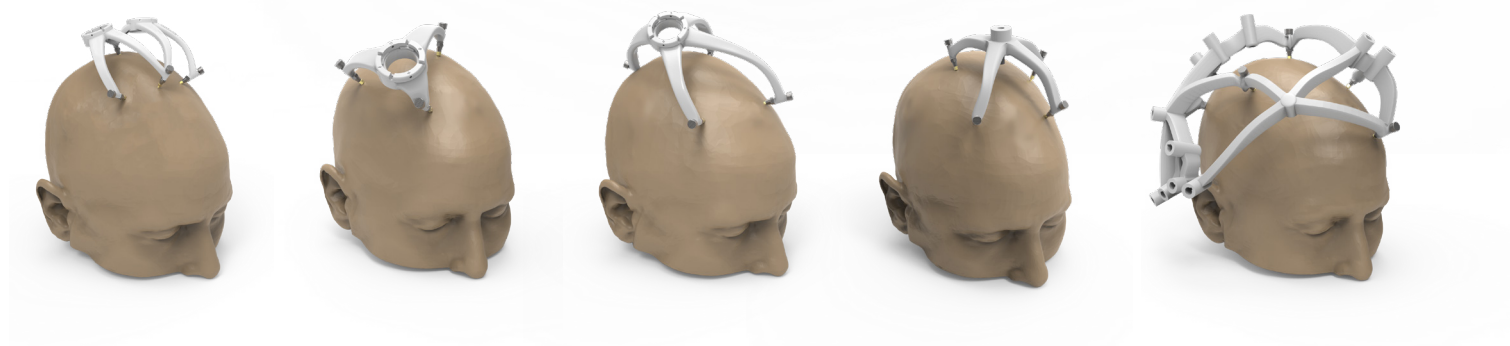


# STarFix Platform Introduction



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# Overview

STarFix™ platforms enable the accurate placement of one or more devices or instruments within the brain. Patient-specific models are available for use in many common types of cranial neurosurgery procedures, including deep brain stimulation, stereoelectroencephalography, and laser ablation.

**For the patient,** the STarFix platforms allow for faster procedures than with traditional stereotactic frames, which grants the patient increased freedom of movement, improving patient comfort during lengthy procedures.



**For the surgeon,** the STarFix Platforms are easy to use and have proven to be as or more accurate than a traditional stereotactic frame\*, minimizing possible error in frame setup. Placing the platform is fast, with the surgical planning step being removed from the OR for the surgeon's convenience.

*\*References available upon request*

**For the hospital,** use of the STarFix Platform minimizes upfront capital investment in traditional stereotactic frames and can shorten operating room time. STarFix platforms are single-use and fabricated for each patient and procedure.

Key features and benefits of STarFix platforms include:

- **Time-Saving Design:** Single-use, patient-specific stereotactic platform for maximum efficiency in the OR
- **Advanced Planning Tools:** Integrated preoperative planning, intraoperative navigation, and postoperative reporting with WayPoint™ Navigator
- **Patient-specific and Collaborative:** STarFix Platform models designed for deep brain stimulation, stereoelectroencephalography, and laser ablation workflows

# System Components

## — Platforms for DBS —



### 3-Leg Unilateral Platform

#### Required Parts:

- 3 WayPoint Anchors
- 3 20mm SS Thumbknobs with Standoff



### 4-Leg Unilateral Platform

#### Required Parts:

- 4 WayPoint Anchors
- 4 20mm SS Thumbknobs with Standoff



### 2H2H Bilateral Platform

#### Required Parts:

- 6 WayPoint Anchors
- 5 20mm SS Thumbknobs with Standoff

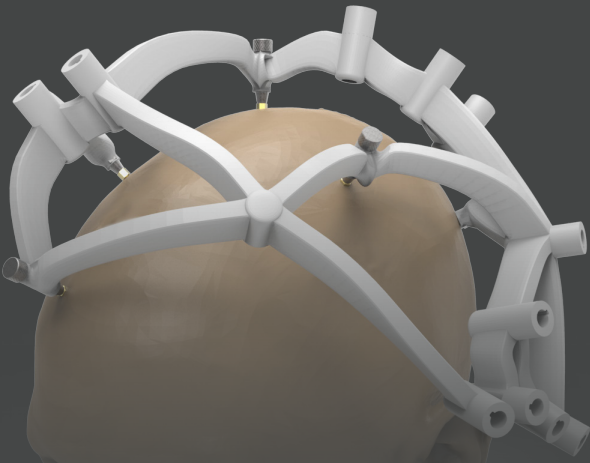


### 2H2B Bilateral Platform

#### Required Parts:

- 6 WayPoint Anchors
- 5 20mm SS Thumbknobs with Standoff

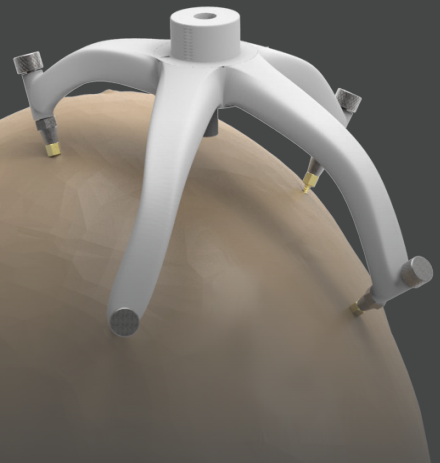




### Multi-Oblique Epilepsy Platform

#### Required Parts:

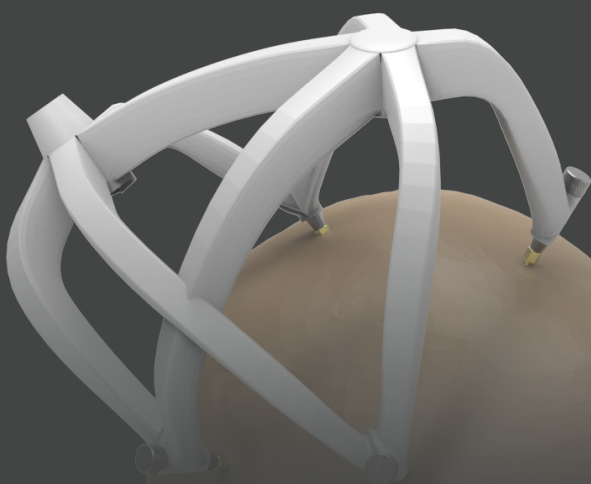
- Appropriate number of WayPoint Anchors
- Appropriate number of 20mm SS Thumbknobs with Standoff



