



microTargeting™ Platform

Adapting the microTargeting™ Drive System to bone anchored fiducial marker stereotactic systems:

Accurate

Confidently place Deep Brain Stimulating™ (DBS™) or lesioning electrodes with assurance of cellular-level confirmation of target.

Efficient

Perform all electrode operations through integrated drive and guide tube system using precise, precalibrated components.

Sample additional tracks without repositioning drive or stereotactic system.

All components are steam sterilizable or isolated with pre-sterilized drape sleeve.

Proven

Hundreds of surgical teams already use FHC's innovative microelectrode technology derived from our over 30 years experience as the world's leading manufacturer of research and clinical microelectrodes.

Innovative

FHC's research heritage and custom fabrication capabilities allow us to work closely with field leaders to further enhance microTargeting™ technology.

Reliable

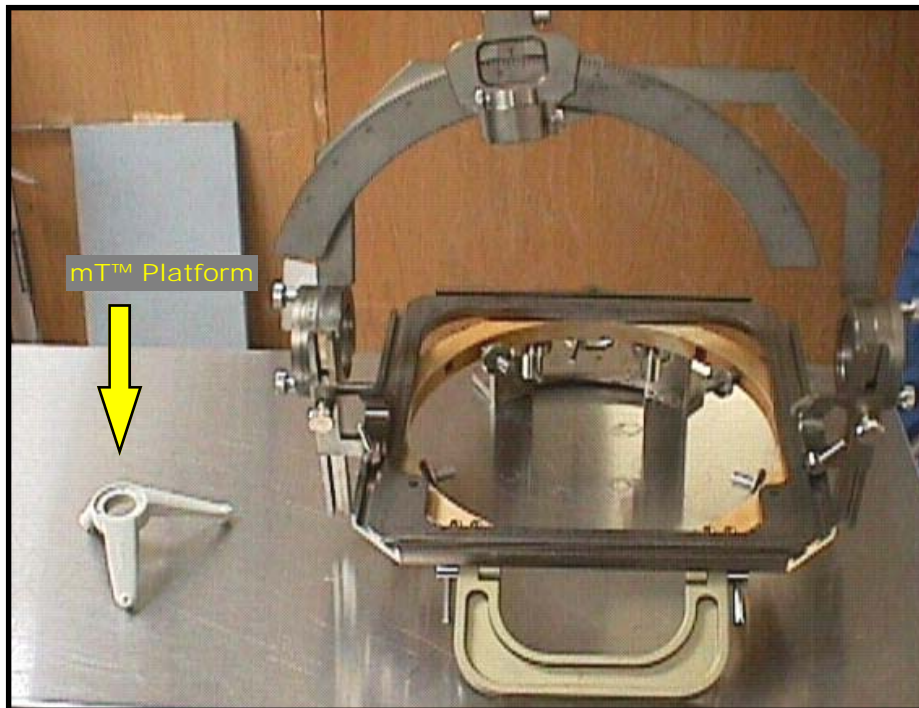
FHC supports microTargeting™ products with comprehensive training, technical support and service.

All microTargeting™ products are cleared for clinical use within the United States and European Union.



- Eliminates any need for stereotactic frames and/or image guidance.
- Dramatically reduces operating room theater and staff time.
- Gives "frame free" comfort and mobility for patients.
- Offers bilateral or multitargeting stimulation/recording options.
- Automatically orients the drive and offsets with patient anatomy.

THE MICROTARGETING™ (mT™) PLATFORM provides accuracy in placement of instrumentation that equals or exceeds currently available target identification methods. Scan accuracy is enhanced because interfering apparatus, such as bulky stereotactic frames, are eliminated.



