Neural microTargeting™ Worldwide

Nexframe®

Stereotactic system

System Manual

L011-500
Revision: B0
Release Date:

Contains instructions for the following products:
DB-2040, NP-1000, MI-1000, MI-2000, SR-10

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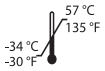
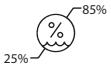
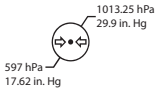
Table of contents

Explanation of symbols on product or package labeling.

Refer to the appropriate product for symbols that apply.

	WARNING/Caution, Consult instructions for important cautionary information.
	Consult the instructions for use.
CE 2862	European Conformity. This device fully complies with Medical Device Regulation (EU) 2017/745 and legal responsibilities as a manufacturer are with FHC, Inc., 1201 Main Street, Bowdoin, ME 04287 USA.
EC REP	Authorized representative in the European Community.
	Medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC and Medical Device Regulation (EU) 2017/745.
	Do not reuse; intended for one use on a single patient, during a single procedure.
	Indicates a medical device that is not to be resterilized.
STERILE EO	Indicates a medical device that has been sterilized using ethylene oxide.
	Indicates a single sterile barrier system.
	Indicates two sterile barrier systems.
	Indicates the date after which the medical device is not to be used.
	Indicates a medical device that should not be used if the package has been damaged or opened.
	Indicates the temperature limits to which the medical device can be safely exposed.
	Indicates the range of humidity to which medical device can be exposed.
	Indicates the range of atmospheric pressure to which medical device can be exposed.
	An item that is known to pose hazards in all MRI enviroments.
LOT	Indicates the batch code so that the batch or lot can be identified.
REF	Indicates the catalog number so that the medical device can be identified.
! USA	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.
	The date when the medical device was manufactured.
MD	Indicates Medical Device
	Importer. Indicates the entity importing the medical device into the EU.

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Nexdrive™ is a trademark of Medtronic, Inc.

Notices

Notice to the user and/or patient: any serious incident that has occurred in relation to the device should be reported to FHC, Inc. as the manufacturer, as well as the competent authority of the Member State in which the user and/or patient is established.

Device description

The Nexframe Stereotactic System is a disposable, frameless, stereotactic guidance system used in conjunction with Medtronic StealthStation Navigation Systems—image-guided surgery (IGS) systems—for intracranial surgical procedures.

Nexframe Stereotactic Tower

The Nexframe Stereotactic System tower consists of three assemblies (Figure 1). The reference frame bracket assembly attaches to the ring assembly with three screws; these two assemblies form the Nexframe base (Figure 2). The ring assembly of the base is attached to the patient's skull. The socket assembly fits over the two retaining blocks on the ring assembly and is secured with the tower thumbscrews (Figure 2).

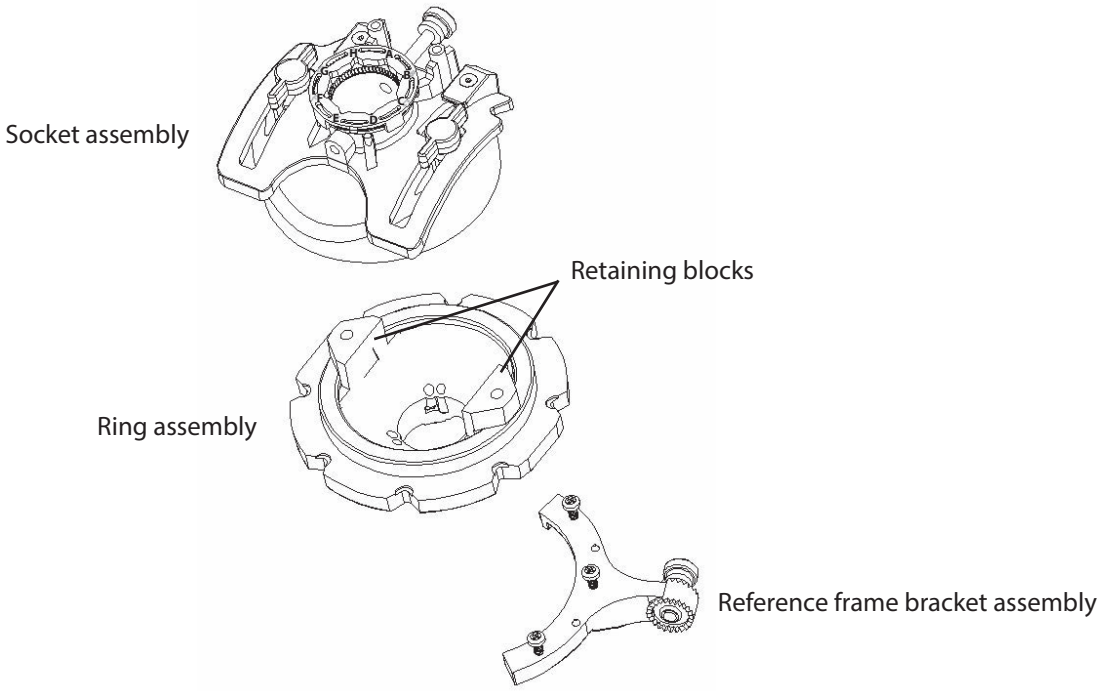


Figure 1. The Nexframe tower assemblies: the socket assembly, ring assembly, and reference frame bracket assembly.

The Nexframe tower: the socket assembly attached to the base

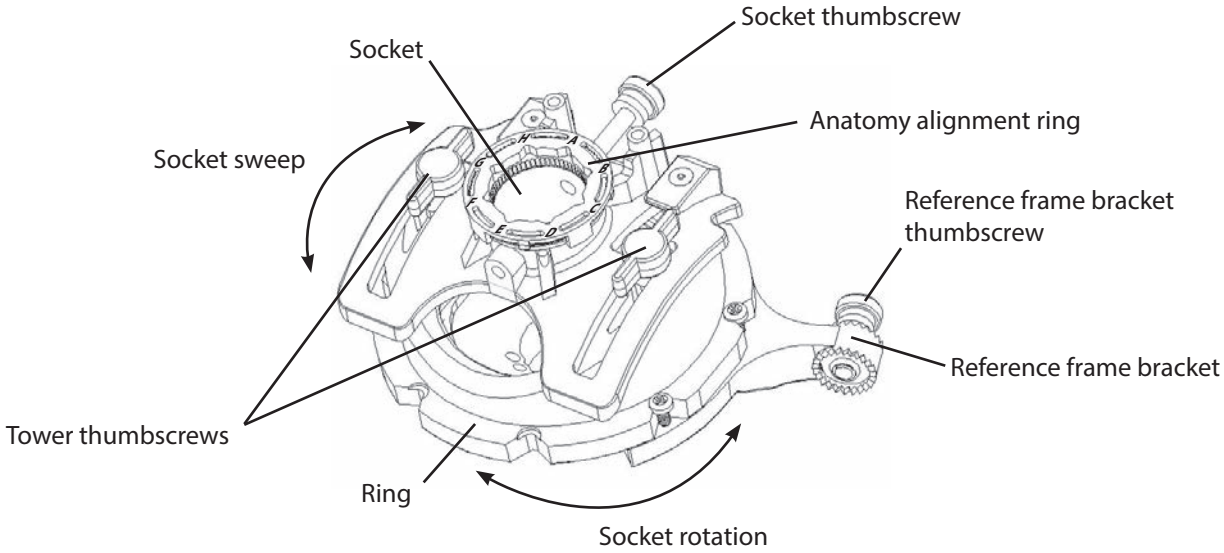
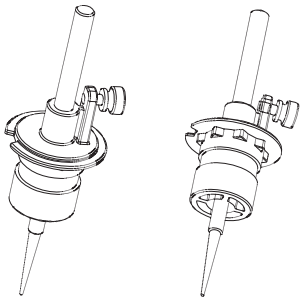


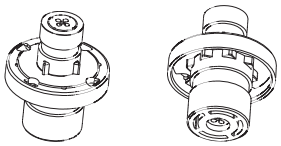
Figure 2. The assembled Nexframe Stereotactic System tower.

Center alignment adapter and center multilumen adapter

The center alignment adapter is used in conjunction with an IGS system alignment probe to align the Nexframe tower to the target. Once the Nexframe tower is aligned, the alignment adapter and probe are removed from the Nexframe tower and the center multilumen adapter (MLA) is inserted. The center lumen of the center MLA corresponds to the target trajectory. The four parallel lumens of the center MLA are spaced 2 mm from the center lumen.



Center alignment adapter (top and bottom view)

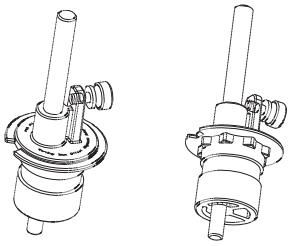


Center multilumen adapter (top and bottom view)

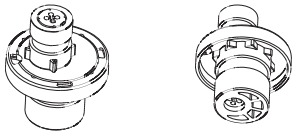
Figure 3. The components used for alignment.

3-mm offset alignment adapter and 3-mm offset multilumen adapter

The 3-mm alignment adapter is available if an entry-point offset is desired. The center lumen of the 3-mm offset MLA is offset from the center alignment by 3 mm. The four parallel lumens are spaced 2 mm apart from the center lumen of the 3-mm offset MLA.



3-mm offset alignment adapter (top and bottom view)



3-mm offset multilumen adapter (top and bottom view)

Figure 4. The components used for 3-mm offset alignment.

Nexprobe Image-guided Probe

The Nexprobe Model NP-1000 Image-guided Probe is used in conjunction with a Medtronic StealthStation Navigation System to align the Nexframe tower to the desired target. The probe can be used with the center alignment adapter or the 3-mm offset alignment adapter.

