



microTargeting™ Microtable™ Platform

Incorporating STarFix™ Guidance

Directions For Use

L011-72 (Rev E0, 2019-04-01)

Contains directions for the following products:

66-MT-D1, 66-MT-D2, 66-MT-D3

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Indications for use

The Microtable™ system is intended to be used with commercially available stereotactic systems for intra-cranial and neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the cranium, brain, or nervous system.

Intended use

The microTargeting™ Microtable™ Platform is intended for use by a neurosurgeon in a standard operating room environment to provide a pre-configured, patient-specific stereotactic guidance platform for use in conjunction with the WayPoint™ Anchor/Locator System, WayPoint™ Planner, WayPoint™ Navigator and compatible positioning and implant devices.

Symbol Key

	WARNING/Caution, Consult instructions for important cautionary information.		Medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.		An item that is known to pose hazards in all MRI environments.
	Consult the instructions for use.		Telephone number		Do not re-use; intended for one use on a single patient, during a single procedure.
	In reference to "Rx only" symbol; this applies to USA audiences only	Rx Only	Caution- Federal law (USA) restricts this device to sale by or on the order of a physician.		
	Indicates the catalog number		Indicates the serial number		

microTargeting™, STarFix™, WayPoint™, and STar™ are trademarks of FHC, Inc. Microtable™ is a trademark of GSB, LLC, in Nashville, TN.

Warnings and Cautions

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

Handling and Use

Handle the microTargeting Microtable 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 the microTargeting Microtable Platform. Follow the assembly and use instructions carefully.

Inventory

66-MT-D1 microTargeting Microtable Platform – Single

66-MT-D2 microTargeting Microtable Platform – Sequential

66-MT-D3 microTargeting Microtable Platform – Staged

The following items are delivered as part of a microTargeting Microtable Platform:

- One (66-MT-D1) or two (66-MT-D2 & 66-MT-D3) 4-leg unilateral platform(s)
- Six (6) extenders (4 for use and 2 extras)
- Three (3) hub thumbknobs (2 for use and 1 extra)
- Gripper torque wrench
- Gripper wrench



Additional items required for operation, available separately:

66-WP-PL: WayPoint Planner

or

66-WP-NV(4.4): WayPoint Navigator

FHC microTargeting Platform planning and design software (WayPoint Planner or WayPoint Navigator) required to plan, verify and submit patient specific microTargeting Multi-Oblique Epilepsy Platform plan for production.

66-WP-RU: WayPoint Anchor Implantation Kit

or

66-WP-IKS: WayPoint Disposable Anchor Implantation Kit

Provides tools and parts needed for the anchor implantation and scanning procedures. See the WayPoint or STarFix Implant and Surgical Kits Directions For Use for details.

66-WP-HW: WayPoint Hex Wrench

66-WP-DH: WayPoint Driver Handle

66-WP-CD: WayPoint Combination Driver Bit

List of specific tools from STar™ Drive Platform Adapter Kit (70-FA-SF) required to remove the WayPoint anchors. Available as individual parts (listed above) or included within the 70-FA-SF kit. Compatible single use tools are also provided as part of the STarFix 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

Trajectories: 1

Number of legs: 4

Coupler: For use with FHC Platform Frame Adapter (70-FA-SF-01) or compatible

Attachment & registration: WayPoint Fiducial Anchors (66-WP-AN5)

Target accuracy: ± 1.00 mm from ideal

Planning & Configuration: WayPoint Planner or WayPoint Navigator

Platform Marking: MR#, patient code (e.g. "SM_ _ _H" for Smith), trajectory name, and platform height.


For cases using the microTargeting Drive the platform height is shown "T=nn" where "nn" is the drive depth that will position the microelectrode tip at target. For other uses the platform height is shown as "TD=nn" where "nn" is the distance from hub mount floor, shown in red, to target.

If needed, convert using these formulas: $TD = T + 90$ or $T = TD - 90$

Cleaning and Sterilization

 **WARNING:** Platforms and hardware are single use devices and should NOT be cleaned prior to 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.

