CLEARPOINT
NEURO

SmartFrame OR System and ClearPointer Optical Navigation Wand

Instructions for Use

Table of Contents

I. Intended Use

SmartFrame OR (Operating Room) Stereotactic System

Indications for Use:

The SmartFrame OR 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 a compatible optical stereotaxic navigation system using preoperative MR and/or CT imaging. These procedures include biopsies, catheter placement and electrode introduction, including the placement of deep brain stimulation (DBS) leads.

Intended Use:

The SmartFrame OR 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.

The ClearPointer Optical Navigation Wand

Indications for Use:

The ClearPointer Optical Navigation Wand is intended to be used in conjunction with the SmartFrame OR Stereotactic System and a compatible optical stereotaxic navigation system for patient registration and navigation.

Intended Use:

The ClearPointer Optical Navigation Wand is intended for use by a Neurosurgeon in a standard operating room environment to place and orient the SmartFrame OR Tower towards a target in the brain along a planned trajectory during stereotactic functional neurosurgical procedures.

Warning: These devices are 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: SmartFrame OR integrates with neuro navigation provided by the StealthStation S8 software. The NexFrame DBS workflow within the Cranial software suites provides complete instructions leading up to just prior to the insertion step, at which point, the surgeon can choose to insert after optical alignment or perform the pre-insertion verification of trajectory (PIVOT) step with iCT for added placement accuracy.

II. Device Description

The SmartFrame OR Stereotactic System is a disposable, frameless, stereotactic guidance system used in conjunction with compatible optical stereotaxic navigation systems for intracranial surgical procedures.

SmartFrame OR Tower & Base

The SmartFrame OR Stereotactic System Tower & Base consists of three assemblies (Figure 1). The base (skull mount or scalp mount) is attached to the patient's skull. Once the base is attached to the patient's skull, the reference frame bracket arm attaches to the base and is secured with a screw. The trajectory aiming tower is then secured to the base using two thumbscrews (Figure 2).

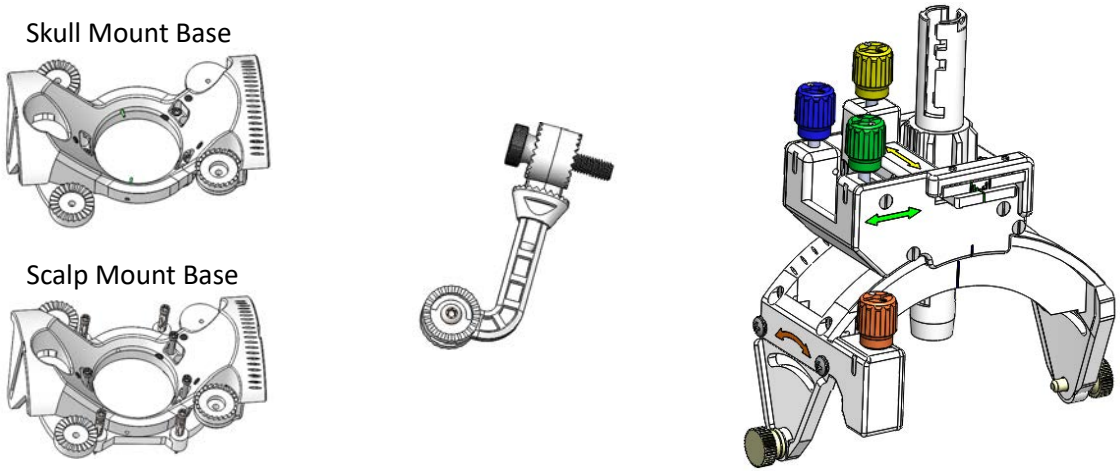


Figure 1. Skull or Scalp Mount Base (Left), Reference Frame Bracket Arm (Middle), and SmartFrame OR Tower (Right)

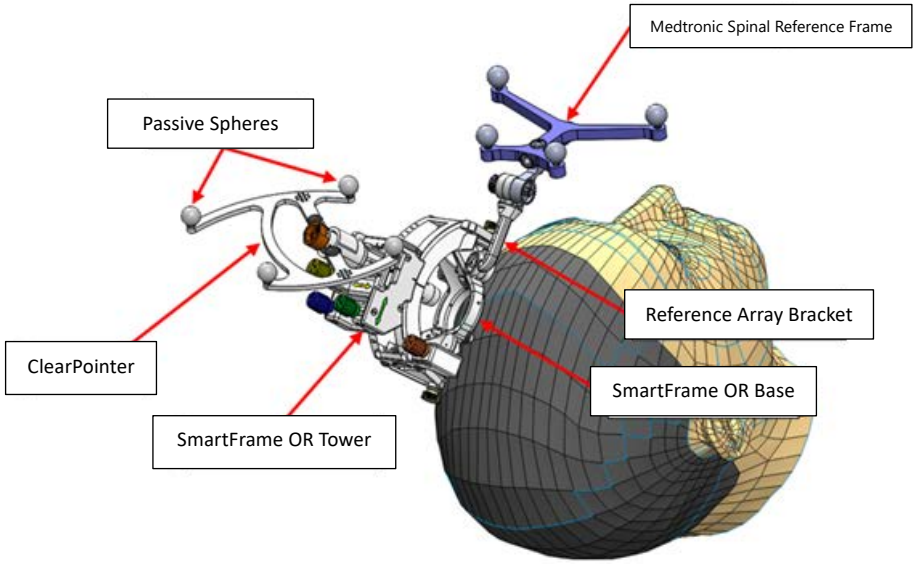


Figure 2. The assembled SmartFrame OR Stereotactic System mount and tower

The ClearPointer Optical Navigation Wand

The ClearPointer Optical Navigation Wand is used in conjunction with compatible optical stereotaxic navigation systems to align the SmartFrame OR tower to the desired target. The pointer attachment is removed after registration tasks and the ClearPointer Array mounts to the trajectory aiming Tower itself.

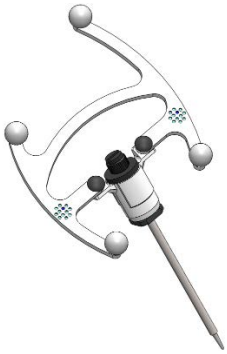


Figure 3. The fully assembled ClearPointer Optical Navigation Wand with reflective spheres and the center alignment adapter included with the SmartFrame OR kit.

Compatible Optical Stereotaxic Navigation System

Table 1 provides a list of compatible optical stereotaxic navigation systems that have been validated for use with the SmartFrame OR System:

Table 1: Optical Stereotaxic Navigation System Validated for use with the SmartFrame OR System	
Optical Stereotaxic Navigation System	**Software Package**
Medtronic StealthStation S8	StealthStation Application 2.0.1
Medtronic StealthStation S8	StealthStation Application 2.1.0

Package Contents:

NGS-SFOR-XG-01	**SmartFrame OR Kit** Content: SmartFrame OR Tower, 2.1mm Device Guide, Dock, 1.7mm Device Lock, 2.1mm Device Lock, Centering Ring, Roll Lock Screws w/washer
NGS-SFOR-SK-01	**SmartFrame OR Skull Mount Base** Content: Skull Mount Base
NGS-SFOR-SM-01	**SmartFrame OR Scalp Mount Base** Content: Scalp Mount Base, Entry Point Locator
NGS-SFOR-CP-01	**SmartFrame OR ClearPointer Kit – StealthStation** Content: ClearPointer, Pointer Attachment, Thumb Screw, Screwdriver, Reference Frame Bracket Arm

Associated Devices:

NGS-SFOR-DG-06	**SmartFrame OR Drill Guide, 5.4mm** Content: 5.4mm Drill Guide, Depth Stop
NGS-SFOR-DG-07	**SmartFrame OR Drill Guide Kit, 3.4 & 4.5mm** Content: 3.4mm Drill Guide, 4.5mm Drill Guide
NGS-SFOR-DS-01	**SmartFrame OR Depth Setter Kit**

	Content: Depth Setter, Thumb Wheel Extender
NGS-SFOR-BSF-01	**Bone Screw Fiducial Kit**
	Content: Bone Screw Fiducials (5), Bone Screw Fiducial Holder, Screwdriver
NGS-SFOR-SPH-01	**NDI Passive Spheres**
	Content: 1 Carton of NDI Passive Spheres, 4 Spheres per pack, 12 packs per carton
NGS-AK-01-11	**SmartFrame Accessory Kit**
	Content: 4 Fr Stylet, 4 Fr Lancet, 4 Fr ID Peel-Away Sheath (2), Ruler, Depth Stop (2)
NGS-DB-45	**SmartTip MR Drill Kit, 4.5-mm**
	4.5-mm Drill Bit, 3.2-mm Drill Bit, Lancet, Depth Stop, Ruler
NGS-GT-01	**SmartFrame Guide Tubes**
	Content: 15 GA Guide Tube, 18 ga Guide Tube and 16 ga Guide Tube
NGS-GT-02	**SmartFrame Guide Tubes .052" / 18 ga**
	Content: .052" Guide Tubes that fit 18 ga devices (5)
NGS-GT-03	**SmartFrame Guide Tubes .060" / 17 ga**
	Content: .060" Guide Tubes that fit 17 ga devices (5)
NGS-GT-04	**SmartFrame Guide Tubes .064" / CP Stylet**
	Content: .064" Guide Tubes that fit ClearPoint Stylets (5)
NGS-GT-05	**SmartFrame Guide Tubes .068" / 16 ga**
	Content: .068" Guide Tubes that fit 16 ga devices (5)
NGS-GT-06	**SmartFrame Guide Tubes .074" / 15 ga**
	Content: .074" Guide Tubes that fit 15 ga devices (5)
NGS-RS-01	**SmartFrame Skull Mount Rescue Screw**
	Content: Skull Mount Rescue Bone Screws (3)
NGS-RS-02	**SmartFrame Scalp Mount Rescue Screw – Long**
	Content: Long Scalp Mount Rescue Bone Screws (3)
NGS-RS-03	**SmartFrame Scalp Mount Rescue Screw – Short**
	Content: Short Scalp Mount Rescue Bone Screws (3)
NGS-BL-01	**Larson Bladed Lancet**
	Content: Bladed Lancet, Depth Stop, Ruler

NOTE: If using devices other than those provided by ClearPoint Neuro, verify the device's fit in the Guide Tube, Device Guide, or Drill Guide, and follow the manufacturer's recommendations.

The SmartFrame OR (Operating Room) Tower is designed to be used with the Scalp Mount Base or the Skull Mount Base, both of which are completely made of plastic, except for the bone screws and stand-off pins. The Tower (**see Figure 2)** attaches to the Base. The Tower, also made of plastic, is designed to provide multi-directional orientation adjustments to the Device Guide, which is housed in the center of the Tower. The Device Guide has a central lumen through which a Peel-Away Sheath and Ceramic Stylet or other suitable devices can be placed and oriented. The Tower, when attached to the Base, provides adjustments in the roll, pitch, X, and Y directions by turning the appropriate thumb wheels. The Device Guide is exchangeable in that it can be replaced with other sized Device Guides to accommodate different instruments.

III. General Warnings and Precautions

Contraindications

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

Single use only – Do not reuse any of the disposable components of the SmartFrame OR system. Components are intended for single patient use only. Do not reuse, reprocess, or re-sterilize these devices. Reuse, reprocessing, or re-sterilization 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.

MR Compatibility - SmartFrame OR has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of SmartFrame OR in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or malfunction.

MR Compatibility – The ClearPointer Optical Navigation Wand has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the ClearPointer Optical Navigation Wand in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or malfunction.

System validation of the image-guided surgery (IGS) system – Perform systematic validation of the image-guided surgery (IGS) system used in conjunction with the SmartFrame OR 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 – The SmartFrame OR and ClearPointer have been tested specifically with StealthStation 8 when including the NexFrame DBS workflows within the cranial suite. Pre-surgically verify your Stealth 8 system is properly configured and able to recognize the ClearPointer four-sphere geometry.