### Monteris Platform

#### Required Parts:

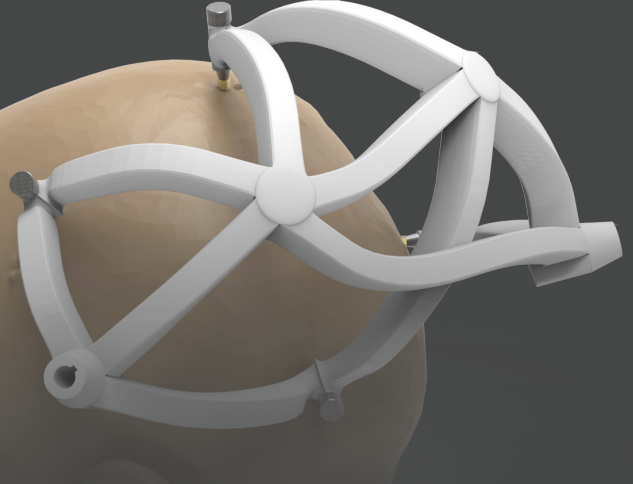
- Appropriate number of WayPoint Anchors
- Appropriate number of 20mm SS Thumbknobs with Standoff



### Single Trajectory Platform\*

#### Required Parts:

- Appropriate number of WayPoint Anchors
- Appropriate number of 20mm SS Thumbknobs with Standoff



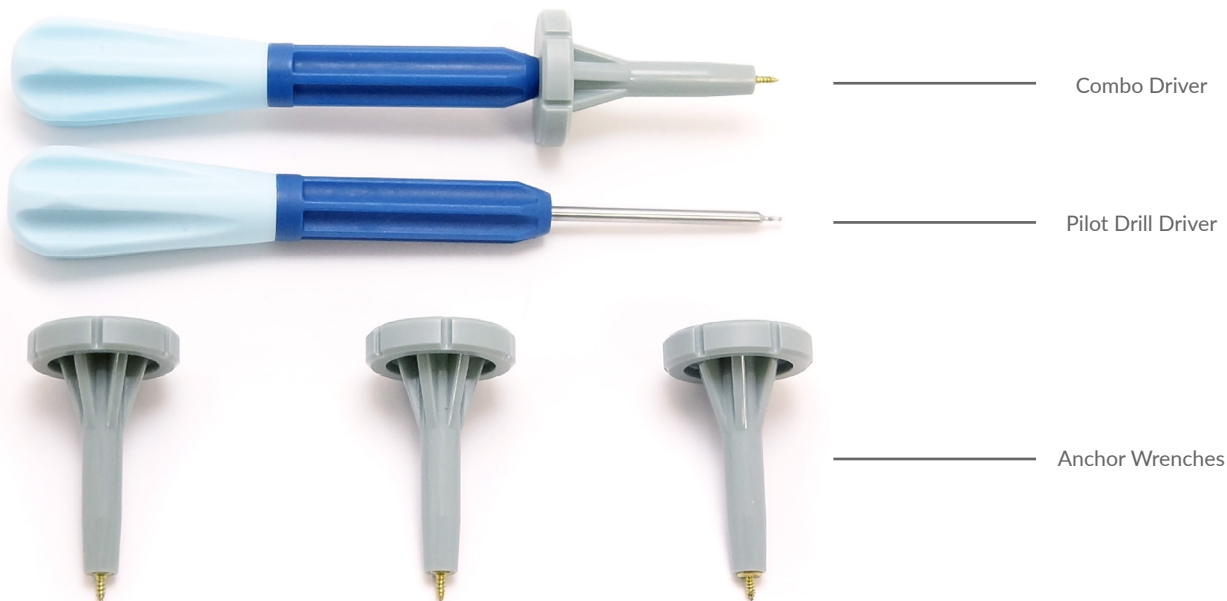
### Dual Trajectory Platform\*

#### Required Parts:

- Appropriate number of WayPoint Anchors
- Appropriate number of 20mm SS Thumbknobs with Standoff