Patented STarFix™ guidance technology was developed by neurosurgeon, Dr. Joel Franck and FHC design engineer Ron Franklin. STarFixtures, Inc. will be developing additional surgical instruments and methods utilizing the unique bone anchored conformable fixture concept. For product updates visit: www.starfixtures.com



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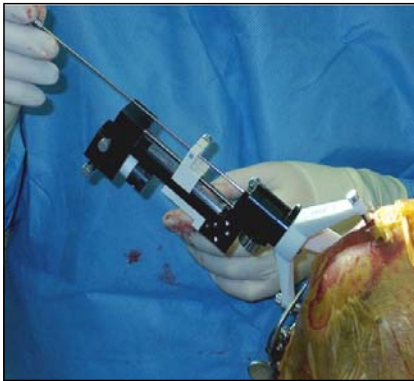


microTargeting™ Platform System Advantages

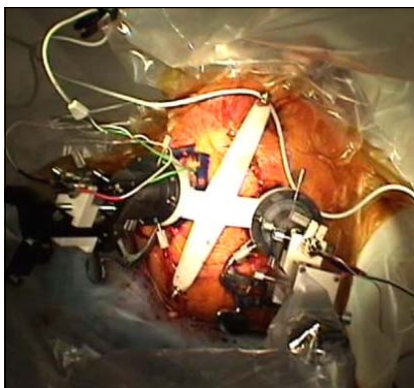
Advantages for Patient, Surgeon, Staff, and Hospital:



Instead of a frame, a mounting set is used to anchor equipment, planning is already done, and setup time the morning of surgery is drastically reduced.



The Platform secures the microTargeting™ Drive to the patient. The system has built in offsets making track selection and change simple.



Confidently attach two systems at the same time.

- **For THE PATIENT**, the microTargeting™ Platform System eliminates the need for a cumbersome, uncomfortable stereotactic frame applied before the scan and attached during surgery. Instead, a mounting set, composed of three or more implanted anchors, is used to register the system to patient anatomy, and to secure the delivery system during surgery. This reduces the need for clamping systems that are required to hold the patient in a fixed position relative to a table for surgery and allows mobility.
- **For THE SURGEON**, the STarFix™ technology used in the microTargeting™ Platform Planning and Design Workstation provides the luxury of a separation between the scanning, planning and surgical procedures. This allows surgical planning after scanning without the pressure of a waiting, uncomfortable, and anxious patient, and provides the confidence of visual validation of the surgical plan and platform design before it is built.

The first stage of the procedure, the placement of mounting set anchors and patient scanning, can be performed as an outpatient procedure a week or more before the scheduled surgery. Placement accuracy of anchors is non-critical; anchors are precisely located and registered to patient anatomy during planning. Scan artifacts normally resulting from conventional stereotactic frames are minimized or eliminated. The microTargeting™ Platform Planning and Design Workstation provides excellent visualization of scan data, simple input or modification of selected points, a simple anatomical atlas model, fusion capability, and designed-in verification safeguards. The system portability allows planning and design to be done after scanning in the surgeon's office, at any convenient time.

During the second stage, the functional neurosurgical procedure, increased patient mobility allows clinical verification to be easily accomplished by neurological examination, including gait and coordination testing. Multiple tracks are available in a 10mm diameter area around the planned trajectory, allowing retargeting. Offset mounting hubs allow a redirection of the planned trajectory, at the time of surgery, in four directions; either 3mm offset at the entry or 6mm offset at target depths.

- **For THE HOSPITAL**, use of the microTargeting™ Platform dramatically reduces operating theater and staff time. On the day of surgery the patient is ready for the procedure and there is no long wait for scans to be processed and the trajectory planned. It minimizes hospital capital investment since it is not necessary to purchase or maintain an image-guided or traditional stereotactic system. The platform itself is a part of a kit, which is considered a patient pass through device, billed as part of the anchor implantation/scanning outpatient procedure.
- **For EASE OF USE**, the quickly attached, lightweight microTargeting™ Platform provides flexibility in mounting location and can be repeatedly attached without rescanning. Simultaneous placement of two or more instruments is possible, and a library of fixture designs allows selection of the best shape or design for the procedure and instrument. Manual registration of image and patient is no longer needed, since the platform provides a stable known reference point in relation to patient anatomy.