Warning: Structures greater than 105 mm from the entry point should not be targeted, as placement accuracy beyond 105 mm has not been validated.

Warning: Do not use the ClearPoint System with instruments that have insertable lengths greater than 30cm as the accuracy of the system has not been verified with instruments greater than this length.

Warning: Do not attach the Scalp Mount Base or Skull 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: Never insert the Peel-Away Sheath without the Stylet tip protruding 1 – 5mm from the end of the Sheath. Inserting the Peel-away Sheath without the Stylet tip protruding can cause severe harm to the patient.

Warning: Do not use a broken ClearPoint Neuro Stylet or Lancet.

Warning: Do not reuse or resterilize. 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: Do not use any components of the SmartFrame OR system on the patient for more than 24 hours.

Warning: The combination of optical alignment and automated registration methods should never be used for DBS lead placement procedures. Benchtop testing demonstrates the combination of optical navigation and automated registration methods produces placement accuracy that can be suitable for procedures such as biopsy and catheter placements when used at the discretion of the surgeon.

Caution: It is recommended that additional sterile products be available for use.

Caution: This device is to be used only by physicians trained by ClearPoint Neuro personnel.

Caution: Do not place the Scalp or Skull 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 OR System.

Caution: Never advance the ClearPoint Neuro Peel-Away Sheath into the brain without the supporting ClearPoint Neuro Ceramic Stylet.

Caution: Do not advance a device through the Device Guide 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.

Caution: Devices that are inserted through the Device Guide (without the Peel-Away Sheath or one of the Device Guides) must be held from the point of insertion into the SmartFrame OR until the device contacts the brain to prevent the device from advancing uncontrollably and possibly injuring the brain upon contact.

Caution: Do not apply more than 0.5 lb_f to the device or any component while using the SmartFrame OR System (i.e. no lateral force(s) against the SmartFrame OR when attached to the patient or while inserting the Stylet into the Peel-Away Sheath).

Caution: Stealth Station User Instructions provide guidance that any motion of the patient due to breathing, tremor, or any other voluntary or involuntary motion during the O-arm scan may lead to registration inaccuracies.

Caution: The PIVOT technique can be utilized with automated registration methods. Follow guidance from the StealthStation user instructions for performing automated registration. Adhere to guidance on motion of the patient due to breathing, tremor, or any other voluntary or involuntary motion during the O-arm scan may lead to registration inaccuracies.

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.

PRECAUTIONS

Re-sterilization – Do not re-sterilize any parts or components of the SmartFrame OR Stereotactic System. Re-sterilizing will damage the devices, making them unusable.

Component handling – Handle all parts and components of the SmartFrame OR Stereotactic System with extreme care. If any part or component is damaged, replacement will be needed. Minimize any forces applied directly to the SmartFrame OR hardware. Handle all components using standard hospital sterile practices. Do not bend or kink the ClearPoint Neuro Peel-Away Sheath

IV. Use Instructions

A. Planning and Preparation

Notes:

- All packaging and components of the SmartFrame OR Stereotactic System should be inspected for any damage prior to the procedure.
- Keep duplicate sterile products ready and available if a product becomes contaminated or is damaged during use and needs to be replaced.
- The SmartFrame OR 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 ClearPoint Bone Screw Fiducials are to be used as a general guide only. Relevant ClearPoint Bone Screw Fiducials product labeling must be reviewed prior to these procedures for detailed instructions on the use of the bone fiducials.
- Adhere to the instructions of any 3rd party device or therapy's Surgical Implantation Manual when used in conjunction with the SmartFrame OR.

1. **Patient Scanning**
    a. A minimum of two scans are necessary for planning and performing procedures with the SmartFrame OR Stereotactic System:
        i. MRI for Planning
        ii. CT for Registration

        Caution: The patient must remain immobile during image acquisition to ensure usable scans.

        Note: The SmartFrame OR Stereotactic System is **not** attached to the patient's skull during pre-operative patient scanning. For the best results, follow imaging parameter setting (i.e., slice thickness and spacing) guidelines in Medtronic Stealth Planning and Navigation product labeling.
    b. Acquire MRI image(/s).
    c. Acquire CT image(s).

        Caution: When bone screw fiducials are placed prior to a specific CT scan, handle the patient with care to prevent accidental bone fiducial loss or loosening as it may remain undetected.
2. **Bone Screw Fiducials**
    a. For procedures in which the ClearPoint Bone Screw Fiducials are used, place a minimum of four (4) fiducials in a non-coplanar array and in accordance with instructions provided by the device's manual.
3. **Intraoperative CT scan**
    a. Acquire CT image(s). Scan to encompass the entire head and all fiducials.
4. **Surgical Planning**

a. Follow instructions in the Medtronic Stealth Planning and Navigation product labeling to create a surgical plan or plans including all Target and Entry location(s).

Note: The SmartFrame OR Stereotactic System allows adjustment for targets up to a depth of 105 mm from the skull surface

Note: The SmartFrame OR Stereotactic System range of motion is 0° - 33° angular Pitch with 26° Roll.

Note: When planning for bilateral procedures, it is recommended that planned entry points have a minimum separation of 4cm when using skull mounts or 4.5 cm when using scalp mounts to safely accommodate two SmartFrame OR bases side by side.

WARNING: Carefully plan an entry point to avoid the following:

- Placing the attachment screws for the SmartFrame OR Base 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 SmartFrame OR Stereotactic System, which may result in target access failure.

5. **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.

a. The patient is prepared for surgery, which may include local or general anesthesia.

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

c. If using the Scalp Mount Base, it is recommended to attach the Medtronic Vertek Arm to the head fixation frame or surgical table.

6. **Optional Non-sterile Registration**

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

a. Attach an appropriate reference frame to the patient via a head strap or another noninvasive device, such as the Vertek Arm.

b. 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.

c. Locate the entry point and mark the scalp.

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

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

B. Mounting the SmartFrame OR Base and Performing the Sterile Registration

1. **ClearPointer Assembly**

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

   a. Remove all components of the ClearPointer Optical Navigation Wand from the Packaging.

   b. Attach the four sterile reflective spheres to the ClearPointer Array's posts and ensure each sphere is fully seated.

      Cautions:

      - Extreme care should be taken when attaching the reflective spheres to avoid contamination, scuffing or other damage to the spheres as well as the wand or array.
      - 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 with the ClearPointer Optical Navigation Wand other than NDI Passive Spheres.

   c. Insert the Pointer Attachment into the center lumen of the ClearPointer Array.

   d. Attach the ClearPointer Thumb Screw to the top of the Pointer Attachment Hub secure it to ensure the Pointer Attachment is fully in the ClearPointer Array (see Figure 4).

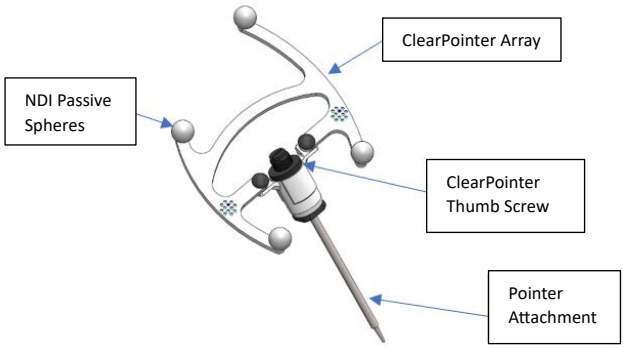


Figure 4: The ClearPointer Optical Navigation Wand with reflective spheres and the Pointer Attachment.

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

   e. Set aside the ClearPointer Optical Navigation Wand Until Step B-3.

2. **Skull Mount Base Mounting**

   Note: if using Scalp Mount Base, proceed to Scalp Mount Base instructions below in Section B-4.

   a. Sterile Preparation

      i. 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.

ii. Incise the scalp with enough space to accept the Skull Mount Base of the SmartFrame OR Stereotactic System.

iii. Drill a 14mm burr hole or appropriately sized access hole into the skull precisely centered over the previously marked Entry location.

Caution: When using a traditional DBS burr hole anchoring device, ensure the diameter of the burr hole is not less than 14mm. It is recommended to undercut the inner table burr hole edges using a Kerrison Rongeur or similar instrumentation.

b. Mounting the Skull Mount Base

i. Position the Centering Ring in the burr hole (not for burr holes smaller than 14 mm). If the burr hole is smaller than 14mm, the Centering Tool is not used.

ii. Position the Base over the Centering Tool or visually center the Base over the burr hole. Orient the base relative to the burr hole as depicted in Figure 5.

iii. Mount the Skull Mount Base with three (3) pre-mounted self-tapping screws to the skull. A manual screwdriver is supplied in the kit.

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.

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

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

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

iv. Check that the Base is secure and does not move. Confirm by feeling and observing for any movement while attempting to impart a rocking motion to the Base after mounting to the skull.

Note: For "Thumb Wheels down" Tower orientation, make sure the gear track is on the posterior side, as shown in Figure 5. For "Thumb Wheels up" Tower orientation, make sure the gear track is on the anterior side.

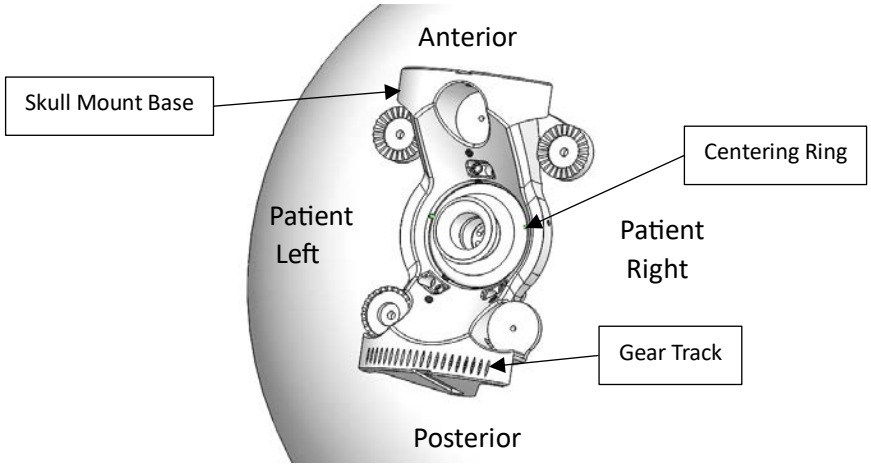


Figure 5: Base Mounting Orientation

Warning: Failing to check that the base is properly secured may result in unintended movement of the Tower and possible harm to the patient.

v. Remove the Centering Ring if used.

vi. Repeat the procedure for a second Base, if required for a bilateral procedure.

c. Attaching the Reference Frame

i. For procedures in which the patient's head is pinned, the reference frame does not need to be moved.

ii. For cases in which the patient's head is unpinned or they are awake, attach the Reference Frame Bracket Arm to one of the three mounting locations on the Base. Secure in place using the Screwdriver provided in the kit.

Note: Position the Reference Frame Bracket Arm so that the Reference Frame will be fully visible by the optical tracker and will not interfere or be blocked by the SmartFrame Tower(s).

iii. Attach the passive spinal reference frame (shown in Figure 6 below) to the SmartFrame OR reference frame bracket starburst providing optimal visibility.

iv. Adjust the three axes of the Reference Frame Bracket Arm as necessary to ensure that the Reference Frame is as orthogonal to the optical position tracker as possible.