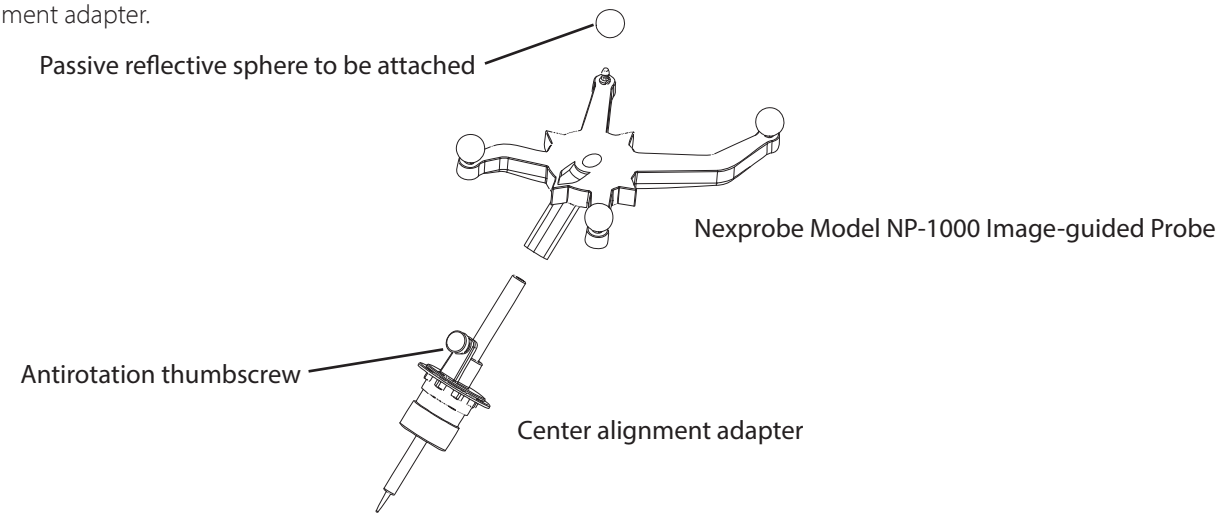


Figure 5. The Nexprobe Model NP-1000 Image-guided Probe with reflective spheres and the center alignment adapter included with the Nexframe DB-2040.

Nexdrive Micropositioning Drives

The Nexdrive Micropositioning Drive attaches to the Nexframe tower by a multilumen adapter and is used for the micropositioning of microelectrodes and leads. The Nexdrive Models MI-1000 and MI-2000 drives are actuated manually. The Nexdrive Model MI-1000 drive has a potentiometer cable, which allows remote viewing of the instrument location via a digital display accessory.

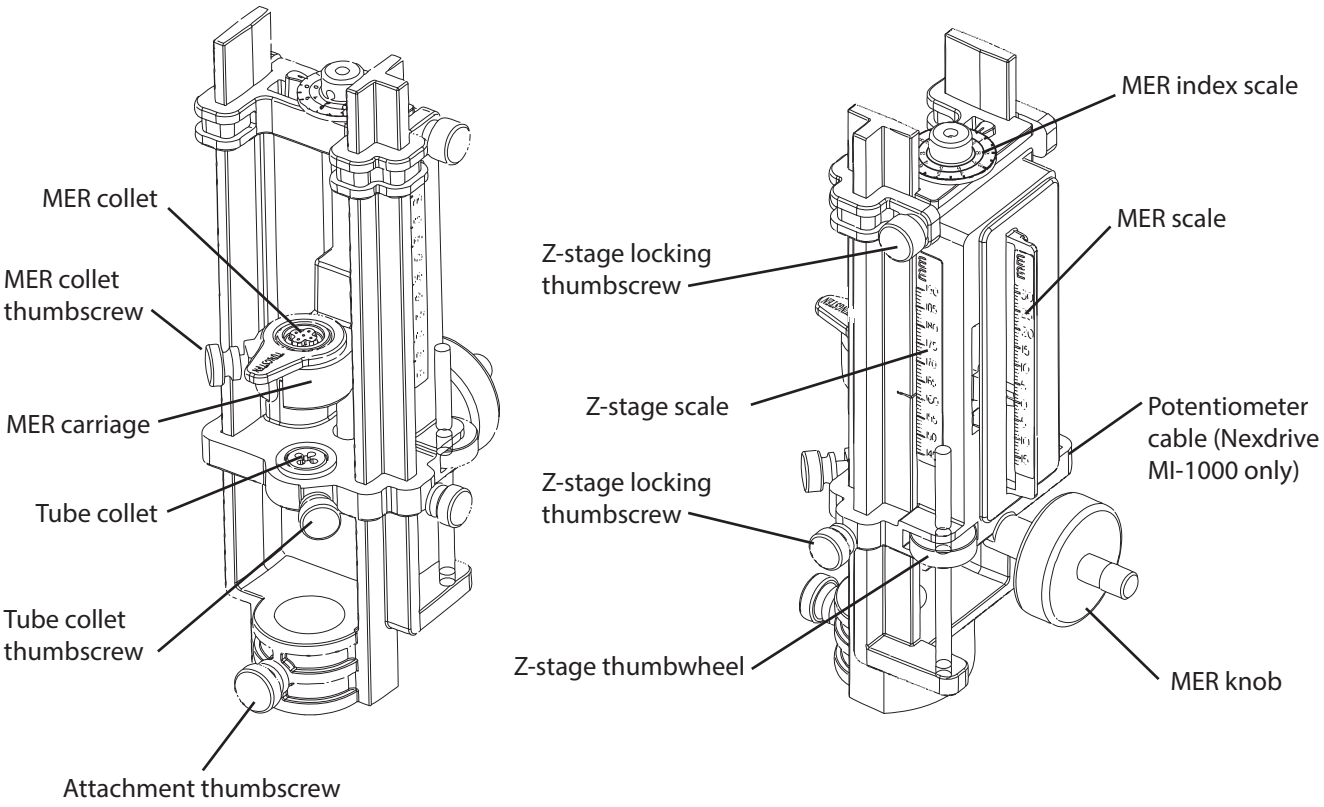


Figure 6. The Nexdrive Models MI-1000 and MI-2000 Micropositioning Drives.

Package contents

Table 1 lists the package contents for each Nexframe Stereotactic System component.

Table 1. Package contents for Nexframe Stereotactic System components

DB-2040 Bilateral Nexframe

Nexframe for Medtronic StealthStation Navigation Systems

- Nexframe socket assembly
- Ring assembly (2)
- Reference frame bracket assembly
- Center alignment adapter
- Center multilumen adapter
- 3-mm offset alignment adapter
- 3-mm offset multilumen adapter
- Product literature

SR-10 1.6 x 10-mm Cranial Bone Screws

- Individually packaged screw (3)

MI-1000 Nexdrive

- MI-1000 Nexdrive with potentiometer cable
- 0.64 mm diameter collet (white)
- 0.89 mm diameter collet (gray)
- Lead holder
- Measurement tube

MI-2000 Nexdrive

- MI-2000 Nexdrive
- 0.64 mm diameter collet (white)
- 0.89 mm diameter collet (gray)
- Lead holder
- Measurement tube

NP-1000 Nexprobe

- Nexprobe subassembly
- 11.5 mm passive sphere (8)

System configurations

Table 2 lists the components needed to form the Nexframe Stereotactic System for supported configurations. The configurations name is used to quickly identify each particular configuration. All Nexframe system configurations listed in table 2 are configured for use with the Medtronic StealthStation Navigation System.

Table 2. Nexframe Stereotactic System catalog number system configurations

DB2031[a]	DB2041	DB2042
• DB-2040 Nexframe • NP-1000 Nexprobe	• DB-2040 Nexframe • MI-1000 Nexdrive • NP-1000 Nexprobe	• DB-2040 Nexframe • MI-2000 Nexdrive • NP-1000 Nexprobe

[a] This system configuration is for use with FHC STar™ Drive micro positioners.

Specifications

The following tables provide requirements and descriptions for component features for the Nexframe Stereotactic System.

Table 3. Navigation system requirements

Navigation system	Supported versions
Medtronic Stealth Planing and Navigation	Cranial 3.0 or greater

Table 4. Nexframe Stereotactic System specifications

Range and spacing	Description
Rotation	360 degrees
Angle	25 degrees
Multilumen spacing	2 mm (center to center)

Table 5. Nexdrive Micropositioning Drive specifications

System full-scale accuracy	±0.25 mm
Repeatability	±0.10 mm
Overall travel	45 mm
Resolution	0.01 mm according to the index scale
MER scale is color-coded	Blue for above target Red for below target
Index scale is color-coded to correspond with the MER scale	Blue for above target Red for below target
MER drive knob	
3 Revolutions	Per 1 mm of instrument travel
Clockwise rotation	Equals instrument advance
Counterclockwise rotation	Equals instrument retract

[a] All measurements are approximate.

Table 6 provides the materials for only those components of the Nexframe Stereotactic System that contact or may likely come into contact with human tissue.

Table 6. Material of components and human tissue contact

Component	Material	Human tissue contact
Nexframe ring assembly		
Ring	Polycarbonate	Direct contact
Seal	Silicone rubber	Direct contact
Bone screws	Titanium	Direct contact
Center alignment adapter	Polycarbonate	Not likely to contact
Tip	Stainless steel	May contact

Compatibility

- The Nexframe Stereotactic System is compatible with the Nexdrive micro-positioning drive for microelectrode recording and lead placement. It is also compatible with some third party micro-positioning drives.
- For information on which third party drives are compatible with the Nexframe Stereotactic System, how to use third party drives in Nexframe procedures, and what adapters and/or accessories are available, contact the drive manufacturer representative and/or reference product information.
- The insertion tubes/cannulas used with the Nexframe system pass through the tube collet of the Nexdrive and the MLA. The holes for the insertion tube to pass through are 1.88 mm in diameter. Nexdrive comes with two (2) MER collets; the white MER collet holes are 0.64 mm in diameter and the grey MER collet holes are 0.89 mm in diameter.
- The insertion tubes/cannulas must be able to pass a Medtronic lead. In order to assure free passage of the lead, the minimum inner diameter of the insertion tube must be at least 1.43 mm.
- The microelectrode length to planned target is 244 mm with the Z-scale set to the Stealth Navigation System Depth to Target and the MER carriage at 0 on the MER scale.
- The distance from the z-scale base, where the insertion tube sits, to target is 214 mm when the z-scale is set to the Stealth Navigation System Depth to Target. The length of the insertion tube will be reduced by the distance above target the neurosurgeon/neurologist wants to start the MER track.
- For specific model numbers and ordering information, contact your Medtronic or FHC representative and/or reference the Medtronic DBS Product List.
- For microelectrodes, insertion tubes and adapters for use with 3rd party micro-positioning drives, contact drive manufacturer representative or consult appropriate product lists.