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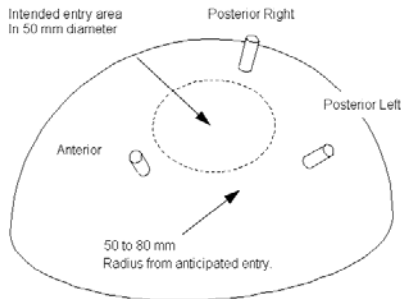


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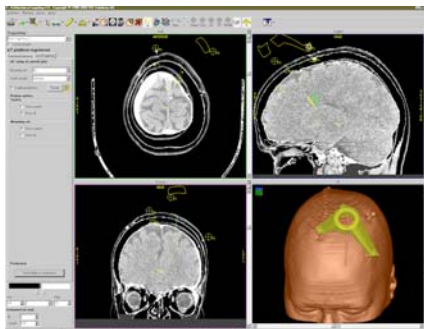


microTargeting™ Platform System Procedure Summary

microTargeting™ Platform Procedures are done in two stages. Anchor implantation and scanning, and pre-operative planning occur approximately one week before surgery.



Positioning WayPoint™ Anchors for a mounting set.



Planning software on the microTargeting™ Platform Planning and Design Workstation.



microTargeting™ Platform in use with the mT™ Drive System.

Anchor implantation and scanning:

1. Implantation does not require OR time.
2. Based on the intended entry area location, implant three WayPoint™ anchors. Anchors should be arranged with one in a generally anterior position and two others spaced about 120 degrees in a 50 to 80mm radius from the anticipated entry. Install a locator pin in the head of each anchor.
3. CT scanning is required for accurate mT™ Platform design. MR images may be fused to the CT in the mT™ Platform Planning and Design software. Care must be taken that the patient does not move during scanning.
4. Scan the patient, then remove locator pins, install anchor plugs, and staple or stitch the wounds over the anchors. Anchors may remain in the patient up to 28 days.

Pre-operative planning:

1. Load the patient scan data into the mT™ Platform Planning and Design workstation.
2. Perform any desired or necessary preliminary functions, such as image fusion or functional target planning. Select the target and entry points. A surgeon's eye view display mode and multiple track view options may be used in the inspection of the planned trajectory.
3. A virtual depiction of the mT™ Platform image will appear in the 2D and 3D images in place on the anchors.
4. Export the mT™ Platform planning files and transmit them to FHC's fabrication facility by direct internet connection. A delivery confirmation will be sent back immediately. A validated mT™ Platform will be sent by expedited carrier within 24 -72 hours.
5. The platform, as well as the mT™ Drive, should be sterilized along with the other mT™ System components in the convenient sterilization tray provided.

Surgery:

1. Position and drape the patient using a non-invasive restraint system; no frame or clamp is necessary.
2. Install the indexing ring in the platform, providing a hard metallic surface for accurate and secure attachment of system components.
3. Expose mounting set anchors, remove anchor plugs, and temporarily attach the platform, with the centered hub installed, for the marking of the burr hole site. Mark, drill, and inspect the burr hole. The Platform may be removed and re-attached multiple times.
4. Re-attach the Platform securely on the patient, and install the assembled drive system. Use the entry offset hub if necessary.
5. Check that the drive is zeroed appropriately above target, then insert guide tube(s) through the electrode carriage near the top of the drive, down through the matrix guide of the positioner, and into the patient. Install mT™ Platform electrode(s).
6. Proceed with microelectrode recording, utilizing a number of built in offsets when selecting subsequent recording track location(s).
7. When target is verified, the DBS lead replaces the recording electrode in the chosen track, with no need to retract the drive from target.