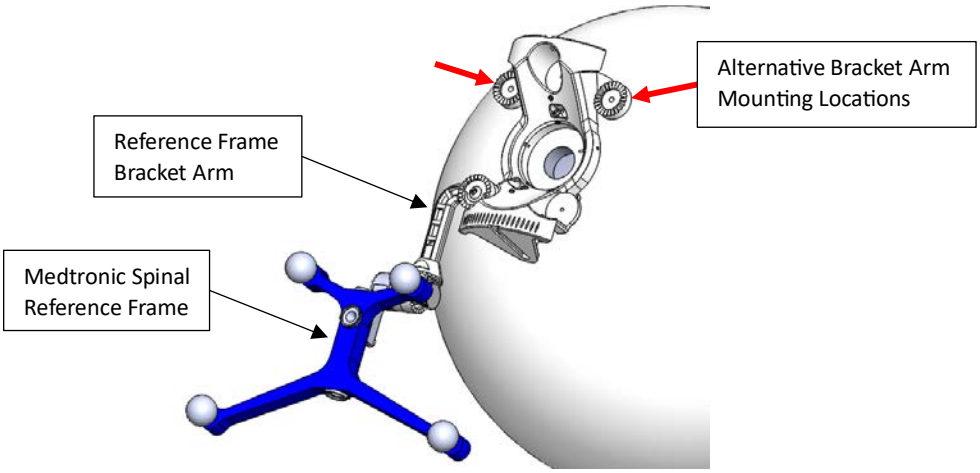


Figure 6: Medtronic Passive Spinal Reference Frame attached to the Skull Mount Base

v. Proceed to Section B-3 to perform Sterile Registration.

3. **Sterile Registration**

a. Choose the "NexProbe" tool file from the StealthStation Navigation System software.

Note: The ClearPointer's 4-sphere array, 45-degree angle, and distance to tip are identical to the NexProbe. Thus, the ClearPointer serves as a functional substitute for NexProbe within the context of the NexFrame workflow.

b. Align the Stealth Navigation system position tracker to include both the passive spinal reference frame and the optical navigation wand, when the wand is in vicinity of the planned and marked Entry point(s).

Caution: The Stealth Navigation system position tracker should be as orthogonal as possible to the surface of the ClearPointer Optical Navigation Wand and the passive spinal reference frame to maximize tracking accuracy. Further, ensure it is positioned at the optimal distance from the surgical field (as indicated by Stealth's UI). An optical position tracker that is within view but not optimally distanced from the surgical field has the potential to negatively impact alignment accuracy.

i. Perform the verification task for the wand according to the appropriate StealthStation Navigation System instructions.

ii. Verify the geometry error for the wand and the geometry error for the passive spinal reference frame from the StealthStation Navigation System tool file according to the appropriate StealthStation Navigation System instructions.

Cautions:

- The individual geometry error for the wand and the passive spinal reference frame should not exceed 0.3 mm when properly aligned to the Stealth Navigation system position tracker. Repeat Section B-1 (ClearPointer Assembly) and steps B-3-a & B-3-b if a geometry error exceeds 0.3 mm.
- If geometry error still exceeds 0.3mm, examine the reflective spheres to identify any particular one(s) that may be contaminated, damaged, or insufficiently seated on the post. Consider replacing as needed before repeating Section B-1 (ClearPointer Assembly) and steps B-3-a & B-3-b (Sterile Registration).
- Do not use the wand if the geometry error for the wand cannot be reduced. A geometry error exceeding 0.3 mm will result in inaccurate alignment to the target.

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

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

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

Caution: When using PointMerge registration, repeat steps iii & iv if registration error metric exceeds 1.0 mm.

Caution: When using O-arm registration, repeat steps iii & iv if verification does not produce satisfactory results.

c. If completing Sterile Registration after Section B-2 (Skull Mount Base Mounting) proceed to Section C (Mounting the SmartFrame OR Tower).

d. If completing Sterile Registration after Section B-4-b (Sterile Registration with ClearPointer Array for Entry Point Location), proceed to Section B-4-c (Entry Point Location and Mounting the Scalp Mount Base).

e. If completing Sterile Registration after Section B-4-e (Registration with Passive Spinal Reference Frame Attached to the SmartFrame Base), proceed to Step B-5.

4. **Scalp Mount Base**

   a. Sterile Preparation

      i. 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.

      ii. Attach an appropriate optical tracking reference frame to a Vertek Arm over the drape according to standard practice.

   b. Sterile Registration with ClearPointer Optical Navigation Wand for Entry Point Location

      i. Perform sterile registration per Section B-2.

   c. Entry Point Location and Mounting the Scalp Mount Base

      i. The Scalp Mount Base has three inner screws and four support pins. The support pins have sharp tips (see Figure 7). The pins have small protective tubes covering them, remove the tubes before proceeding.

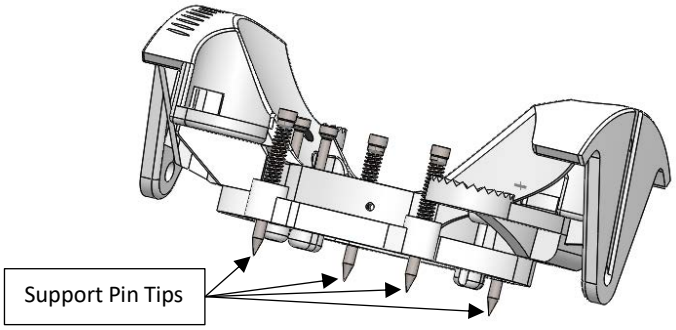


Figure 7: SmartFrame OR Scalp Mount Base

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

      ii. The Scalp Mount Base has four adjustable height support pins and three self-tapping bone screws (see Figure 8).

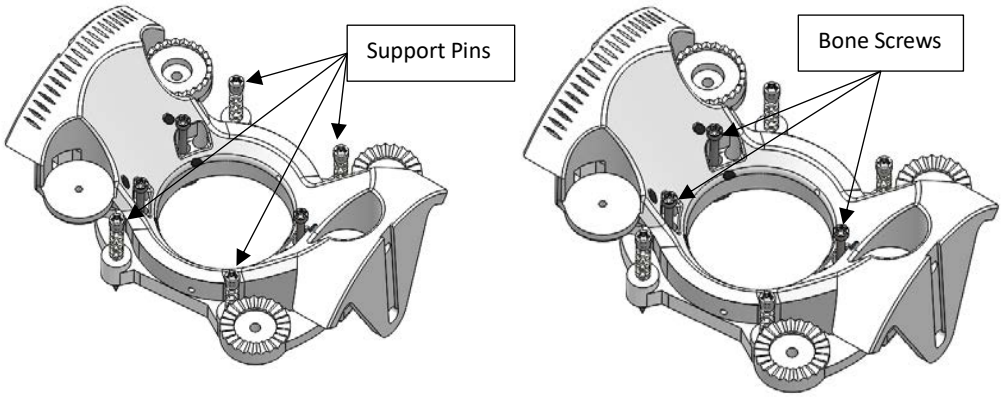


Figure 8: SmartFrame OR Scalp Mount Base

      iii. Assemble the Entry Point Locator to the Scalp Mount Base as shown in Figure 9.

iv. Insert the verified ClearPointer into the Entry Point Locator and tighten the Entry Point Locator thumb screw (Figure 9).

Figure 9: Assembled Scalp Mount Base, Entry Point Locator, and ClearPointer Optical Navigation Wand

v. Move the Scalp Mount Base with the Entry Point Locator and ClearPointer Optical Navigation Wand over the patient's head near the existing burr hole location (if present) or marked Entry point on the scalp until the ClearPointer aligns with the desired Entry point as displayed on the Stealth Station. The Scalp Mount Base should be oriented with respect to the patient as shown in Figure 10.

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

Caution: For bilateral procedures in which two Bases will be mounted, ensure the appropriate plan for the correct side is selected on the StealthStation.

vi. The Entry Point Locator can be pivoted like a joystick while aligning the Base with the Entry Point. Correctly aligning the angulation of the Entry Point Locator prior to finalizing the Base position optimizes positional accuracy.

vii. Angle the Entry Point Locator to match the planned trajectory.

viii. Place the Base on the patient's head and Mount the Scalp Mount Base. Make sure the Base is oriented as shown in Figure 10.

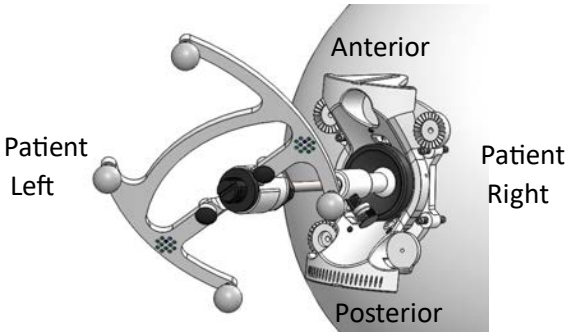


Figure 10: Base Orientation on Patient's Head

Note: For "Thumb Wheels down" Tower orientation, make sure the gear track is on the posterior side, as shown in Figure 5. For "Thumb Wheels up" Tower orientation, make sure the gear track is on the anterior side.

ix. Begin securing the Bone Screws to the skull through the scalp. 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. The Entry Point Locator stem may be moved out of the way for easier access to the screws (see Figure 11).

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.

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

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

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

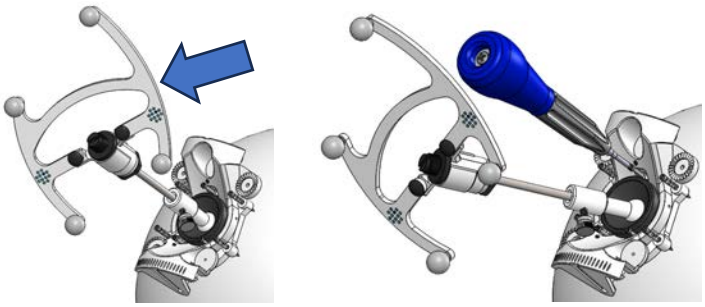


Figure 11: Entry Point Locator Stem being pivoted to make access to screws easier.

x. While screwing in the bone screws, check the security of the Scalp Mount Base repeatedly and check that the Base can lift off the scalp as it becomes secure in the skull.

xi. Once the bone screws are secure in the skull, deploy the four outer support pins by screwing them down using the manual screwdriver provided in the SmartFrame OR package. 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.

Caution: It is recommended to deploy the support pins in a manner that most evenly raises the base. Use a small number of rotational turns on one pin before moving onto another, until all 4 have been deployed by this equivalent small amount. Return to the first pin and deploy additional rotations before moving onto another. Deploying the support pins carefully and sequentially will assist in raising the Base evenly and prevent over-torquing or deformation of the Base shape.

xii. 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.

Warning: Failing to check the base is properly secured may result in unintended movement of the Tower and possible harm to the patient.

xiii. If mounting a second Scalp Mount Base for a bilateral procedure, repeat Section B-4-c for a second Base.

Note: Change the selection of trajectory plans to the other side on the Stealth Station prior to beginning the Base Mounting procedure for the second side.

d. Moving the Reference Frame

Note: If desired, the Vertek Arm Reference Frame can be utilized for the remainder of the procedure. If using the Vertek Arm Reference Frame, proceed directly to Section C.

i. Detach Reference Frame attached to the Vertek Arm and set aside.

ii. Attach the Reference Frame Bracket Arm to one of the three mounting locations on the base. Secure in place using the Screwdriver provided in the kit.

Note: Position the Reference Frame Bracket Arm so that the Passive Spinal Reference Frame will be fully visible by the optical tracker and not interfere or be blocked by the SmartFrame Tower(s).

iii. Attach the passive spinal reference frame (shown in Figure 12 below) Reference Frame Bracket Arm attached to the Base. Attach the Reference Frame to the Bracket Arm.

iv. Adjust the three axes of the Reference Frame Bracket Arm as necessary to ensure that the Reference Frame is as orthogonal to the optical navigation's position tracker as possible.