⚠ **WARNING:** Using the incorrect microelectrodes and insertion tubes could result in serious patient injury or death.

Indications for Use/Intended Use

Nexframe Stereotactic System

Indications for Use:
The Nexframe Stereotactic System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures performed in conjunction with the use of an image Guided Workstation System using preoperative MR and/or CT imaging. These procedures include biopsies, catheter placement and electrode introduction.

Intended Use:
The Nexframe Stereotactic System is intended for use by a Neurosurgeon in a standard operating room environment to guide compatible neurosurgical devices along a planned trajectory to the specified target in the brain during stereotactic functional neurosurgical procedures.

Nexprobe Image-guided Probe

Indications for Use:
The Nexprobe Image-guided Probe is intended to be used in conjunction with the Nexframe Stereotactic System and the Medtronic StealthStation® Navigation Systems for patient registration and navigation.

Intended Use:
The Nexprobe Image-guided Probe is intended for use by a Neurosurgeon in a standard operating room environment to place and orient the Nexframe Tower towards a target in the brain along a planned trajectory during stereotactic functional neurosurgical procedures.

Nexdrive Micropositioning Drive

Indications for Use:
The Nexdrive Micropositioning Drives are intended to be used in conjunction with the Nexframe Stereotactic System for the precise positioning of microelectrodes, stimulating electrodes, implantable electrodes, or other instruments in the brain or nervous system.

Intended Use:
The Nexdrive Micropositioning Drives are intended use by a Neurosurgeon in a standard operating room environment to move compatible neurosurgical devices along a planned trajectory at precise distances from planned target in the brain during stereotactic functional neurosurgical procedures.

Contraindications

Follow the general guidelines concerning the suitability of neurosurgery involving the insertion of electrodes, instruments, or devices into the brain or nervous system.

⚠ WARNINGS

Single use only – Unless otherwise indicated, do not reuse any component. Components are intended for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

MRI – Do not perform MRI with any part of the Nexframe Stereotactic System (see Table 1 for a list of all component parts) attached to the patient.

System validation of the image-guided surgery (IGS) system – Perform systematic validation of the image-guided surgery (IGS) system used in conjunction with the Nexframe Stereotactic System according to the IGS system manufacturer guidelines to ensure system accuracy and efficacy. Error magnitudes can vary for different IGS systems. If the IGS system is not validated prior to performing the surgical procedure, there is a greater potential for trajectory and depth error.

Image-guided surgery (IGS) system compatibility and accessories – Verify the compatibility of the image-guided surgery (IGS) system and accessories before use with the Nexframe Stereotactic System.

Compatible microelectrodes - Using the incorrect microelectrodes and insertion tubes could result in serious patient injury or death.

Precautions

Storage temperature – Do not store or transport the Nexframe Stereotactic System components or accessories above 57 °C (135 °F) or below -34 °C (-30 °F). Temperatures outside this range can damage device components.

Environmental conditions for storage and transport of the Nexdrive MI-1000 Micropositioning Drive – Store and transport the Nexdrive Model MI-1000 Micropositioning Drive under the following conditions:

- Temperature: -34 °C to 57 °C (-30 °F to 135 °F)
- Atmospheric pressure: 597 hPa to 1013.25 hPa (17.62 in. Hg to 29.9 in. Hg)
- Relative humidity: 25% to 85%

Resterilization – Do not resterilize any parts or components of the Nexframe Stereotactic System, including the Nexdrive Micropositioning Drive. Resterilizing will damage the devices, making them unusable.

Component handling – Handle all parts and components of the Nexframe Stereotactic System, including the Nexdrive Micropositioning Drive, with extreme care. If any part or component is damaged, replacement will be needed.

Known adverse events

Microelectrode Recording (MER) involves the use of sterile metal probes which are inserted into the brain during surgery. This use may cause a hemorrhage with a known adverse event effect rate of 1-2%.

Instructions for use: Preparatory procedures

Notes:

- All components of the Nexframe Stereotactic System should be inspected for any damage prior to the procedure.
- Keep duplicate sterile product ready and available if a product becomes contaminated or is damaged during use and needs to be replaced.
- The Nexframe Stereotactic System is designed for use by physicians who are trained in stereotactic procedures with the StealthStation Navigation System.
- These instructions when referring to the use of the StealthStation Navigation System and components are to be used as a general guide only. Relevant StealthStation Navigation System product labeling must be reviewed prior to these procedures for detailed instructions on the use of the IGS system.
- These instructions when referring to the use of the Unibody Bone Fiducials are to be used as a general guide only. Relevant Unibody Bone Fiducial product labeling must be reviewed prior to these procedures for detailed instructions on the use of the bone fiducials
- These instructions when referring to the use of the Stimloc Burr Hole Cover are to be used as a general guide only. Relevant Stimloc Burr Hole Cover product labeling must be reviewed prior to these procedures for detailed instructions on the use of the burr hole cover.

Patient scanning

A minimum of two scans are necessary for planning and performing procedures with the Nexframe Stereotactic System
MRI for planning
CT for registration

⚠ **Caution:** The patient must remain immobile during the scans to ensure usable scans.

Notes: The Nexframe Stereotactic System is not attached to the patient's skull during patient scanning. For best results, follow imaging parameter setting (i.e.. slice thickness) guidelines in Medtronic Stealth Planing and Navigation product labeling.

MRI

1. Acquire MRI image/s.

CT

⚠ Caution: Handle the patient with care to prevent accidental bone fiducial loss or loosening.

1. Place a minimum of 5 implantable bone fiducials (see Unibody Bone Fiducials Technical Manual).
2. Acquire CT image/s.
   – Scan to encompass the entire head and all fiducials.
3. A head wrap or other protection is recommended to prevent fiducial loss after scanning is completed.

Surgical planning

Notes:

- The Nexframe Stereotactic System allows adjustment for target depths 70–100 mm from the skull surface. Corresponding probe depths are 75 - 105 mm for the Nexprobe Image-guided Probe.
- The Nexframe Stereotactic System range of motion is 0° - 25° angular with 360° rotation.
  1. Follow instructions in the Medtronic Stealth Planning and Navigation product labeling to create a surgical plan or plans.
     –Select a target location.
     –Select an entry point (ie, the burr hole location).

⚠ **WARNINGS:**

Carefully plan an entry point to avoid:

– placing the attachment screws for the Stimloc Burr Hole Cover or the Nexframe Stereotactic System in a cranial suture or on cranial bone that is damaged or diseased, or is less than 5mm thick, which may result in an unstable platform for the devices and injury to the patient.

– range of motion limitations for the Nexframe Stereotactic System, which may result in target access failure. Use the Cone of Reachability function (see the Medtronic Stealth Planning ans Navigation product labeling) to verify that the intended target can be reached from the chosen entry point (burr hole location). Be aware that a more lateral approach may be needed for certain head shapes.

Patient preparation

Note: These instructions for patient preparation are provided as a guide only. Consult the relevant StealthStation Navigation System product labeling for detailed patient preparation instructions.

1. Immobilize the patient with a head restraint of choice, or use the Medtronic model PH-2500 passive headrest if appropriate for the patient.

Optional nonsterile initial registration

Note: Used for stereotactic targeting of desired burr hole locations.

1. Attach the image-guided reference frame to the patient via a headstrap or another noninvasive device.
2. Perform PointMerge® or O-arm® registration procedure described in Medtronic Stealth Navigation instructions.

⚠ Caution: When using PointMerge® registration, ensure the fiducials are clean and free of any foreign matter for the pointer tip to fully seat in the divots. If the pointer tip is not fully seated in the divot, registration will not be accurate.

3. Locate the entry point and mark the scalp or the skull surface.

Note: It is recommended to denote the entry location on the skull surface.

Sterile preparation

1. Prep and drape the patient according to standard practice.

Note: Ensure bone fiducials are prepped and accessible for registration through the sterile drape for sterile registration.

2. Incise the scalp with enough space to accept the ring assembly of the Nexframe Stereotactic System.
3. Drill a 14-mm burr hole precisely centered over the previously marked entry location on the skull surface.

⚠ Caution: Ensure the diameter of the burr hole is not less than 14 mm. If the burr hole is less than 14 mm in diameter, the Nexframe Stereotactic System will not have full range of motion for targeting access.

Notes:

Bevel the burr hole to ease access to the brain.
Remove any bone shavings with a curet to ensure proper implantation of the Stimloc Burr Hole Cover. Remove the lower burr hole shelf to allow access for mapping the anatomy with multiple parallel trajectories.

Assembling the Nexframe Stereotactic System over the Stimloc Burr Hole Cover base

⚠ Cautions:

- Do not overtighten the screws. If a power screwdriver is used, perform final tightening of each screw using a manual screwdriver to prevent device damage.
- If the Nexframe requires screw replacement, use SR-10 1.6 x 10-mm Cranial Bone Screws which are available separately.

1. Refer to the manual for the Stimloc Burr Hole Cover for instructions to mount the Stimloc base over the burr hole using the centering tool.

⚠ **Caution:** Mount the Stimloc base with the screws oriented medial to lateral to ensure proper orientation for the Nexframe ring assembly.

2. Place the Nexframe component assemblies, if required, on the surgical table (Figure 7).

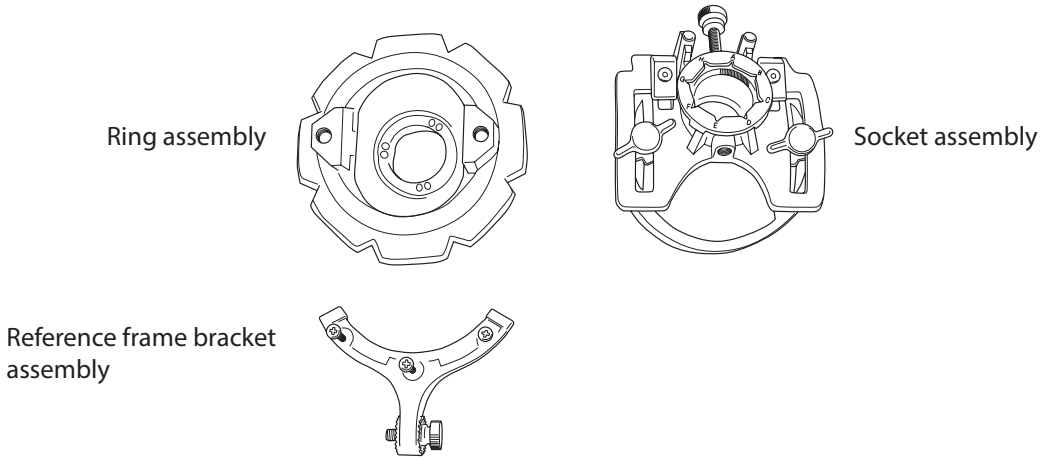


Figure 7. Disassemble the Nexframe tower into the three assemblies.

