

Description

The WayPoint™ System Implantation Kit (66-WP-IK) includes the following items, each available as a replacement part:

(1) WayPoint™ Sterilization and Storage Case	66-WP-SC
(1) WayPoint™ Hex Wrench	66-WP-HW
(1) WayPoint™ Manual Driver Handles	66-WP-DH
(1) WayPoint™ Combination Driver Bit	66-WP-CD
(1) WayPoint™ Assist Drill Bit	66-WP-DB
(4) WayPoint™ Anchors 5mm (pkg of 3)	66-WP-AN5
(4) WayPoint™ Anchor Plugs (pkg of 3)	66-WP-AP
(4) WayPoint™ Locator Pins (pkg of 3)	66-WP-LP
(1) Osteomed 1.2mm Pilot Drill	68-OM-PD
(1) Osteomed Single Use Sterile Power Driver	68-OM-SD

Note that the following components within this kit are single use items: 66-WP-AN5, 66-WP-AP, 66-WP-LP, 68-OM-PD, and 68-OM-SD.

Optional Accessory

WayPoint™ Anchors 4mm (pkg of 3)	66-WP-AN
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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 system.

Intended Use

The WayPoint™ Anchor/Locator System is intended for use with the WayPoint™ Platform and Drive Systems, in conjunction with VoXim® microTargeting™ and WayPoint™ Planner.

The WayPoint™ Anchor/Locator System provides tools and components for the implantation of anchors to be used as mounting sets in WayPoint™ Platform based surgical procedures.

The tools and components of the WayPoint™ System do not change the indications for use of the WayPoint™ Stereotactic System.

Sterility

The WayPoint™ Anchor/Locator System components must be sterilized prior to each use.

- **Steam Protocol:**

Sterilizer Type:	Prevacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	8 minutes
Minimum dry time:	40 minutes
Configuration	Wrapped

- **Sterrad Protocol** Sterrad 100S full cycle

Tools must be thoroughly cleaned, using a disinfectant solution, and then wiped with a distilled water dampened cloth after each use, prior to re-sterilization.

WayPoint™ Anchors, Plugs, and Pins are single use items and must be disposed of appropriately after use.

Warnings

- Do not drill or install anchors in bone that is less than 4.5mm thick, or in bone that is weakened or diseased.
- Do not use anchors that exhibit any sign of looseness. Replace anchors and rescan if necessary.
- A WayPoint™ Locator Pin must be screwed in to the depth of its built in stop to provide accurate registration.
- WayPoint™ Locator pins may come in contact with non-sterile items during scanning procedures. Wipe locator pins and the area around the wounds with antiseptic before the hex wrench and combination driver are applied for locator pin removal.
- Do not allow WayPoint™ Anchors to remain implanted for more than 28 days.
- Follow appropriate warnings when using accessory drills.

Cautions

- For the most secure fit of the WayPoint™ Anchors, advance drill and driver tools as perpendicular to the skull as possible, and do not permit them to ‘wobble’ during advancement.
- Avoid over tightening anchors, pins and plugs, as this can strip bone, shear an anchor, or otherwise damage components.
- Instruct the patient to avoid situations that could affect or disrupt the implanted anchors and to be cautious about infection.
- Always use the WayPoint™ Hex Wrench to secure anchors when installing or removing pins or plugs.

Scanning

WayPoint™ Anchors, Anchor Plugs, and Locator Pins are CT visible. The patient’s head must be kept immobile while being scanned. Ensure that all Locator Pins are completely within the scan field of view.

CT Scan requirements:

- Contiguous slices; no gaps between slices
- No overlapping slices
- Slice thickness no greater than 1.25mm
- Pixel size less than 1mm (0.5 to 0.8mm for best results)
- Gantry tilt angle of zero



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

MR Scan requirements:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 2.9-W/kg for 15 minutes of scanning

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.

See platform technical source manual for complete CT and MR scanning parameters.

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Disclaimer: FHC, Inc. does not accept liability for injury or damage to equipment that may result from misuse of the microTargeting™ Drive system or its components.