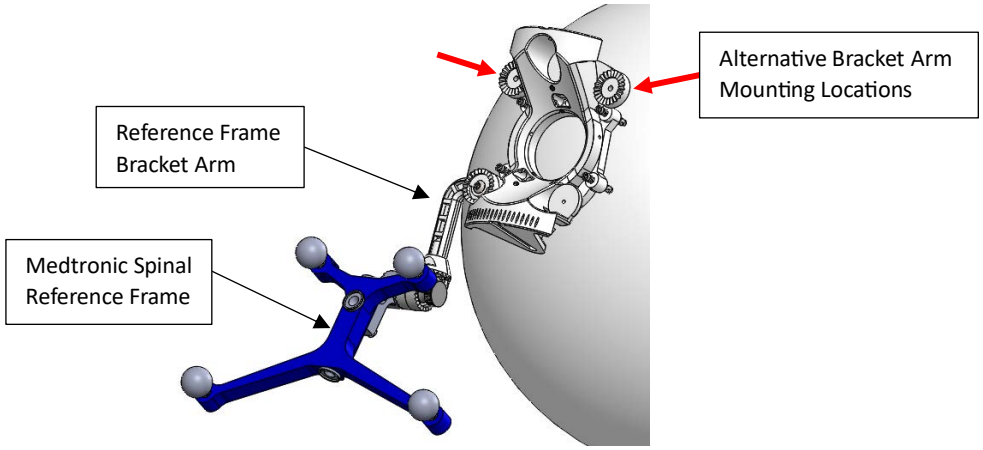


Figure 12: Medtronic Passive Spinal Reference Frame attached to the Scalp Mount Base.

e. Registration with Reference Frame Attached to the SmartFrame Base

i. Re-perform the sterile registration step per Section B-3.

5. Once the Base(s) are attached to the skull and registration with the Reference Frame mounted to one of the Bases has been completed, the SmartFrame OR Tower is ready to be mounted.

C. Mounting the SmartFrame OR Tower

1. **Attaching the SmartFrame OR Tower**

   a. Orient the Tower, relative to the Base, by placing the colored thumb wheels of the Tower toward the gear side of the Base. For standard Base orientation, this should be the side closer to the floor (see Figure 13). Verify that the range marker associated with each of the colored thumbwheels is zeroed-out at the center range by looking at the range marker associated with each colored wheel.

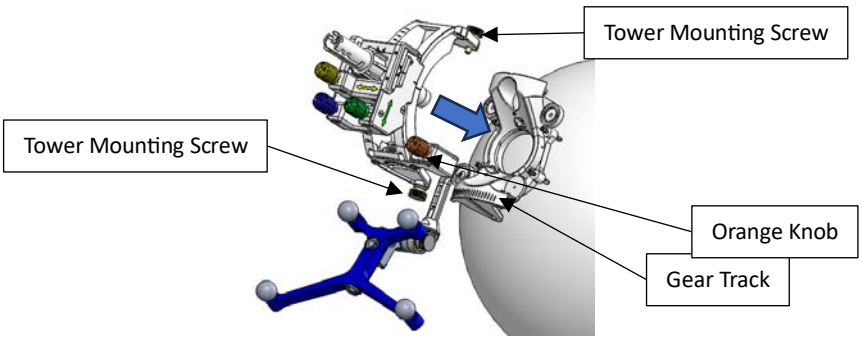


Figure 13: Tower Attachment Orientation with respect to the Base

   b. Mount the Tower onto the Base by first loosening, then grasping the Tower Mounting Screws. Grasp the Tower by the top rectangular gear housing. Align each Tower Mounting Screw with the mating grooves on the Base (see Figure 13). Slide the Tower into place and ensure the Tower Mounting Screws seat into the lower mounting holes in the base.

   Caution: Avoid applying pressure to the colored thumb wheels while grasping the Tower.

   Caution: For proper orientation of the Tower to the Base, ensure the orange thumb wheel of the Tower is on the same side as the gear track on the top surface of the Base.

   c. Tighten the two Tower Mounting Screws and confirm that the screws are completely seated on the Base.

   Warning: The stability of the SmartFrame OR Base and Tower assembly should be checked prior to moving to the next step. An unstable attachment of the SmartFrame OR 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.

   d. Remove the Roll Lock Screws w/rust-colored washer from the SmartFrame OR package to pre-mount in SmartFrame OR. Screw in partially to the appropriate location on the SmartFrame OR (see Figure 14). Ensure the Roll Lock Screw is not tight. The screw will be tightened later in the procedure.

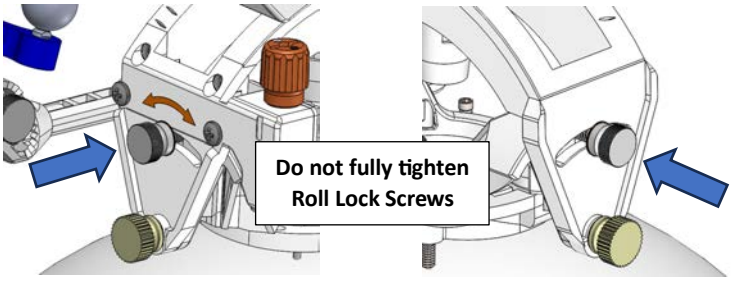


Figure 14: Roll Lock Screws w/rust-colored washer

Caution: The Roll Lock Screw should not be tightened until final positioning is selected during later portion of the procedure. If the Roll Lock Screw is tight during roll dial adjustments, the trajectory movement will be affected and may result in an inappropriate alignment.

D. SmartFrame OR Alignment with the ClearPointer Array

Note: Relevant product labeling for the StealthStation Navigation System being used must be reviewed prior to use for detailed alignment instructions using the ClearPointer Optical Navigation Wand.

1. Loosen and separate the Thumb Screw on the ClearPointer Optical Navigation Wand and remove the Pointer Attachment from the ClearPointer Array.
2. Slide the ClearPointer Array over the central device support of the SmartFrame OR Tower. Secure the ClearPointer Array to the Tower until it bottoms out (see Figure 15).

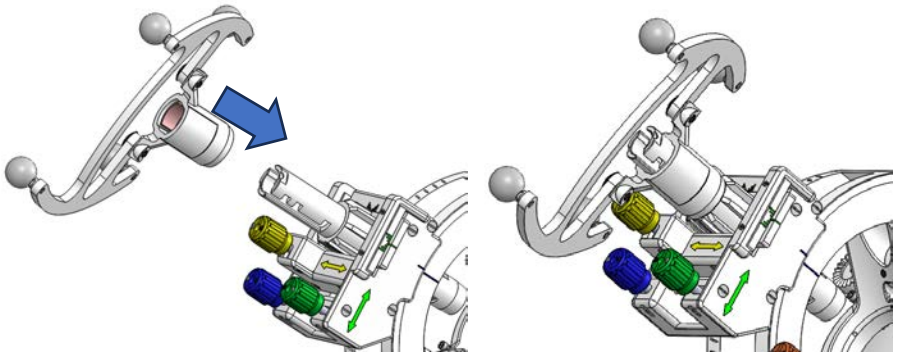


Figure 15: ClearPointer Array attaches to the SmartFrame OR Tower device support

3. Insert the Device Guide into the central lumen of the device support until it bottoms out and twist the cap counterclockwise until the cap locks into the Device Support (see Figure 16).

   Note: Refer to the technical specifications for identifying which Guide should be inserted, based on the size of the instrument intended for insertion.

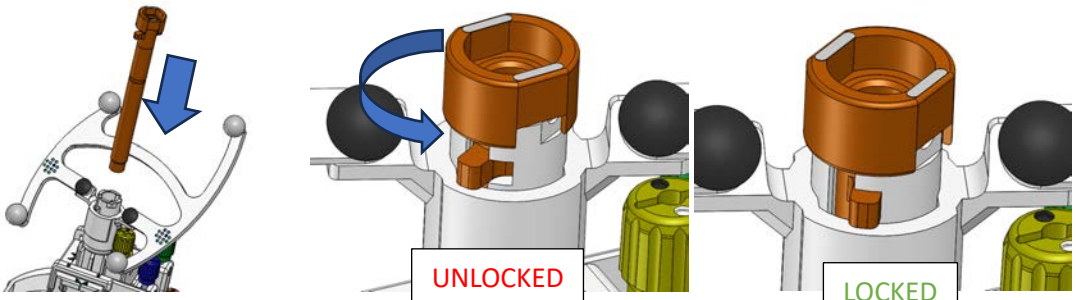


Figure 16: Inserting and Securing a Guide in the SmartFrame OR Tower

4. Orient the ClearPointer Array and/or adjust the position of the Stealth Navigation system position tracker such that they are as orthogonal as possible. The surface of the ClearPointer Array and the Reference Frame should be as orthogonal as possible to the position tracker to maximize tracking accuracy. The position tracker should be placed with optimal distance from the surgical field (as indicated by Stealth's UI).

   Note: The ClearPointer Array is able to freely rotate around the SmartFrame OR Tower device support to adjust their position at any point during the procedure without interfering with the alignment of the SmartFrame OR Tower.

Note: It is recommended to position them optimally prior to the start of the alignment process and leave them in this position for the duration of alignment if possible.

Note: If one of the colored thumbwheels is difficult to reach due to the position of the ClearPointer Array's positioning, use the provided Thumbwheel Extender provided with the Depth Setter Kit to avoid repositioning the ClearPointer Array to a sub-optimal orientation relative to the optical position tracker (see Figure 17). The distal end of the Thumbwheel Extender has a flexible cable that can bend while rotating the dials to optimize thumbwheel operation without blocking either the ClearPointer Array or Reference Frame.

Figure 17: Thumbwheel Extender

5. Reverify the geometry error for the wand and the geometry error for the reference frame according to the appropriate Stealth Station Navigation System instructions.
6. Select the appropriate Navigation screen to display on the StealthStation Navigation System workstation.
7. Utilizing the orange (roll) and the blue (pitch) thumbwheels on the SmartFrame OR Tower, adjust the angulation of the SmartFrame OR Stereotactic System until it is aligned with the intended target by observing the Guidance screen on the StealthStation.

   Caution: Before finalizing pitch/roll alignment with the optical navigation, **it is important to zoom-in on the navigation system display to finalize alignment.** Failure to do so will likely result in false feedback that the trajectory is fully aligned and increase the potential for suboptimal alignment accuracy.

   Caution: The ClearPointer Array should continue to remain as orthogonal as possible to the Stealth Navigation System optical position tracker throughout the alignment process to maximize tracking accuracy. If one of the thumbwheels is difficult to reach due to the position of the ClearPointer Array's positioning, use the provided Thumbwheel Extension (see Figure 18) to avoid repositioning the ClearPointer Array away from orthogonally facing the optical navigation tracker.

   Caution: For procedures in which the surgeon anticipates using the iCT PIVOT Technique, it is not recommended to adjust yellow (X) or green (Y) knobs during the initial alignment process. These thumbwheels should remain at the centered position to ensure maximum potential range of motion if their adjustment is required later in the workflow.

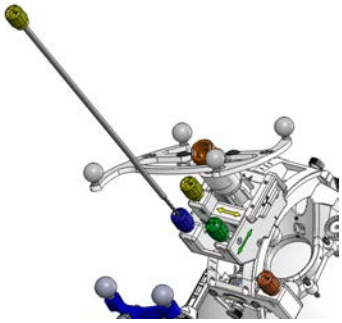


Figure 18: Thumbwheel Extender inserted into the blue (pitch) knob for remote operation.

8. Once angular alignment has been sufficiently achieved, tighten both Roll Lock screws simultaneously to prevent additional Tower movement in the roll direction.

Note: In the event any inadvertent movement of the SmartFrame OR Tower occurs, loosen the Roll Lock screw and re-align in Guidance view as appropriate.

9. After alignment has been completed, reset the entry point on the StealthStation. Obtain a depth-to-target reading from Stealth Navigation system and record this depth information for later reference. Proceed to Procedure Options below for next steps.

