SMARTFrame Array MRI-Guided Trajectory Frame

INSTRUCTIONS FOR USE

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I. Intended Use

The ClearPoint Array System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. The ClearPoint Array System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion including deep brain stimulation (DBS) lead placement. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR Conditional implants and devices. The user should consult the "Navigational Accuracy" section of the User's Guide to assess if the accuracy of the system is suitable for their needs.

PRECAUTION: The ClearPoint Array System can be used in conjunction with MR Conditional, but not MR Unsafe DBS Leads or DBS Leads for which MR Testing was not performed. Placement of MR Conditional deep brain stimulation (DBS) electrodes using the ClearPoint Array System should be performed in accordance with the instructions for use for such MR Conditional DBS electrodes. The user should carefully review the instructions for use for such MR Conditional DBS electrodes prior to undertaking a procedure with the ClearPoint Array System. Scanning a patient using conditions other than those given in the DBS electrode instructions for use may cause severe injury or death.

Warning: This device is intended for single use only. Contents of unopened, undamaged package are sterile. Do not re-sterilize.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Note: For a complete procedure description, refer to ClearPoint Array User's Guide.

II. Device Description

Package Contents:

NGS-SFA-01-2	**SMARTFrame Array MRI-Guided Trajectory Frame**
	Stereotactic Frame, Targeting Stem, Entry Point Locator, Scalp Mount Base, 4.5mm Center Drill Guide, 4.5mm Offset Drill Guide, 3.4mm Drill Guide Tube, 3.4mm Center Insertion Guide, 3.4mm Offset Insertion Guide, 2.1mm Guide Tube, Dock, 1.7mm Device Lock, 2.1mm Device Lock, Screwdriver, Centering Ring, Roll Lock Screws w/ washer
NGS-SFA-02-2	**SMARTFrame Array MRI-Guided Trajectory Frame – MR Burr Hole Kit**
	Stereotactic Frame (with Targeting Stem), Scalp Mount Base, 3.4mm Center Insertion Guide, 3.4mm Offset Insertion Guide, 2.1mm Guide Tube, Dock, 1.7mm Device Lock, 2.1mm Device Lock, Screwdriver, Centering Ring, Roll Lock Screws w/ washer
NGS-SFA-03-2	**SMARTFrame Array MRI-Guided Trajectory Frame – MR Drilling Kit**
	Stereotactic Frame (with Targeting Stem), Scalp Mount Base, 4.5mm Center Drill Guide, 4.5mm Offset Drill Guide, 3.4mm Drill Guide Tube, 3.4mm Center Insertion Guide, 3.4mm Offset Insertion Guide, 2.1mm Guide Tube, Dock, 1.7mm Device Lock, 2.1mm Device Lock, Screwdriver, Centering Ring, Roll Lock Screws w/ washer

Associated Devices:

NGS-SFA-DG-03	**SmartFrame Array Offset & Center Guides, 5.4mm**
	5.4mm Center Guide, 5.4mm Offset Guide Tube and 5.4mm Depth Stop
NGS-SFA-TE-01	**SMARTFrame Array Thumb Wheel Extension Set**
	SmartFrame Array Thumb Wheel Extension
NGS-SFA-GT-01	**SmartFrame Array Guide Tube Kit**
	1.7mm Guide Tube, 2.5mm Guide Tube and Device Lock, 3.1mm Guide Tube and Device Lock
NGS-AK-01-11	**SMARTFrame Accessory Kit**
	4 Fr Stylet, 4 Fr Lancet, 4 Fr ID Peel-Away Sheath (2), Ruler, Depth Stop (2)

NGS-AK-11-5	**SMARTFrame Accessory Kit — 5 Fr**
	5 Fr Stylet, 5 Fr Lancet, 5 Fr ID Peel-Away Sheath (2), Ruler, Depth Stop (2)
NGS-AK-11-7	**SMARTFrame Accessory Kit — 7 Fr**
	7 Fr Stylet, 7 Fr Lancet, 7 Fr ID Peel-Away Sheath (2), Ruler, Depth Stop (2)
NGS-SG-01-11	**SMARTGrid Planning Grid**
	Marking Grid and Marking Tool
NGS-DB-45	**SMARTTip MRI Drill Kit, 4.5mm**
	4.5mm Drill Bit x 220 mm, 3.4mm x 220 mm Drill Bit, Lancet, Depth Stop, Ruler
NGS-DB-45-S	**SMARTTip MRI Drill Kit, 4.5mm, Short Drill Bits**
	4.5mm Drill Bit x 170 mm, 3.4mm x 170 mm Drill Bit, Lancet, Depth Stop, Ruler
NGS-HD-01	**SMARTTwist MRI Hand Drill**
	Hand Drill
NGS-PD-02-L	**MR Neuro Procedure Drape Tapered - Long**
	MR Neuro Procedure Drape Tapered, Marker Pen
NGS-PD-03-L	**MR Neuro Procedure Drape Tapered w/ Extension - Long**
	MR Neuro Procedure Drape Tapered w/ Extension, Marker Pen
NGS-PD-04	**MR Neuro Scanner Bore Drape w/ Extension**
	MR Neuro Scanner Bore Drape w/ Extension
NGS-PD-05	**MR Neuro Patient Drape**
	MR Neuro Patient Drape, Marker Pen, Cable Cover
NGS-RS-02	**SMARTFrame Scalp Mount Rescue Screw – Long**
	Long Scalp Mount Rescue Bone Screws (3)
NGS-RS-03	**SMARTFrame Scalp Mount Rescue Screw – Short**
	Short Scalp Mount Rescue Bone Screws (3)
NGS-BM-05	**SMARTFrame Fiducial**
	Fiducials (5)
NGS-CG-01	**Wharen Centering Guide**
	Wharen Centering Guide

Caution: If using devices other than those provided by ClearPoint Neuro, verify the devices fit in the Device Lock, Guide Tube, and all Guides, and follow the manufacturer's recommendations regarding MRI Compatibility prior to use.

The SMARTFrame Array Scalp Mount Base, used to attach to the patient's head, is completely made of plastic, except for the bone screws and stand-off pins which are both made of Titanium. The SMARTFrame Array tower, also completely made of plastic, (**see Figure 1)** attaches to the Base and together is designed to provide multi-directional orientation adjustments in the Operating Room using the Probe Adapter, with Surgical Navigation System (SNS) probes or universal trackers. The Probe Adapter includes a Titanium Tracker Rod that can be used to attach a SNS universal tracker. The SMARTFrame Array tower also provides orientation adjustments in the MRI Scanner using the Targeting Stem. The Targeting Stem has a fluid-filled column that is MRI visible. The SMARTFrame Array tower, when attached to the Scalp Mount Base, provides adjustments in the roll and pitch directions by turning the appropriate thumb wheels. It also offers six discrete offset positions in the X-Y direction. Once aligned, the Targeting Stem is replaced with the Center or Offset Guides and Guide Tubes for insertion of different sized instruments. **See Figure 2.**
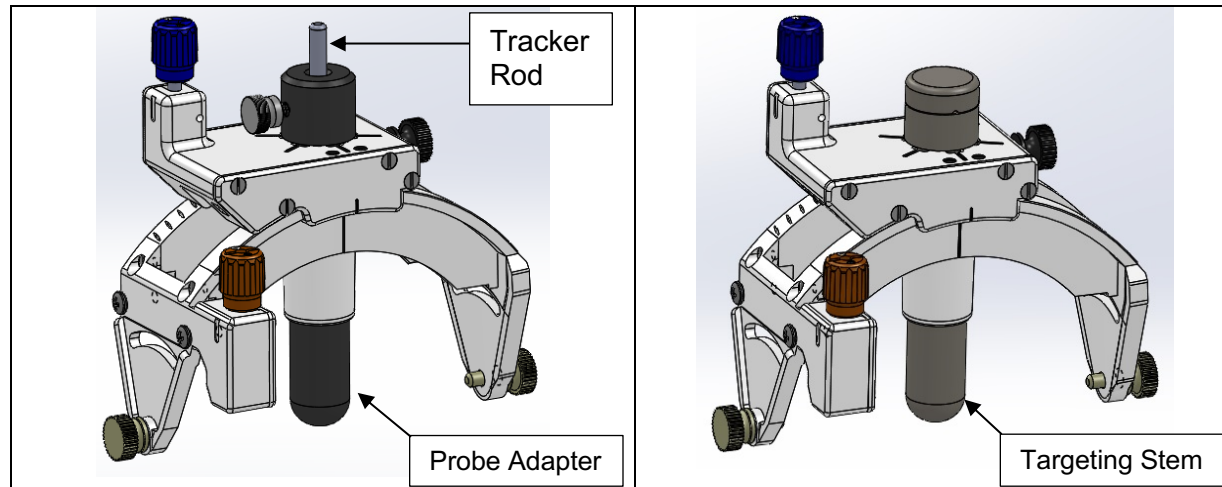
Tracker Rod

Probe Adapter

Targeting Stem

Figure 1: SMARTFrame Array Tower with Probe Adapter (Left) and Targeting Stem (Right)

Discrete Offset Position Markers

Probe Adapter/ Targeting Stem/ Center or Offset Guide Locking Thumb Screw
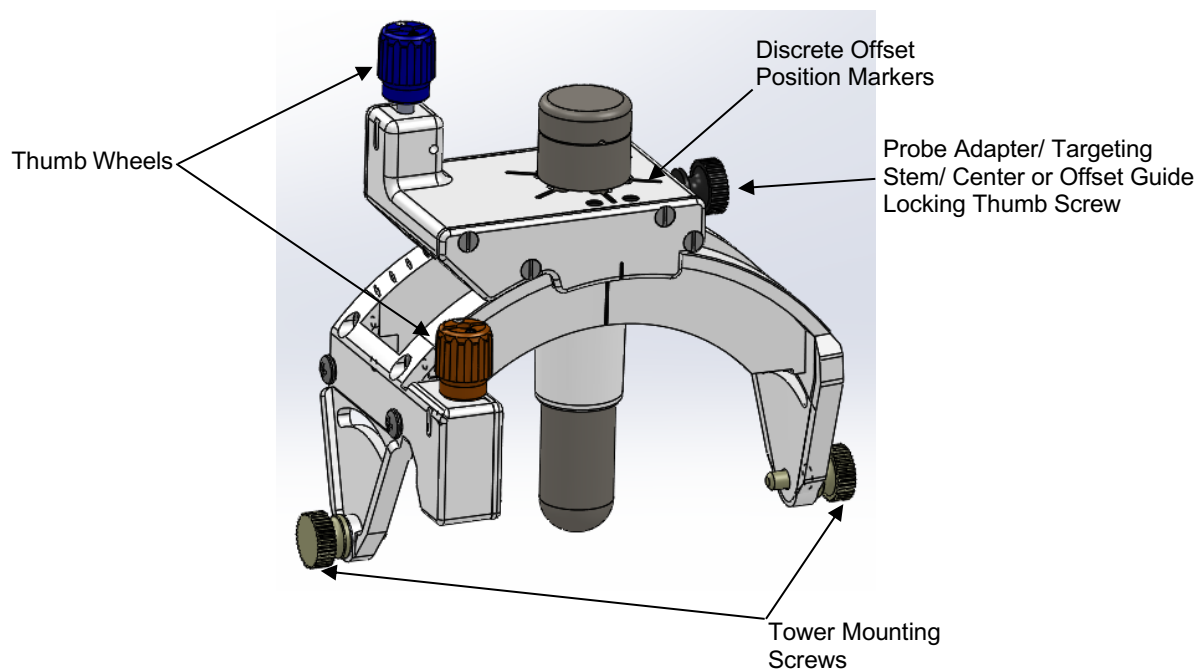
Thumb Wheels

Tower Mounting Screws

Figure 2: SMARTFrame Array Tower Components

The adjustments can be made by directly turning the thumb wheels or by using the ClearPoint Neuro Thumb Wheel Extension Set. The Thumb Wheel Extension Set is an approximately 60 cm long accessory that can be attached to the SMARTFrame Array and utilized to rotate the thumb wheels while the patient is inside the MR scanner bore.

Pre-alignment is defined as performing an initial alignment to trajectory using a surgical navigation system (SNS) or using the SMARTFrame Array prior to performing a final alignment using real-time MR imaging. Real-time MR imaging is used to verify the final trajectory, align the SMARTFrame Array to it, and then insert the desired device. Pre-alignment using an SNS is not intended to provide accurate stereotactic placement. The final alignment and insertion must be performed using real-time MR images.

Warning: ALWAYS perform confirmation of the entry point and trajectory using real-time MRI scans with ClearPoint Array software prior to inserting a device in the brain. Pre-alignment performed with a Surgical Navigation System is not intended to provide accurate stereotactic placement.

III. General Warnings and Precautions

Caution:	The device is intended for single–use-only and is provided sterile. Do not re-sterilize.
Warning:	Structures greater than 125 mm from the entry point should not be targeted, as placement accuracy beyond 125 mm has not been validated.
Warning:	Do not use the ClearPoint System with instruments longer than 30 cm as the accuracy of the system has not been verified with instruments greater than this length.
Warning:	Do not attach the Scalp Mount Base Assembly to damaged or diseased bone. Only attach to stable bone to ensure a solid platform.
Warning:	Before using the System on patients under the age of 16 years, measure the skull thickness on a CT scan to ensure that the system can be secured safely onto the skull.
Warning:	When used with pediatric patients with open cranial sutures, take precautions to avoid placement that may result in placement of a screw into a cranial suture.
Warning:	Verify scanner is within calibration prior to scanning. Performing procedures in an uncalibrated scanner may result in unreliable planned trajectories and navigation instructions, leading to possible patient injury.
Warning:	Do not use a broken ClearPoint Neuro Stylet or Lancet.
Warning:	All tools and ancillary equipment and devices must be MR compatible when performing scanning. When labeling is unclear, assume the device is not compatible. Always follow the manufacturer's instructions.
Warning:	Prior to or after opening the SMARTFrame Array package, verify there is no leakage (fluid) visible on the Tower, or packaging. Do not use any device if leakage is identified.
Warning:	There are no known and reliable means of cleaning, disinfecting, repairing, and sterilizing these devices that returns them to original specifications and renders them safe and effective for reuse.
Warning:	ALWAYS perform confirmation of the trajectory using real-time MRI scans with ClearPoint Array software prior to inserting a device in the brain**.**
Caution:	It is recommended that additional sterile products be available for use.
Caution:	The planned trajectory must allow for a 30 cm long device to be placed into the top of the assembled SMARTFrame Array without interfering with the bore of the MRI machine.
Caution:	This device is to be used only by physicians trained by ClearPoint Neuro personnel.
Caution:	When performing a burr hole procedure, A 14 mm burr hole is required for the ClearPoint Neuro SMARTFrame Array System for optimum range of motion for trajectory acquisition.
Caution:	Do not place the Scalp Mount Base Assembly bone attachment screws in the cranial suture area.
Caution:	The compatibility of neurological instruments and devices should be evaluated before use with the ClearPoint Neuro SMARTFrame Array System.
Caution:	Never advance the ClearPoint Neuro Peel-Away Sheath into the brain without the supporting ClearPoint Neuro Stylet.
Caution:	Do not apply more than 0.5 lb$_f$ to the device or any component while using the SMARTFrame Array System. Examples are force against the SMARTFrame Array when attached to the patient or the force to insert the Stylet or Lancet into the Peel-Away Sheath.
Caution:	Orient the SMARTFrame Array on the patient's skull in such a manner as to prevent interference of the Thumb Wheel Extension Set with the bore of the scanner.
Caution:	Use extreme caution when moving the scanner bore over the patient.
Caution:	When used in an IMRIS suite, confirm that the Thumb Wheel Extension Sets have clearance and that the Head Coil cable is clear so that the IMRIS scanner can move freely without injuring the patient, damaging the Head Coil cable, or breaching the sterile field created by the Bore and Patient Drapes.
Caution:	Do not over-torque the Bone Screws. Over-torquing the Bone Screws may lead to screw breakages.
Caution:	If using a Power Driver with an adjustable speed setting to secure the SmartFrame Base Bone Screws, use low speed settings to avoid breaking the Bone Screws.
Caution:	It is not recommended to use a Power Driver to deploy the Standoff Pins. Using a Power Driver may result in over-deploying the pins, which may dislodge or warp the Scalp Mount Base.
Note:	Any serious incident that has occurred in relation to the device shall be reported to ClearPoint Neuro.
Note:	Safe disposal of the device: The device shall be treated as biohazardous materials and shall be disposed of accordingly per hospital policy.