## — Kit Components —

### WayPoint Disposable Implantation Kit

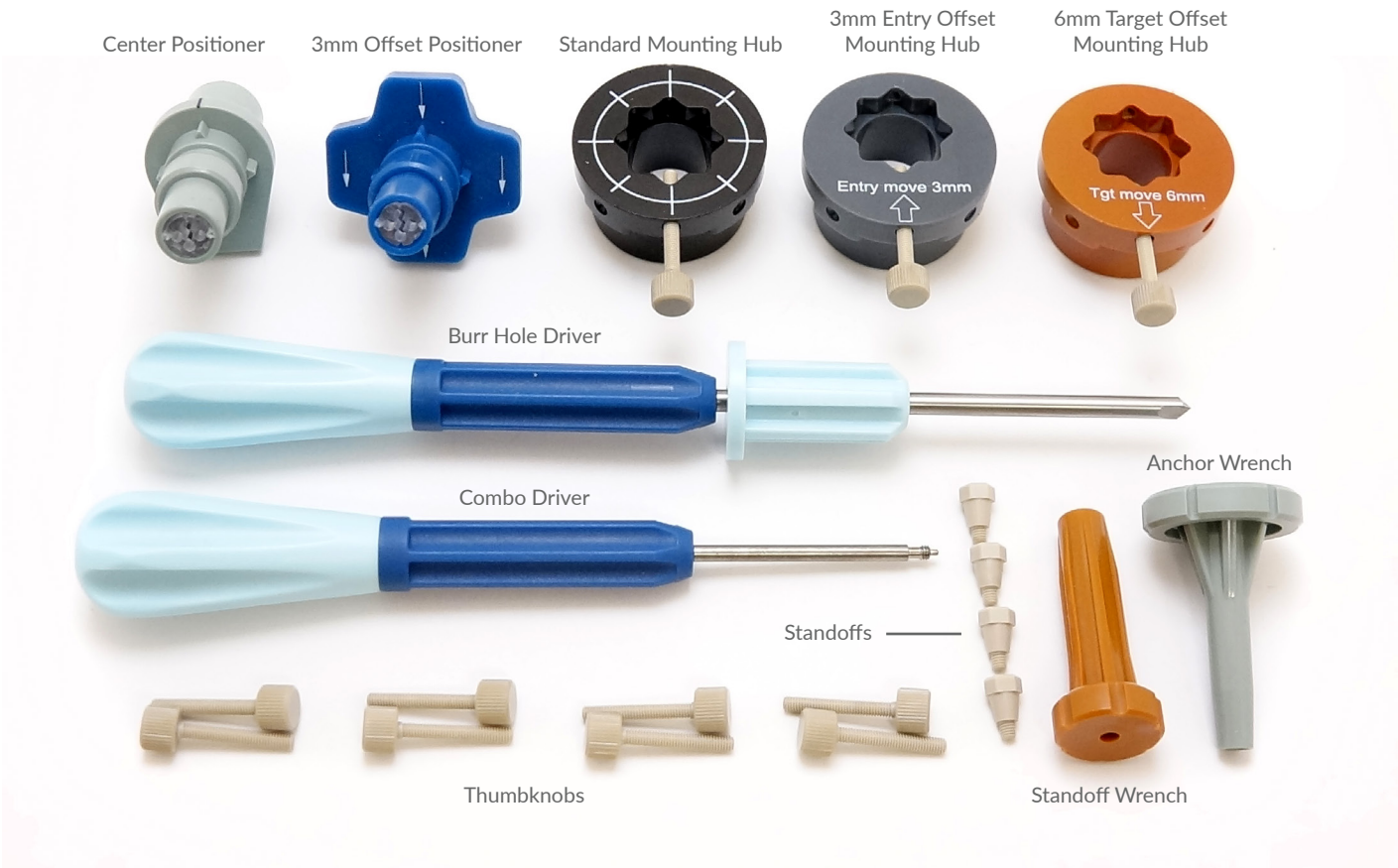


### WayPoint Reusable Implant Kit



\* 5mm Anchors and Pilot Drill Bit are not reusable they are single use for a single patient. Both sold separately.

WayPoint Disposable Surgical Kit



WayPoint Disposable Bilateral Kit





## MR Lead Insertion Tube Components and Setup

SLS Components (part numbers 66-WP-ID-01 and 66-WP-ID-02) include:

1. Inserter
2. Lead Holder
3. Thumbknobs
4. Lead Measurement Fixture
5. Drape Support

Accessories Sold Separately:

6. 66-MP-EM / Burr Hole Marker
7. 66-WP-SW / Standoff Wrench
8. 66-WP-HW / Hex Wrench
9. 66-WP-DH / Manual Handle
10. 66-WP-CD-01 / Combination Driver
11. 66-MP-EM / Burr Hole Marker Bushing
12. 70-FA-SF-01 / STar SteriSuite Case
13. 67-00-1 / Sterilization Tray

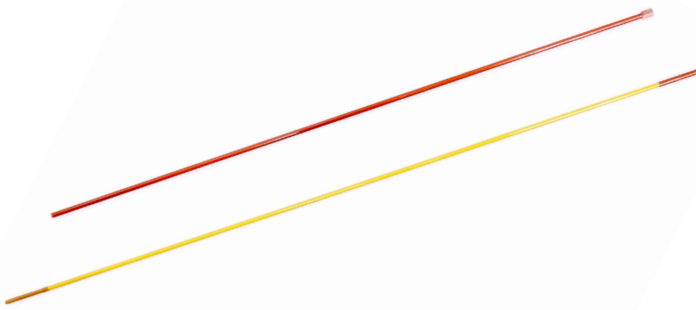
Additionally required for use:

- 66-WP-SKS / WayPoint Disposable Surgical Kit
- 66-AC-DC / LeadLoc
- 66-IT-MR1 or 66-IT-MR3 / MR Lead Insertion Tube