E. Measuring out Instrument Insertion Depth

1. **Option 1: ClearPoint Neuro Depth Setter**
    a. Lay the instrument into the V-groove of the Depth Setter so that the non-inserted end of the device is hanging out of the Depth Setter.
    b. Using the "SMARTFRAME OR" offset Scale, position the inserted end of the instrument at the depth mark corresponding to the depth value shown on the StealthStation (see Figure 19).

    Note: The ruler displays the known height of the SmartFrame OR Tower such that the exact insertion depth obtained from the Stealth Station can be measured without requiring the addition of this value to the prescribed depth.

    c. Mark the instrument at the point where the instrument exits the v-groove on the Depth Setter using a sterile marker.
    d. Position a Depth Stop on the depth mark on the instrument and secure with the thumb screw. The Depth Stop should bottom out on the left-side edge of the Depth Setter.

    Note: The inserted depth of the Instrument is defined by the length of the inserted tip of the Instrument to the distal face of the Depth Stop.

    Caution: Do not over tighten the thumb screw on the Depth Stop to avoid damage to the instrument.

    e. Remove the assembled instrument from the Depth Setter.

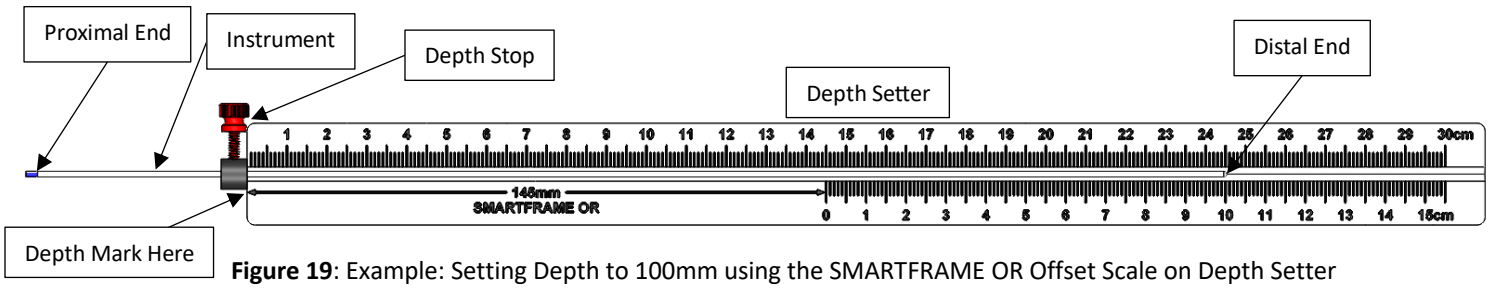


Figure 19: Example: Setting Depth to 100mm using the SMARTFRAME OR Offset Scale on Depth Setter

2. **Option 2: Standard Metric Ruler**
    a. Obtain the depth value shown on the StealthStation.
    b. Calculate the total depth by adding 145mm to the depth value provided by the StealthStation.

    Note: Adding 145mm to the depth value accounts for the added height of the SmartFrame OR Tower when setting instrument depth.

    c. Mark the target's depth on the instrument using the Ruler and a Marking Pen and the calculated depth value.
    d. Position the Depth Stop on the depth mark on the instrument and tighten the red thumb screw.

    Note: The inserted depth of the instrument is defined by the length of the inserted tip of the instrument to the distal face of the Depth Stop.

    Caution: Do not over tighten the thumb screw on the Depth Stop to avoid damage to the instrument.

F. Procedure Options

1. The remaining instructions are divided into procedural paths. Follow the instructions applicable to the device being used with the SmartFrame OR Stereotactic System.
2. **Procedures utilizing a Twist Drill access hole prior to Device Insertion**: For procedures in which a burr hole has not already been created and for which a smaller Twist Drill access hole must be made prior to Device Insertion (refer to **section G)**.
3. **Procedures utilizing the ClearPoint Neuro Stylet and Peel-Away Sheath**: Procedures that require a Peel-Away Sheath with Stylet to insert a device that cannot be inserted without support or to create a path to target (refer to **section H)**.
4. **Procedures utilizing the PIVOT Technique** (Pre-Insertion Verification of Trajectory): For procedures in which a pre-insertion iCT scan is used to inform XY stage adjustments closer to the pre-planned target (refer to **section I)**.
5. **Direct insertion Procedures**: Procedures that do not need placement of the Peel-Away Sheath with Stylet (refer to **section K**).

   Caution: The compatibility of neurological instruments and devices should be evaluated before use with the ClearPoint Neuro SmartFrame OR System and SmartFrame OR Accessories.

G. Utilizing a Twist Drill Access Hole

1. If intending to perform the PIVOT technique utilizing a Twist Drill Access Hole, it is recommended that the PIVOT step be completed before and after drilling the access hole. **Refer to Section I**.
2. **Exchanging the Device Guide with the Drill Guide**
   a. To use the provided Twist Drill bits, the Device Guide must be removed, and the appropriately sized Drill Guide must be inserted into the SmartFrame OR Tower. Refer to the Technical Specification section for a list of the Twist Drill Bits and the appropriately sized Drill Guides for each.
   b. Twist the Device Guide clockwise so that the tabs of the Cap disengage from the slots on the device support column of the SmartFrame OR Tower (see Figure 20). Then, pull the Device Guide out by holding onto the Cap portion and pulling away from the support.

      Caution: Avoid exerting any lateral loads on the Tower during this process, to avoid unintentionally shifting the Tower's trajectory.

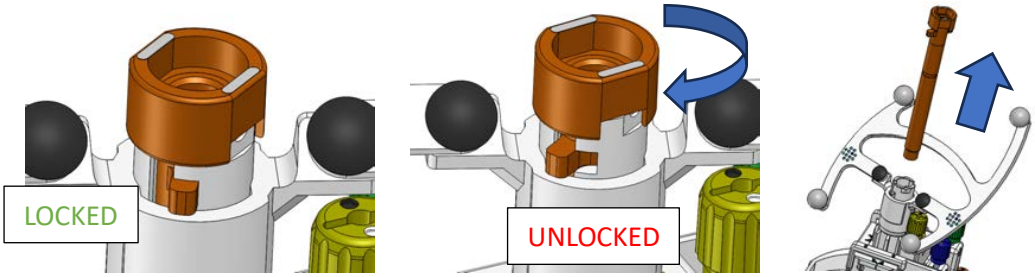


Figure 20: Removing the Device Guide

   c. Insert the desired Drill Guide into the support column so that the tabs on the Drill Guide fit into the slots of the support column. Twist the Drill Guide so that the tabs engage the slots to lock it into position (see Figure 21).

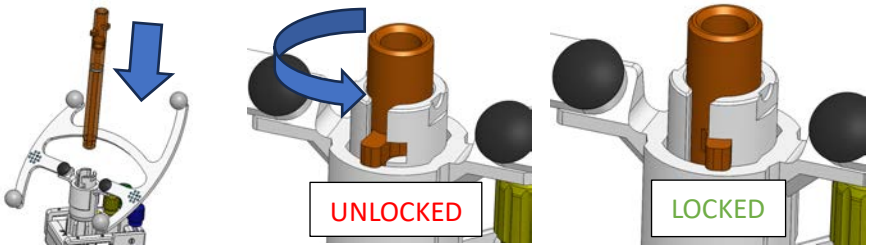


Figure 21: Inserting and Securing the Drill Guide

   d. Create the access hole using the SmartTip Drill Bit. Refer to the SmartTip Drill Bit Instructions for Use for details.
   e. Once the access hole has been created, choose the appropriate-sized Device Guide, and insert it into the support column as described above. The steps for inserting and securing the Device Guide are identical to the Drill Guide.

      Note: Refer to the technical specifications for identifying which Guide should be inserted, based on the size of the instrument intended for insertion.
   f. Refer back to **Section F** (Procedure Options) to determine the next appropriate step.

H. Assembling the ClearPoint Neuro Stylet and Peel-Away Sheath

1. Remove the Dock and Device Lock (see Figure 23) from the SmartFrame OR package.

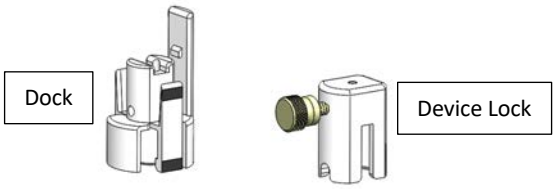


Figure 23: Dock and Device Lock

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

   Note: The distal end of the Stylet has a bull nose tip and the non-inserted end of the Stylet is denoted with a **blue** marking.

3. Mark the target's depth on the Stylet using the Ruler and Marking Pen with the depth value obtained from Stealth Station following the instructions in **Section F** (Measuring out Instrument Insertion Depth).

   Caution: Do not over tighten the red thumb screw on the Depth Stop to avoid damage or breakage of the Stylet

   Warning: Do not use a broken ClearPoint Neuro Stylet or Lancet.

4. Set aside the measured Stylet. Remove a Peel-Away Sheath from the Accessory Kit and separate the red hub to peel away approximately one (1) inch of the Sheath. Place the Peel-Away Sheath through the Dock such that the unpeeled portion extends out the bottom of the Dock, while the peeled portion extends out of the top portion of the Dock near the backboard extension piece. See Figure 24.

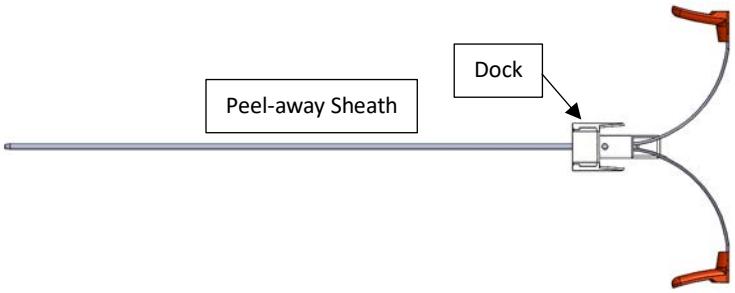


Figure 24: Peel-Away Sheath Inserted into the Device Dock

5. Drape the peeled sheath portions directly over the black painted side elements of the Dock, one per side. Holding the peeled sheath portions over the black line posts, secure the sheath in place by snapping the Device Lock onto the Dock, making sure to orient the Device Lock so that the white thumb screw opposes the backboard extension piece of the Dock (see Figure 25).

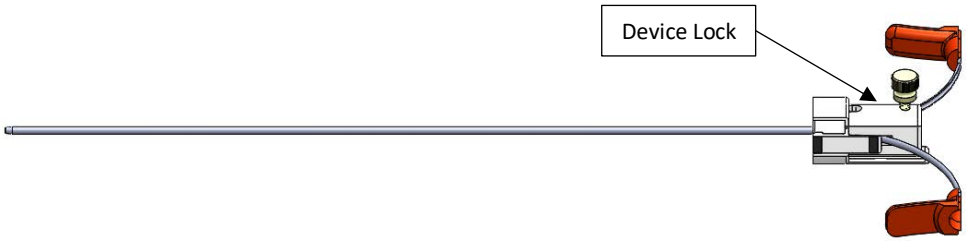


Figure 25: Device Lock attached to Dock and Pee-Away Sheath

6. Confirm the Device Lock center aperture is open and not occluded by the white thumb screw. Insert the measured Stylet into the Peel-Away Sheath Dock and Device Lock assembly until the distal face of the Depth Stop is touching the proximal face of the Device Lock. Then tighten the white thumb screw of the Device Lock.

   Caution: Do not over tighten the white thumb screw on the Device lock to avoid damage or breakage of the Stylet.