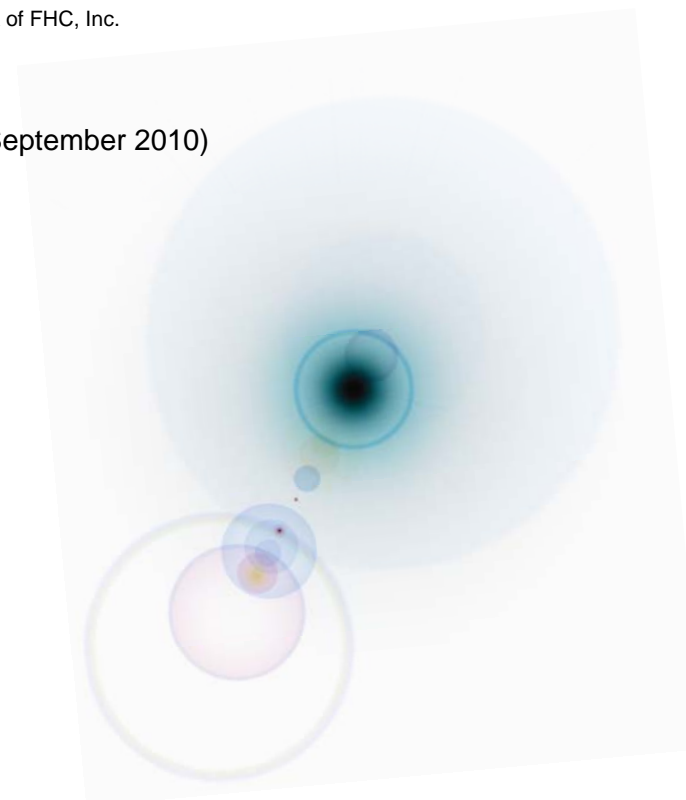


European Conformity. This device fully complies with MDD Directive 93/42/EEC and legal responsibilities as a manufacturer are with FHC, Inc. 1201 Main Street, Bowdoin, ME 04287 USA

WayPoint™ Anchor/ Locator Implantation Kit

WayPoint™ is a trademark of FHC, Inc.

L011-40 (Rev. F0, September 2010)



! USA

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

FHC

“Innovation through collaboration”

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WayPoint™ Anchor/Locator System Implantation Kit

Directions For Use

- Follow aseptic technique throughout. The implant procedure does not need to be done in an OR setting.
- Mark the intended anchor points on the patient's scalp (see the WayPoint™ Platform User Manual for placement guidance).
- Assemble drill and driver tools.
- Using local anesthesia, for each anchor installation:
 - ◊ Create an 10-15mm incision through scalp and muscle tissue and scrape the pericranium from the anchor site.
 - ◊ If desired, use the Assist Drill to create a pilot hole. Alternately, use the Power Driver and Pilot Drill Bit to create a pilot hole. When using the Power Driver, refer to the Osteomed AutoDriver™ Battery Powered Screw Driver Product Information and Instructions for Use for safe operation of the device.
 - ◊ Attach an anchor to the wrench and driver tools (figure 1).
 - ◊ Install the anchor in the skull with a clockwise rotation of the wrench and driver tools (figure 2).
 - ◊ Use the wrench to support the anchor while twisting the driver counterclockwise out from the anchor (figure 2). If using the WayPoint™ PosiDriver, lift straight up once the anchor is seated and the driver has disengaged.
 - ◊ Use the wrench to support the anchor while twisting a locator pin clockwise into the anchor with the driver tool (figure 3).
 - ◊ Carefully pull the driver and wrench from the anchor (figure 3). Note that the Power Driver should not be used to install locator pins.
 - ◊ Inspect the attachment of the anchor to the skull and the pin to the anchor. Locator pins must be screwed in to the depth of their built in stop. Anchors must be tight. Replace stripped anchors in a new location.
- Repeat the anchor installation procedure for all anchor sites and any additional sites where a locator is desired.
- Scan the patient.
- Wipe locator pins and the area around the wounds with antiseptic before pin removal.
- Use the wrench to support anchors while removing pins (figure 4).
- Use the wrench to support anchors while installing plugs (figure 5).
- Stitch and bandage anchor site wounds appropriately.
- Use the wrench to support anchors when removing plugs prior to mounting a microTargeting™ Platform during an surgical procedure (figure 6).