MR Lead Insertion Tube Components and Setup

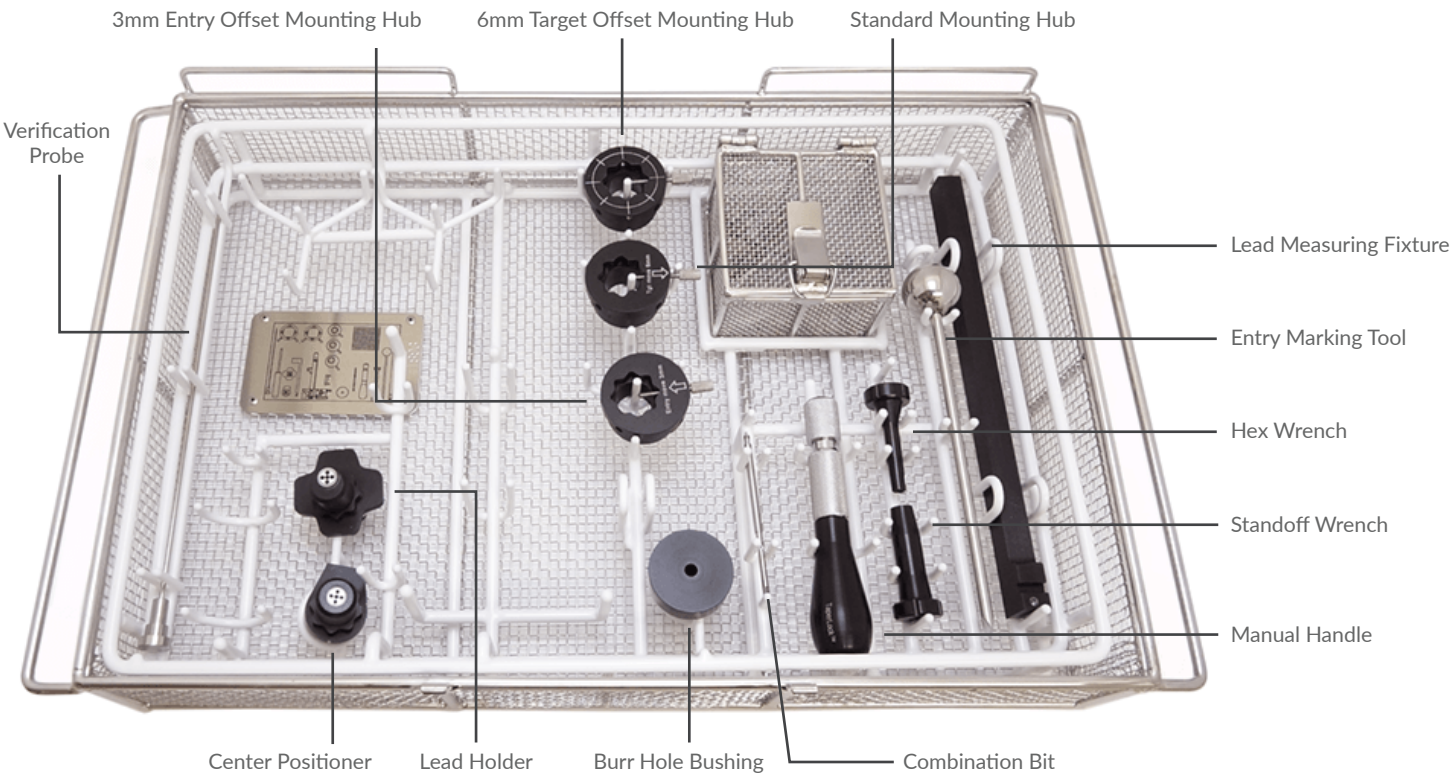


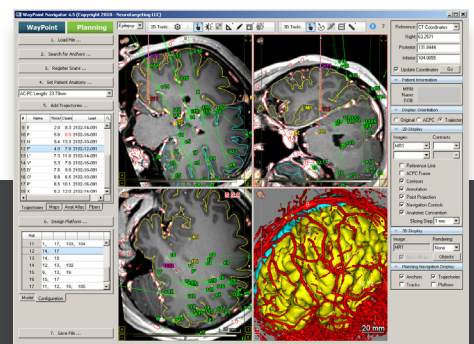
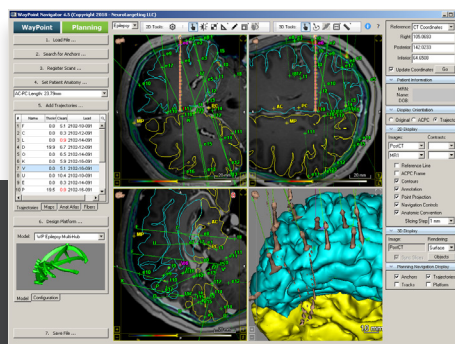
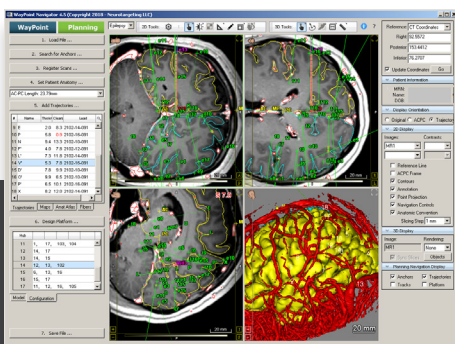
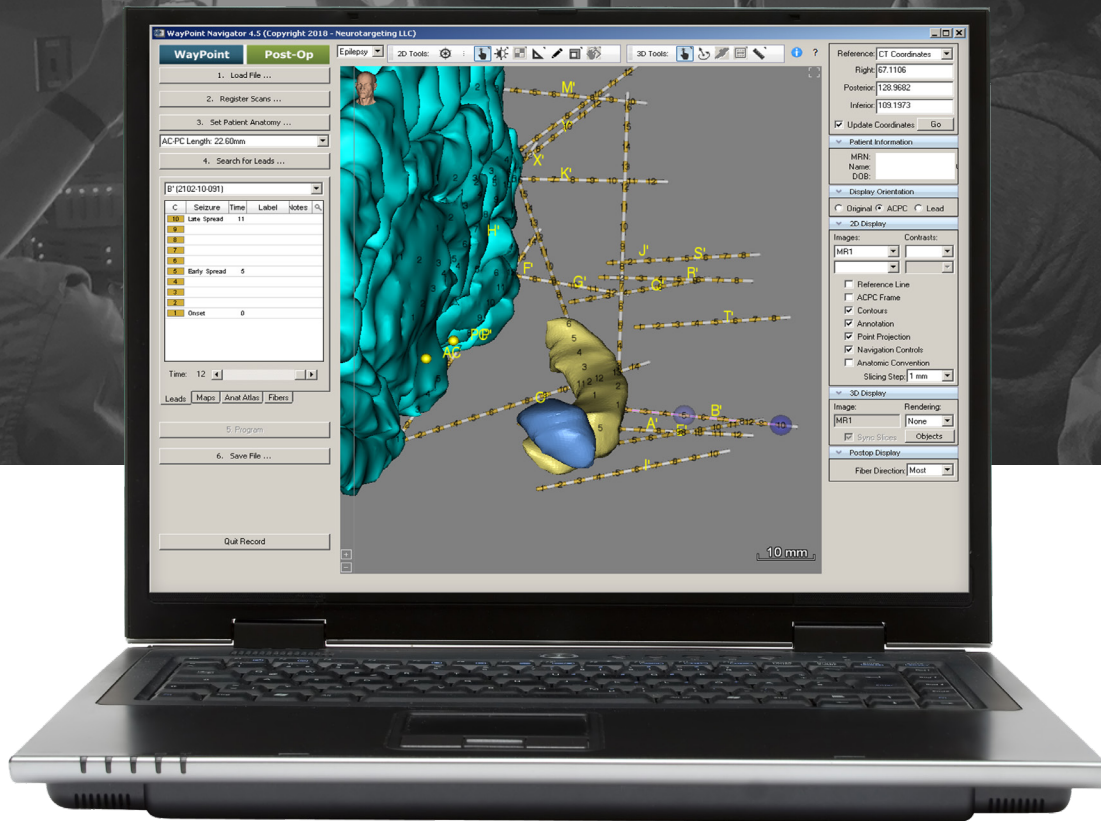
MR Lead Insertion Tube



Insertion Tube Tray

STarFix Platform Adapter Kit



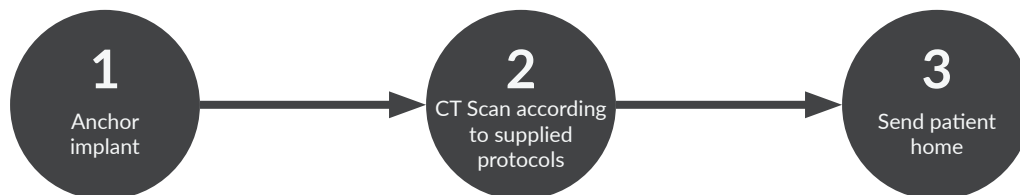


FHC's WayPoint Navigator is a dynamic stereotactic planning and guidance system that offers patient specific procedures for individuals with neurodegenerative disorders. The system is used to accurately position tools used for deep brain stimulation (DBS), stereoelectroencephalography (SEEG), and laser interstitial thermal therapy (LITT).

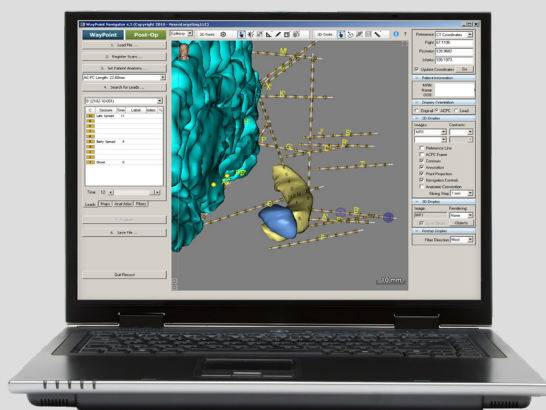
# Procedure Overview

Anchor Implant & Imaging

A seven day cycle is routine for most platform users, however, anchor implants and trajectory planning can be done up to 28 days before surgery offering flexibility for the surgeon and patient.