General Precautions

- Handle all components using standard hospital sterile practices.

- Do not bend or kink the ClearPoint Neuro Peel-Away Sheath.

- Handle the ClearPoint Neuro Stylet and Lancet carefully to avoid breaking.

- Minimize any forces applied directly to the SMARTFrame Array.

- The following disposable components are MR Conditional: the SmartGrid, the Scalp Mount Base, the SMARTFrame Array, and the SMARTFrame Array Thumb Wheel Extension Set.

1.5T & 3T Environment Compatibility:

Non-clinical testing has demonstrated the ClearPoint Array System is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla

- Spatial gradient field of 5000 Gauss/cm

- Maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning.

In non-clinical testing, the ClearPoint Array System produced a temperature rise of less than 1°C at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR scanning in a 1.5T GE Signa MR scanner with Excite ver. 11.0 software and in a 3T Siemens Magnetom Trio MR scanner with ver. VB17 software.

IV.   Use Instructions

A.   Preparation

The SMARTFrame Array is packaged with a double sterile barrier: a tray with a sealed Tyvek lid is placed inside a sealed mylar/Tyvek pouch. Each SMARTFrame Array package contains the devices necessary for a uni-lateral procedure. A bi-lateral procedure will require opening two (2) SMARTFrame Array packages.

Warning: Do not use the SMARTFrame Array or any of the components if the packaging is damaged.

If performing pre-alignment by starting the procedure in the Operating Room, proceed to Section B and use the Entry Point Locator with the Scalp Mount Base.

If starting the procedure in the MRI Room, proceed to Section C and use the SmartGrid to find the entry point.

B.   Using the Entry Point Locator in the Operating Room

This is a pre-alignment workflow. It may be used when it is desired to obtain an approximate alignment using a Surgical Navigation System prior to performing final alignment and device placement in the MR Scanner using real-time MR Images.

Warning: ALWAYS perform confirmation of the entry point and trajectory using real-time MRI scans with ClearPoint Array software prior to inserting a device in the brain. Pre-alignment performed with a Surgical Navigation System is not intended to provide accurate stereotactic placement.

1.   Attach a Surgical Navigation System (SNS) Universal Tracker to the Tracker Rod. Calibrate the Rod-and-Tracker with the SNS per the system's instructions. Alternatively, a Surgical Navigation System Probe may be used with the Entry Point Locator.

Caution: The Entry Point Locator has an inner diameter of 4.1 mm (0.160"). If using an SNS Probe, verify the Probe has a good fit inside the Entry Point Locator. If the Probe is too loose, it may result in excessive error during Entry Point location and preliminary alignment.

2.   Remove the Entry Point Locator from the SMARTFrame Array Kit Tray and assemble it to the Scalp Mount Base as shown in **Figure 3**.
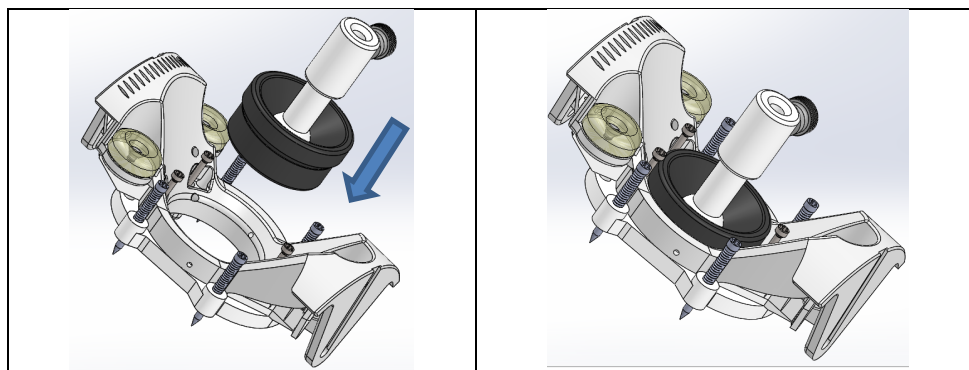

Figure 3: Scalp Mount Base with Entry Point Locator

3. Insert the calibrated Tracker Rod with the Universal Tracker into the Entry Point Locator and tighten the Entry Point Locator thumb screw (**Figure 4, Left**). Alternatively, insert the Surgical Navigation System Probe into the Entry Point Locator (**Figure 4, Right**).
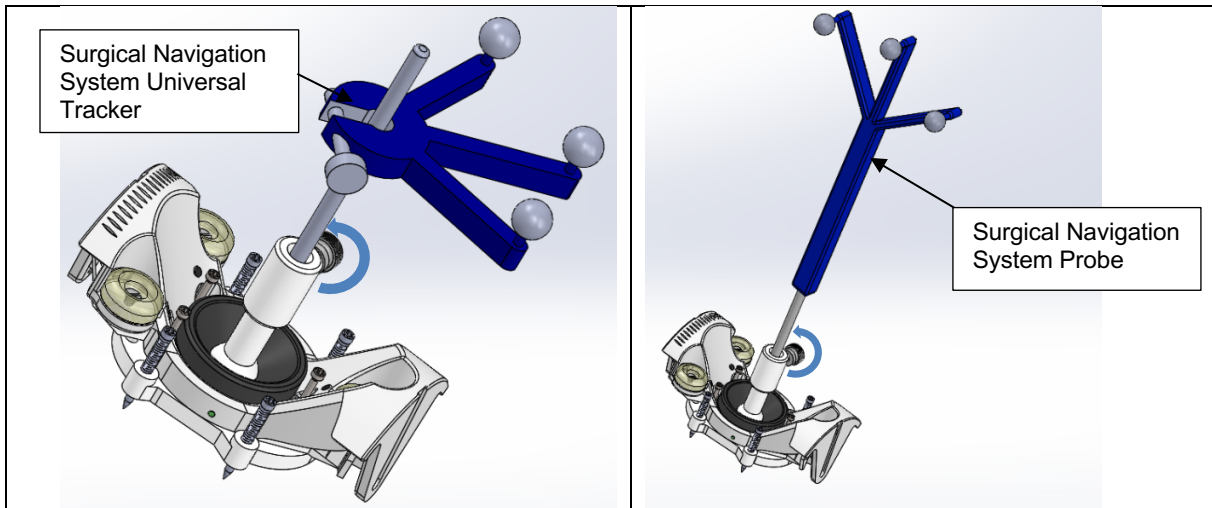

Surgical Navigation System Universal Tracker

Surgical Navigation System Probe

Figure 4: Entry Point Locator with SNS Universal Tracker (Left) and with SNS Probe (Right)

4. Move the Base with the Entry Point Locator and Tracker over the patient's head until the Rod aligns with the desired entry point as displayed on the Surgical Navigation System.

    Caution: The pin tips are sharp and may scratch the patient's head if they contact the patient's head while the Base is moved into position. Exercise care in moving the Base over the patient's head.

5. The Entry Point Locator can be pivoted like a joystick while aligning the Base with the Entry Point.

6. Place the Base on the patient's head and Mount the Scalp Mount Base.

7. Begin securing the Bone Screws to the skull through the scalp. Refer to **Section D** for detailed instructions for securing the Scalp Mount Base to the Skull. The Entry Point Locator stem may be moved out of the way for easier access to the screws. **See Figure 5.**

8. Once the Base is securely mounted, proceed to **Section E**.
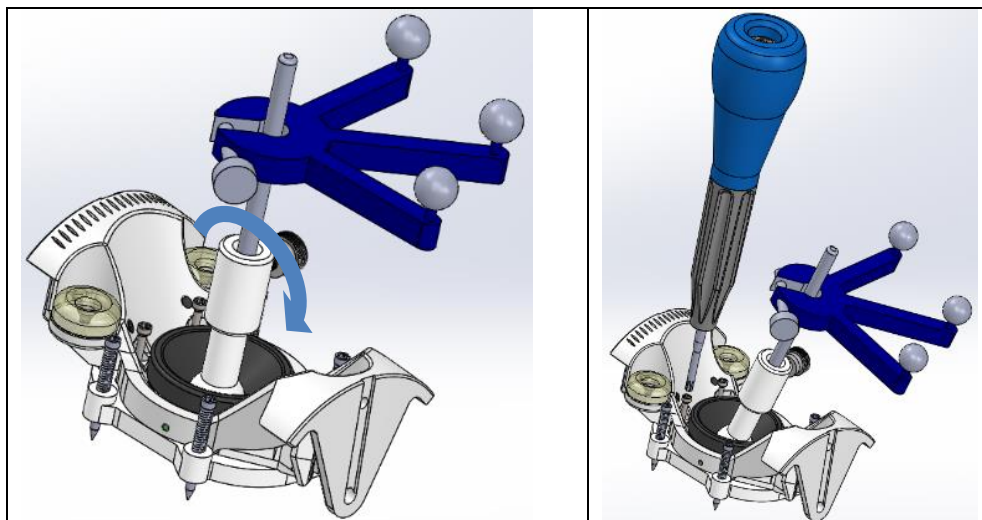
Figure 5: Entry Point Locator Stem being pivoted to make access to screws easier. Universal tracker is shown, but Probe may also be used.

C.   Using the SmartGrid in the MRI to find the Entry Point

1. The Patient's head shall be prepared just prior to surgery by either shaving the entire head and applying incise tape or by shaving the area that will be covered with the Marking Grids and the area around them.

2. The patient's head is positioned outside the scanner at the head end of the scanner.

3. Position and secure the patient in an appropriate head fixation frame to immobilize the patient's head and select an appropriate imaging coil(s) to achieve desired image quality and provide access to the procedure site.

   Caution: The patient's head must remain immobile throughout the procedure.

4. Install ClearPoint Neuro MR Neuro Procedure Drape following the Instructions for Use (IFU).

   Caution: Examine the SmartGrid packaging for any damage or leaks. Verify there is no leakage (fluid) visible on the SmartGrid or its packaging. Do not use the SmartGrid if leakage is identified.

5. Determine and mark the location for burr-hole following the SmartGrid IFU.

6. If identifying points on the scalp with an Fiducial is desired, follow the SMARTFrame Fiducial IFU.

7. The Wharen Centering Guide may also be used to mark the entry point. Follow the Wharen Centering Guide IFU if that method is desired.

8. Once the entry point is identified and the SmartGrid is removed, attach the SMARTFrame Array Scalp Mount Base to the skull.

9. **See Section D for detailed instructions on securing the Base to the patient's skull**.

10. Once the Base(s) are securely attached to the skull, the SMARTFrame Array Tower is ready to be mounted.

11. **See Section E for detailed instructions on attaching the SMARTFrame Array Tower to the Base**. Once the Tower is attached, proceed to **Section G**.

D.   Mounting the Scalp Mount Base

1. This section provides instructions for securing the Scalp Mount Base to the patient's skull. This procedure may be performed in either the Operating Room or in the MRI Scanner. The method of securing the Scalp Mount Base to the skull is identical in either workflow.

2. The Scalp Mount Base has three inner screws and four support pins. The support pins have sharp tips. **See Figure 6**. They have small protective tubes covering them. Remove the tubes before proceeding.
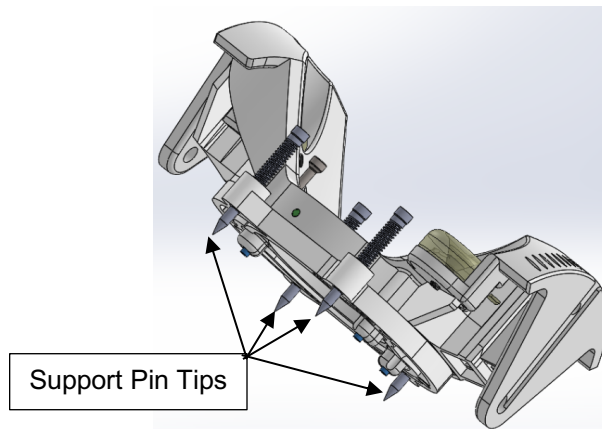

Support Pin Tips

Figure 6: SMARTFrame Array Scalp Mount Base

Note: The Scalp Mount Base is intended for use with a maximum scalp thickness of 9 mm using the pre-loaded screws, and 11 mm using the Long Rescue Screws. Usage with thicker scalps may prevent the Scalp Mount Base from being stabilized properly.

Note: In order to use the Scalp Mount Base for scalp thicknesses from 9 to 11 mm, ensure that only Long Rescue Screws are used.

