FHC
Neural microTargeting™ Worldwide

WayPoint™ Anchor/Locator Implantation Kit

Directions For Use

L011-40 (Rev N0, 2021-05-18)

Contains directions for the following products:

66-WP-AN, 66-WP-AN1, 66-WP-AN2, 66-WP-AN5, 66-WP-CD, 66-WP-CD-01, 66-WP-DH, 66-WP-HW, 66-WP-LP, 66-WP-PD, 66-WP-P2, 66-WP-RU, 66-WP-SC

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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 by neurosurgeons in a clinical or standard operating room environment to implant fiducial anchors used to plan patient specific microTargeting stereotactic platform used in neurosurgical procedures.

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.	EC REP 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.	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.
REF Indicates the catalog number so that the medical device can be identified.	Date when the medical device was manufactured.
LOT Indicates the manufacturer's batch code so that the batch or lot can be identified.	Indicates the date after which the medical device is not to be used.
SN Indicates the serial number so that a specific medical device can be identified.	MR Conditional - an item that has been demonstrated to pose no known hazard in a specified MRI environment with specified conditions of use.
RFID Indicates the use of Radio-Frequency Identification (RFID).	NON STERILE Indicates a medical device that has not been subjected to a sterilization process.
MD Indicates Medical Device	
Instructions for end of life disposal.	
Do not re-use: intended for one use on a single patient, during a single procedure.	

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

Warnings and Cautions

⚠ **WARNING:** Do not drill or install anchors in bone that is less than 4.5mm thick, or in bone that is weakened or diseased.

⚠ **WARNING:** Do not use anchors that exhibit any sign of looseness. Replace anchors and rescan if necessary.

⚠ **WARNING:** A WayPoint Locator Pin must be screwed in to the depth of its built in stop to provide accurate registration.

⚠ **WARNING:** 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 locator pin is removed.

⚠ **WARNING:** Do not allow WayPoint Anchors to remain implanted for more than 28 days.

⚠ **Caution:** 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.

⚠ **Caution:** Avoid over tightening anchors and pins, as this can strip bone, shear an anchor, or otherwise damage components.

⚠ **Caution:** Instruct the patient to avoid situations that could affect or disrupt the implanted anchors and to be cautious about infection.

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

Inventory

Reusable components - 66-WP-RU

Sterilization and Storage Case: 66-WP-SC

Manual Driver Handle: 66-WP-DH

Combination Driver Bit: 66-WP-CD
or Combination Driver Bit with collar:
66-WP-CD-01(not shown)

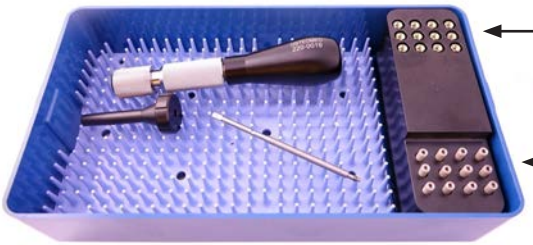
Hex Wrench: 66-WP-HW

Single use components

Pilot Drill Bit: 66-WP-PD (Qty 1)
66-WP-P2 (Qty 5)

5mm Anchors: 66-WP-AN5 (Qty 1)
66-WP-A2 (Qty 50)

Locator Pins: 66-WP-LP (Qty 4)



5mm Anchors
(Optional Anchor Size -
4mm Anchors: 66-WP-AN)

Locator Pins

RFID The products referenced in this document satisfy the FDA's Unique Device Identification Direct Marking requirement though the use of Radio-Frequency Identification (RFID). The RF air protocol is compliant with ISO-18000-6C EPC Global Class 1 Generation 2, and operates at frequencies in the band of 902-928MHz (UHF). The Unique Device Identification number retrieved from the RFID can be used to access product information through the FDA's Global Unique Device Identification Database (GUDID), which is available on the FDA's website.

Cleaning

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, pins, and pilot drill bit are single use items and must be disposed of appropriately after use.

Listed are the detergents and cycles that FHC has validated. Detergents listed are from Ecolab. If other neutral or alkaline detergents are used, testing should be done by the hospital to ensure product is not damaged. Detergents should be prepared per manufacturers recommendations.

Method	Protocol			
Manual	**Phase**	**Duration**	**Component/Notes**	**Detergent Type**
	Soak	5 minutes in detergent solution	Immerse all parts separated from each other. Actuate devices during soaking.	Asepti Wash Plus liquid
	Wipe		User detergent dampened cloth to wipe tray and insert. Use brushes to reach hard to clean areas.	
	Sonicate	10 minutes minimum	Tray fully loaded with parts in sonication unit with detergent.	Asepti Wash Plus liquid
	Rinse		Reverse Osmosis/ de-ionized water	
	Dry		Use clean soft cloth	
OR				
Automated	**Phase**	**Recirculation Time (in minutes)**	**Water Temperature**	**Detergent Type**
	Pre-Wash 1	2	Cold tap water	N/A
	Enzyme Wash	2	Hot tap water	Asepti Wash Plus or Sekusept AR
	Wash 1	2	65.5°C	Asepti Wash Plus or Sekusept AR
	Rinse 1	2	Heated tap water	N/A
	Pure Water Rinse	0:10	Heated	Asepti Rinse or Sekusept FNZ or Sekumatic Multiclean
	Dry	7	115°C	N/A