Planning



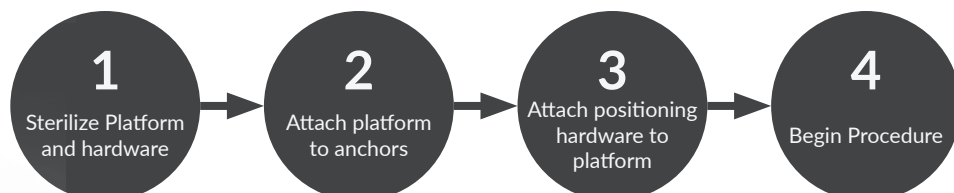
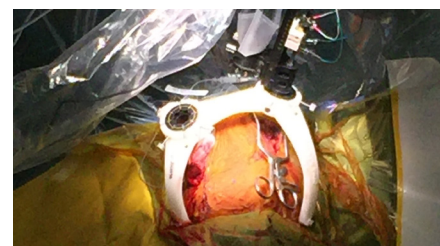
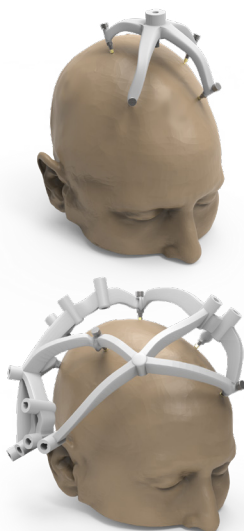
## Platform planning using WayPoint Navigator Software:

1. Merge CT and MR scans
2. Locate anchors
3. Identify AC/PC
4. Select targets and entry points
5. Select platform from library
6. View 3-D model
7. Pack and upload files to FHC's secure FTP website

Build



Day of Surgery





## Sterilization and Scanning

This document provides best practices and is not intended to replace the referring surgeon's specific instructions.

- The target area may be 100 slices or more from the area of the anchors at the top of the head, and the anchors may be 25 or more slices from each other. Motionless scans are required for targeting accuracy, therefore, the patient must be still during the entire imaging process.
- The scanner technician should always check the quality of the scan images for displaced slices indicating movement.

### Recommended Scan protocols

CT	<ul style="list-style-type: none"><li>• Whole head</li><li>• Slices <math>\leq 1.25</math> mm thick</li><li>• No gantry angle</li><li>• Contiguous slices with equal spacing</li></ul>
Axial T1 MRI	<ul style="list-style-type: none"><li>• Whole head</li><li>• Slices <math>\leq 1</math> mm thick</li><li>• No gantry angle</li><li>• Contiguous slices with equal spacing (up to 2mm can be used but can effect accuracy of Atlas)</li></ul>
Axial T2 MRI	<ul style="list-style-type: none"><li>• Whole head</li><li>• Slices 1-2 mm thick</li><li>• Flared, if desired encompassing target area*</li><li>• No gantry angle</li></ul>

\*Confirm target location with surgeon prior to T2 scan. (Targeting the STN, GPi, or VIM may require scans from the lower part of the ear to the middle of forehead.)

### Patient Preparation

- Align the patient's head axially in the scanner, to ensure a gantry angle of zero.
- Secure the patient's head to the headrest with tape. Towels may be used to pad the head and to help prevent movement. Be careful not to disturb the anchors/headframe bars.
- Secure the patient's arms and use pillows or restraints on other parts of the body to make the patient comfortable and relaxed, and to limit movement.
- Inform the patient of the importance of holding still, as the accuracy of the procedure depends on a good scan. The surgeon may recommend light sedation if needed.

### Scanning Requirements

- Single Pass, Slice by slice; or
- Single spiral image acquisition

Note: multiple pass images can have gaps or other problems with slice thickness that can affect accuracy or targeting.

**STarFix™ Platform** CT scan should start 2.5cm above the anchors and end 2.5cm past the target. (The extra space on the top and bottom ensures there is no distortion and allows the search algorithm to work.)

**Frame** CT scan needs to start just below the top ring of the frame and end just above the bottom ring of the frame. This will prevent artifact from impeding the registration of the CT and MRI.

**Field of view** should include the entire head, but should not be too large. Standard stereotactic frame head protocols are often too large, causing unnecessary time in the scanner, large scan files, and tissue discrimination.



## Scanning Requirements

1. With patient present, prepare a 3-D reconstruction of the scans and inspect quality. Streaking, blurring, and rotated slices will require a re-scan of the patient.
2. Ensure the titanium anchor/frame bars are plainly visible and stand out from the bone by setting up the CT for best anchor/frame visibility.

Note: for new sites: It is good practice to allow the surgeon to review the first few scans for suitability prior to the patient leaving the hospital or the scan area.

## Scan Storage

- Prepare the digital image data in uncompressed DICOM format according to the surgeon's instructions. (Do not use jpg or bmp formats.)
- Store scans on a CD-R, CD-RW, or DVD. Do not use Magneto Optical Disks.
- CT and MRI scans must be loaded in one folder (not in multiple folders with smaller scan sections).
- Disk should be given to the surgeon as soon as possible to allow for planning.

Non-clinical testing demonstrated that the WayPoint Anchor is MR-Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

### Static magnetic Field

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field 720-Gauss/cm or less

### MRI-Related Heating

In non-clinical testing, the WayPoint Anchor produced the following temperature rise during MRI preformed for 15min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, Wi) MR system:



### WayPoint Anchor MRI Information

The WayPoint Anchor was determined to be MR-conditional according to the terminology specified in the Highest temperature change +1.5°C