3. The Scalp Mount Base has four adjustable height support pins and three self-tapping bone screws. **See Figure 7**.
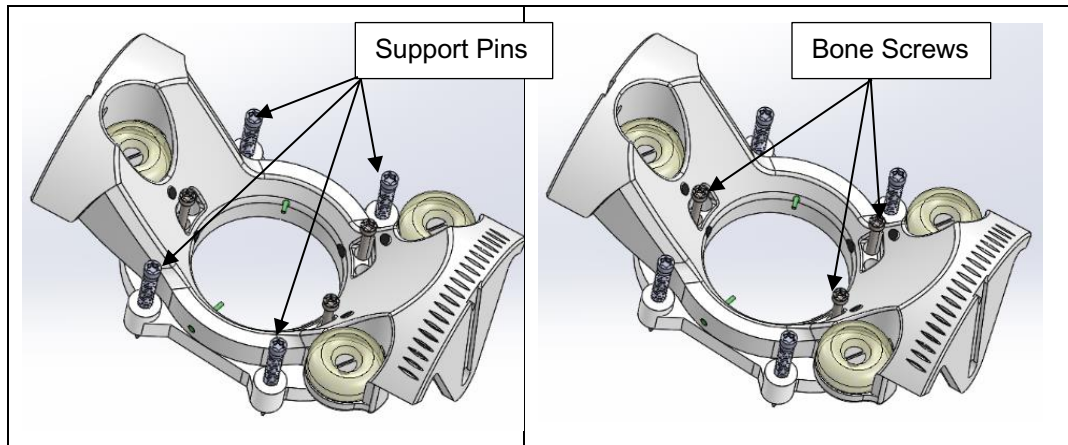
Figure 7: SMARTFrame Array Scalp Mount Base

Note: In the event a replacement screw is required for securing the Scalp Mount Base, additional Scalp Mount Screws (3) can be provided. See "Associated Devices" in Section II for ordering information on Rescue Screws.

Note: A second set of screw mounting holes are located in the Scalp Mount Base adjacent to the preloaded screw holes.

Note: Ensure the Scalp Mount Base orientation matches the orientation displayed in the ClearPoint Array Software.

Caution: Only ClearPoint Neuro-provided screws should be used for securing the Scalp Mount Base.

4. Mount the Scalp Mount Base with the three (3) pre-mounted self-tapping screws to the skull. A manual screwdriver is supplied in the kit. While screwing in the bone screws, check the security of the Base repeatedly and check that the Base can lift off the scalp as it becomes secure in the skull.

    Caution: Do not over-torque the Bone Screws. Over-torquing the Bone Screws may lead to screw breakages.

    Note: The Screws used in the Base include a T8 Torx driver geometry for driving the screws.

5. Once the bone screws are secure in the skull, deploy the four support pins by screwing them down. The support pins will penetrate the scalp and will stop against the skull. The further they are deployed down, the more the Base will rise away from the scalp.

    Caution: It is not recommended to use a Power Driver to deploy the Standoff Pins. Using a Power Driver may result in over-deploying the pins, which may dislodge or warp the Base.

6. Repeatedly check the security of the Base during this operation. Once the Base is secure, proceed to the next step. Check that the Scalp Mount Base is secure and does not move. Confirm by feeling and observing for any movement while attempting to impart a rocking motion to the Scalp Mount Base after mounting to the skull.

7. Once the Base(s) are securely attached to the skull, the SMARTFrame Array tower is ready to be mounted.

E.   Attaching the SMARTFrame Array Tower to the Base

This section provides instructions for attaching the SMARTFrame Array tower to the Base. This part of the procedure may be performed in the Operating Room or in the MRI Scanner. The method of attaching the Tower to the Base is identical for either workflow.

1. Orient the Tower, relative to the Base, by placing the thumb wheels of the Tower toward the two fiducial marker side of the Base. Mount the Tower onto the Base by first loosening then grasping the Tower Mounting Screws.

2. Grasp the Tower by the top rectangular gear housing. Align each screw with the mating grooves on the Base. **See Figure 8.** Slide the Tower into place and ensure screws seat into the mounting holes on the Base. Tighten the Tower side thumb screw to secure the Probe Adapter inside the tower.

    Caution: Avoid applying pressure to the Tower Thumb Wheels while grasping the Tower.

3. Tighten the two Tower Mounting Screws and confirm that the screws are completely seated with the Base.
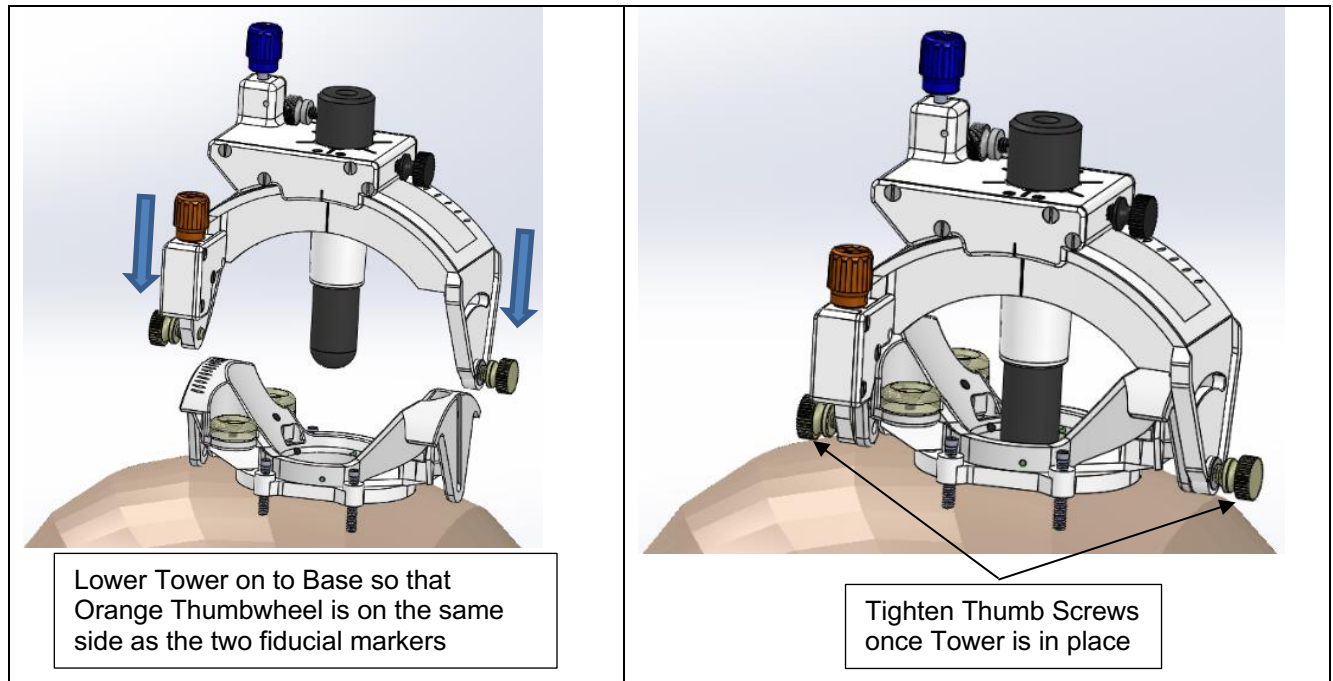
Lower Tower on to Base so that Orange Thumbwheel is on the same side as the two fiducial markers

Tighten Thumb Screws once Tower is in place

Figure 8: Assembling the Tower to the Base

Warning: The stability of the SMARTFrame Array should be checked prior to continuing. An unstable attachment of the SMARTFrame Array may result in an incorrect alignment to target or movement of the inserted device.

Caution: The Tower will mount securely to the Base. If the Tower moves relative to the Base, it is not mounted correctly.

4. Remove the two Roll Lock Screws w/ washer from the SMARTFrame Array package to pre-mount in SMARTFrame Array. Screw in partially to the appropriate location on the SMARTFrame Array. **See Figure 9.** Ensure the Roll Lock Screws with washer are not tight. These screws will be tightened later in the procedure.

Roll Lock Screw inserted but not tightened

Roll Lock Screw inserted but not tightened
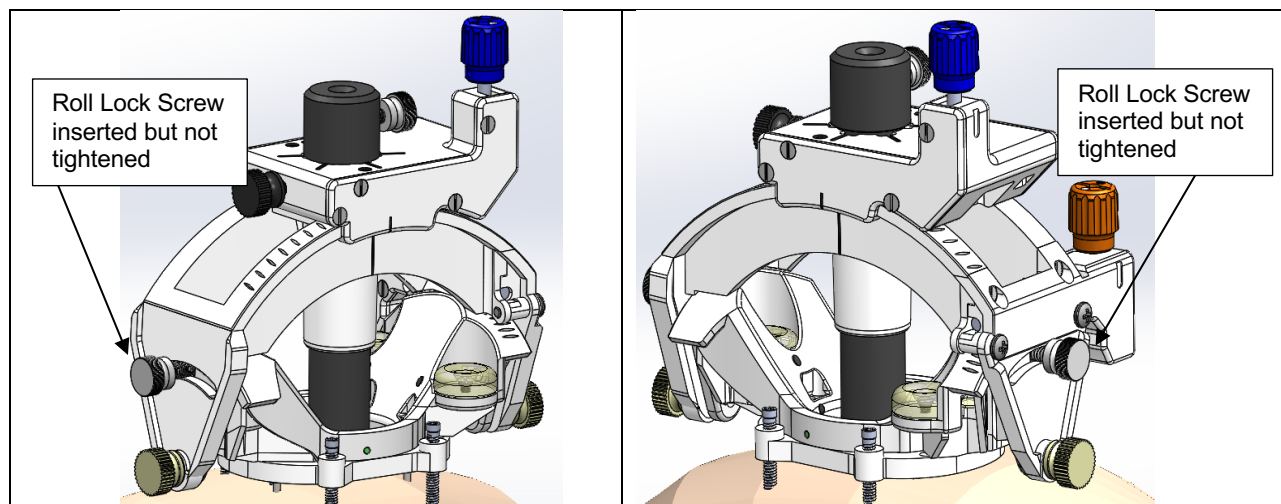
Figure 9: Roll lock screws inserted into SMARTFrame but not tightened

Caution: The Roll Lock Screw w/ washer should not be tightened until final positioning is selected. If the Roll Lock Screw w/ washer is tight during roll adjustments, adjustments will be affected and may result in inappropriate alignment.

F. Align the Tower to the Desired Trajectory

This is a pre-alignment workflow. It may be used when it is desired to obtain an approximate alignment using a Surgical Navigation System prior to performing final alignment and device placement in the MR Scanner using real-time MR Images.

Warning: ALWAYS perform confirmation of the entry point and trajectory using real-time MRI scans with ClearPoint Array software prior to inserting a device in the brain. Pre-alignment performed with a Surgical Navigation System is not intended to provide accurate stereotactic placement.

1. Once the Base is securely mounted, adjust the Entry Point Locator Stem by pivoting it so that the SNS Probe or Universal Tracker Rod aligns with the desired trajectory. This provides confirmation that the Base position is adequate to reach the trajectory.

Note: **If the Base position is not adequate, retract the support pins and untighten the screws. Lift the Base off the patient's head. Then, repeat steps in Section D.**

2. After confirming that the desired alignment to trajectory can be obtained, remove the Entry Point Locator from the Base by pulling it out. **See Figure 10**.
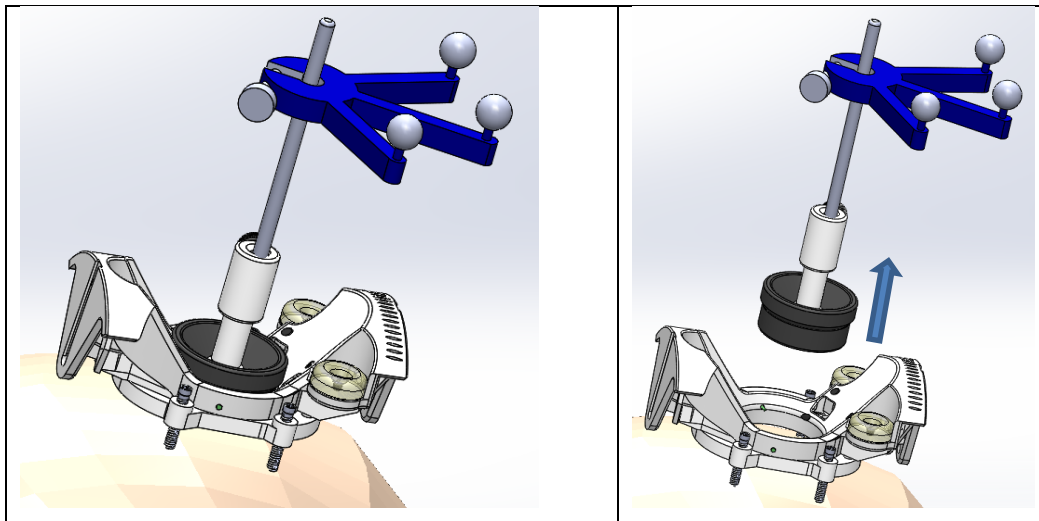
Figure 10: Entry Point Locator is removed by pulling it out of the Base

3. Attach the SMARTFrame Array tower to the Base. **See Section E for detailed instructions on attaching the Tower to the Base**.

4. Once the Tower is secured on the Base, insert the Universal Tracker Rod or SNS Probe into the Tower Probe Adapter, and secure it with the Thumbscrew. The Rod or Probe may be placed at any vertical position inside the Probe Adapter. **See Figure 11.**
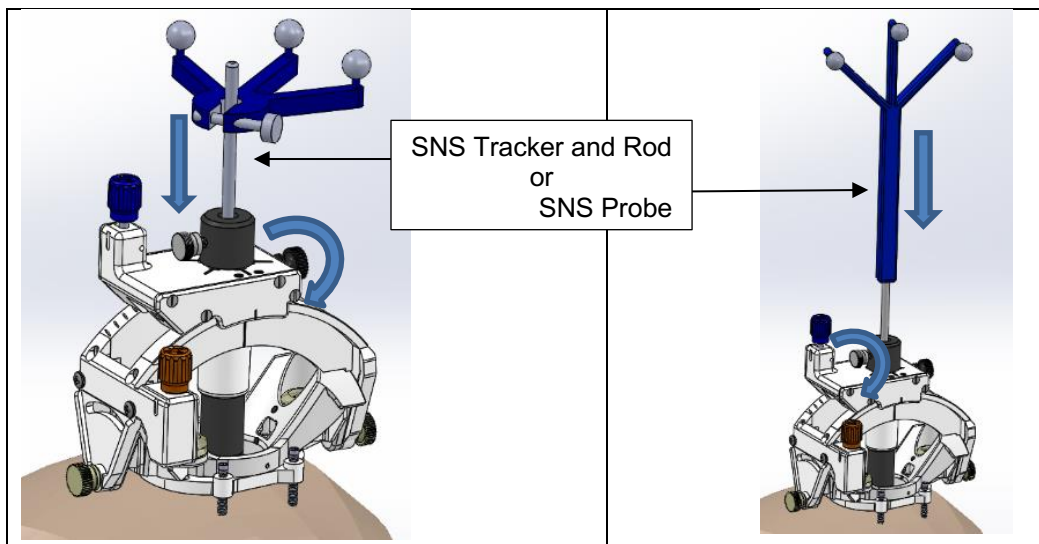
Figure 11: SMARTFrame Array with SNS Universal Tracker or SNS Probe inserted into the Tower Probe Adatper

5. Once the SNS Universal Tracker or SNS Probe is secured in the Tower, the blue (pitch) and orange (roll) thumbwheels on the Tower may be used to align the Rod or Probe to the desired trajectory.