3. Orient reference frame bracket on base ring to provide clear line of sight to Stealth Navigation camera.
4. Position the center hole of the Nexframe ring over the Stimloc base with the two screw holes placed towards the patient anterior (Figure 8) to maximize stability.

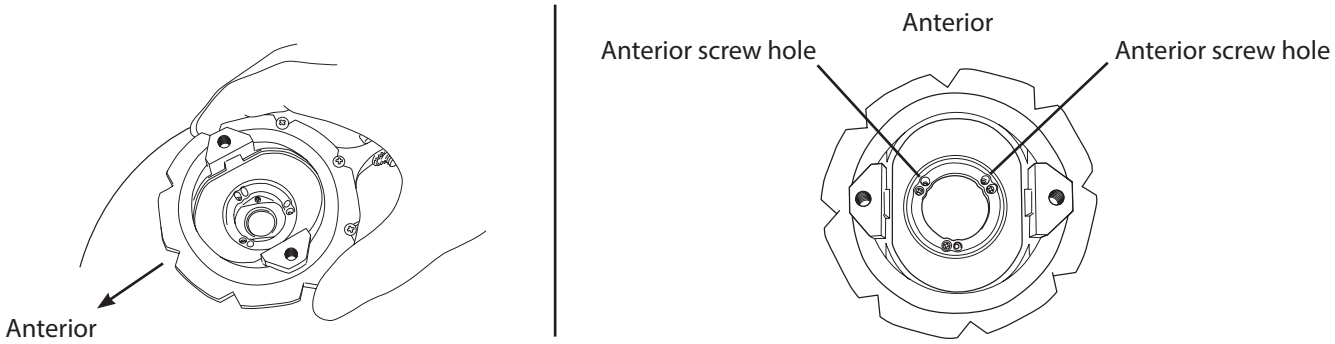


Figure 8. Place the ring over the Stimloc base with the two screw holes opposite the reference frame bracket facing anterior.

5. Tighten the three attachment ring screws in a successive, gradual, alternating pattern.
6. Lift and rock the Nexframe ring to ensure all attachment screws are tight and no motion is felt (Figure 9).

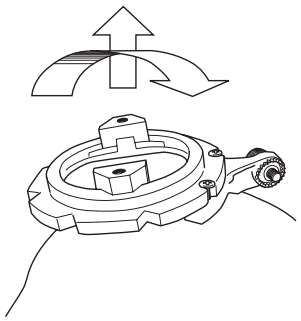


Figure 9. Lift and rock the ring to ensure all attachment screws are tight.

7. Assemble the Nexframe base by attaching the reference frame bracket assembly to the ring assembly by inserting the three screws in the grooves of the ring and tightening the screws.
8. Retighten any loose screws.

⚠ **WARNING:** The Nexframe ring must be secure to the skull to ensure targeting accuracy.

Note: The optional holes (Figure 10) may be used for additional screw attachments if ring stability is unsatisfactory. Only use SR-10 1.6 x 10-mm Cranial Bone Screws which are available separately.

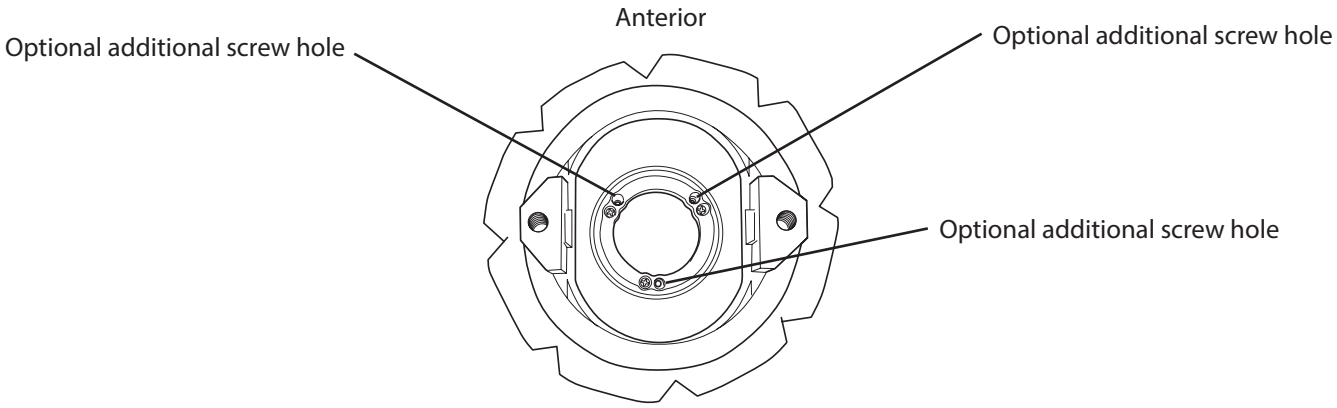


Figure 10. Optional additional screw holes.

9. Attach the socket assembly by placing it over the ring and aligning it with the retaining blocks (Figure 11).

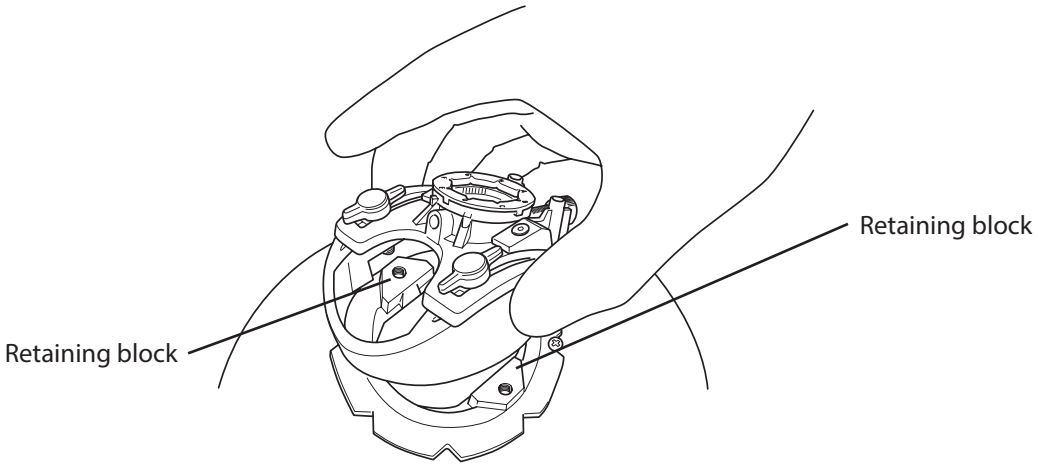


Figure 11. Position the socket assembly over the ring.

10. Loosely thread each tower thumbscrew into each retaining block (Figure 12).

⚠ Caution: Use care when threading the tower thumbscrews to prevent cross threading.

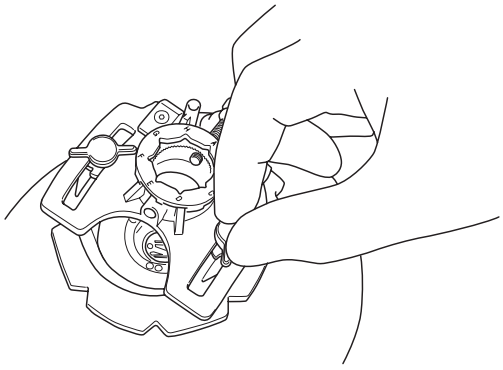


Figure 12. Tighten the two tower thumbscrews.

Instructions for use: Aligning the Nexframe Stereotactic System

IGS system setup and sterile registration with the Nexprobe Model NP-1000 Image-guided Probe

Note: Relevant product labeling for the StealthStation Navigation System and probe being used must be reviewed prior to use for detailed instructions for setup and registration.

1. Remove the Nexprobe Model NP-1000 Image-guided Probe (Figure 13) from the packaging.

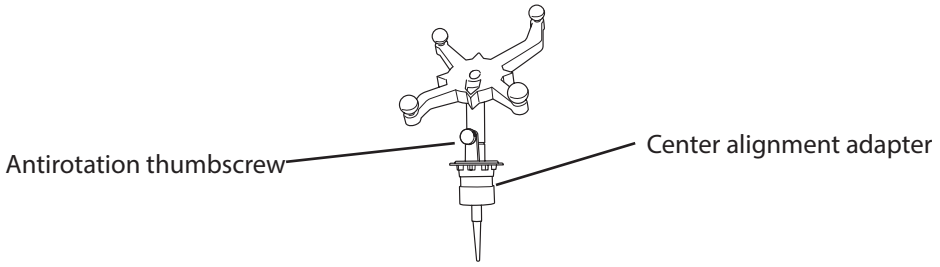


Figure 13. The Nexprobe Model NP-1000 Image-guided Probe with reflective spheres and the center alignment adapter attached.

2. Attach the four sterile reflective spheres to the probe and ensure they are fully seated.

⚠ Cautions:

- Extreme care should be taken when attaching the reflective spheres to avoid contamination, scuffing or other damage.
- Ensure the reflective spheres remain free of blood, fluid, or other contaminants (such as glove powder) throughout their use in the procedure.
- Do not use other reflective spheres not packaged with the Nexprobe Model NP-1000 Image-guided probe.

3. Choose the "Nexprobe" tool file from the StealthStation Navigation System software.
4. Attach the probe to the center alignment adapter from the DB-2040 Nexframe and fully tighten the antirotation thumbscrew (Figure 13).

   Note: Examine the reflective spheres to ensure they are free of blood, fluid, or other contaminants, such as glove powder.