Sterilization

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

Method	Protocol	
Steam	**Prevacuum wrapped:** (in 2 layers of 1-ply polypropylene wrap [1]) Preconditioning Pulses: 3 Exposure time: 8 minutes at 132°C (270°F) Minimum Dry Time: 40 minutes [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: 18 minutes at 134°C (273°F) Minimum Dry Time: 30 minutes [2] Cycle was validated using Halyard Health H300 wrap
Sterrad™	**Sterrad™ 100S full cycle**	

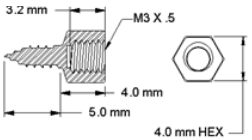
Specifications

Sterilization and Storage Case (66-WP-SC)

- Re-usable
- Holds 12 anchors, 12 locator pins, manual driver handle, hex wrench, combination bit and pilot drill

Anchors
(66-WP-AN, 66-WP-AN1, 66-WP-AN5)

- Single-use, titanium
- 1.5mm self-drilling, self-tapping bone screw

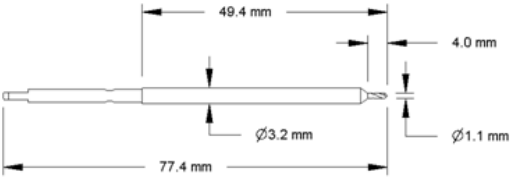


Manual Driver Handle (66-WP-DH)

- Re-usable
- Manual handle for combination driver bit and pilot drill

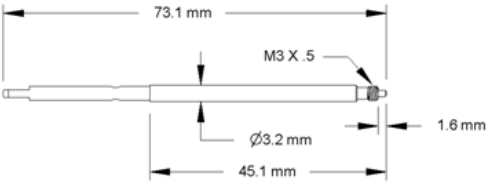
Pilot Drill Bit
(66-WP-PD, 66-WP-P2)

- Single-use, stainless steel
- Works with manual driver handle or Osteomed Power Driver



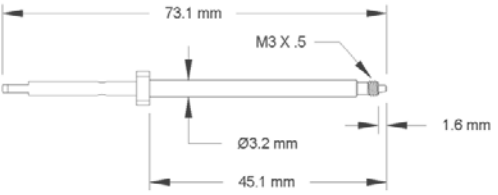
Combination Driver Bit
(66-WP-CD)

- Re-usable, stainless steel
- Works with manual driver handle or Osteomed Power Driver



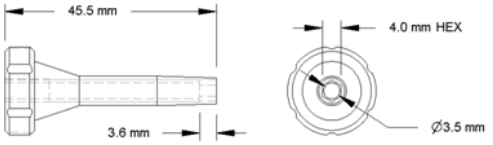
Combination Driver Bit w/Collar
(66-WP-CD-01)

- Re-usable, stainless steel
- Works with manual driver handle or Osteomed Power Driver



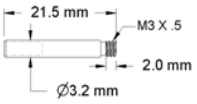
Hex Wrench (66-WP-HW)

- Re-usable, Black hard-coat aluminum



Locator Pin (66-WP-LP)

- Single-use, PEEK and stainless steel



Illustrative Procedure

Follow aseptic technique throughout. The implant procedure does not need to be done in an OR setting.

Additionally, refer to the Fiducial Placement Template DFU (L011-40-05) for information on how to position anchors around approximate entry point locations.

1. Assemble drill and driver tools.

2. Use local anesthesia for each anchor installation:
   A. Create a 10-15mm incision through scalp and muscle tissue and scrape the pericranium from the anchor site.

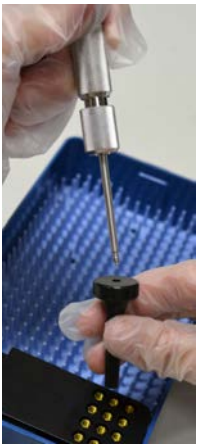
   B. Create a pilot hole using one of the two methods described below.

Use the Manual Handle and the Pilot Drill Bit to create a pilot hole, particularly if the patient's bone is dense or if the surgeon encounters any difficulty fully seating the anchors.

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.

C. Attach an anchor to the wrench and Combination Driver Bit.

Single Anchor



D. Install the anchor in the skull with a clockwise rotation of the wrench and Combination Driver Bit. (shown right)

E. Use the wrench to support the anchor while twisting the driver counterclockwise out of the anchor. If using the Power Driver, lift straight up once the anchor is seated and the driver has disengaged.

F. Inspect the attachment of the anchor to the skull. Anchors must be tight. Replace stripped anchors in a new location. Note that if anchors are not fully seated in the skull, they should be tightened by hand with the hex wrench.

G. Close each anchor wound.

H. Repeat this process for all remaining anchors.

3. Scan the patient.

4. Once scans have been checked to ensure that all anchors are displayed properly, patient may be released.

Disposal: Dispose of Single use components according to Hospital protocol.

Medtronic FrameLink Users

1. When using FrameLink software for planning, locator pins must be installed prior to scanning. Attach and tighten pins using fingers.

2. 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.
3. Scan the patient.
4. Wipe locator pins and the area around the wounds with antiseptic before pin removal.
5. Remove pins while holding anchor with fingers.
6. Stitch and bandage anchor site wounds appropriately.

Scanning Protocol

WayPoint Anchors, and Locator Pins are CT visible. The patient's head must be kept immobile while being scanned. Ensure that all locator pins, if used, 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 and locator pins are 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 of 720-Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the WayPoint Anchor produced the following temperature rise during MRI performed for 15-min 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.

Therefore, the MRI-related heating experiments for the WayPoint Anchor at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +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 mm2	144 mm2		463 mm2	621 mm2
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, Pennsylvania.