   Note: **Refer to the neuronavigational system manufacturer's Instructions for Use for tracking the orientation of calibrated instruments. A trajectory-view on the image-guided neuronavigational system is recommended for trajectory alignment.**

6. After aligning to the desired trajectory, remove the SNS Universal Tracker or SNS Probe by loosening the Probe Adapter Thumbscrew and pulling the Universal Tracker or Probe out of the Adapter.

7. If desired, the access hole may be created. The SMARTFrame Array center drill guide may be used to assist in drilling the access hole. **If the access hole is not going to be created at this time, skip to Step 14**.

8. Tighten the two Roll Lock Screws fully. **See Figure 12**.
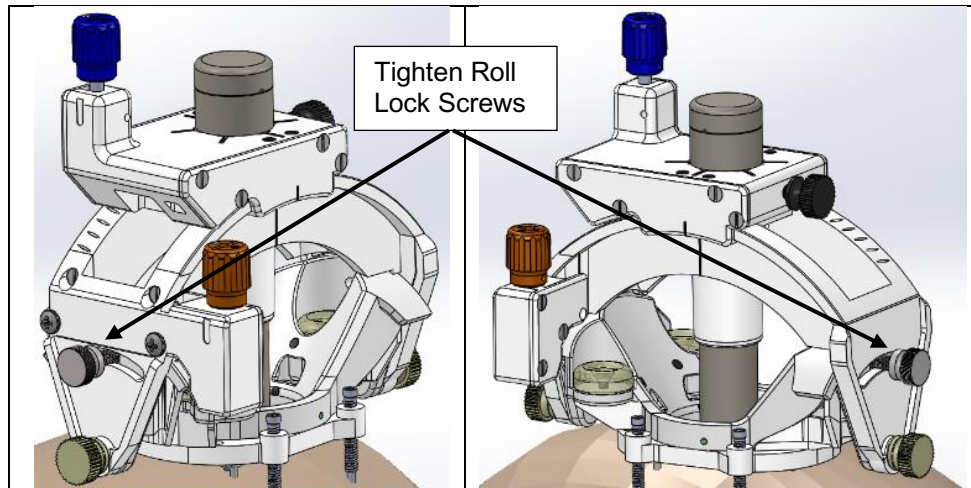
Figure 12: Roll Lock Screws tightened onto SMARTFrame Array Tower

9. Remove the SNS Probe Adapter from the Tower by loosening the Tower side thumb screw and pulling the Probe Adapter out of the Tower. **See Figure 13**.

10. If creating the access hole in the Operating Room, insert the Center Drill Guide (**see Figure 15**), which is colored black and has a hole through its center with a slotted feature on the top surface. **See Figure 14 (Left)**. **DO NOT use the Offset Drill Guide at this time.** The Offset Drill Guide has a tab with a white line and a hole that is not centered within the Guide. **See Figure 14 (Right)**.

   Caution: **The Drill Guides and Drill Guide Tubes are compatible with ClearPoint Neuro's MRI Drill Bits. If using non-ClearPoint Neuro drill bits, verify MR safety and fit with the Drill Guides prior to use**.

   Note: **If creating the access hole in the OR, always use the Center Drill Guide, since all alignment was performed with the center position**
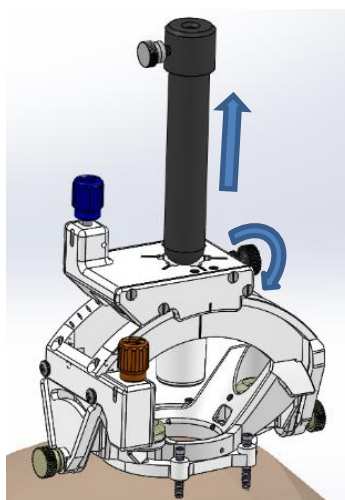
Figure 13: Removing the Optical Probe Adapter from the SMARTFrame Array Tower

Center Drill Guide. Hole is centered in the guide.

Offset Drill Guide. Hole is offset from the center, and guide has a tab with a white line.
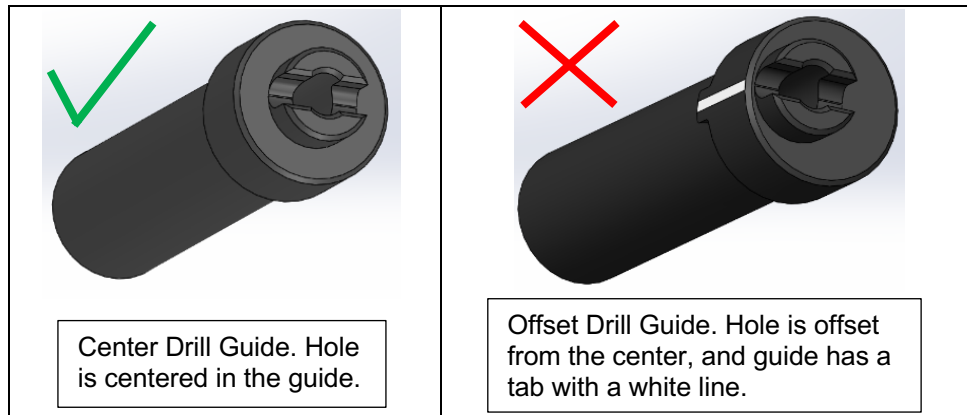
Figure 14: Center Drill Guide (Left) and Offset Drill Guide (Right). <u>Only use the Center Drill Guide if creating an access hole in the OR</u>.
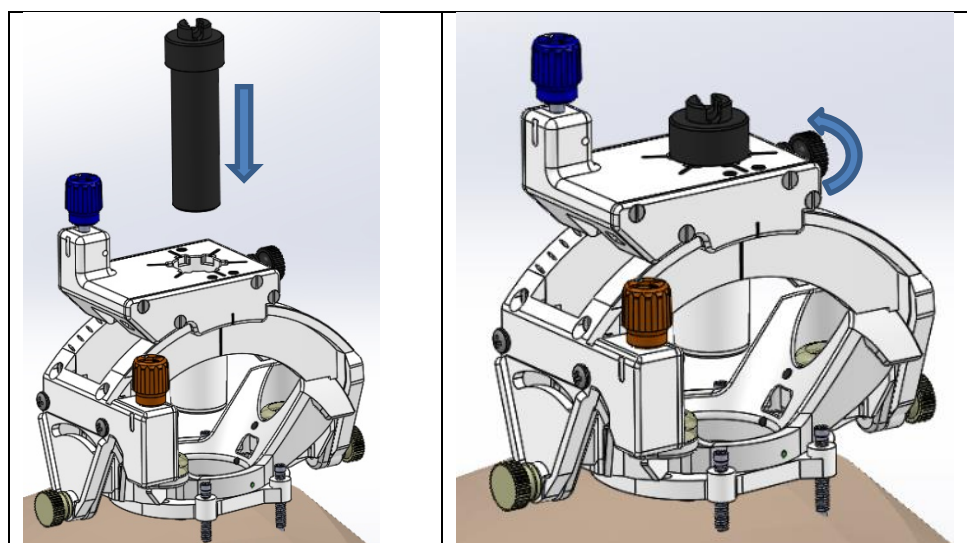

Figure 15: Inserting the Center Drill Guide into the SMARTFrame Array Tower

11. Once the Access Hole has been created, remove the Drill Guide from the SMARTFrame Array tower. It is removed in the same manner as removing the Probe Adapter. Loosen the side thumbscrew and pull the Drill Guide out of the tower. **Go to Step 14**.

12. Remove the Probe Adapter from the Tower by loosening the Tower side thumb screw and pulling the Probe Adapter out of the Tower. **See Figure 16 (Left).**

    Note: If using NGS-SFA-02-2 MR Burr Hole Kit or NGS-SFA-03-2 MR Drilling Kit, the Targeting Stem will already be pre-loaded into the Tower, so replacing the Probe Adapter with the Targeting Stem is unnecessary. Proceed to Step 14.

13. Remove the Targeting Stem from the packaging tray and insert it into the SMARTFrame Array Tower until it bottoms out. Then, tighten the Tower side thumb screw to secure the Targeting Stem in the Tower. **See Figure 16 (Middle) and (Right)**.
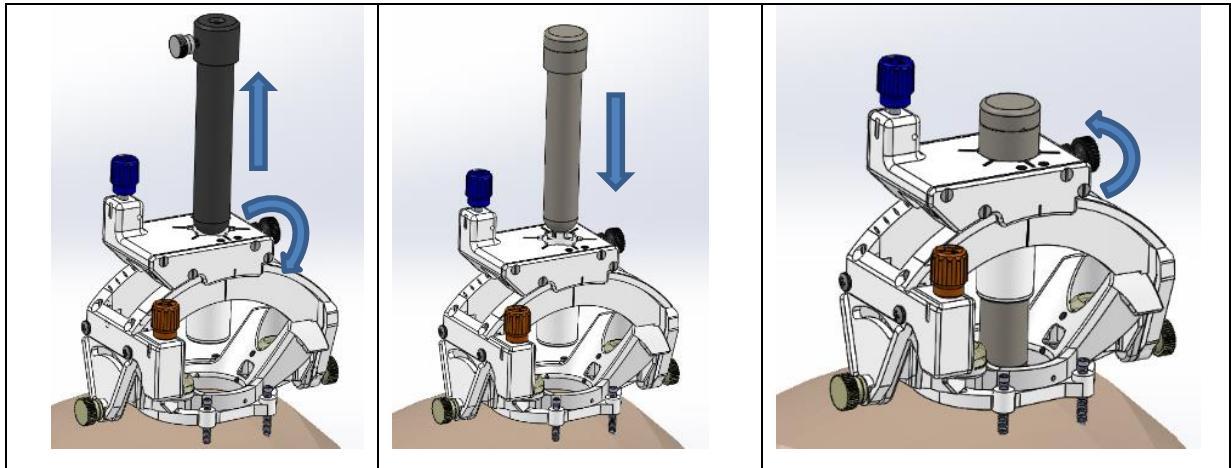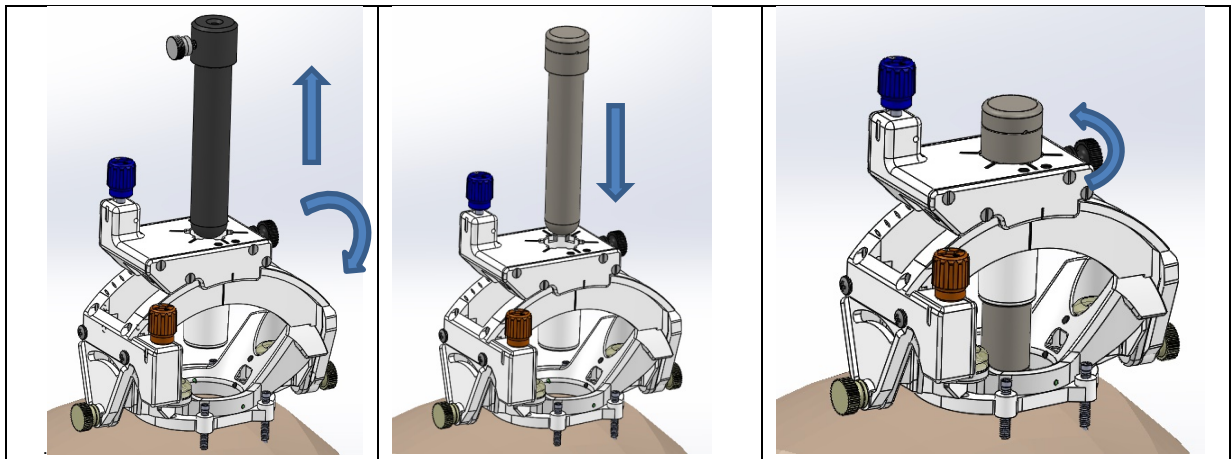
Figure 16: Removing the Probe Adapter (Left), Inserting the Targeting Stem (Middle), and Locking the Targeting Stem in the Tower (Right)

14. **At this point, the procedure continues in the MRI Room**. Create a sterile barrier around the SMARTFrame before transferring patient to an MR suite. Use current best hospital practices to maintain sterility. Once in the MRI Scanner Room, **Proceed to Section H.** Note that none of the grid steps need be performed, since the Base is already mounted.

    Warning: ALWAYS perform confirmation of the entry point and trajectory using real-time MRI scans with ClearPoint Array software prior to inserting a device in the brain. Pre-alignment performed with a Surgical Navigation System is not intended to provide accurate stereotactic placement.

G.   MRI Workflow

1. The Tower is provided with an SNS Probe Adapter assembled to it. Remove the Probe Adapter and replace it with the Targeting Stem, provided in the packaging tray.

    Note: If using NGS-SFA-02-2 MR Burr Hole Kit or NGS-SFA-03-2 MR Drilling Kit, the Targeting Stem will already be pre-loaded into the Tower, so replacing the Probe Adapter with the Targeting Stem is unnecessary. Proceed to Section H after reading the warning and caution statements in Section G.

2. Remove the Probe Adapter from the Tower by loosening the Tower side thumb screw and pulling the Probe Adapter out of the Tower. **See Figure 17 (Left).**

3. Remove the Targeting Stem from the packaging tray and insert it into the SMARTFrame Array tower until it bottoms out. Then, tighten the Tower side thumb screw to secure the Targeting Stem in the Tower. **See Figure 17 (Middle) and (Right).**

Figure 17: Removing the Probe Adapter (Left), Inserting the Targeting Stem (Middle), and Locking the Targeting Stem in the Tower (Right)

    Warning: The stability of the SMARTFrame Array should be checked prior to continuing. An unstable attachment of the SMARTFrame Array may result in an incorrect alignment to target or movement of the inserted device.

    Caution: The Tower will mount securely to the Base. If the Tower moves relative to the Base, it is not mounted correctly.

    Caution: The Roll Lock Screws should not be tightened until final positioning is selected. If the Roll Lock Screws are tight during roll adjustments, adjustments will be affected and may result in inappropriate alignment.

