 6 Sur Cra 43 A-200
Edificio LUGO Oficina 1406
Medellín-Colombia














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 system.

Intended Use

The Fiducial Placement Template is intended for use by a Neurosurgeon in a clinical setting to aid proper placement of WayPoint Anchors around the approximate location of the entry point for the planned trajectory or trajectories.

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
	In reference to "Rx only" symbol: this applies to USA audiences only.		Authorized representative in the European Community.
Rx Only	Caution —Federal Law (USA) restricts this device to sale by or on the order of a physician.		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 manufacturer's batch code so that the batch or lot can be identified.		Indicates medical device that has not been subjected to a sterilization process.
	Indicates Medical Device		
	Date when the medical device was manufactured.		

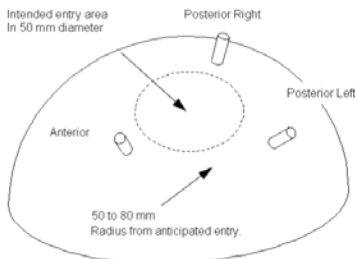
WayPoint™, microTargeting™, and STarFix are trademarks of FHC, Inc.

Implanting anchors and scanning:

1. Implant anchors. Based on the intended location of entry point(s), implant three or more WayPoint Anchors under local anesthesia following the more detailed instruction in the next section, "Implantation of WayPoint Anchors."

Three anchors are required for a unilateral fixture (66-MP-FT). The anchors should be arranged with one in a generally anterior position and two others spaced about 120 degrees in a 50-80 mm radius from the anticipated entry point. While they should be implanted as normal as possible to the skull, exact placement and angularity is not critical. If uncertain of the entry point location, a wider separation of 100mm from entry point and/or more anchors may be used. A template (66-DA-FT) is provided to assist the surgeon in placement. A WayPoint Locator Pin, or optional compatible fiducial systems available separately, should be inserted in the cup of each anchor prior to scanning (only if FrameLink is being used for surgical planning). This provides visibility and allows registration of the anchors to patient anatomy in the scans.

Four anchors are required to create a bilateral fixture (66-MP-BT), which provides for two fixed targets in a single device, one target on each side of the patient's brain. Basically the above implant process is followed twice with left and right side mount sets sharing anterior and posterior anchors.



WARNING: The accuracy of the microTargeting™ Platform depends on the use of a CT scan as its primary dataset. While MRI targeting may be done through fusion to the CT scan, MRI alone will not provide sufficient accuracy for microTargeting Platform construction due to MRI distortion error.

2. Scan the patient. A CT scan is required for accurate microTargeting Platform design. 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.

Implantation of WayPoint Anchors:

The implantation of WayPoint Anchors may be done between 3 to 28 days before the intended surgery. Generally, a week is recommended to allow sufficient time for receiving and verifying the design, and the construction and delivery of an microTargeting Platform. Contact FHC for availability of expedited delivery options.

The microTargeting Platform's STarFix™ technology ensures that the placement of the WayPoint Anchors, on which it depends, is easy and non-critical. The positioning of the anchors should be planned based on the location of intended entry. In most functional surgery, this location varies little for known target locations, though patient anatomy may require alternative locations. Surgeon experience is the best guide for predetermining the entry point location. Often patient scans have been done during diagnosis, and they may be helpful in selecting entry points. In this case the pre-scans can be loaded into the microTargeting Platform Planning Workstation and the trajectory planning feature used to get a general idea of entry point location. If a bilateral procedure or multi-targeting is to be performed, an additional entry point or even several locations may be required.

Based on the intended location of the entry point, implant at least 3 anchors per trajectory, following the procedure in the WayPoint Anchor/Locator System Directions For Use. For the unilateral microTargeting Platform, the anchors should be arranged with one in an anterior position and 2 more at about 120 degrees at a 50-80 mm radius from the anticipated entry point. While they should be implanted as normal as possible to the skull, exact placement and angularity is not critical. It is actually better to not try to get the locations at exactly the same distance or angle from entry, as it is easier to visually identify the mounting orientation of the finished platform.

If uncertain of the entry point location, or if the skin needs to be retracted to expose a large area of skull, a wider separation of up to 100 mm and/or more anchor locations may be used.

It is possible through careful planning to combine anchor locations for bilateral or multi-target procedures. This will reduce the number of anchors implanted in the patient, but will prevent simultaneous targeting, and may create less than ideal platform shapes.

Other considerations for placement are the locations of routes for tunneling DBS leads, or of previous surgical procedures, and these areas should be avoided. A flexible template is provided to assist in selection of locations, but the above directions should always be adhered to. Also see the microTargeting Platform design considerations in the next section.

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 4.5mm or where the possibility of skull penetration above blood vessels is present.

Scanning:

WARNING: As in other forms of stereotactic surgery in which targeting dependson scanned images, it is important that the patient does not move during thescan. The target area may be 100 slices or more from the area of the marker/anchors at the top of the head, and the fiducial markers may be 25 or more slices from each other. The accuracy of both the custom microTargeting Platform andthe selected trajectory depend on the fact that the patient does not move. Ahead holder, tape or even mild anesthesia or sedation may be required at thesurgeon's discretion. The scanner technician should always check the quality ofthe scan images and for displaced slices indicating movement. A poor qualityscan should not be used for microTargeting Platform design.

Attach locator pins (see the WayPoint Instructions For Use) to the anchors and scan the patient, ensuring good visibility of the locators in the scan. Follow the manufacturer's recommendations for scanning protocols, but in general, a small field of view is recommended, resulting in a larger image of the head. All anchors and locator pins must be completely within the field of view and must not touch the image border. The following parameters are strongly recommended and will provide the best accuracy for picking marker points and for designing a platform.

Anchor Placement

Basic 3 legged unilateral microTargeting Platform:

The best formed and supported basic platforms will be generated using the template in the orientation shown. The implants should be done centered in the indicated implant areas. (Slight differences in placement within the areas is actually an advantage as it will make determining the correct orientation of the finished platform easier.) If the location of the entry point is uncertain, placing the implants at the outer boundaries of the areas will give the greatest latitude for moving it during planning. Additional implants allowing a choice of mounting set combinations may also be done, though the selection of sets of three implants for secondary mounting sets must also follow the above guidelines.