Illustrative Procedure

Figure 1: Application of Driver to Anchor through Wrench

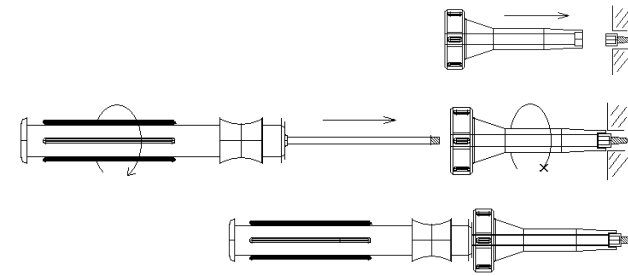


Figure 2: Application of Anchor to Patient

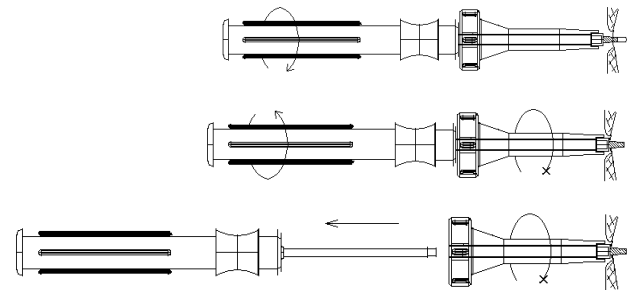


Figure 3: Application of Locator Pin to Anchor

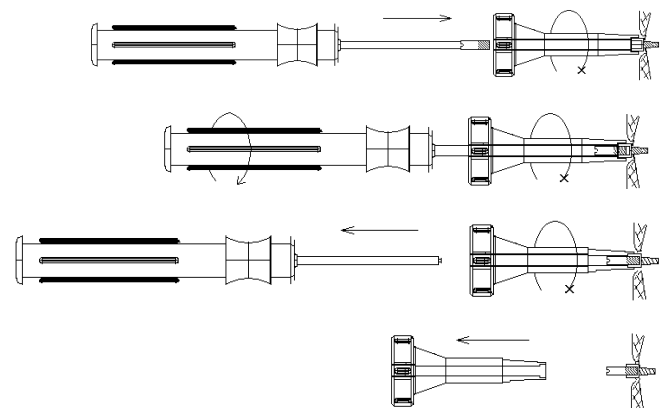


Figure 4: Removal of Locator Pin from Anchor

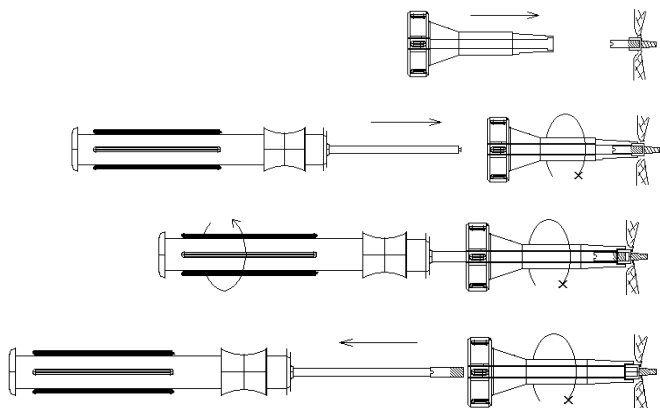


Figure 5: Application of Plug to Anchor

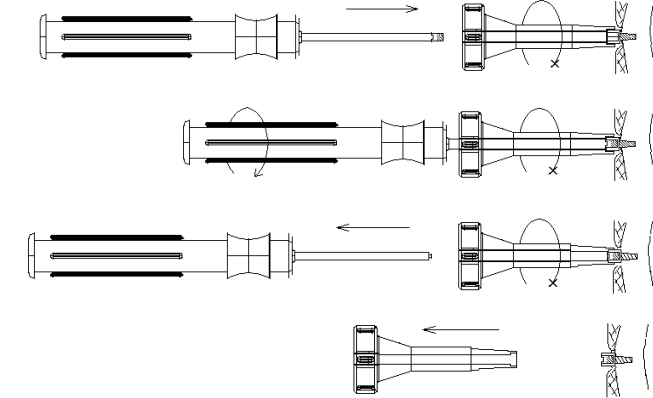


Figure 6: Removal of Plug from Anchor