## Artifact Information

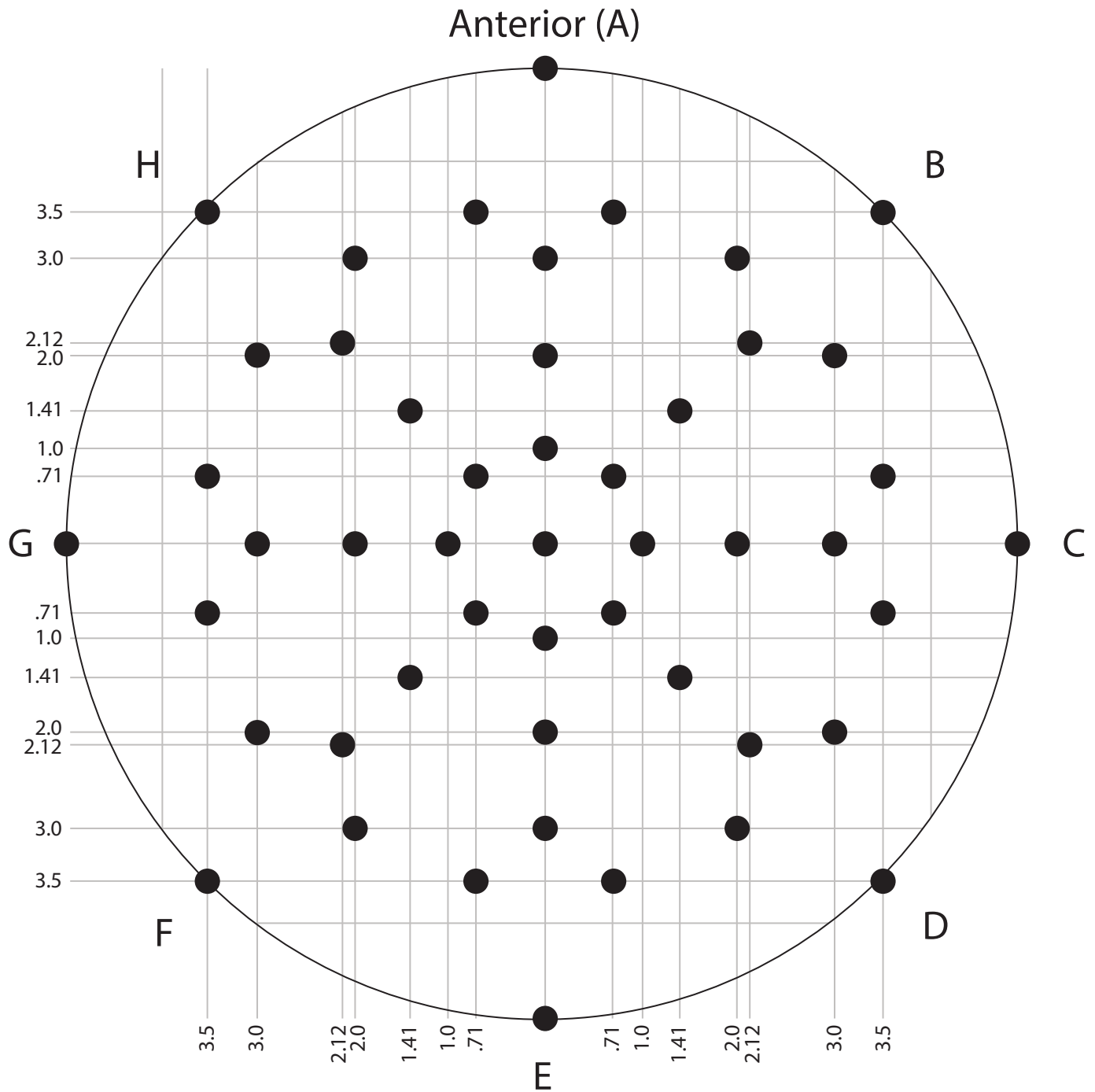
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the WayPoint Anchor. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	205 mm <sup>2</sup>	144 mm <sup>2</sup>	463 mm <sup>2</sup>	621 mm <sup>2</sup>
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

American Society for Testing and Materials (ASTM) International, Designation: F2503-08. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA.

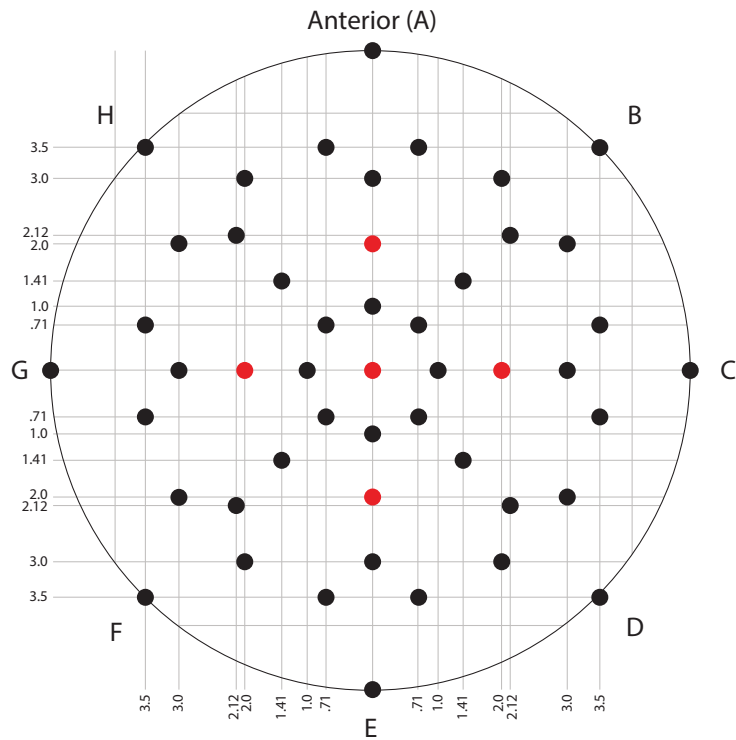
## Target Offset Charts

Forty-nine parallel trajectories available using center hub and positioners



## Center Hub, Center Positioner

Five parallel trajectories available



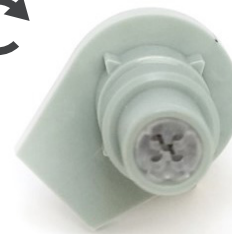
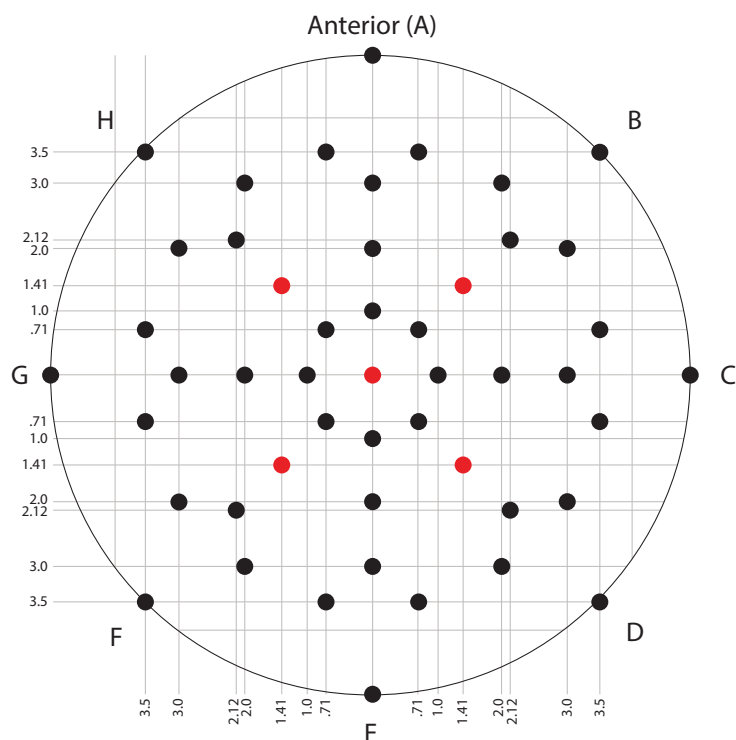
Center Positioner