H. Attachment of the Thumb Wheel Extension Set

1. Remove the Thumb Wheel Extension Set from its sterile barrier package. **See Figure 18**.
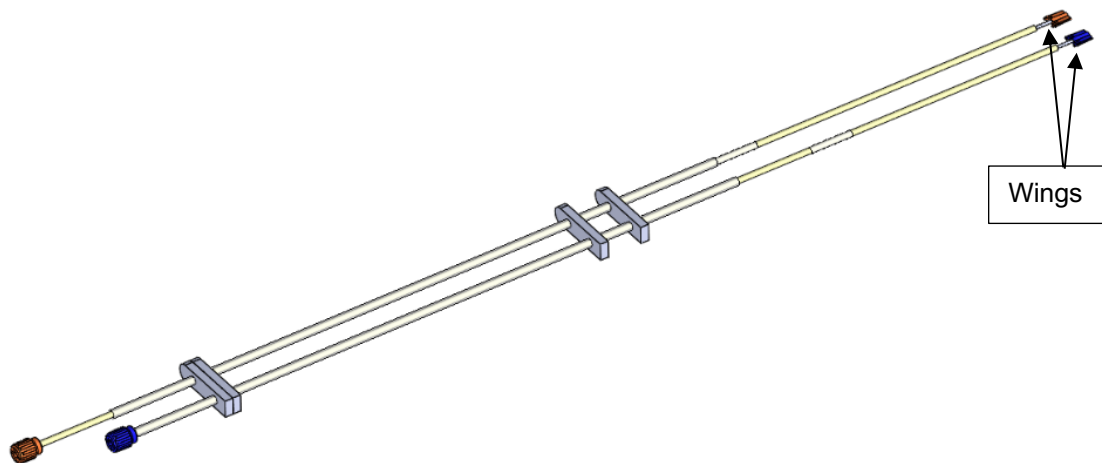

Wings

Figure 18: Thumbwheel Extension

2. Attach the distal ends (wings) of the Thumb Wheel Extension Set to the matching colored thumb wheels on the SMARTFrame Array. **See Figure 19**.

3. The Thumb Wheel Extension Set thumb wheels may require rotation to properly orient the wings into the SMARTFrame Array thumb wheels. The wings should slide to the bottom of the thumb wheels and seat into place. **See Figure 19**.
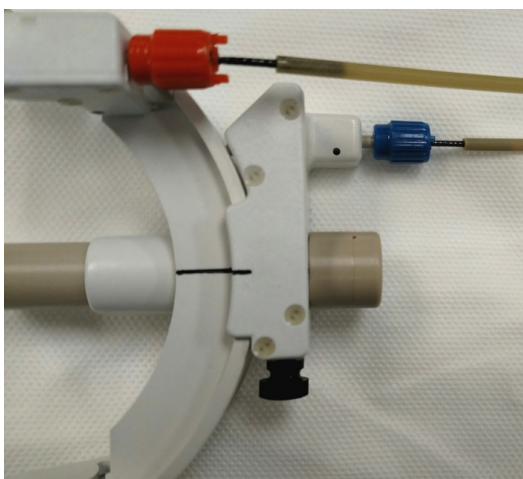
Figure 19: Thumbwheel Extension wings seated into SMARTFrame Thumbwheels

I. Set Trajectory

Note: A clear understanding of and training to the ClearPoint Array User's Guide is required to complete the following steps.

1. Move the patient's head to the isocenter of the MR scanner and complete the appropriate scans to gain the information necessary to begin the "Navigate" portion of the procedure.

2. The thumb wheels are color coded: Pitch is Blue, Roll is Orange. **See Figure 20.**
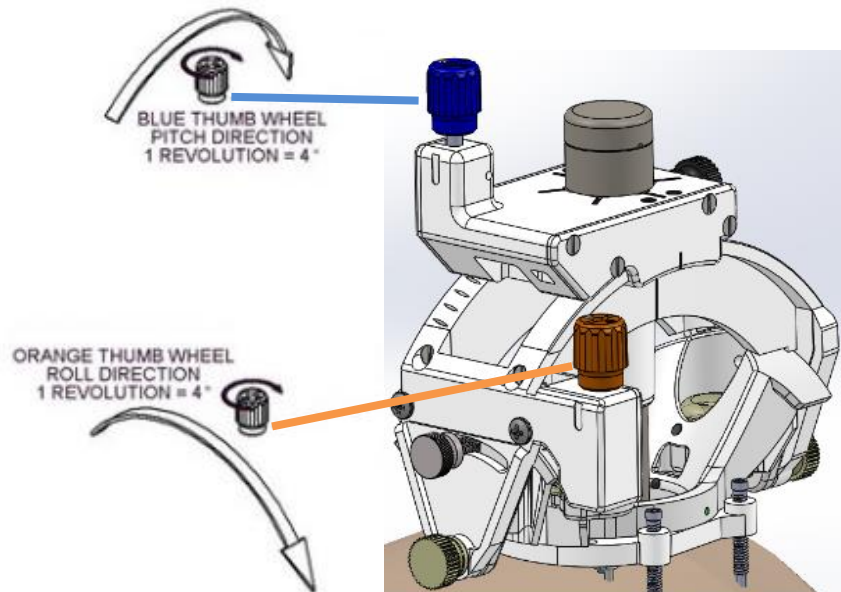
Figure 20: SMARTFrame Array Thumbwheel Directions

3. Using the 'Required Adjustment' information from the ClearPoint Array Workstation, adjust the SMARTFrame Array to the desired trajectory. The SMARTFrame Array trajectory is adjusted by turning the two thumb wheels directly on the Tower or by turning the associated thumb wheels on the Thumb Wheel Extension Set.

4. If a change in the entry point is desired, an offset channel may be selected in the ClearPoint Array software prior to making angular adjustments. Selecting an offset channel will result in angular adjustments being made such that the selected channel is aligned with the desired target point. See the ClearPoint Array User's Guide for instructions on selecting an offset channel to change entry point.

5. **If the desired Entry Point is too far to reach with any of the offset channels, the Scalp Mount Base may be removed and remounted such that the Entry Point can be reached. See Section IV.R, Step 7 on instructions for removing the Base.**

6. The angular adjustments are made with the Pitch and Roll thumb wheels which will orient the SMARTFrame Array to align the selected channel with the desired target point.

   Note: The Tower movements are limited to +/- 26 degrees in roll and +/- 33 degrees in pitch directions.

   Note: The center-to-center distance of the offset guide positions is 3.0 mm.

   Caution: Once the trajectory is established, ensure the Thumb Wheels do not move.

   Caution: Care should be taken not to induce side loading of the Tower Assembly during device insertion.

7. The Targeting Stem of the SMARTFrame Array is now aligned with the Target based on the selected channel.

8. Verify that the selected channel aligns to the target or select any of the other channel positions to set the desired trajectory (see ClearPoint Array User's Guide for detailed instructions on selecting a channel).

   Caution: Any subsequent angular adjustments that use the Pitch and Roll thumb wheels will require using "Make further adjustments" in the "Navigate" portion of the software.

9. Once the trajectory is set and the desired channel is selected, use the roll locking screws to secure the position of the Frame in the pitch-roll direction.

   Caution: Avoid bumping or applying excessive loads to the Tower or Cannula after the trajectory is set.

10. Once the roll lock screws are secured, remove the Targeting Stem by unlocking the tower side thumb screw and pulling the stem out. **See Figure 21** .
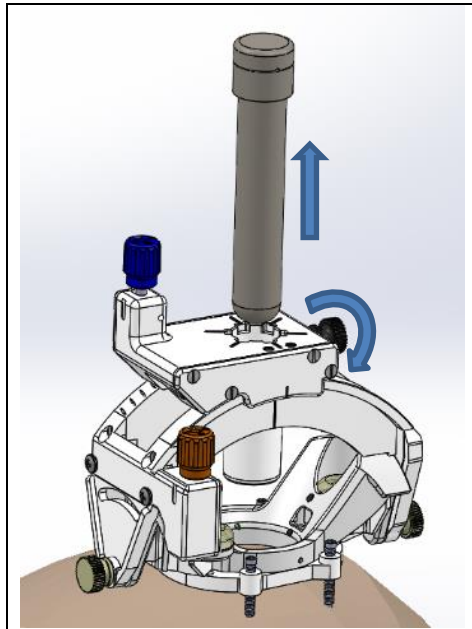
Figure 21: Removing the Targeting Stem from the SMARTFrame Array tower

11. **If the access hole was already created, proceed directly to Section K. Otherwise, continue to Section J.**

J.   Using the Drill Guides in the MRI (not required if the Access Hole was already created)

Note: Drill Guides are not required if the access hole has already been created. **If the access hole has already been created, proceed directly to Section K.**

Caution: The Drill Guides and Drill Guide Tubes are compatible with ClearPoint Neuro's MRI Drill Bit Kits (NGS-DB-45 and NGS-DB-45-S). If using non-ClearPoint-Neuro drill bits, verify MR safety and fit with the Drill Guides prior to use**.**

1. **Fully tighten both roll locking screws**. If the center channel position was selected during final alignment, use the Center Drill Guide. **See Figure 22 (Left)**. If one of the outer channels was selected during final alignment, use the offset drill guide **See Figure 22 (Right)**. The offset guide has a tab with a white line on the side near the offset hole.

Center Drill Guide. Hole is centered in the guide.
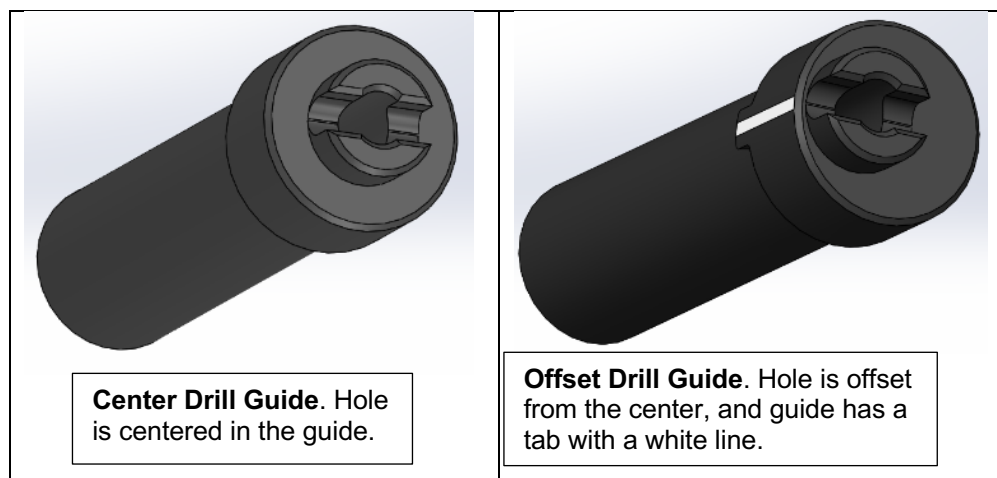
Offset Drill Guide. Hole is offset from the center, and guide has a tab with a white line.
Figure 22: Center Drill Guide (Left) and Offset Drill Guide (Right)

2. If the CENTER GUIDE was selected, insert it into the SMARTFrame Array tower until it fully stops. Then, tighten the tower side Thumbscrew. Skip to Step 6.

3. If the OFFSET GUIDE was selected, line up the side tab with the channel position line on the tower. The orientation dots on the tower match those shown in the Software. **See Figure 23** and **Figure 24**.
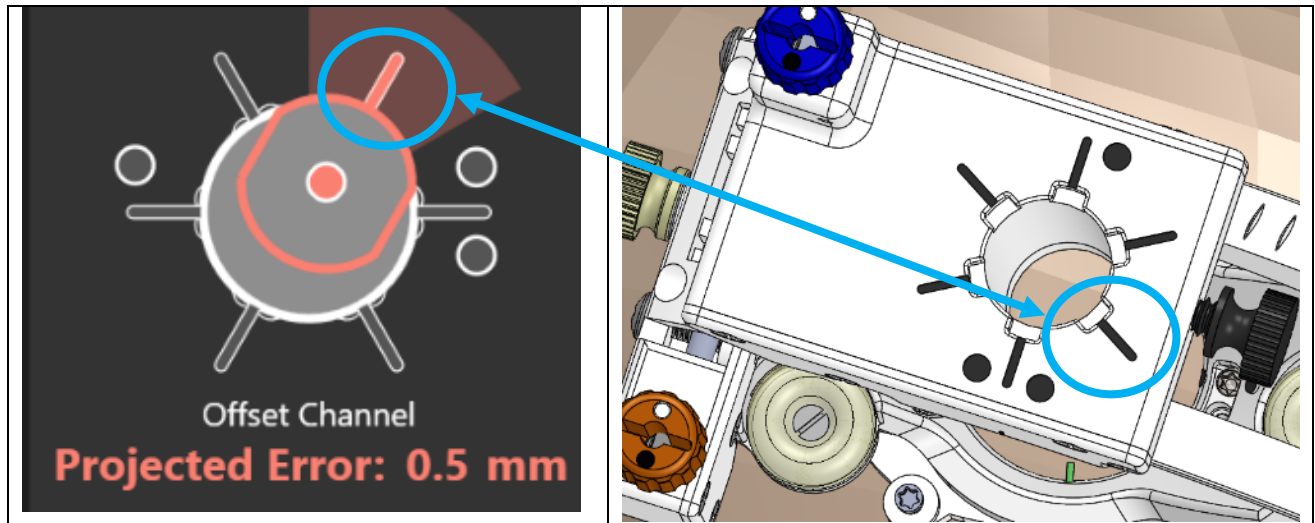
Figure 23: Offset channel selected in the software (Left), and the corresponding position on the SMARTFrame Array tower (Right)

4. Insert the Guide so that the tab clicks into the slot that corresponds to the selected channel. **See Figure 24**.

Tab with White Line

Selected Offset Channel
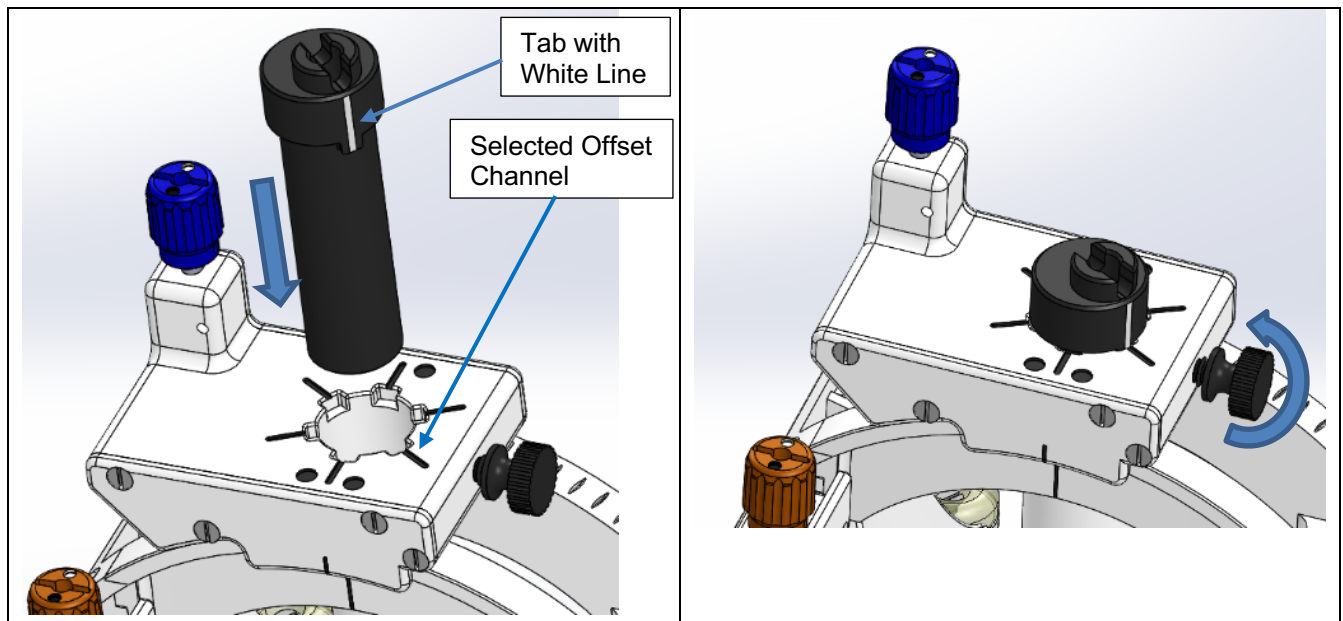
Figure 24: Offset Drill Guide Inserted into the desired offset position on the SMARTFrame Array tower

5. Verify that the Drill Guide is positioned in the channel selected in the ClearPoint Array software. The orientation dots on the tower match up with those shown on the software. **See Figure 25**. If it is not, loosen the tower side thumbscrew, raise the Drill Guide and rotate it until the tab (white line) aligns with the correct position. Then, repeat Step 4.