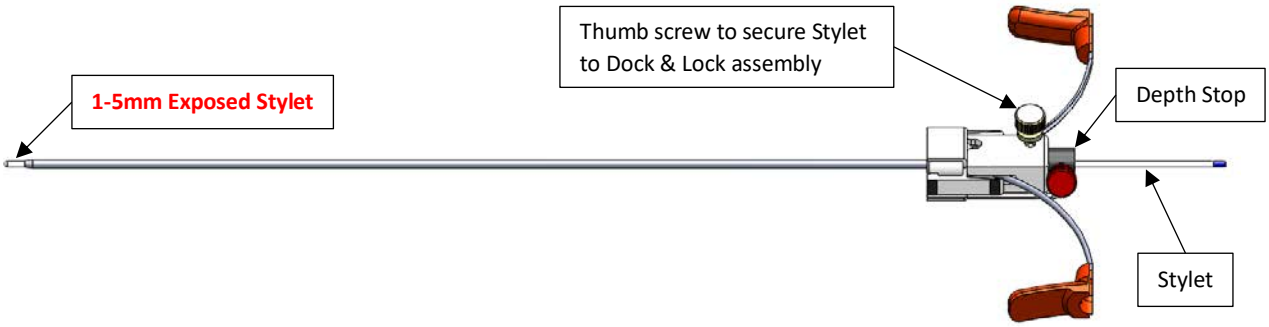


Figure 26: Inserting Ceramic Stylet into the Peel-Away Sheath

7. For device insertion, the distal end of the Stylet should protrude between one (1) and five (5) mm from the end of the Sheath. If the Stylet is not protruding, pull on both ends of the red hubs to peel the Sheath until the distal end of the Stylet is visible beyond the Sheath, and protrudes between one (1) and five (5) mm. A slight resistance may be felt as the Sheath is peeled over the distal end of the Stylet.

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

8. If performing the PIVOT Step, proceed to **Section I** (Pre-Insertion Verification of Trajectory).
9. If ready to insert the Peel-Away Sheath and Stylet to Target, proceed to **Section J** (Inserting the ClearPoint Neuro Peel-Away Sheath and Stylet).

I. Pre-Insertion Verification of Trajectory (PIVOT) Technique

Note: Proceed with this Section only after completion of the Peel-Away Sheath and Stylet assembly (**Section H**).

Depending on the accuracy requirements of the procedure, the user may elect to follow the below optional steps to execute the Pre-Insertion Verification Of Trajectory (PIVOT) Technique. The PIVOT Technique described below utilizes an iCT image to calculate a trajectory projection prior to device insertion and may prescribe additional X-Y frame adjustments on the SmartFrame OR Tower to improve placement accuracy. The PIVOT Technique and the SmartFrame OR System provide accuracy as noted in Table 6 in the Technical Specifications section.

Caution: The PIVOT technique can be utilized with automated registration methods. Follow guidance from the StealthStation user instructions for performing automated registration. Adhere to any guidance on motion of the patient due to breathing, tremor, or any other voluntary or involuntary motion during the O-arm scan may lead to registration inaccuracies.

Caution: The Z-plane or depth accuracy can only be verified by the user during real-time iCT intraoperative imaging during placement of the instrument. Follow all instructions for Stealth Station Navigation System and O-Arm iCT to obtain intraoperative depth assessments.

Note: If performing PIVOT, the ClearPointer Array can be removed from the SmartFrame Tower, if desired. Remove the Device Guide, followed by the ClearPointer Array. Then re-insert the Device Guide.

1. Insert the distal end of the Peel-Away Sheath & Stylet Assembly into a Depth Stop. Do not tighten the Depth Stop at this step.
2. Insert the Peel-Away Sheath and Stylet Assembly into the SmartFrame OR Device Guide to the level of dura without disturbing or violating dura. If dura was opened during a prior step in the procedure, take care to avoid touching or violating pia at this step (see Figure 27).

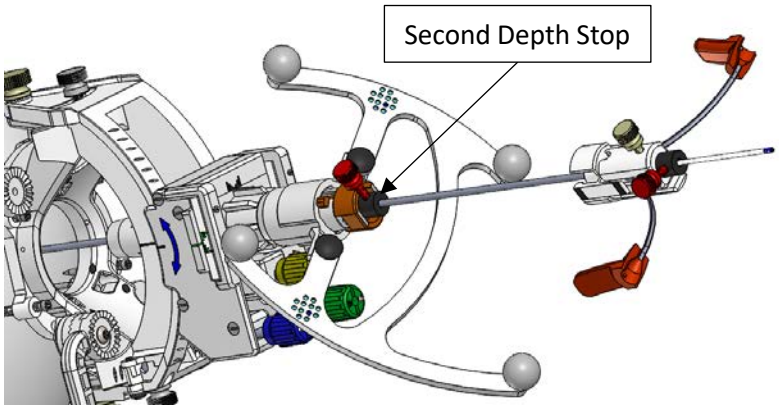


Figure 27: Stylet positioned (Ex: Skull Surface) for PIVOT iCT scan.

Note: If utilizing an open dura approach, employ best practices for CSF loss management as a significant loss of CSF could potentially result in brain shift, leading to inaccurate placement.

Note: It is recommended that the PIVOT steps be performed before and after creating a twist drill hole, to ensure that the tower trajectory did not shift during drilling.

Note: If completing PIVOT steps prior to creation of a Twist Drill access hole, the Stylet will rest on bone rather than dura. If an incision has not been made at this point, a small stab incision should be created to facilitate the Stylet directly touching the surface of the skull prior to completing any subsequent steps below.

3. Secure the Depth Stop around the Peel-Away Sheath & Stylet Assembly to maintain the appropriate pre-insertion depth (above dura, above pia, or resting on bone).
4. Obtain an iCT scan, ensuring the field of view is sufficiently positioned to capture superior elements above the skull including the SmartFrame OR Base and as much of the Stylet as possible without cutting off the lower elements of the skull such that Stealth fusion would be negatively impacted.

   Note: Low dose iCT has been shown to be sufficient for properly visualizing the ceramic stylet and registering the resulting image back to the designated reference scan.
5. Import and merge this scan into Stealth and create a new trajectory Plan without modifying any elements of the previously existing trajectory plan(s). This new Plan will be used to assess and compare the existing trajectory alignment to desired surgical plan. Set the Entry of this new trajectory on the center axis of the most proximal point of the Stylet that can be visualized on the new scan. Set the Target on the center axis of the distal end near the tip of the Stylet.

   Note: Ensure that the center of the Stylet's axis is selected for both points on the Stylet trajectory to ensure accurate virtual extension of the line down to surgical target depth.
6. On the StealthStation, scroll through the probe's eye view to the level immediately proximal to skull where the SmartFrame OR Base can be visualized. Rotate the viewport orientation to match the orientation of the SmartFrame OR Base as mounted on the patient's skull. See Tables 2 & 3 for the correct Base orientation.

Table 2: Tower and Image Orientation Guidance – KNOBS DOWN

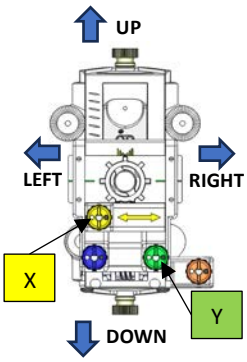
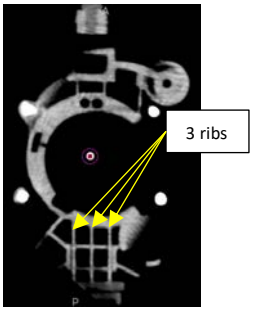
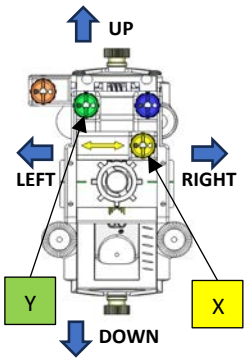
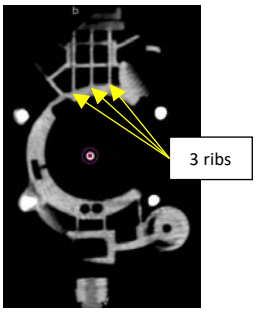
Thumb Wheel	Direction of desired Trajectory Adjustment	Thumb Wheel rotation direction	Tower Orientation on Patient's Head as viewed by User	On-Screen Orientation of Image
X (yellow) **1 Rotation = 1mm**	RIGHT	Clockwise	 Tower is mounted on patient's head "**knobs down**".	 Rotate image on StealthStation to vertically align the three ribs, so that they are on the **BOTTOM** of the image.
	LEFT	Counter-Clockwise		
Y (green) **1 Rotation = 1mm**	UP	Clockwise		
	DOWN	Counter-Clockwise		

Table 3: Tower and Image Orientation Guidance – KNOBS UP				
Thumb Wheel	**Direction of desired Trajectory Adjustment**	**Thumb Wheel rotation direction**	**Tower Orientation on Patient's Head as viewed by User**	**On-Screen Orientation of Image**
X (yellow) **1 Rotation = 1mm**	RIGHT	Counter-Clockwise	 Tower is mounted on patient's head "**knobs Up".**	 Rotate image on StealthStation to vertically align the three ribs, so that they are on the **TOP** of the image.
	LEFT	Clockwise		
Y (green) **1 Rotation = 1mm**	UP	Counter-Clockwise		
	DOWN	Clockwise		

Note: This on-screen rotation of the image is important to align the imaging of the Base with the SmartFrame OR Tower's X-Y stage.

Note: It can be helpful to utilize a combination of the Stealth Station's A/P & L/R markings in the viewport in combination with identifiable element(s) of the SmartFrame OR Base, such as the top two bone screw holes in the anterior aspect of the Base, the structural rib design, and/or the attached reference frame bracket arm.

7. After orienting the image, scroll down in Probe's Eye view along the stylet's projected trajectory until reaching the surgical target plane.
8. Using the measurement tool, obtain two measurements from the Stylet's projected placement ("Target") compared to the originally planned target; one measurement in the X-direction and one in the Y-direction (see Figure 28). Record the magnitude and directionality of the discrepancies between the two noting the desire to move from the new Plan's projected placement back to the original surgical plan (e.g., reduce error to plan)
9. If the discrepancy is sufficiently large enough that an additional SmartFrame OR adjustment is desired, convert these measurements into X (yellow) and Y (green) thumb wheel changes.
Note: Thumb wheel rotation conversion should rely on the known specification that 1 full rotation of either the X or Y thumb wheel is equivalent to a translational move of 1mm.

   Note: Thumb wheel rotations are fractionally accurate as well (e.g., 1/4 turn corresponds to a .25 mm adjustment change).

   Note: The SmartFrame OR X/Y Frame Stage is capable of +/- 2.5mm of translational movement.