5. Attach the appropriate reference frame (Figure 14 shows an example) to the Nexframe reference frame bracket.

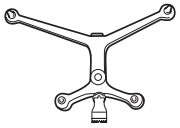


Figure 14. Medtronic passive spinal reference frame (shown without the reflective spheres).

6. Align the Stealth Navigation system camera to include both the reference frame and the probe, when the probe is in vicinity of Nexframe.

⚠ Caution: The Stealth Navigation system camera should be as orthogonal as possible to the surface of the probe and the reference frame to maximize tracking accuracy.

7. Perform the verification task for the probe according to the appropriate StealthStation Navigation System instructions.
8. Verify the geometry error for the probe and the geometry error for the reference frame from the StealthStation Navigation System tool file according to the appropriate StealthStation Navigation System instructions.

⚠ Cautions:

- The individual geometry error for the probe and the reference frame should not exceed 0.3 mm when properly aligned to the Stealth Navigation system camera. Repeat steps 2-8 if a geometry error exceeds 0.3 mm.

*If geometry error still exceeds 0.3mm, replace reflective spheres and repeat steps 2-8.

- Do not use the probe if the geometry error for the probe cannot be reduced. A geometry error exceeding 0.3 mm will result in inaccurate alignment to the target.

9. Perform PointMerge® or O-arm® registration procedure described in Medtronic Stealth Navigation instructions.

⚠ Caution: When using PointMerge® registration, the probe should be as perpendicular as possible to the registration divots to maximize accuracy.

10. Verify accuracy of selected registration method using procedure described in Medtronic Stealth Navigation instructions.

⚠ Caution: When using PointMerge® registration, repeat steps 9-10 if registration error metric exceeds 1.0 mm.

⚠ Caution: When using O-arm® registration, repeat steps 9-10 if verification does not produce satisfactory results.

Nexframe Stereotactic System alignment with the Nexprobe Model NP-1000 Image-guided Probe

Note: Relevant product labeling for the StealthStation Navigation System being used must be reviewed prior to use for detailed alignment instructions using the Nexprobe Model NP-1000 Image-guided Probe.

1. If optional offset alignment is needed, refer to "Optional 3-mm offset alignment" on page 15 for alignment using the 3-mm offset alignment adapter.
2. Insert the Nexprobe Model NP-1000 Image-guided Probe (attached to the center alignment adapter) into the Nexframe socket and tighten the socket thumbscrew.

⚠ **WARNING:** Verify that the alignment adapter (attached to the probe) is fully seated in the Nexframe socket. Failure to fully seat the alignment adapter will result in depth error.

Note: Reset plan entry point to match Nexprobe assembly tip per Stealth Navigation instructions.

3. Reverify the geometry error for the probe and the geometry error for the reference frame according to the appropriate Stealth Station Navigation System instructions.

⚠ Caution: The individual geometry error for the probe and the reference frame should not exceed 0.3 mm when properly aligned to the IGS system camera. A geometry error exceeding 0.3 mm will result in inaccurate alignment to the target.

4. Select the appropriate Navigation screen to display on the StealthStation Navigation System workstation.
5. Adjust the Nexframe Stereotactic System until it is aligned with the intended target or trajectory according to these alignment instructions in combination with the StealthStation Navigation System instructions.
   – Set the Nexframe tower with the access window posterior and lateral.
   – Make sure Nexprobe face is orthogonal to the Stealth Navigation system camera.
   – Sweep the tower and observe the path on the guidance screen (Figure 15).

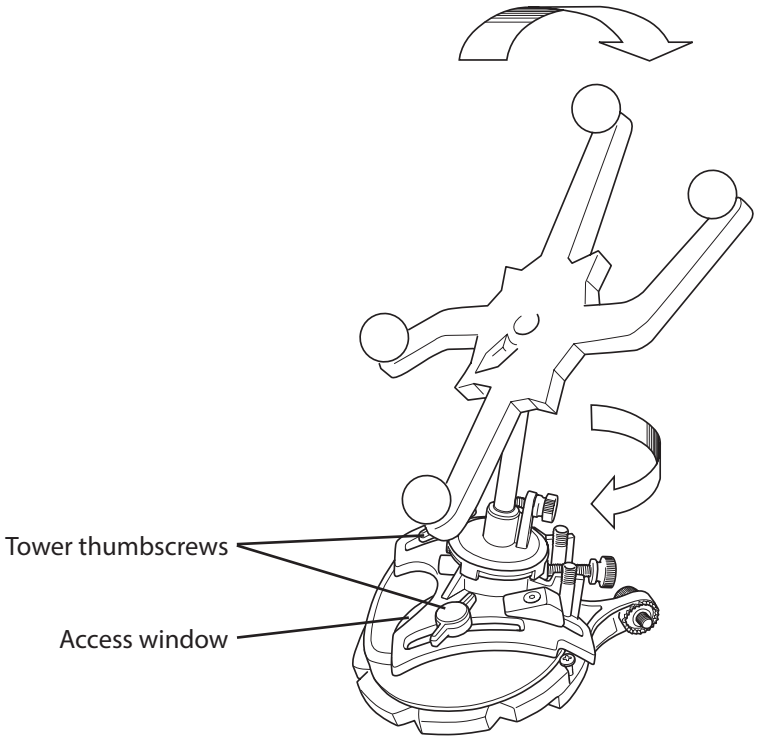


Figure 15. Sweep and rotate the socket assembly.

   – Rotate the tower several degrees and sweep again; note the new path on the screen.
   – Adjust the rotation to move the sweeping path to cross the intended target.
   – Repeat the sweep until alignment to the target is achieved.
   – Fully tighten the two tower thumbscrews (Figure 15).

⚠ **WARNING:** Ensure the tower thumbscrews are fully tightened and the target alignment is maintained to ensure targeting accuracy. In the event any inadvertent movement of the Nexframe tower occurs, check the alignment to ensure targeting accuracy.

⚠ Caution: The probe surface should continue to remain as orthogonal as possible to the Stealth Navigation system camera to maximize tracking accuracy.

6. Obtain a depth-to-target reading from Stealth Navigation system and record on the appropriate depth chart.

   Note: The Nexframe Stereotactic System allows adjustment for target depths 70–100 mm from the skull surface. Depths for the Nexprobe Image-guided Probe are 75–105 mm.

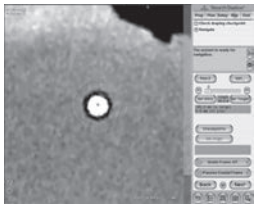


Figure 16. StealthStation Guidance View screen.

7. Remove the probe and center alignment adapter assembly.
8. Proceed to Anatomy alignment.

Anatomy alignment

⚠ **WARNING:** Do not use the anatomy alignment feature if the 3-mm offset alignment adapter is used. Review operative planning as appropriate.

1. Align the anatomy alignment ring by loosening the socket thumbscrew, inserting the center alignment adapter into the Nexframe socket and rotating the center alignment adapter to align the "A" to the patient anterior (Figure 17).

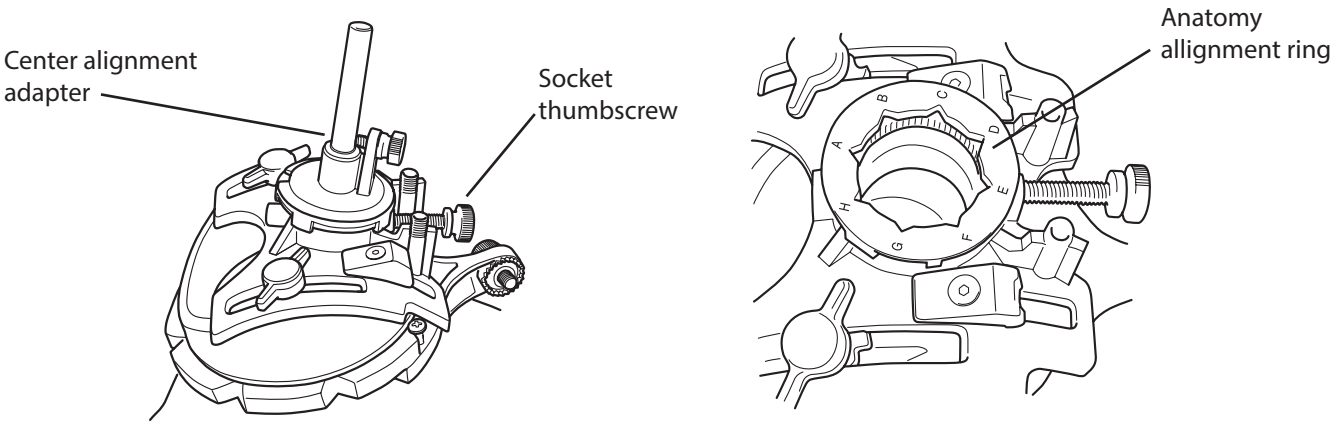


Figure 17. Align the "A" on the anatomy alignment ring to the patient anterior by rotating the center alignment adapter.

2. Remove the center alignment adapter and attach the center multilumen adapter (Figure 18) with the lumen pattern aligned to the patient anatomy.

⚠ **WARNING:** Ensure the multilumen adapter (MLA) is fully seated in the Nexframe socket. Failure to fully seat the MLA will result in depth error.

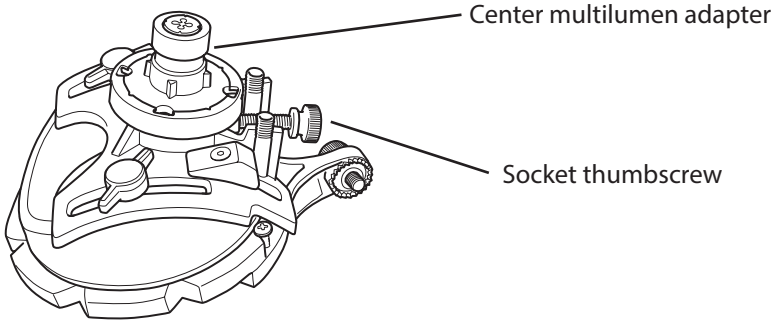


Figure 18. Attach the center multilumen adapter aligned to the patient anatomy.

3. Tighten the socket thumbscrew.

Notes:

- The center lumen corresponds to the target trajectory and should be used for the initial MER pass.
- The parallel lumens of the center multilumen adapter are spaced at 2 mm center to center.