Selected Channel

Offset Channel
Projected Error: 0.5 mm

Offset Drill Guide Position
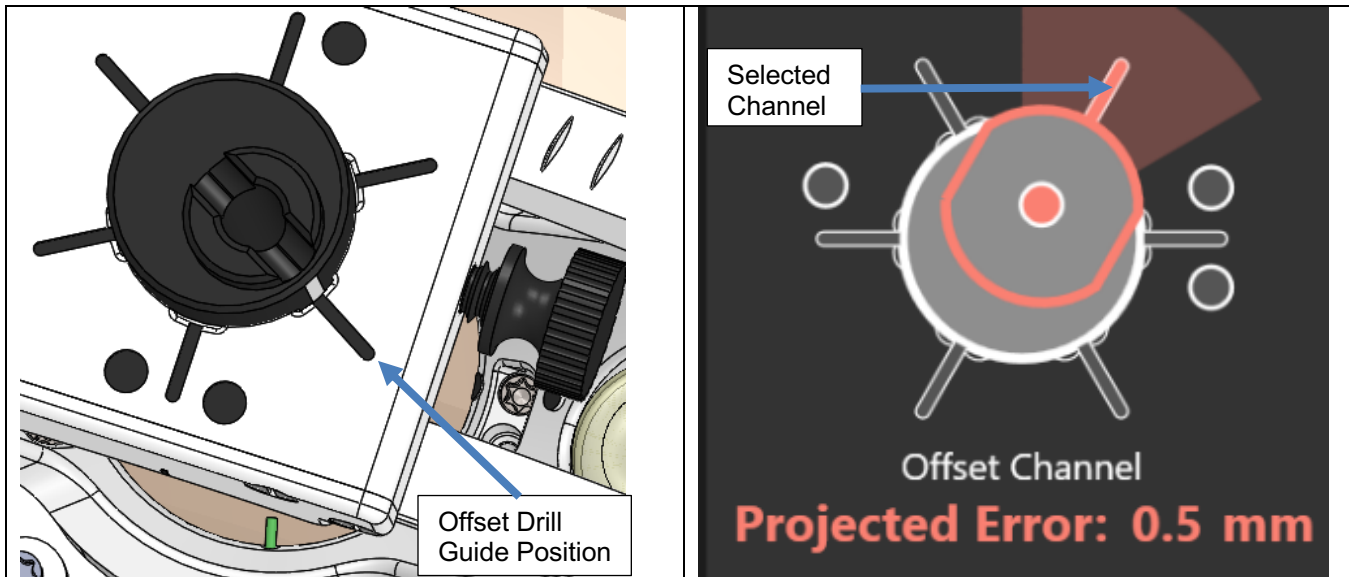
Figure 25: Offset Drill Guide inserted into the position that was selected in the ClearPoint Array Software

6. Once the Drill Guide is locked in place, a drill bit may be used to create the access hole.

7. The Drill Guide will accept a ClearPoint Neuro 4.5mm Drill Bit. If using the ClearPoint Neuro 3.4mm Drill Bit is desired, then the Drill Reducer Tube must be inserted into the Drill Guide prior to drilling. If using a 4.5mm Drill Bit, proceed with drilling and skip to Step 10. If using the 3.4mm Drill Bit see Step 8.

8. Remove the Drill Reducer Tube from the tray and insert it into the Drill Guide such that the tabs on the Reducer Tube line up with the slots on the Drill Guide.

9. Insert the Reducer Tube until it stops and the Reducer Tubes are fully engaged in the Drill Guide slots. This operation is the same whether using the Center Drill Guide or Offset Drill Guide. **See Figure 26**.

Drill Reducer Tabs

Guide Slots
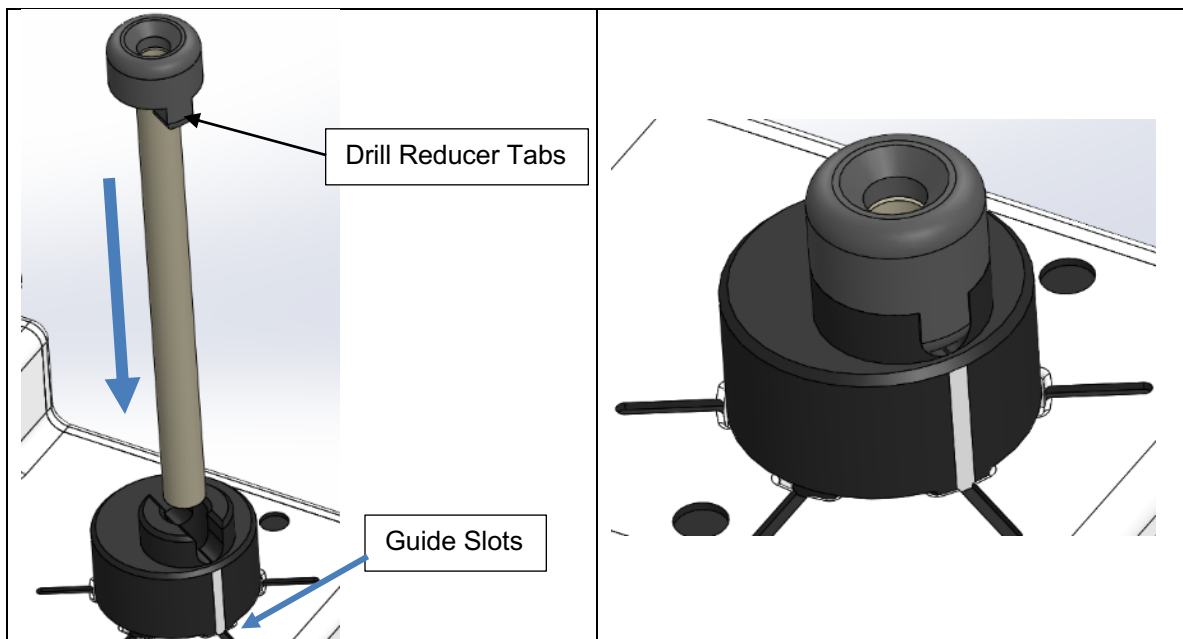
Figure 26: Drill Reducer Inserted into Drill Guide

10. Once the access hole is drilled, remove the Drill Guide by loosening the Tower Side Thumbscrew and pulling the Drill Guide out.

K. Using the Insertion Guides

1. Once the trajectory and desired channel position is confirmed, use either CENTER Insertion Guide or the OFFSET Insertion Guide to prepare for device insertion. The insertion guides are blue with "racetrack" features on the top. **See Figure 27**.

2. Use the CENTER Insertion Guide if the center channel was selected. Use the OFFSET Insertion Guide if one of the outer channels was selected. The Offset Insertion Guide has a White Line and a Tab on its side, and the hole is offset from the center. **See Figure 27**.

CENTER INSERTION GUIDE

OFFSET INSERTION GUIDE

Tab

White Line
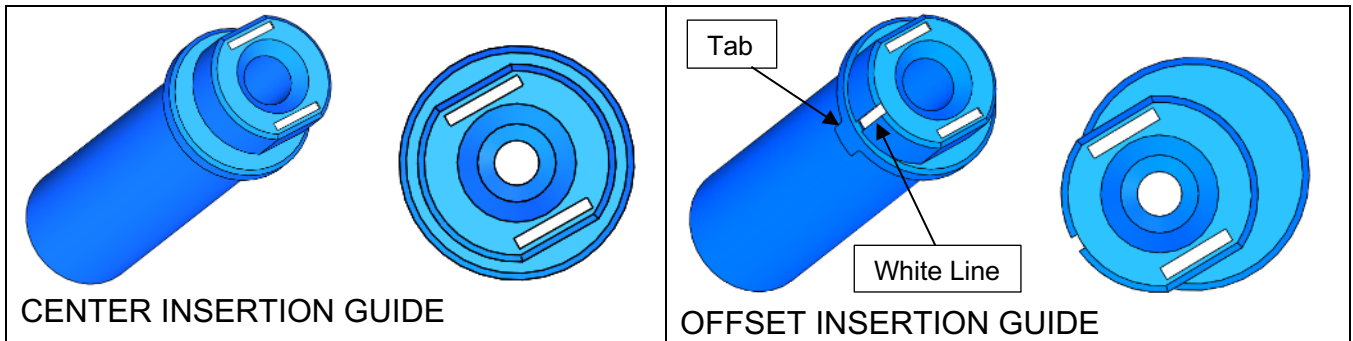
Figure 27: Center Insertion Guide (Left) and Offset Insertion Guide (Right)

3. If using the CENTER Insertion Guide, insert the Guide into the Tower until it stops. Then, tighten the Tower Side Thumbscrew to lock it into place.

4. If using the OFFSET Insertion Guide, line up the side tab with the channel position line on the tower. The orientation dots on the tower match those shown in the Software. **See Figure 28**.

Offset Channel
Projected Error: 0.5 mm
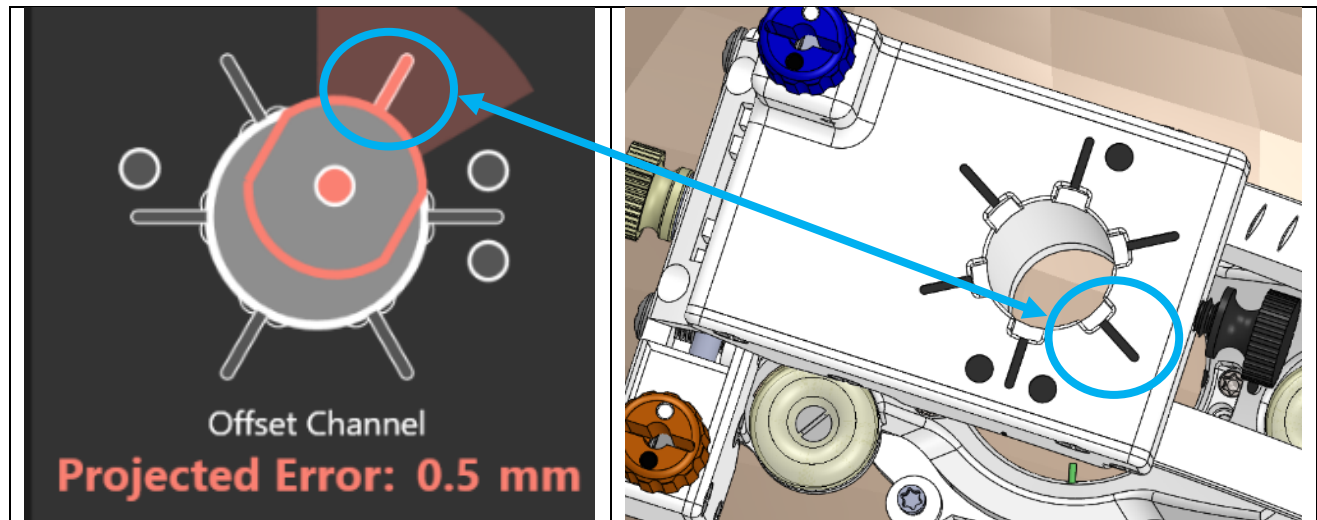
Figure 28: Offset channel selected in the software (Left), and the corresponding position on the SMARTFrame Array tower (Right)

5. Insert the OFFSET Insertion Guide so that the tab clicks into the slot that corresponds to the selected channel. **See Figure 29**.
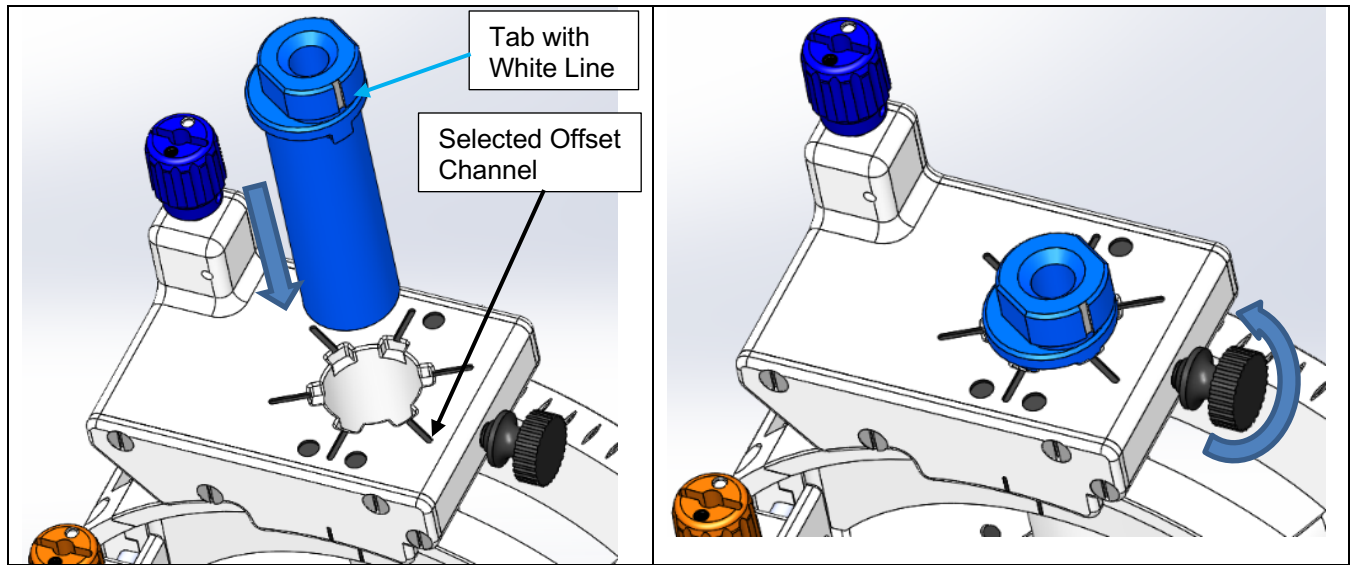
Figure 29: Offset Insertion Guide Inserted into the desired offset position on the SMARTFrame Array tower