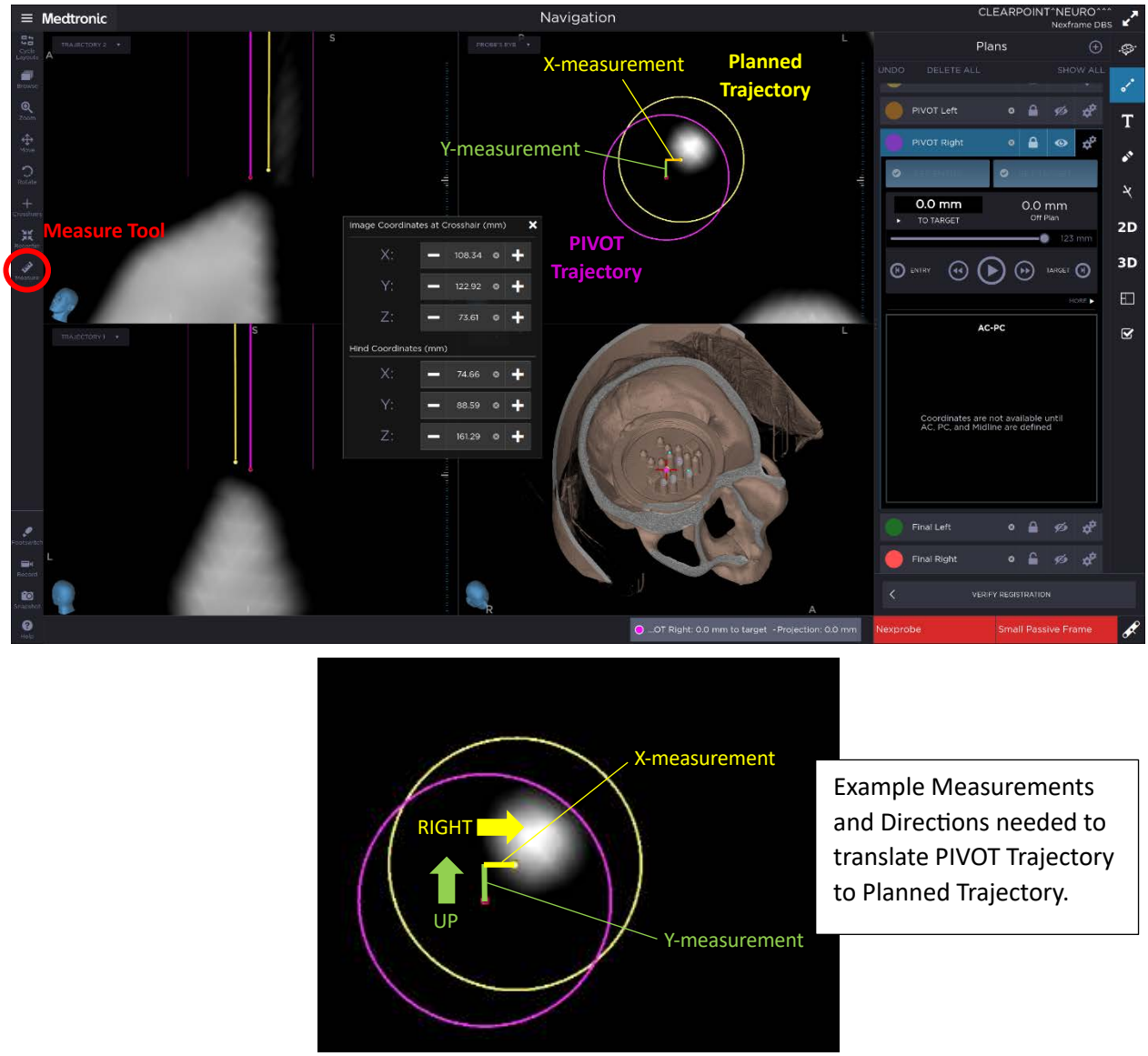


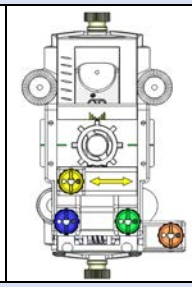
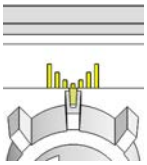
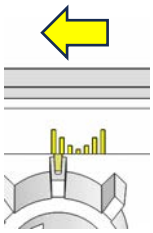
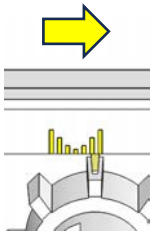
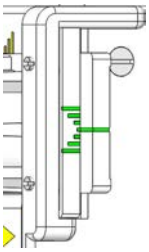
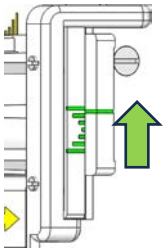
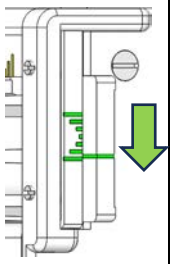
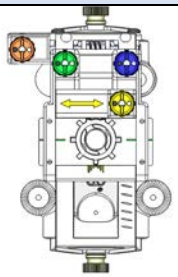
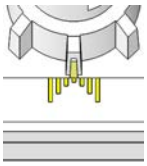
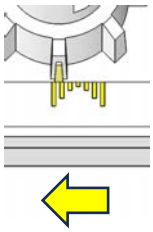
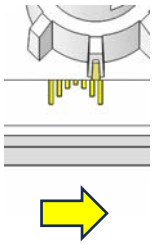
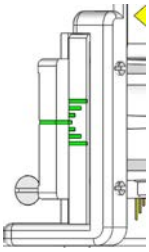
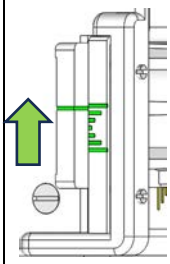
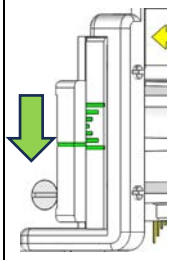
Figure 28: X & Y Measurements between the Stylet projected target, and the planned target, taken on the StealthStation

10. Remove the Peel-Away Sheath & Stylet Assembly from the SmartFrame OR Device Guide and remove the secondary Depth Stop used to position the Assembly for iCT. Set aside the Depth Stop and Assembly.

11. Use the X-measurement obtained from Stealth to adjust the yellow thumb wheel. Use Tables 2 & 3 above to determine the direction of rotation.

12. Use the Y-measurement obtained from Stealth to adjust the green thumb wheel. Use Tables 3 & 4 above to determine the direction of rotation.

    Caution: Carefully observe the Yellow (X) and Green (Y) Range Markers on the SmartFrame OR Tower's stage to verify translational moves have been made in the correct direction. See Table 4 and Figure 29. If an incorrect move is made, reverse the turn until the Range Markers are re-zeroed and then perform the correct turns.

Table 4: X & Y Axis Scales and relative movement of Device Support Marker with respect to the Scales							
Tower Orientation on Patient's Head as viewed by User		**X-AXIS**			**Y-AXIS**		
		Zero	**Adjustment Left**	**Adjustment Right**	**Zero**	**Adjustment Up**	**Adjustment Down**
KNOBS DOWN							
KNOBS UP							

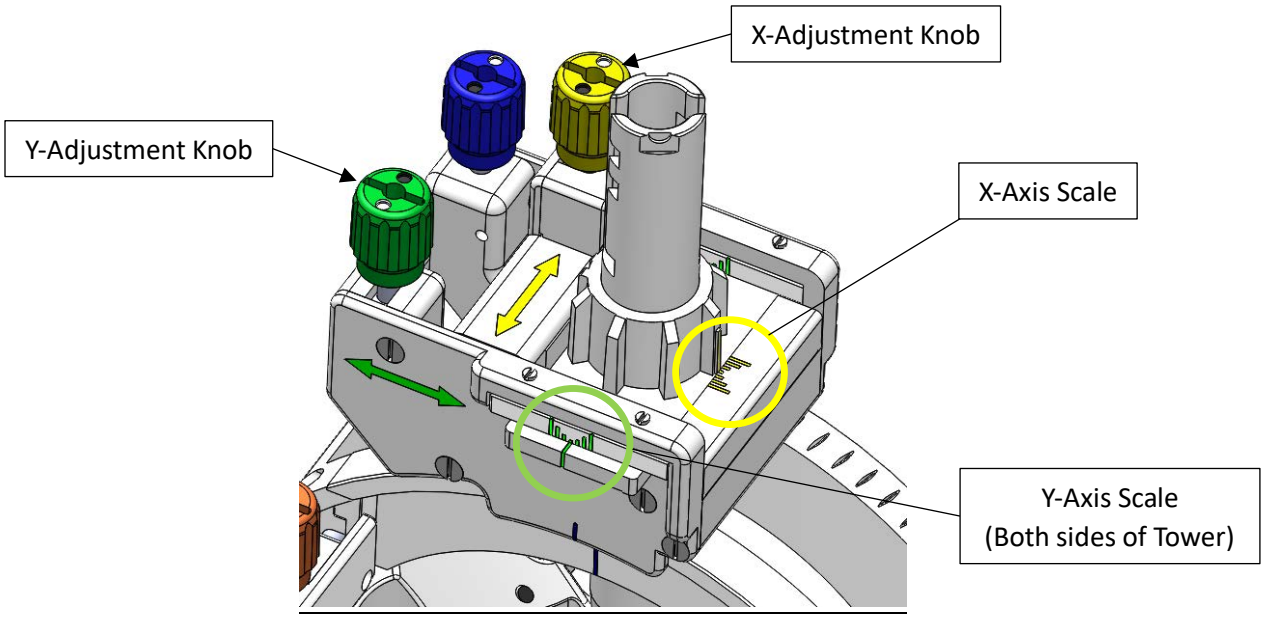


Figure 29: Location of X & Y Axis Scales

J. Inserting the ClearPoint Neuro Peel-Away Sheath and Stylet

Note: Perform this section only after completing the assembly of the Peel-Away Sheath and Stylet. Refer to Section H.

1. If the dura has not yet been opened, pierce the dura using the Larson Bladed Lancet or another instrument for opening the dura.
2. Insert the inserted tip end of Peel-Away Sheath & Stylet Assembly into the cap of the Device Guide.

   Warning: **Do not insert the Peel-Away Sheath without the Stylet tip protruding 1 – 5mm from the end of the Sheath.** Inserting the Peel-away Sheath without the Stylet tip protruding can cause severe harm to the patient.

   Warning: Do not apply a lateral load to the Peel-Away Sheath and Stylet during insertion. This may cause damage to the device and cause the Stylet to follow an unintended trajectory.
3. As insertion approaches the full measured target depth, orient the Dock such that the black lines match up with the flat aspects of the Device Guide Cap (marked with white lines) (see Figure 30).

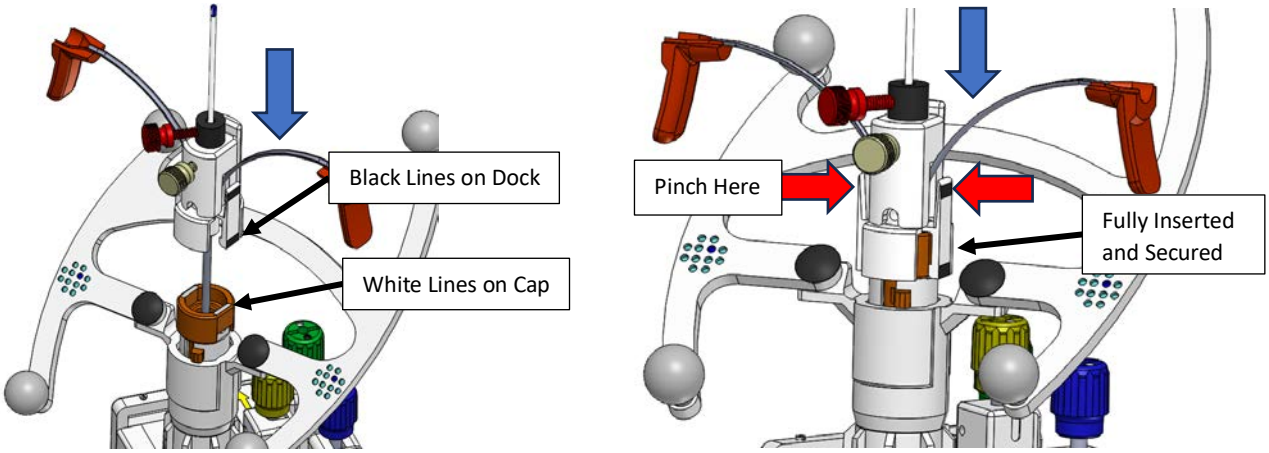


Figure 30: Inserting the Peel-Away Sheath & Stylet Assembly into the SmartFrame OR Tower

Note: It may be necessary to pinch the center of the Lock and Dock Assembly to flare out the Dock elements with black paint and facilitate easier attachment to the Cap.

The Peel-Away Sheath & Stylet Assembly is inserted to full target depth when it cannot be advanced further and fits securely over the Cap of the Device Guide (See Figure 30).

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

4. **Device Insertion through Peel-Away Sheath with 17 GA (1.45mm) inner diameter.**
   a. Loosen the Device Lock white thumb Screw and remove the Stylet from the Peel-Away Sheath.
   b. 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.
   c. Insert the device into the top of the Peel Away Sheath through the Device Lock.