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microTargeting™ Platform System Purchasing Information

Kits make purchase of correct microTargeting™ Platform System components and compatible accessories simple.

microTargeting™ Platform System Configuration Recommendation:

Reusable Components:

66-WP-IK	WayPoint™ Implantation Kit
66-EL-WS	mT™ Planning and Design Workstation
66-FA-SF	mT™ Platform Adapter Kit
66-IT-04	mT™ Platform Array Insertion Tube Set (Single tube set available)
66-AC-AR	Array Electrode Carrier and Clamps.
66-CN-DB	DBS™ Extension Arm and Depth Stop Cap.
66-ZD-MD	mT™ Manual Drive
66-DA-ME	mT™ Drive Power Assist with Display Assembly
66-EL-MS	mT™ Drive Power Assist Controller / Display Module

Single Use Components:

MTDWBP(AR)(MP1)	Pre-sterilized tungsten differential recording electrode pre-measured for mT™ Platform use. Other electrodes are available.
MP-KIT-01	WayPoint™ hardware, fiducial template, attachment screws, and a custom built microTargeting™ Platform. Kits are available for alternate fiducial systems, or for bilateral procedures.
66-DA-SD	Package of 20 sterile drape sleeves for motor attachment

Services:

MP-INSTALLATION
Installation services, included with purchase of Platform System include setup of planning and design workstation, verification of CT and MR scan compatibility and acquisition.

MP-INSERVICE
On-site training and assistance, included with purchase of Platform System.

MP-1YRSERVICE
Service Contract. Contact microTargeting™ Support for details.

For more product information, pricing, and to learn about supplemental service contracts please contact microTargeting™ Support at 1-800-326-2905 (toll free in US and Canada), or 207-666-8190.

WayPoint™ Implantation Kit

The WayPoint™ Anchor/Locator System is recommended for all mT™ Platform cases. The WayPoint™ Implantation kit includes an initial supply of WayPoint™ anchors, plugs and locator pins, as well as the unique WayPoint™ combination driver and wrench tools, which are used to securely implant anchors and install or remove locator pins and anchor plugs. The included sterilization tray securely holds components as well as a small hand drill, which is available separately, if needed. WayPoint™ components are cleared for use in the United States only at this time.

mT™ Planning and Design Workstation

The mT™ Planning and Design Workstation is a portable laptop computer with planning software, configuration and model files installed. Installation of the planning workstation in the hospital, or planning site, and verification of CT and MR compatibility and acquisition, as well as in-service training on the software, are included with the purchase of an mT™ Planning and Design Workstation.

mT™ Platform Adapter Kit

The mT™ Platform Adapter Kit includes a storage/sterilization case, two indexing rings, center, entry offset and target offset hubs, center and 3mm offset positioners, drive mount, a unique burr hole marking tool, the convenient DBS™ measurement fixture tool, tools and cleaning brushes. Two smaller sterilization trays are included to hold small parts and spare thumbscrews. The sterilization case includes space for the mT™ Drive and DBS™ extension arm, which are sold separately. Electrode carrier and guide tube sets are available separately, as are recording electrodes. In-service training is included with the purchase of the mT™ Platform Adapter Kit.

mT™ Platform Adapter Kit - Bilateral Setup

Sites that perform bilateral procedures may choose this version of the mT™ Platform Adapter kit. Included in its sterilization/storage case are two each of the adapter components, arranged such that two drives and DBS™ extension arms, available separately, may be conveniently stored.

MP Kits

MP kits include anchoring and fiducial marker hardware, template(s), index ring attachment screws, platform foot thumbscrews, and custom designed mT™ Platform(s). MP kits come in two shipments: the first includes components for the implantation and scanning procedures; the second includes custom platform(s) with attachment screws and thumbscrews. Contact microTargeting™ Support for information on kit availability.

Service Contracts

Service contracts are available, providing insurance beyond the manufacturer's warranty. Contact FHC's microTargeting™ Support for details.

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