Center Hub

## Center Hub, Center Positioner Rotated

Rotate positioner to access four alternative parallel trajectories



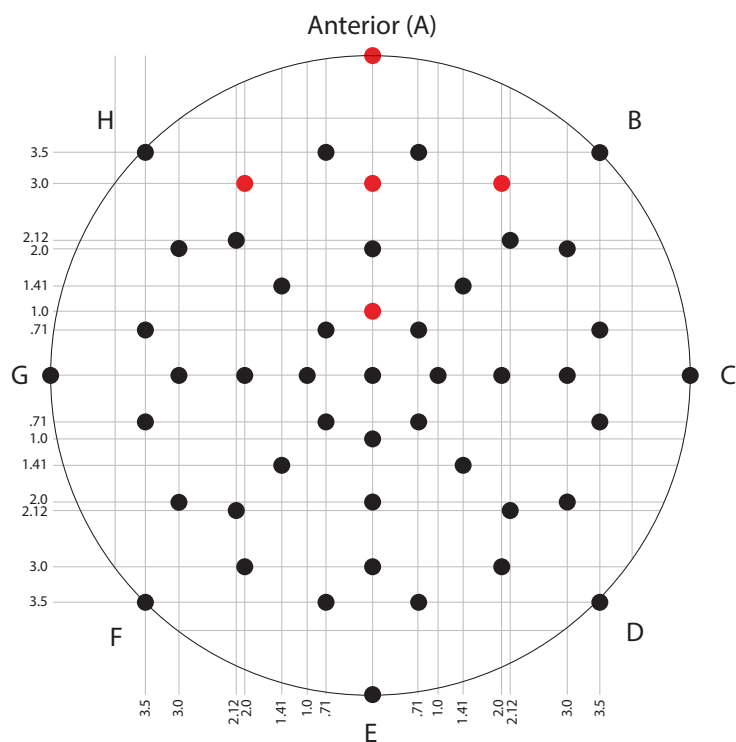
Center Positioner



Center Hub

## Center Hub, 3mm Offset Positioner

Five parallel trajectories available at 3mm offsets from center array



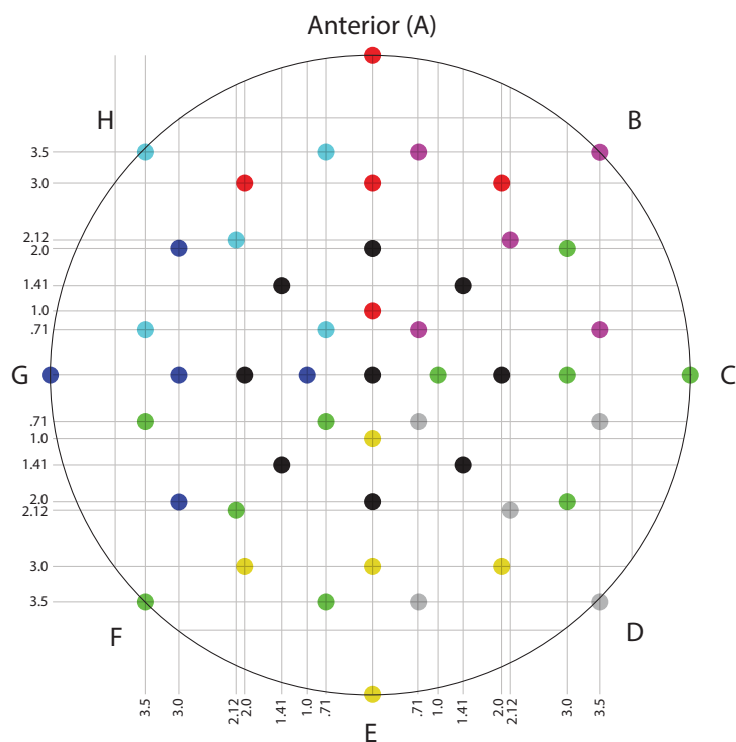
3mm Offset Positioner



Center Hub

## Center Hub, 3mm Offset Positioner

Rotate positioner to access thirty-five alternative parallel trajectories



3mm Offset Positioner



Center Hub



# Platform Ordering Information

## Platform Only



**MP-KIT-P-BI**  
Bilateral Platform



**MP-KIT-P-SB**  
2 Staged Bilateral Platforms



**MP-KIT-P-U3**  
Three-Legged Unilateral Platform



**MP-KIT-P-U4**  
Four-Legged Unilateral Platform

## Consumables

### Fiducial Marker Implant



#### WayPoint Anchors

66-WP-AN5 — 5mm WayPoint Anchor (qty 1)  
66-WP-AN1 — 5mm WayPoint Anchor (qty 50)  
66-WP-AN2 — 4mm WayPoint Anchor (qty 5)



#### WayPoint 1.1mm Pilot Drill Bit

66-WP-PD (qty 5)



#### WayPoint Implant Kit

66-WP-IKS



#### Osteomed Single Use Sterile Power Driver

68-OM-SD



#### Optional Fiducial Marker Template

68-DA-FT-02

### Surgical Implant



#### SS Thumbknobs & Standoffs

MP-KIT-ME — 20mm SS Thumbknob (qty 50)  
MP-KIT-MF — 13mm SS Thumbknob (qty 50)  
MP-KIT-MG — 20mm PEEK Thumbknob (qty 20)  
MP-KIT-MH — SS Standoff (qty 50)  
MP-KIT-MJ — PEEK Standoff (qty 20)



#### WayPoint Platform Surgical Kit

66-WP-SKS

### CT/MRI Direct Targeting



#### WayPoint Inserter Kit

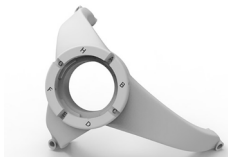
66-WP-ID



#### WayPoint Disposable Bilateral Kit

66-WP-BKS

## Standard DBS Kits



#### MP-KIT-01D

Three-Legged Unilateral Platform Kit w/ D Hardware

#### Shipment Includes:

- 1 ea. 3 Legged Unilateral Platform
- 3 ea. WayPoint Anchors
- 3 ea. 20mm SS Thumbknob w/ Standoff
- 1 ea. OsteoMed™ Single Use Sterile Power Driver
- 1 ea. WayPoint 1.1mm Pilot Drill Bit