6. Verify that the Offset Insertion Guide is positioned in the channel selected in the ClearPoint Array software. The orientation dots on the tower match up with those shown on the software. **See Figure 30**. If it is not, loosen the tower side thumbscrew, raise the Offset Insertion Guide and rotate it until the tab (white line) aligns with the correct position. Then, repeat Step 6.
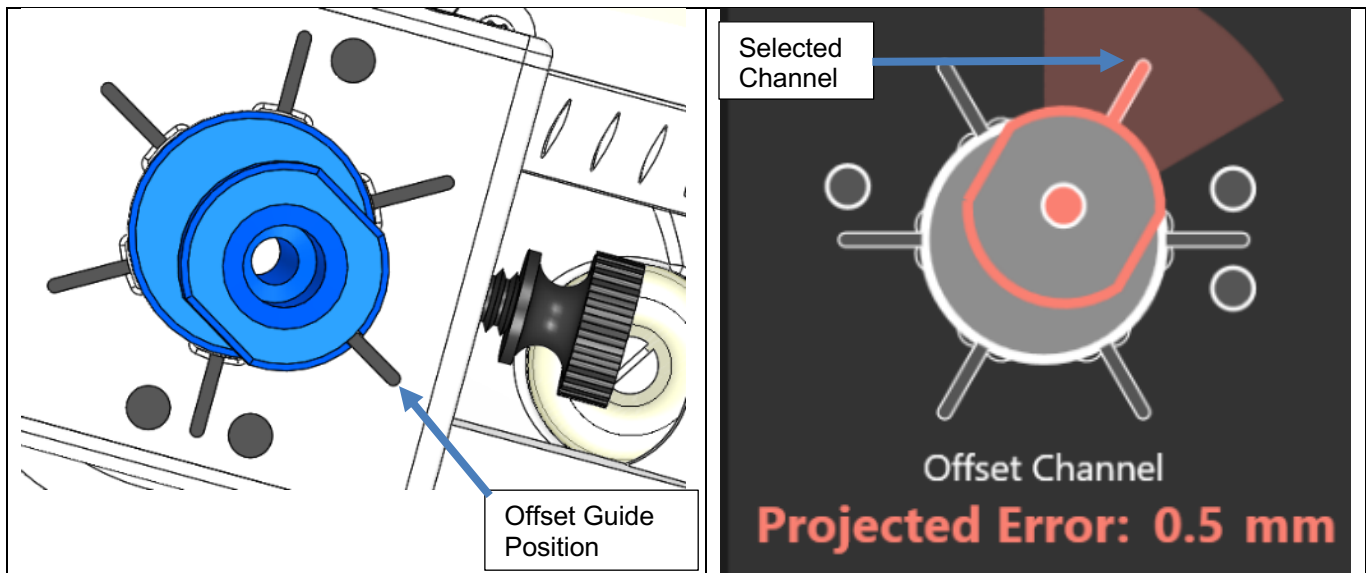
Figure 30: Offset Guide inserted into the position that was selected in the ClearPoint Array Software

7. Once the position of the Offset Insertion Guide is verified to be in the selected channel, verify the size of the device to be inserted.

8. If using the Guide Tube is desired, then insert the Guide Tube into the Insertion Guide's inner diameter such that the top of the Guide is below the top surface of the Insertion Guide. **See Figure 31**.
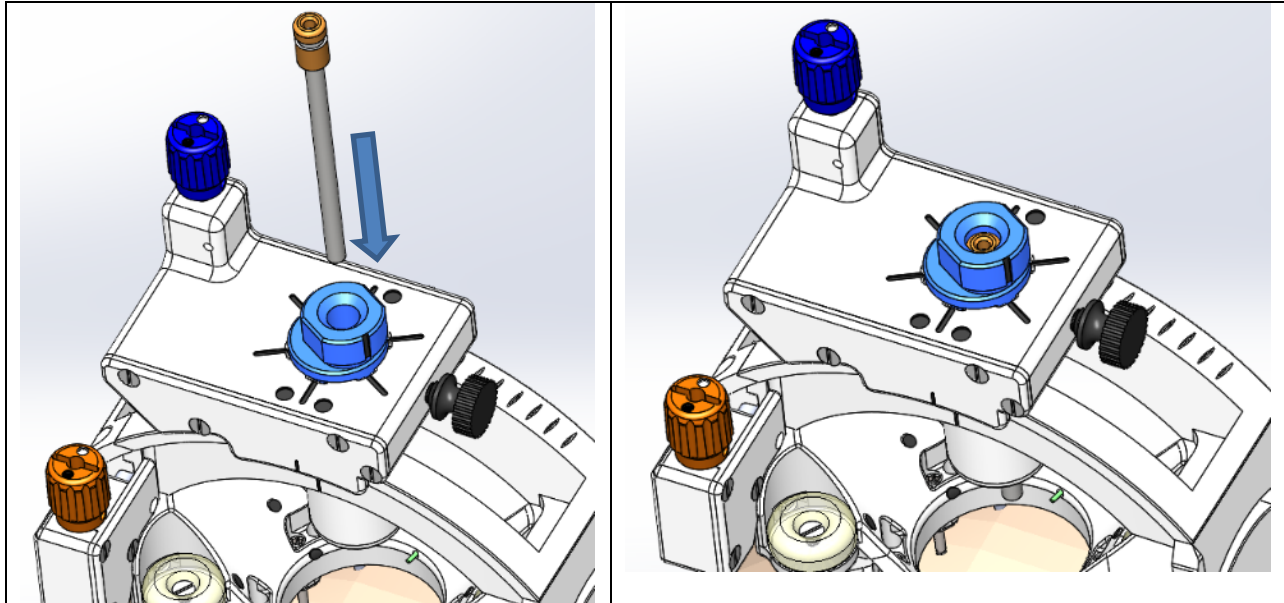
Figure 31: Guide Tube inserted into Insertion Guide

PROCEDURE OPTIONS

The remaining instructions are divided into procedural paths. Follow the instructions applicable to the device being used with the SMARTFrame Array.

Procedures utilizing the ClearPoint Neuro Stylet and Peel-Away Sheath

Procedures that require a Peel-Away Sheath with Stylet to confirm position by scanning and/or to create a path to the target. See Section M.

Direct insertion procedures

Procedures that do not need placement of the Peel-Away Sheath with Stylet. See Section P.

Caution: The compatibility of neurological instruments and devices should be evaluated before use with the ClearPoint SMARTFrame Array and SMARTFrame Accessory Kits.

L.   Navigational Accuracy

The device can provide a trajectory for placement of tools to targets within the brain. The radial (X-Y) plane trajectory error is < 2.0 mm at a 99% confidence interval. The angular error is < 1^O at a 99% confidence interval.

Caution: **The Z-plane or depth accuracy can only be verified by the user during real-time MR intraoperative imaging during placement of the instrument.**

M.   Procedures utilizing the ClearPoint Neuro Stylet and Peel-Away Sheath

The following section covers procedures where the Peel-Away Sheath with Stylet is used to create a path to the target and/or scanning to confirm target acquisition.

Note: Identify the Stylet and the Lancet in the tray before removing them. The Stylet has a bull-nose tip, whereas the Lancet has a pointed tip. Make sure the Stylet is removed first.

Note: The 5 Fr / 7 Fr Lancet has a protective cover on the pointed tip. This should be removed before use.

Peel-Away Sheath / Stylet Preparation and Insertion

1. Remove the Dock (**see Figure 32 Left**) and Device Lock (**see Figure 32 Right**) from the SMARTFrame Array package.
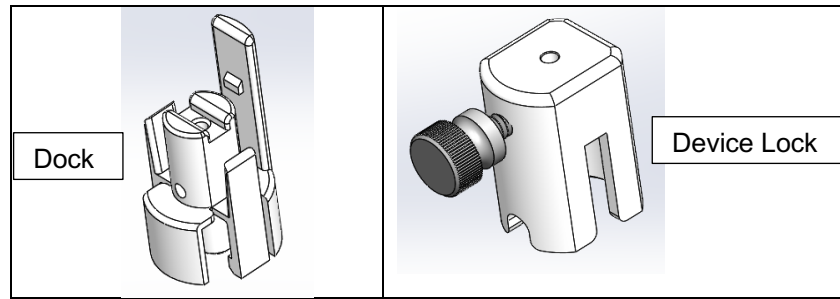
Figure 32: Dock (Left) and Device Lock (Right)

Note: Use the Dock and Lock provided in the SMARTFrame Array Kit with corresponding Stylet.

2. Remove the Peel-Away Sheath, the Stylet, and the Depth Stop from the Accessories package. Confirm that the Stylet has a bull nose tip.

Note: The distal end of the Stylet has a bull nose tip, and the proximal end of the Stylet is denoted with a blue marking.

Note: When Sheath/Stylet insertion is used only for trajectory and position conformation, it may be desired to stop short of the target, leaving undisturbed tissue for the final device. Subtract this distance "offset" from the depth value provided by the ClearPoint Array Software.

3. Mark the target's depth on the Stylet using the Ruler and Marking Pen with the depth value from the ClearPoint Array Software.

4. Position the Device Lock on the depth mark on the Stylet and tighten the thumb screw. The inserted depth of the Stylet is defined by the proximal side face of the Device Lock to the distal tip of the Stylet. Confirm the length using the Ruler. **See Figure 33**.

5. When utilizing the Depth Stop, the inserted depth of the Stylet is defined by the distal side face of the Depth Stop to the distal tip of the Stylet. **See Figure 34**. Slide the Stylet into Device Lock until Depth Stop rests on top of Device Lock. Then tighten Device Lock. Confirm the length using the Ruler.
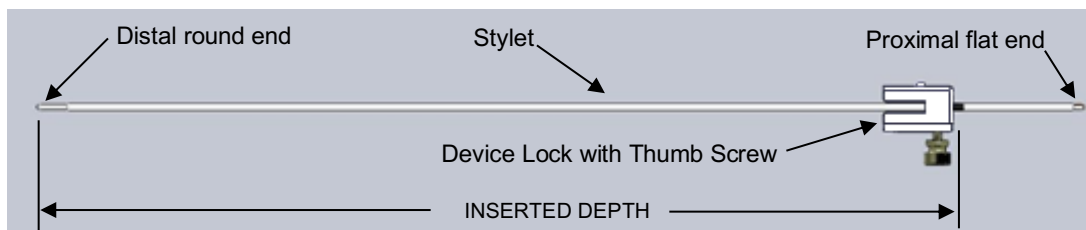
Figure 33: Device Lock attached to the Stylet
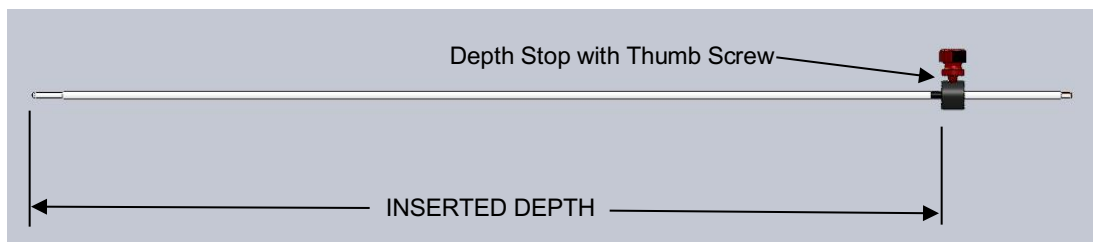
Figure 34: Stylet with Depth Stop attached to the Insertion Depth

6. A Lancet has been provided as an alternate method to create an insertion point in the dura and/or pia. If using the Lancet proceed to step 7. If not using the Lancet, proceed to step 14.

7. Remove the Lancet from the Accessory package.

   Caution: The distal end of the Lancet has a pointed tip, and the flat proximal end is denoted with a <u>green</u> marking. Handle the Lancet near the proximal end. Avoid contacting the distal end.

8. Place a Depth Stop on the Lancet such that the distance from the distal point of the Lancet to the Depth Stop is approximately 1 inch greater than the distance from the inside of the dura or pia to the top of the SmartFrame Array tower.

9. Remove one of the Peel-Away Sheaths from the Accessory Kit.

10. Separate the hub and peel away approximately 4 inches of the Sheath.

11. Insert the Lancet into the Peel-Away Sheath until the pointed end protrudes approximately one (1) to eight (8) millimeters. A slight resistance should be felt. If the Depth Stop interferes with the Sheath before the Lancet can be fully inserted, peel the sheath away further until the Lancet can be fully inserted.

12. By holding the exposed proximal end of the Lancet, insert the Lancet through the Targeting Stem and through the burr hole until it contacts the dura or pia. Gently push on the Lancet until the dura and/or pia is pierced.

13. After piercing the dura and/or pia, withdraw the Lancet-Sheath Assembly from the Targeting Stem.

14. Remove a new Peel-Away Sheath from the Accessory Kit and separate the hub and peel away approximately one (1) inch of the Sheath. Place the Peel-Away Sheath through the Dock.

15. Insert the peeled Sheath sides into the grooves of the Dock. **See Figure 35**.
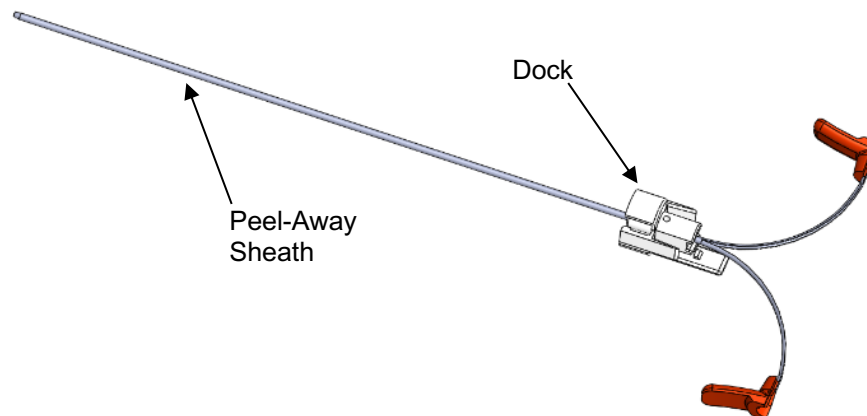
Figure 35: Peel-Away Sheath Inserted into Dock

16. Insert the Stylet into the Sheath. The distal end of the Stylet should protrude between one (1) and five (5) mm from the end of the Sheath. If it is not protruding, pull on both ends of the hub, peel the Sheath until the distal end of the Stylet protrudes between one (1) and five (5) mm. A slight resistance should be felt**.**

17. Insert the Stylet into Dock until Device Lock mates and snap locks to Dock. **See Figure 36**.

   Note: While peeling the Sheath to expose the Stylet tip, the force should be steady and peel smoothly.