Optional 3-mm offset alignment

⚠ **WARNINGS:**

To avoid trajectory error from the intended target:

- Do not use the "Anatomy alignment" procedure on page 16 if the 3-mm offset alignment adapter is used. Review operative planning as appropriate.
- Ensure the 3-mm offset multilumen adapter matches the orientation of the 3-mm offset alignment adapter.

1. Remove the center alignment adapter.
2. Insert the 3-mm offset alignment adapter in the desired direction to adjust the entry point. Note which letter of the anatomy alignment ring shows in the 3mm offset alignment adapter window (Figure 19).

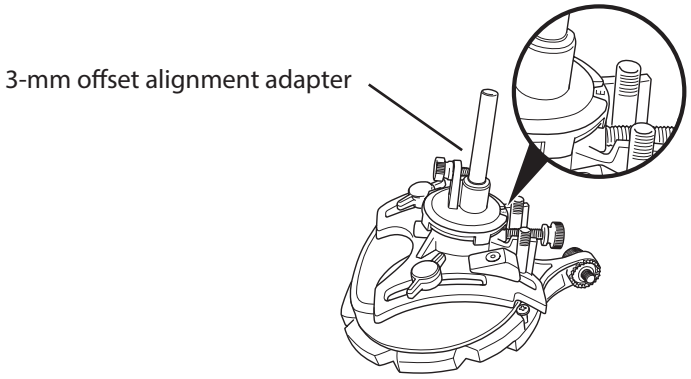


Figure 19. Insert the 3-mm offset alignment adapter and adjust.

3. Attach the Np-1000 Nexprobe.
4. Align to the target.
5. Reset entry point in Stealth system plan.
6. Remove the 3-mm offset alignment adapter and the alignment probe.
7. Insert the 3-mm offset multilumen adapter (MLA) in the identical location as the 3-mm offset alignment adapter aligning window in 3mm offset MLA with letter noted in step 2 (Figure 20).

   Note: Only the center hole of the 3-mm offset MLA will be aimed at the target.

⚠ **WARNING:** Ensure the multilumen adapter (MLA) is fully seated in the Nexframe socket. Failure to fully seat the MLA will result in depth error.

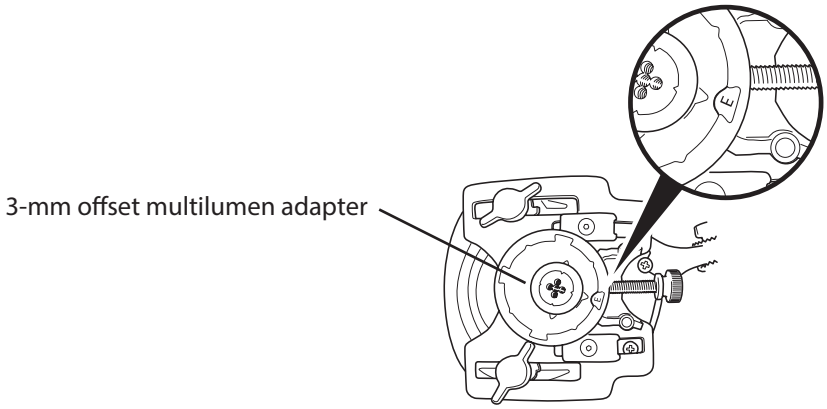


Figure 20. Insert the 3-mm offset multilumen adapter in the identical location as the 3-mm offset alignment adapter.

Instructions for use: Micropositioning

Using the Nexdrive Micropositioning Drives

⚠ Cautions:

- Avoid the use of liquids on or near the Nexdrive Micropositioning Drive, as well as the accessories. If liquids come into contact with these devices, damage to the drive and accessories may occur.
- Use care when placing the sterile cable that attaches any accessory to the Nexdrive Micropositioning Drive to avoid any force or pulling on the drive.
- Evaluate the compatibility of all microelectrodes and tubes before use with the Nexdrive Micropositioning Drive.

Depth chart for the Nexdrive Micropositioning Drive

Figure 21 provides a depth chart showing the Nexdrive Micropositioning Drive in relation to the Nexframe Stereotactic System components, probes, microelectrode, and lead, all in relation to the target.

Note: Shown with example microelectrode and insertion tubes.

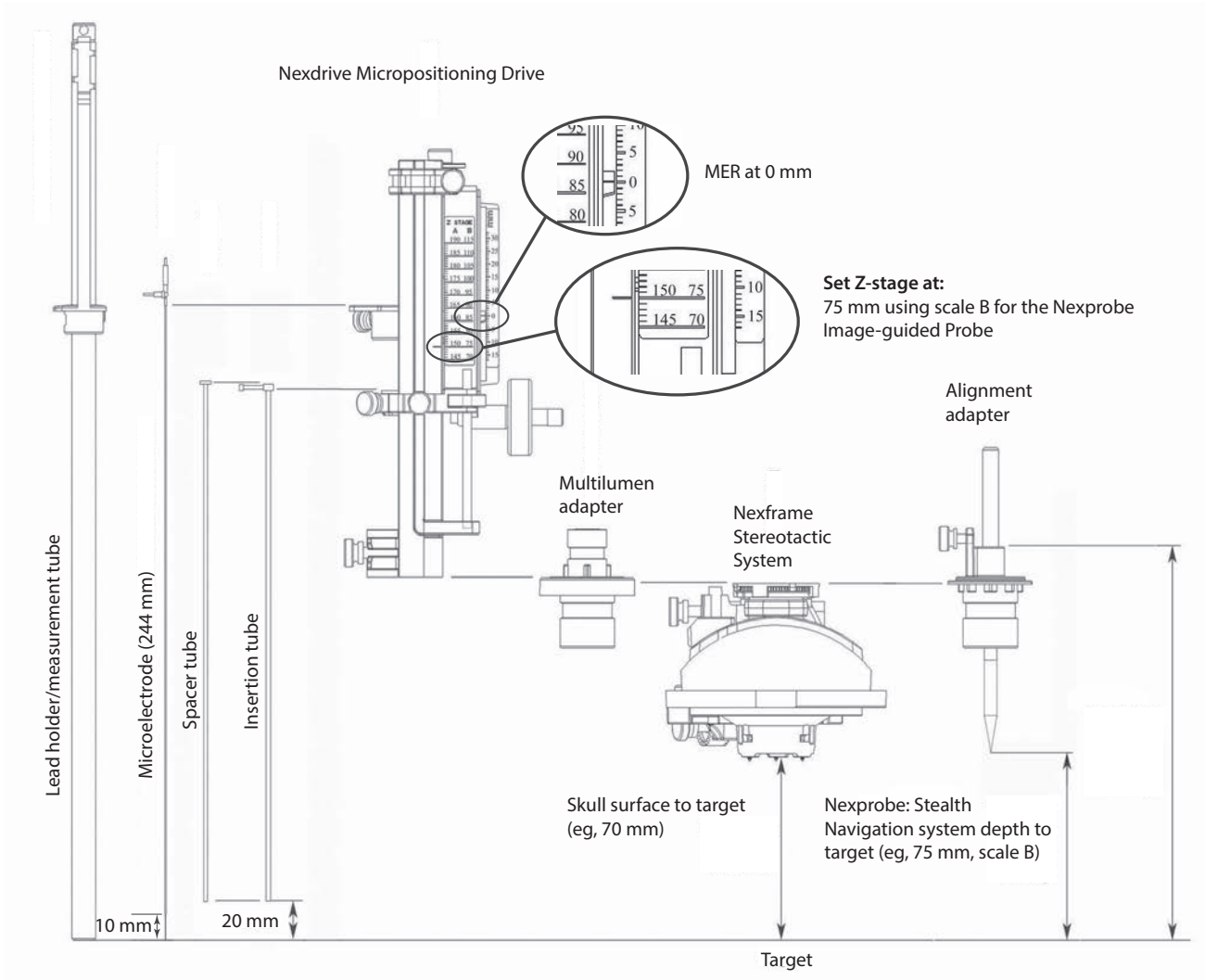


Figure 21. Depth chart for the Nexdrive Micropositioning Drive (all measurements are approximate).

Introducing microelectrodes with the Nexdrive Micropositioning Drive

Note: The Nexdrive Micropositioning Drive shown in the figures in this section are representative of all Nexdrive models.

⚠ **WARNING:** Minimize lateral forces to the Nexframe Stereotactic System and the Nexdrive Micropositioning Drive when the insertion tube is inserted in the brain.

⚠ Cautions:

- The Nexdrive Micropositioning Drive is intended to introduce only one (1) microelectrode at a time.
- Do not bend the microelectrode, insertion tube, the stylet, or the spacer tube. If any microelectrode, tube or stylet is bent, replacement is required.

Notes:

- All models of the Nexdrive Micropositioning Drive allow adjustment for target depths 70–100 mm from the skull surface. Corresponding probe depths are 75–105 mm for the Nexprobe Image-guided Probe.
- The MER collets are color-coded and labeled for identification. Two MER collets are provided: tungsten (white, 0.64-mm diameter) and platinum/iridium (gray, 0.89-mm diameter).

1. Set the Nexdrive Micropositioning Drive to the appropriate Z-depth as determined by the Stealth Navigation system and adjust the MER carriage for the proper approach distance.
2. Attach the drive to the multilumen adapter and tighten the attachment thumbscrew (Figure 22).

⚠ **WARNINGS:**

- The stability of the Nexdrive assembly should be checked prior to continuing. An unstable attachment of the drive may result in inaccurate alignment to target or movement of the surgical instrument.
- Use the Z-stage scale "B" when using the Nexprobe NP-1000 Image-guided Probe. Failure to use the correct scale for the alignment probe will result in depth error.
- Always keep the stylet in place during the insertion of the insertion tube or when the insertion tube is not in use.

⚠ Caution: The Z-stage should be adjusted and secured to the proper target depth prior to attachment of the drive to the Nexframe tower.

- Do not adjust the Z-stage when the drive is attached to the Nexframe tower or when an insertion tube is inserted into the patient.