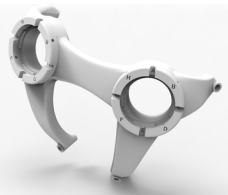


#### MP-KIT-14D

Four-Legged Unilateral Platform Kit w/ D Hardware

#### Shipment Includes:

- 1 ea. 4 Legged Unilateral Platform
- 6 ea. WayPoint Anchors
- 5 ea. 20mm SS Thumbknob w/ Standoff
- 1 ea. OsteoMed™ Single Use Sterile Power Driver
- 1 ea. WayPoint 1.1mm Pilot Drill Bit

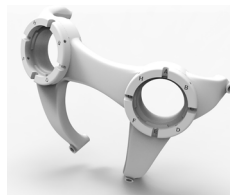


#### MP-KIT-02D

Bilateral Platform Kit w/ D Hardware

#### Shipment Includes:

- 1 ea. Bilateral Platform
- 6 ea. WayPoint Anchors
- 5 ea. 20mm SS Thumbknob w/ Standoff
- 1 ea. OsteoMed™ Single Use Sterile Power Driver
- 1 ea. WayPoint 1.1mm Pilot Drill Bit



#### MP-KIT-02D-ST

2 Staged Bilateral Platforms Kit w/ D Hardware

#### Shipment Includes:

- 2 ea. Bilateral Platform
- 6 ea. WayPoint Anchors
- 10 ea. 20mm SS Thumbknob w/ Standoff
- 1 ea. OsteoMed™ Single Use Sterile Power Driver
- 1 ea. WayPoint 1.1mm Pilot Drill Bit

Note: Kits available for sale in the US only.

## MR Compatible Direct Targeting Kits

 <p><b>MP-KIT-01C</b> Three-Legged Unilateral Platform Kit w/ C Hardware</p> <p>Shipment Includes:</p> <ul style="list-style-type: none"> <li>• 1 ea. 3 Legged Unilateral Platform</li> <li>• 3 ea. WayPoint Anchors</li> <li>• 3 ea. 20mm <b>PEEK</b> Thumbknob w/ Standoff</li> <li>• 1 ea. OsteoMed™ Single Use Sterile Power Driver</li> <li>• 1 ea. WayPoint 1.1mm Pilot Drill Bit</li> </ul>	 <p><b>MP-KIT-14C</b> Four-Legged Unilateral Platform Kit w/ C Hardware</p> <p>Shipment Includes:</p> <ul style="list-style-type: none"> <li>• 1 ea. 4 Legged Unilateral Platform</li> <li>• 6 ea. WayPoint Anchors</li> <li>• 5 ea. 20mm <b>PEEK</b> Thumbknob w/ Standoff</li> <li>• 1 ea. OsteoMed™ Single Use Sterile Power Driver</li> <li>• 1 ea. WayPoint 1.1mm Pilot Drill Bit</li> </ul>
 <p><b>MP-KIT-02C</b> Bilateral Platform Kit w/ C Hardware</p> <p>Shipment Includes:</p> <ul style="list-style-type: none"> <li>• 1 ea. Bilateral Platform</li> <li>• 6 ea. WayPoint Anchors</li> <li>• 5 ea. 20mm <b>PEEK</b> Thumbknob w/ Standoff</li> <li>• 1 ea. OsteoMed™ Single Use Sterile Power Driver</li> <li>• 1 ea. WayPoint 1.1mm Pilot Drill Bit</li> </ul>	 <p><b>MP-KIT-02C-ST</b> 2 Staged Bilateral Platforms Kit w/ C Hardware</p> <p>Shipment Includes:</p> <ul style="list-style-type: none"> <li>• 2 ea. Bilateral Platform</li> <li>• 6 ea. WayPoint Anchors</li> <li>• 10 ea. 20mm <b>PEEK</b> Thumbknob w/ Standoff</li> <li>• 1 ea. OsteoMed™ Single Use Sterile Power Driver</li> <li>• 1 ea. WayPoint 1.1mm Pilot Drill Bit</li> </ul>

Note: Kits available for sale in the US only.

## Disposable DBS Kits

 <p><b>MP-KIT-U3</b> Three-Legged Unilateral Platform Kit</p> <p>Shipment Includes:</p> <ul style="list-style-type: none"> <li>• 1 ea. 3 Legged Unilateral Platform</li> <li>• 1 ea. Disposable Fiducial Placement Kit</li> <li>• 1 ea. Disposable Surgical Kits</li> <li>• 1 ea. OsteoMed™ Single Use Sterile Power Driver</li> </ul>	 <p><b>MP-KIT-U4</b> Four-Legged Unilateral Platform Kit</p> <p>Shipment Includes:</p> <ul style="list-style-type: none"> <li>• 1 ea. 4 Legged Unilateral Platform</li> <li>• 1 ea. Disposable Fiducial Placement Kit</li> <li>• 1 ea. Disposable Surgical Kits</li> <li>• 1 ea. OsteoMed™ Single Use Sterile Power Driver</li> </ul>
 <p><b>MP-KIT-SQB</b> Bilateral Platform Kit</p> <p>Shipment Includes:</p> <ul style="list-style-type: none"> <li>• 1 ea. Bilateral Platform</li> <li>• 1 ea. Disposable Fiducial Placement Kit</li> <li>• 1 ea. Disposable Surgical Kits</li> <li>• 1 ea. OsteoMed™ Single Use Sterile Power Driver</li> </ul>	 <p><b>MP-KIT-STB</b> 2 Staged Bilateral Platform Kits</p> <p>Shipment Includes:</p> <ul style="list-style-type: none"> <li>• 2 ea. Bilateral Platform</li> <li>• 1 ea. Disposable Fiducial Placement Kit</li> <li>• 2 ea. Disposable Surgical Kits</li> <li>• 1 ea. OsteoMed™ Single Use Sterile Power Driver</li> </ul>

Note: Kits available for sale in the US only.

## — Multi-Oblique Platform Only —

### MP-KIT-P-ES

Multi-oblique  
Single Trajectory Platform



### MP-KIT-P-ED

Multi-oblique  
Dual Trajectory Platform



### MP-KIT-P-EO

Multi-oblique  
Epilepsy Platform



#### Additional Items:

- QTY 66-DH-40 40mm Dual Depth Stop Holder
- QTY 66-WP-IKS Disposable Implant Kit
- QTY 68-OM-SD 1 ea. OsteoMed™ Single Use Sterile Power Driver
- QTY 66-WP-PD 1 ea. WayPoint 1.1mm Pilot Drill Bit
- QTY 66-WP-AN5 1 ea. WayPoint Anchors
- QTY 66-IT (A06) 1 ea. 165mm Insertion Tube

L012-12, Rev D1 2021-12-09



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