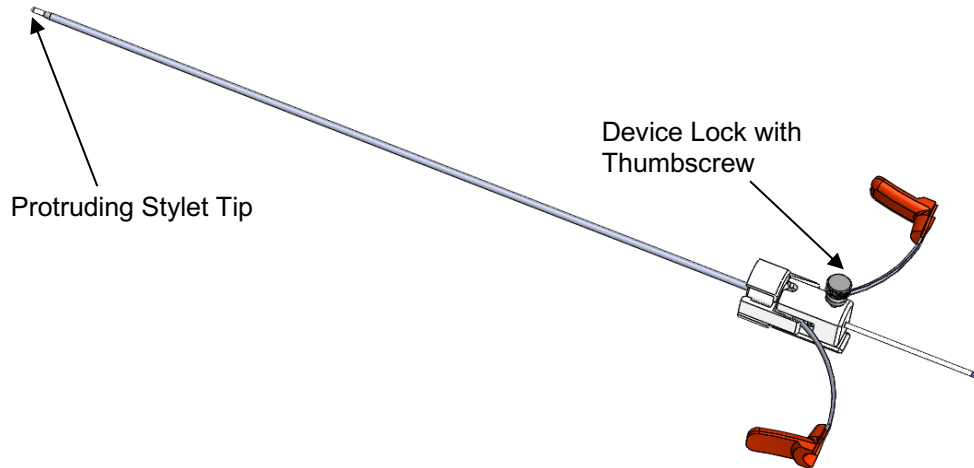   **Caution:** Do not over tighten the thumb screw on Device Lock or Depth Stop to avoid damaging the Stylet.

Protruding Stylet Tip

Device Lock with
Thumbscrew

Figure 36: Dock and Lock Assembled to Stylet and Sheath

Caution: DO NOT insert Peel-Away Sheath and Stylet through the SMARTFrame Array tower without the Guide Tube in place**.** Without the Guide Tube in place, the Sheath-Stylet may not follow the desired trajectory when inserted into the brain.

18. Insert the tip of the Stylet Assembly into the proximal end of the Insertion Guide.

19. During insertion, view the advancement of the Stylet Assembly on the ClearPoint Array Software as appropriate. This insertion and visualization may be performed in 1/3 increments. **See Figure 37 for Stylet Assembly inserted into SMARTFrame Array.**

Note: **Use the information from the ClearPoint Array Software to confirm the acceptability of the trajectory.**
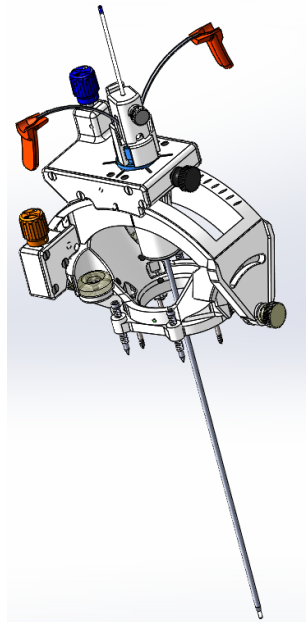
Figure 37: Stylet-Sheath-Dock-and-Lock Assembly Inserted into SMARTFrame Array

Warning: Do not adjust SMARTFrame Array while Stylet Assembly is inserted. If the trajectory needs to be modified, completely remove the Stylet Assembly prior to adjusting the SMARTFrame Array.

Caution: Do not over tighten thumb screw on Device Lock or Depth Stop to avoid damaging the Stylet.

Note: Devices that do not require the Peel-Away Sheath for insertion shall skip the steps below and go to **Section P**.

N. Device Insertion through Peel-Away Sheath

Caution: If device to be inserted is not to be imaged, position the patient's head outside the scanner at the head end of the scanner.

1. Loosen the Device Lock thumb screw and remove the Stylet from the Peel-Away Sheath.

2. Use the Depth Stop or marking pen to mark the inserted depth on the device.

    Caution: Do not over tighten the Depth Stop which could damage the device.

3. Insert the device into the top of the Peel-Away Sheath through the Device Lock.

    Caution: Do not advance a device through the Targeting Stem or Peel-Away Sheath that is not resistant to compression and that may change in length with insertion. This may prevent accurate placement relative to the desired target.

4. Advance the device until the Depth Stop or the mark rests on top of the Device Lock.

5. Tighten the thumb screw of the Device Lock onto the device.

    Caution: Do not over tighten Device Lock which could damage the device.

6. If appropriate, remove the Peel-Away Sheath by simultaneously pulling both ends of the split red hub until the Sheath is entirely removed in two pieces.

O. Complete the Procedure

If not already complete, complete the procedure per the device manufacturer's IFU and standard surgical practices.

P. Direct Insertion Procedures

Note: **This section covers preparation and direct insertion of devices that are 1.7 mm to 3.1 mm in diameter.**

Preparation and Insertion

Note: Verify the device that is to be inserted corresponds to the size of the Guide Tube provided in the SMARTFrame Array Kit or the SMARTFrame Array Guide Tube Kit in the table below. The Guide Tubes in the SMARTFrame Array Guide Tube Kit are labeled with the device size that fits into the Guide Tube.

Device Diameters		SMARTFrame Array Kit
0.067 inch	1.7 mm	NGS-SFA-GT-01
0.083 inch	2.1 mm	NGS-SFA-01-2
0.098 inch	2.5 mm	NGS-SFA-GT-01
0.122 inch	3.1 mm	NGS-SFA-GT-01

Caution: **If using a device size that is not listed, always verify the fit with the SmartFrame Array Kit's Dock, Lock, and Guide Tube prior to using the device with the SmartFrame Array.**

1. If the device to be inserted is not to be imaged, position the patient's head outside the scanner at the head end of the scanner.

2. If the Stylet Assembly was used previously, remove the Stylet Assembly including the Peel-Away Sheath, Device Lock, Stylet, and Depth Stop (if used) from SMARTFrame Array and separate these components from one another.

3. If necessary, insert the Guide Tube into the Insertion Guide. **See Figure 38 Left**.

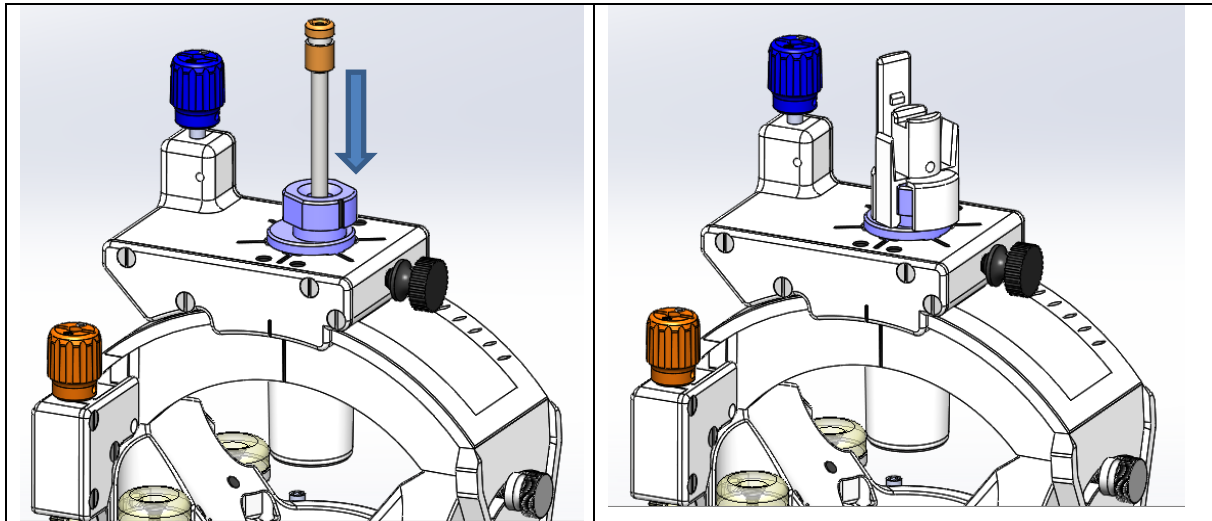4. Insert and snap lock the Dock in place. **See Figure 38 Right**.

Figure 38: Inserting Guide Tube (Left) and Attaching Dock (Right) to the SMARTFrame Array Tower

5. Insert the device into the top of the Device Lock.

6. Set the inserted depth on the device from the distal end of the device to the top of the Device Lock using the Ruler. Lock the device to the Device Lock with the thumb screw. Verify the measured inserted depth. Alternately, the bottom of the Depth Stop can be located at the appropriate position and locked into place on the device with the thumb screw prior to inserting the device into the Device Lock. **See Figure 33** and **Figure 34** for similar placement of the Depth Stop or Device Lock onto Stylet.

   Caution: Do not over tighten the thumb screw which could damage the device.

7. Insert the device into the Dock through the Guide Tube until the Device Lock snaps and locks onto the Dock.

   Caution: Do not advance a device through the Guide Tube that is not resistant to compression and that may change in length with insertion. This may prevent accurate placement relative to the desired target.

8. Perform the procedure as intended.

Q.   Complete the Procedure

If not already complete, complete the procedure per the device manufacturer's IFU and standard medical practices.

R.   System Removal

Note: It is recommended that the system removal be performed with the patient's head outside of the scanner bore at the head end of the scanner.

Warning: Ensure device (if present) is secure per the manufacturer's instructions before removing SMARTFrame Array components or movement of the device could occur.

1. Remove the Thumb Wheel Extension Set by holding the appropriate Thumb Wheel on the SMARTFrame Array, while pulling gently on the corresponding Thumb Wheel Extension wing.

2. Loosen the thumb screw on the Device Lock.

3. Remove the Dock and Device Lock Assembly by squeezing the clips to separate it from the SMARTFrame Array. **See Figure 39.**
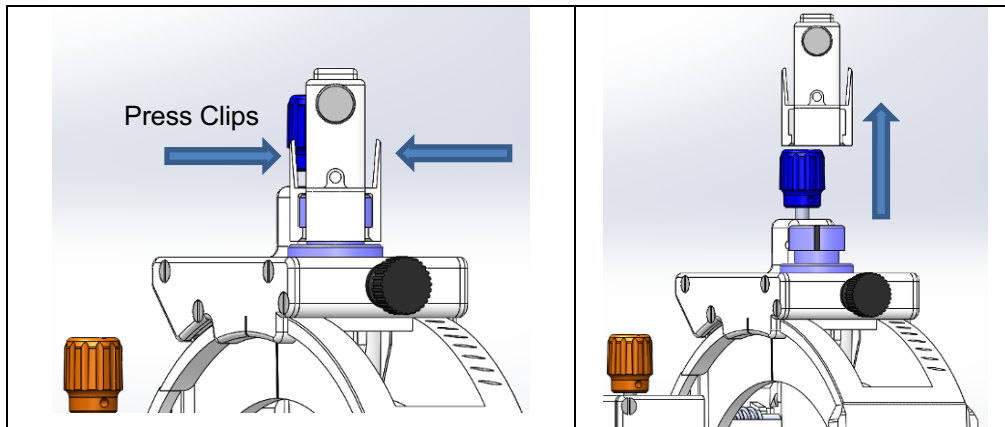
Figure 39: Removing the Dock and Lock

4. Slide the Dock and Device Lock Assembly completely off.

5. Remove the Roll Lock Screw w/ washer.

6. Loosen the Tower Mounting Screws and separate the Tower from the Base.

7. Remove the Base from the skull by unscrewing the standoff pins first, and then unscrewing the titanium bone screws.

   Caution: Avoid torquing the Base during the removal of the Base as this may break the remaining screws.

   Caution: Do not over-torque the Bone Screws when removing them from the skull. Over-torquing the Bone Screws may lead to screw breakages.

S.   Storage and Technical Specifications

Storage

o   Store in a cool dry place.

Technical Specifications

SMARTFrame Array

o   **Device Accuracy**

   The SMARTFrame Array can guide a rigid device to the intended brain target with an error of less than 2.0 mm.

o   **Overall height (top of Device Lock)** - 108 mm (4.25")

o   **SMARTFrame Array Kit Guide Inner Diameters (all Kits have these Guides)**

Guide	Inner Diameter (mm)
Center Insertion Guide	3.4
Offset Insertion Guide	3.4
Center Drill Guide	4.6
Offset Drill Guide	4.6

o   **SMARTFrame Array Offset & Center Guides, 5.4mm**

Guide	Inner Diameter (mm)
Center Insertion Guide	5.4
Offset Insertion Guide	5.4

o   **Guide Tube Inner Diameter**

Guide Tube Color	Guide Tube ID (mm)	Location	
Orange	1.7	NGS-SFA-GT-01	Guide Tube Kit
White	2.1	NGS-SFA-01	SMARTFrame Array Kit
Dark Blue	2.5	NGS-SFA-GT-01	Guide Tube Kit

Guide Tube Color	Guide Tube ID (mm)	Location	
Green	3.1	NGS-SFA-GT-01	Guide Tube Kit

o **Device Lock Inner Diameter**

Device Lock Color	Device Lock ID (mm)	Location	
None	1.7	NGS-SFA-01	SMARTFrame Array Kit
Black	2.1	NGS-SFA-01	SMARTFrame Array Kit
Blue	1.9	NGS-SFA-GT-01	Guide Tube Kit
Green	2.5	NGS-SFA-GT-01	Guide Tube Kit

o **Range of Movement**

Orientation	Travel	Travel per 1 Rotation of Thumb Wheel	Thumb Wheel Color
Roll	± 26°	4°	Orange
Pitch	± 33°	4°	Blue
Adjacent Offset Channels have a 3.0mm center-to-center distance			

SYMBOL	DEFINITION	SYMBOL	DEFINITION
MR	MR Safe	MR	MR Conditional
MR	MR Unsafe		Fragile, handle with care
	Consult instructions for use		Single use
	Do not resterilize	NON STERILE	Non sterile
	Use by date	LOT	Batch code
REF	Catalogue number	STERILE EO	Sterilized using ethylene oxide
	Do not use if the product sterilization barrier or its packaging is compromised	STERILE R	Sterilized through irradiation
	Keep away from sunlight		Keep dry
	Date of Manufacture		Manufacturer
	Not made with natural rubber latex		Double sterile barrier system
	Non-pyrogenic	**Rx Only** or **℞ Only**	Prescription device
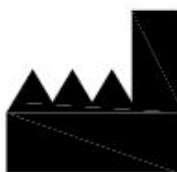
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