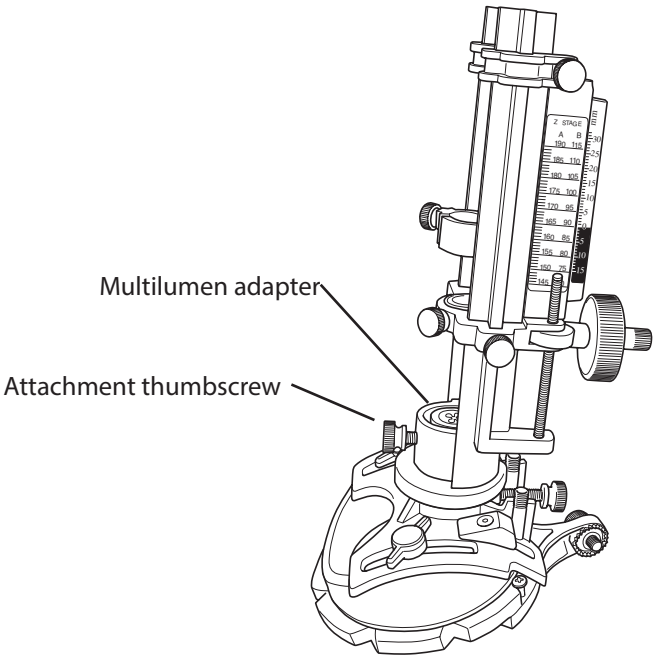


Figure 22. Attach the drive to the multilumen adapter and tighten the attachment thumbscrew.

3. Insert the stylet into the insertion tube. Insert the insertion tube with the stylet into the center lumen of the tube collet down through the corresponding lumen of the multilumen adapter (Figure 23). Secure the insertion tube by tightening the tube collet thumbscrew.

   Note: Brain penetration occurs with this step.

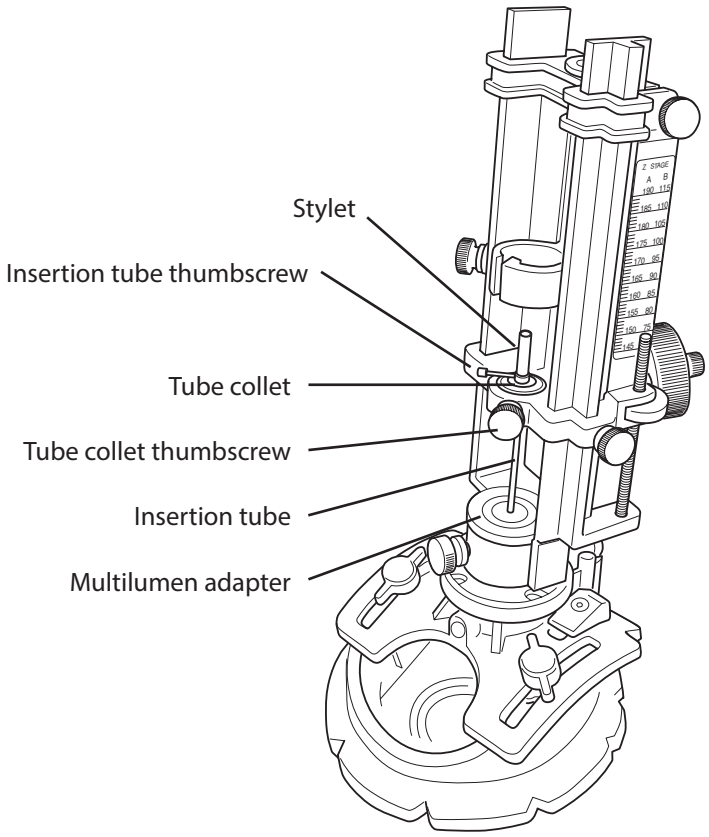


Figure 23. Insert the insertion tube with the stylet into the appropriate lumen of the tube collet and down through the multilumen adapter.

4. Remove the stylet, insert the spacer tube into the insertion tube, and secure with the insertion tube thumbscrew if applicable (Figure 23).

Notes:

- For care and handling of the microelectrode, consult the microelectrode manufacturer's instructions.

⚠ **Caution:** Retract the microelectrode tip prior to handling to prevent damage.

- Zero on the MER scale represents the microelectrode tip at target depth.

⚠ **WARNINGS:**

- The MER collet with the appropriate diameter must be attached to the drive prior to microelectrode insertion and used to retain the microelectrode, otherwise microelectrode depth error will occur.
- Ensure the microelectrode is fully seated in the MER collet prior to securing with the thumbscrew. Failure to seat the microelectrode will result in an inaccurate target location.
- Investigate the cause before proceeding if undue resistance is encountered during microelectrode advancement or retraction.
- Remove the Nexdrive Micropositioning Drive after removing microelectrodes and insertion tubes and verify the alignment of the Nexframe Stereotactic System with the appropriate alignment adapter and Stealth Navigation system, if it is suspected that undue force has been placed on the stereotactic system or the drive. Undue forces on the devices may alter the original target alignment.
- Do not adjust the Z-stage when the Nexdrive Micropositioning Drive is attached to the Nexframe Stereotactic System or when an insertion tube is inserted into the patient. Adjustment of the Z-stage will result in insertion tube advancement or retraction.

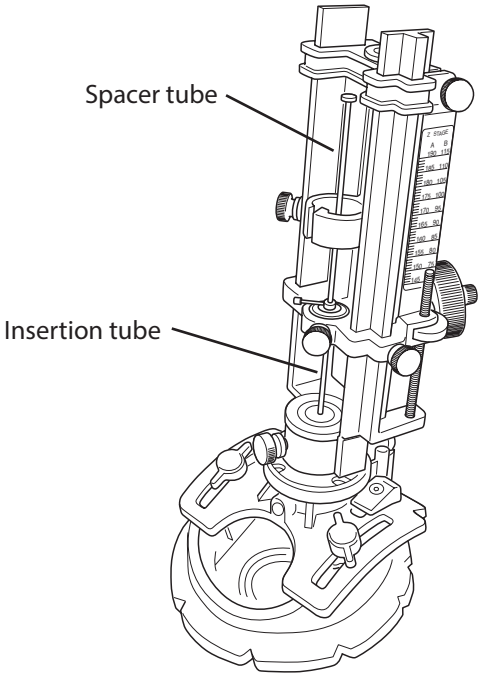


Figure 24. Remove the stylet and insert the spacer tube.

5. Insert the MER collet and insert the microelectrode into the spacer tube until head of microelectrode rests on collet. Extend microelectrode tip, tighten the MER collet thumbscrew (Figure 25).

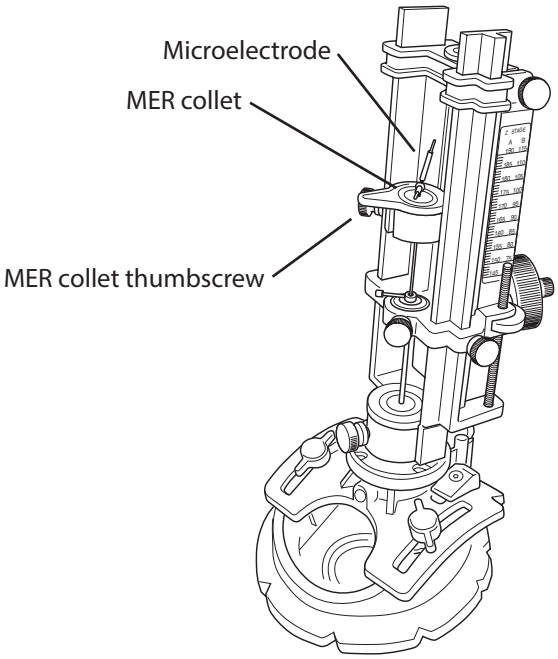


Figure 25. Insert the MER collet and the microelectrode. Tighten the MER collet thumbscrew.

6. Connect the MER equipment and perform MER according to standard practice.
7. Advance or retract the microelectrode by turning the MER knob or by actuating the FHC power assist system as applicable.
8. Adjust MER carriage leaving microeletrode tip at desired target.

Notes:

The MER and index scale are color-coded: blue for above the target and red for below the target.

Three turns of the MER knob correspond to 1 mm of instrument travel for the Nexdrive Models MI-1000 and MI-2000. For additional parallel trajectories:

– For 3-mm offset instructions, see "Optional 3-mm offset chart" on page 21.

Introducing the lead with the Nexdrive Micropositioning Drive

1. Loosen MER Collet thumbscrew. Remove the microelectrode, the MER collet, and the spacer tube.
2. Set the lead length with the measurement tube (ie, set the desired contact for the target) (Figure 26).Tighten Lead Holder thumbscrew.

   Note: The measurement tube is for use with 40-cm leads only.

⚠ **WARNING:** Use care when handling the DBS lead. If damage occurs (eg. breaking, cutting, nicking, flattening, stretching, ect.)
to the lead during the procedure, do not implant the lead. Use a new lead.

⚠ Caution: Ensure the measurement tube is fully seated into the lead holder prior to lead measurement. Failure to fully seat the tube will result in depth error.

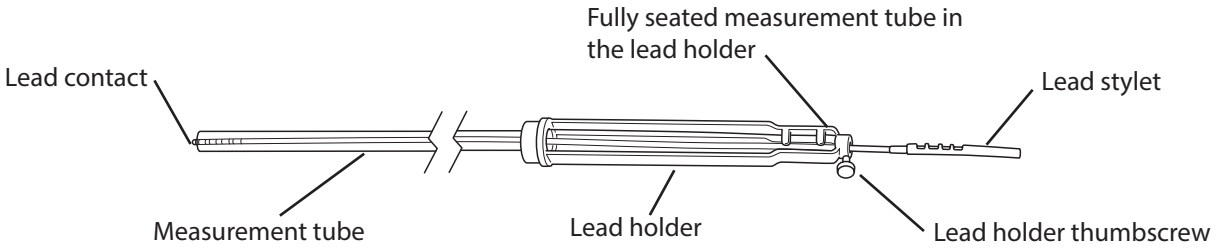


Figure 26. Use the measurement tube to set the lead length.