Sterilization Instructions

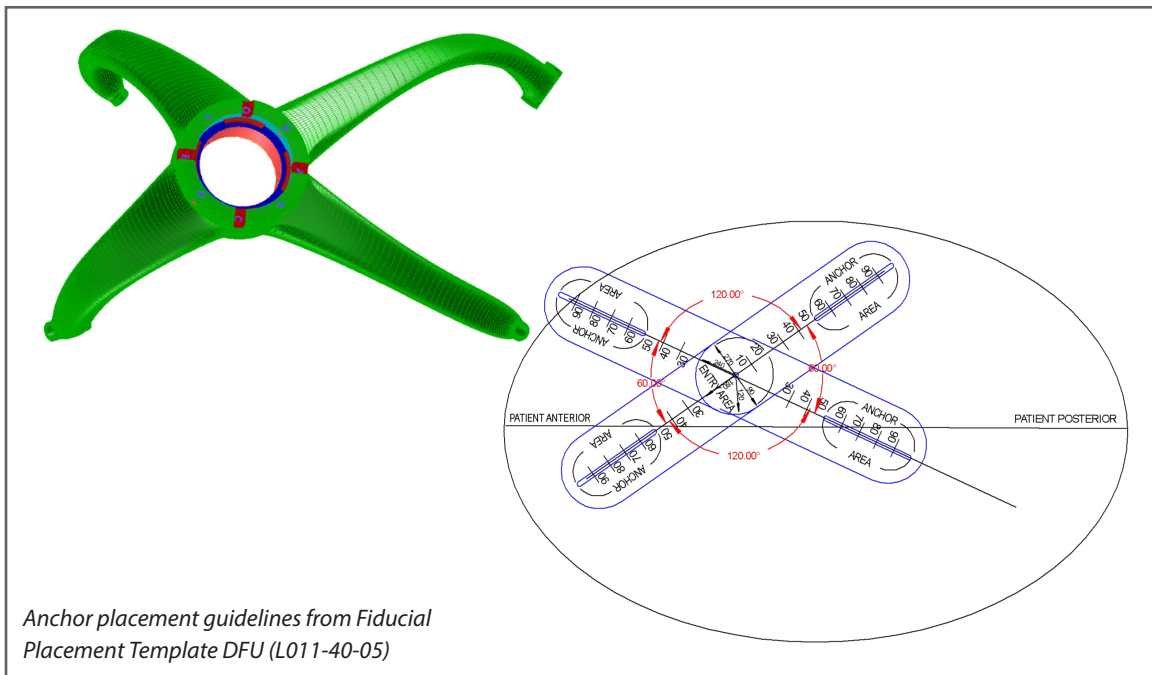
Platform(s) and small sterilization tray with all other parts should be placed in a suitably sized container and sterilized as described below.

Method	Protocols	
Steam	Prevacuum wrapped (for immediate use): (in 2 layers of 1-ply polypropylene wrap*) Preconditioning Pulses: 3 Exposure time: 4 minutes at 132°C (270°F)	Prevacuum wrapped: (in 2 layers of 1-ply polypropylene wrap*) Preconditioning Pulses: 3 Exposure time: 4 minutes at 132°C (270°F) Dry time: 25 minutes
	* Cycle was validated using Halyard Health H600 wrap	

Procedure

Anchor Placement Guidelines

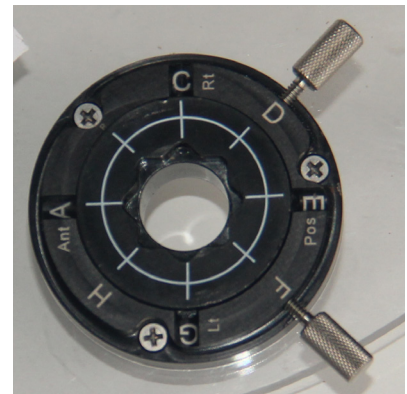
Proper placement of the fiducial anchors is important to generate optimal platform geometry. The Fiducial Placement Template DFU (L011-40-05) describes ideal anchor locations for each DBS platform model that can be easily measured using the disposable fiducial placement template. When using the microTargeting Microtable Platform, follow guidelines for the 4-legged unilateral microTargeting Platform.



Surgery

Pre-Use Checkout

1. Inspect platform to assure that there are no breaks in the Microtable and that the coupler and each legs are firmly attached to the clear plate.
2. Verify that the information on the label attached to the platform matches scheduled patient.
3. Insert hub thumbknob into one of the available holes on the side of the microtable coupler.
4. Assemble STar Drive platform adapter hub, positioned, and Star Drive into coupler to verify fit.
5. Verify availability of at least 4 extenders, gripper torque wrench, and manual gripper wrench.

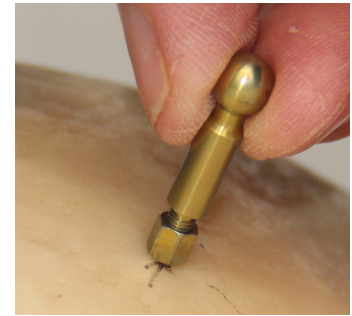


Placing the Microtable

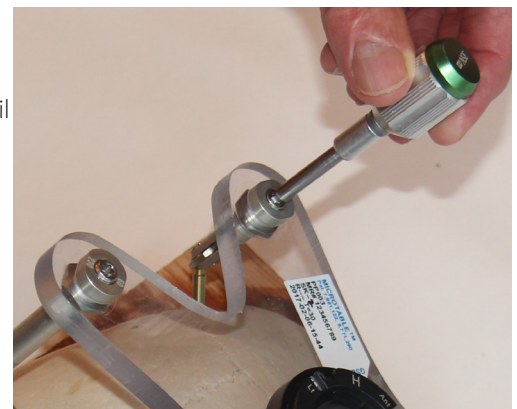
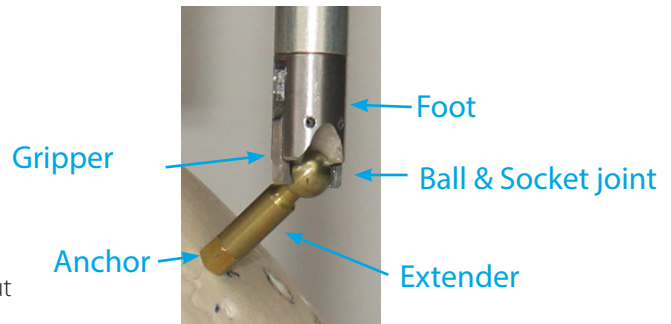
1. Manually screw extenders into each anchor as shown.
2. Orient the Microtable so that the hemispherical divots at the end of the foot at the bottom of each leg rest on the balls of the extenders.