3. Remove the measurement tube and insert the lead and the lead holder assembly into the drive (Figure 27).

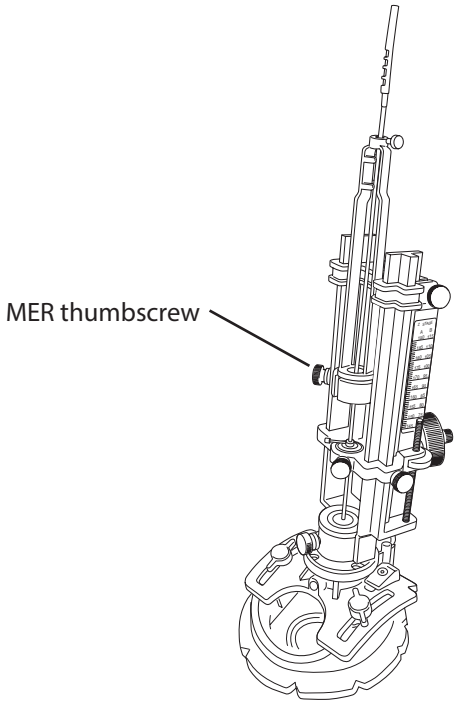


Figure 27. The lead holder and the lead.

4. Insert the lead down into the insertion tube.
5. Secure the lead holder with the MER thumbscrew (Figure 27).
6. Perform test stimulation to confirm the placement of the lead contacts.
7. After the lead is placed and confirmed, proceed to "Instructions for use: Anchoring the lead" on page 22.

Optional 3-mm offset chart

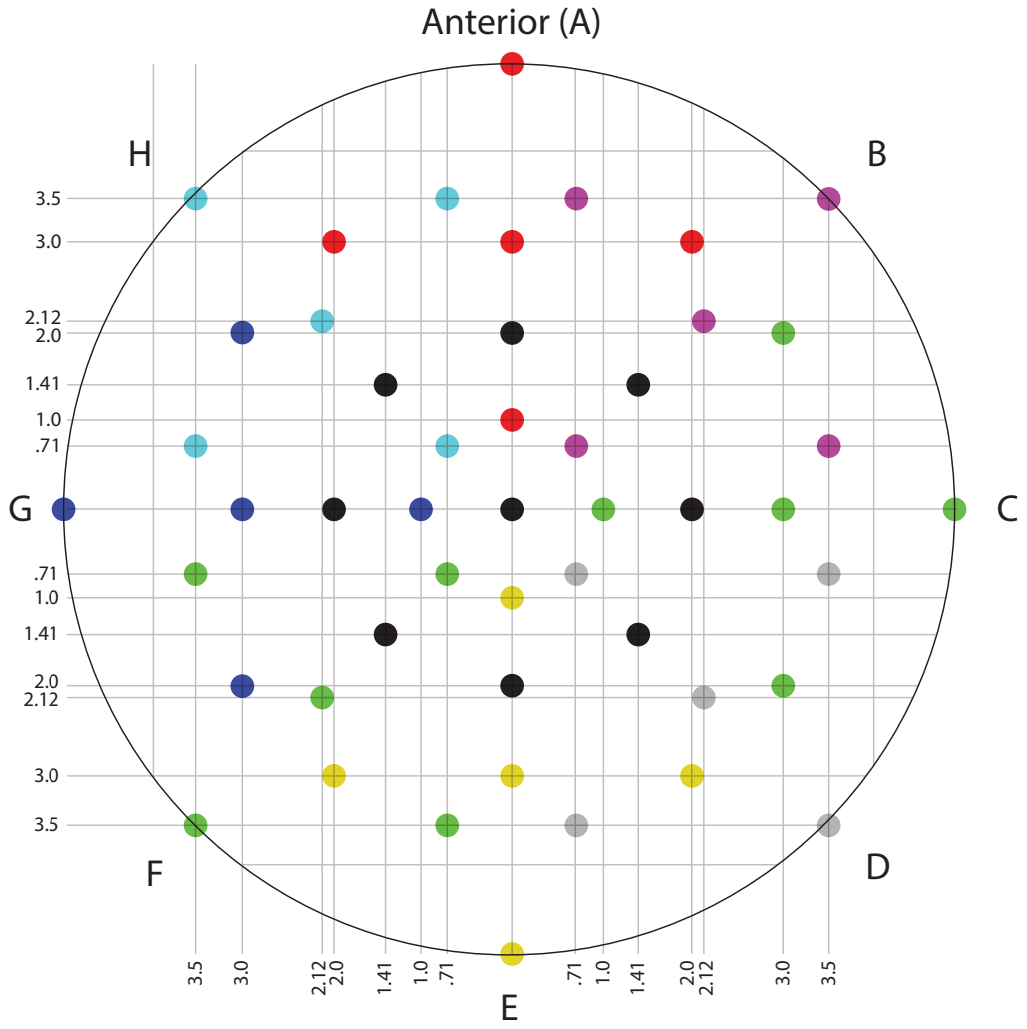


Figure 28. 3-mm offset chart (measurements in mm).

⚠ **Caution:** At extreme angles, outer offset lumens may not be available.

Note: The center lumen of the offset multilumen adapter corresponds to a 3-mm parallel trajectory to the original target trajectory. The parallel lumens of the offset multilumen adapter are spaced at 2 mm.

1. Retract the MER carriage to a depth of zero or to the desired approach distance (ie, 15 mm above the target).
2. Disconnect the microelectrode wires from the MER equipment.

⚠ **Caution:** Retract the microelectrode tip prior to handling to prevent damage.

3. Loosen the MER collet thumbscrew and remove the microelectrode.
4. Remove the MER collet.
5. Loosen insertion tube thumbscrew, remove the spacer tube.
6. Insert the stylet into the insertion tube.
7. Loosen tube collet thumbscrew, remove the stylet and insertion tube assembly.
8. Loosen the attachment thumbscrew or knob and remove the drive from the center multilumen adapter.
9. Loosen the Nexframe socket thumbscrew and remove the center multilumen adapter.
10. Attach the 3-mm offset multilumen adapter to the Nexframe socket in the position for the desired offset.
11. Secure the 3-mm offset multilumen adapter to the Nexframe socket with the socket thumbscrew.
12. Attach the drive to the 3-mm offset multilumen adapter and secure with the attachment thumbscrew or knob.
13. Refer back to the appropriate microelectrode introduction section for reintroduction:
    For the Nexdrive: "Introducing microelectrodes with the Nexdrive Micropositioning Drive" on page 17.

Instructions for use: Anchoring the lead

Note: Refer to the manual for the Stimloc Burr Hole Cover for detailed instructions for anchoring the lead. Use the steps here that refer to the Stimloc Burr Hole Cover as a guide only.

1. Loosen tube collet thumbscrew, retract the insertion tube to expose the lead.
2. Capture the lead with the Stimloc support clip with the appropriate insertion tool (Figure 29).

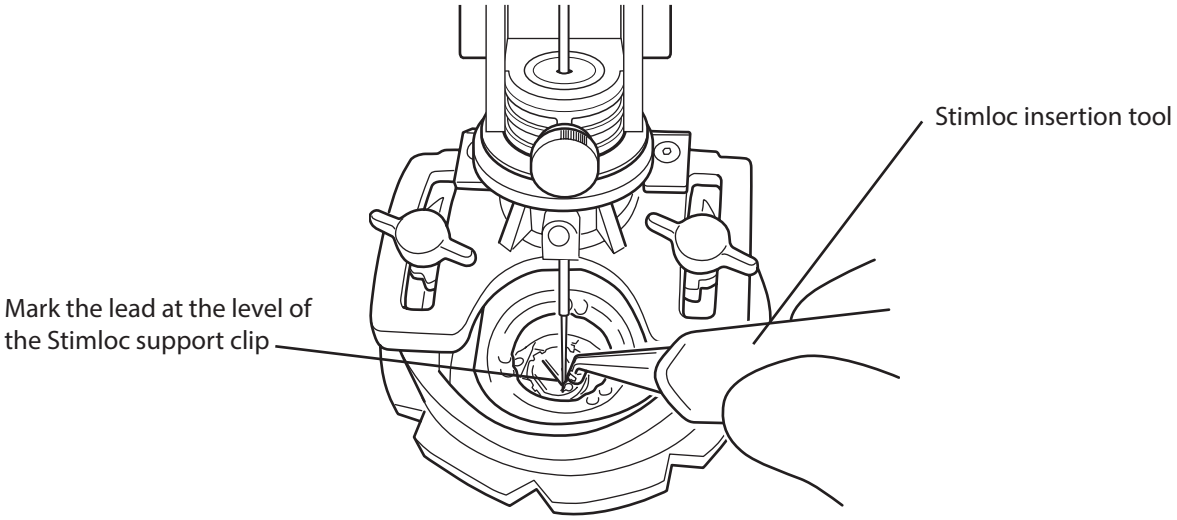


Figure 29. Capture the lead with the Stimloc support clip using the appropriate insertion tool.

3. With a sterile pen, mark the lead at the level of the Stimloc support clip (Figure 29).
4. Remove the lead stylet.
5. Release the lead from the lead holder by loosening the lead holder thumbscrew and remove the lead holder from the drive.
6. Remove the insertion tube.
7. Retract the lead down into the Nexframe assembly.

⚠ **Caution:** It is recommended that the lead is retracted down into the Nexframe assembly before dismantling the Nexframe Stereotactic System to minimize the chance of lead movement.

8. Loosen the attachment thumbscrew or attachment knob and remove the drive.
9. Loosen the tower thumbscrews and remove the socket assembly from the ring assembly.
10. Unscrew the ring attachment screws and remove the ring and reference frame bracket assembly.
11. Route the lead into the Stimloc base exit slot and snap the Stimloc cap onto the base (Figure 30).

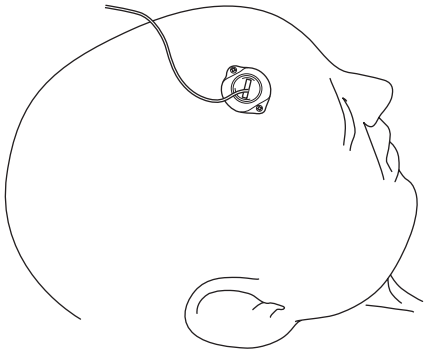


Figure 30. The lead anchored with the Stimloc Burr Hole Cover.

12. Refer to the appropriate neurostimulator manual for instructions to connect the lead to the neurostimulator.

Disposal Instructions

Dispose of all components according to Hospital Protocol.