The Microtable will fit in only one orientation, which can be determined by turning the table so that the abbreviation "Ant" etched into the black rim around the central hole is roughly anterior.



3. Once the Microtable is in position, use the gripper torque wrench to partially tighten each of the grippers. Do not tighten enough to cause the wrench to click, but only enough to ensure that each of the extender balls is captured loosely in its divot. If the wrench clicks, loosen the gripper somewhat to restore looseness.
4. After all legs have been partially tightened, complete the tightening of the gripper on each leg in turn by applying the torque wrench until it clicks, indicating that the proper force has been applied.
5. Verify that the Microtable is firmly attached by attempting to move the Microtable relative to the patient. No movement should occur.



Attaching the STar Drive

The following instructions are for attaching the STar Drive centered on the planned trajectory using the microTargeting Platform adapter kit (70-FA-SF-01). Once the Microtable is attached, the operation and use of the components of the platform adapter kit and the STar Drive are the same as when used with the microTargeting platform. Please refer to the STar Drive Adapter Kit for microTargeting Platform DFU (L011-44) for detailed instructions and additional positioning options.

1. Place the center hub from the microTargeting platform Adapter into the Microtable coupler and secure using the hub thumbknob.
2. Insert the center positioner from microTargeting Platform Adapter kit into the center hub and secure with screw on the side of the hub. The center positioner may be oriented in any of the eight possible 45° positions.
3. If using STar Drive Power Assist, place the motor in sterile drape sleeve and attach as described in the microTargeting Controller Power Assist System DFU (L011-80) or in the microTargeting Star Drive System DFU (L011-1007).
4. Place the STar Drive on the positioner post in any of the four possible positions and secure with the thumbknob on the side of the drive.

Configuring Target Depth

5. When using Microtable with the STar Drive, the correct depth setting for positioning the tip of a "platform length" microelectrode at target is indicated on the Microtable label as "T=xx". The value of xx is 90 less than the platform height selected during planning, that is $T = \text{platform height} - 90$.

Platform Removal

6. Remove STar Drive, positioner, and hub from the Microtable coupler and return those parts to the STar Drive sterilization try.
7. Use the gripper torque wrench or the gripper wrench to loosen the grippers enough to allow the Microtable to be lifted off the extenders.
 - If needed, the Microtable can be reattached and removed as many times as required with no loss of accuracy.
8. Remove extenders from anchors and place in small parts basket for return to FHC.
9. 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 is necessary.
 - If anchors Remain - cover anchors suitably to protect them and prevent infection.
 - To remove anchors - use anchor wrench and combo driver included in the microTargeting Platform Adapter Kit to remove anchors from skull.

Microtable and Tools Return

All components that were delivered with the Microtable (refer to inventory on page 4) must be returned to FHC.

The Microtable System is to be decontaminated utilizing the following decontamination/cleaning procedure:

Point-of-Use Cleaning:

1. Wipe the Microtable and accessories clean of any visible soil using a damp towel.
2. Keep the Microtable and accessories moist by wrapping them in a wet towel.
3. Place the wrapped device and accessories into the cleaning tray.
4. Transport to the dedicated cleaning work area for decontamination.

Decontamination:

The following cleaning process is to take place at the Health Care Facility to decontaminate the device prior to shipment back to FHC, Inc.


5. Place gripper wrenches in small parts basket along with all extenders and hub thumbknobs originally supplied.
6. Decontaminate the Microtable and small parts basket with all parts.

The following automated washer, detergent and cycle have been validated and are recommended for the de-contamination process:

Automated washer: Steris 444 Wahser
Detergent: Asepti Wash Plus

Cleaning Protocol			
Phase	Recirculation Time (minutes)	Water Temperature	Detergent Type and Concentration (If applicable)
Pre-wash	2:00	Cold tap water	N/A
Enzyme Wash	2:00	Hot tap water	Asepti Wash Plus 1/4 oz/gal
Wash 1	2:00	65.5°C (Set Point)	Asepti Wash Plus 1/4 oz/gal
Rinse 1	2:00	66°C	N/A
Purified water (PURW) rinse	0:10	66°C	N/A
Drying	7:00	115°C	N/A

7. Return all parts to the FHC representative or ship them using the provided pre-addressed return shipping container.

 **WARNING:** If the Microtable is NOT going to be returned to FHC, all of the used device components should be discarded following patient use.