      Caution: Do not advance a device through the 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.

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

e. Tighten the white thumb screw of the Device Lock onto the device.

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

f. Remove the remainder of the Peel-Away Sheath by simultaneously pulling both ends of the split red hub until the Sheath is entirely removed in two pieces.

Note: Pull the Peel-Away Sheath handles straight during extraction. Do not twist or rotate the Peel-Away Sheath during extraction (see Figure 31).

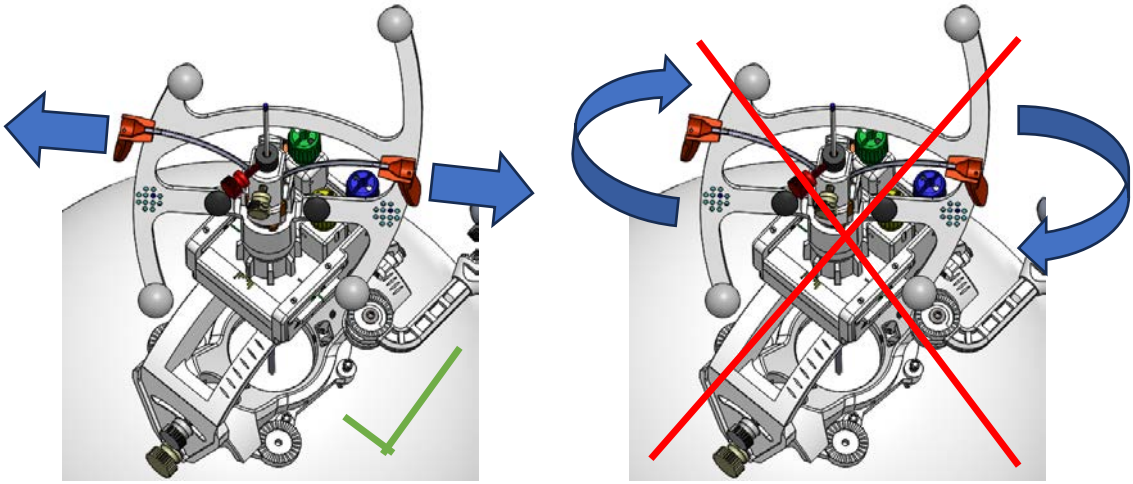


Figure 31: Direction of Pull to Peel back Peel-Away Sheath

5. **Electrode Insertion & Procedure Completion with Traditional Burr Hole Cover**

a. For DBS lead placements, evaluate the lead placement by appropriate means such as imaging or intraoperative stimulation.

Warning: Increasing the number of DBS Lead penetrations increases the probability of hemorrhage. The necessity for an acute DBS lead revision should be minimized using techniques of target localization, such as imaging, to correctly place the DBS Leads on the first attempt.

b. Secure the electrode following manufacturer's guidelines after removing the Peel-Away Sheath.

c. It is recommended that the electrode be marked with a permanent marker directly above the clip to verify it does not shift position.

d. Loosen the white thumb screw of the Device Lock and the red thumb screw of the Depth Stop.

Caution: Ensure both screws are sufficiently loose such that the electrode's upper contacts will not snag on them during subsequent steps.

e. Remove the electrode's stiffening stylet per manufacturer's guidelines.

Note: *The stylet should remain in place throughout DBS Lead insertion and adjustments.*

f. Carefully pull the electrode down through the SmartFrame OR Tower until it is completely free from the Tower and entirely below all Tower elements.

g. Secure the electrode following manufacturer's guidelines.

h. Remove Roll Lock Screws from the SmartFrame OR Tower and set aside.

i. Carefully loosen the Tower Mounting Screws on the SmartFrame OR Tower to remove the Tower from the Base.

Note: If completing a bilateral procedure and the tower will be reused for a second side, it can be placed on the second side Base after re-zeroing the green and yellow knobs X/Y knobs. To complete the second side of a bilateral procedure, repeat all appropriate steps starting from **Section C** (Mounting the SmartFrame OR Tower).

j. Remove the Base from the skull by unscrewing the bone screws.

K. Direct Instrument Insertions

Note: This section covers preparation and direct insertion of Instruments that are 1.24 mm to 2.15 mm without the use of a Peel-Away Sheath.

1. **Preparation and Insertion**

Note: SmartFrame OR Device Guides and Guide Tubes are available to provide compatibility with various diameter instruments. See the chart below to determine whether a Device Guide or Guide Tube is required for the diameter instrument being used. All Tubes are color coded for identification. When using a Guide Tube for an instrument with a smaller OD than the standard 2.1mm Device Guide, the Guide Tube is inserted into the 2.1mm Device Guide, followed by instrument insertion.

Table 5: Guide Tube, Device Guide, and Device Lock Pairing

Instrument Diameters		Guide Tube		Device Guide		Device Lock
mm	GA	Description	Catalog #	Description	Catalog #	Type
1.24 mm	**18 GA**	18 GA Guide Tube (blue)	NGS-GT-02	2.1mm Device Guide	NGS-SFOR-XG-01	Standard
1.47 mm	**17 GA**	17 GA Guide Tube (black)	NGS-GT-03	2.1mm Device Guide	NGS-SFOR-XG-01	Standard
ClearPoint 4 Fr Stylet		.064" Guide Tube (green)	NGS-GT-04	2.1mm Device Guide	NGS-SFOR-XG-01	Standard
1.65 mm	**16 GA**	16 GA Guide Tube (orange)	NGS-GT-01 or NGS-GT-05	2.1mm Device Guide	NGS-SFOR-XG-01	Standard
1.80 mm	**15 GA**	15 GA Guide Tube (white)	NGS-GT-01 or NGS-GT-06	2.1mm Device Guide	NGS-SFOR-XG-01	Large (black)
2.11 mm	**14 GA**	None required	N/A	2.1mm Device Guide	NGS-SFOR-XG-01	Large (black)

Note: The Device Guides and Guide Tubes are distinguished by the colored bands (blue, orange, etc.) on the hub end (see Figure 33).

Note: The Device Locks can be found in the SmartFrame OR Tray. The large Device Lock will be in its own pouch with a black marking on top for identification (see Figure 32).

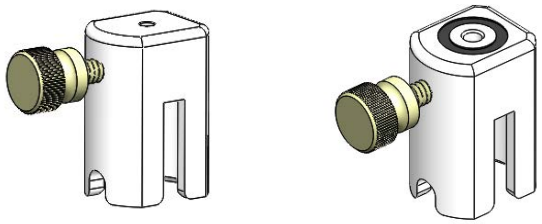


Figure 32: Standard Device Lock (Left) and Large Device Lock (Right)

a. If the Stylet and Peel-Away Sheath Assembly were used previously, remove the Assembly including the Peel-Away Sheath, Device Lock, Stylet, Dock, and Depth Stop from SmartFrame OR Tower and separate these components from one another.

b. If necessary, remove the current Device Guide from the SmartFrame OR Tower, select the appropriate Device Guide, and secure the new Device Guide in the SmartFrame OR Tower as described in previous sections.

c. If necessary, select the appropriate Guide Tube and insert the Guide Tube into the 2.1mm Device Guide (see Figure 33).

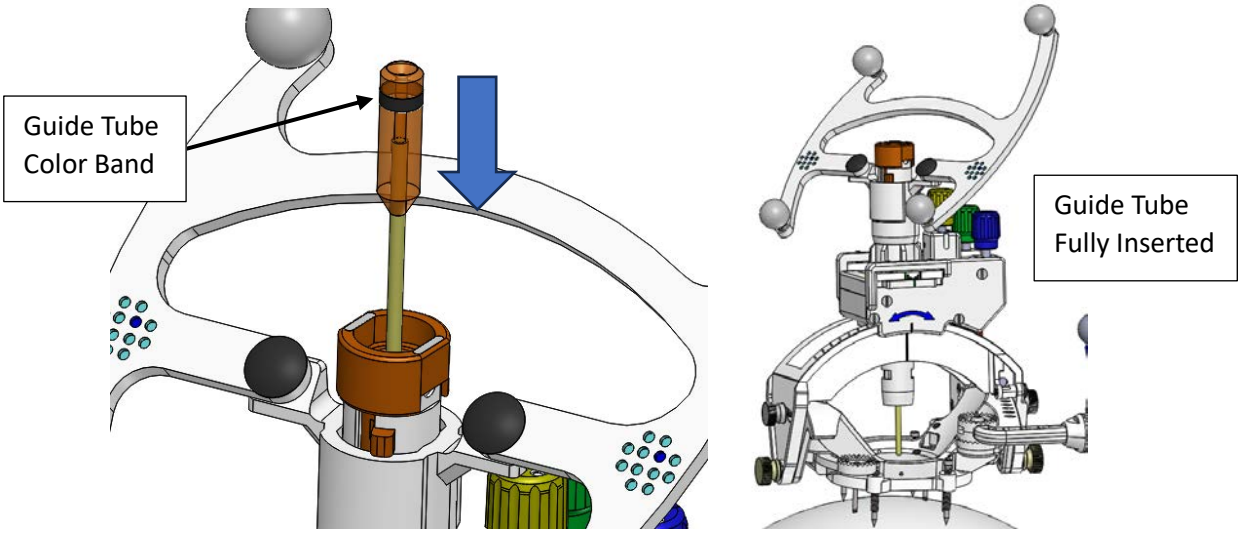


Figure 33: Inserting a Guide Tube into the 2.1mm Device Guide

Caution: The Guide Tubes are only compatible with the 2.1mm Device Guide. If using a Guide Tube, make sure the 2.1mm Device Guide is inserted in the SmartFrame OR Tower.

d. Select the correct sized Device Lock (standard or large) and snap the Lock onto the Dock until secured.

e. Orient the Device Lock & Dock assembly such that the black lines match up with the flat aspects of the Guide Cap (marked with white lines). Attache the Device Lock & Dock Assembly onto the Cap portion of the selected Device Guide (see Figure 34).

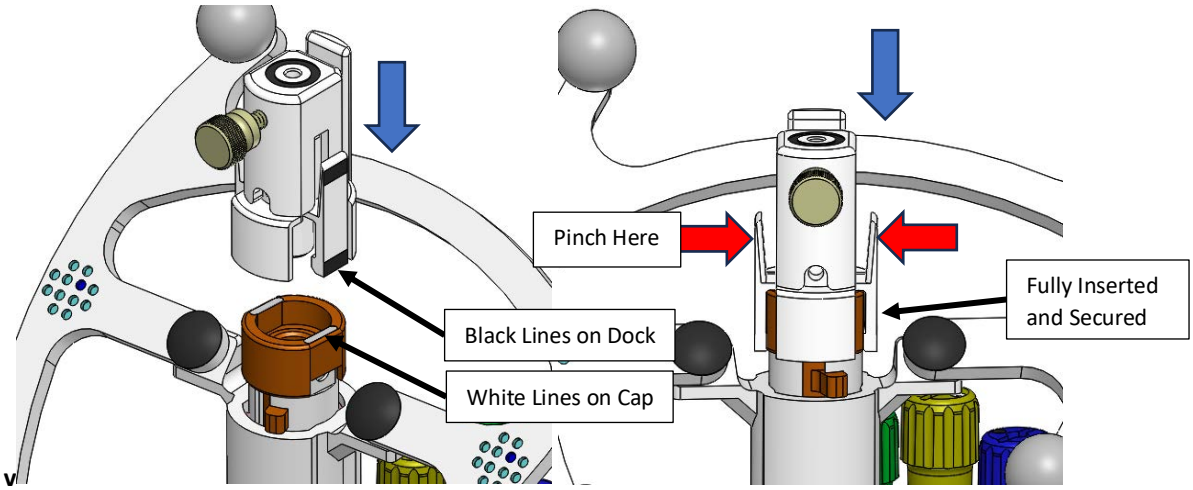


Figure 34: Attaching the Dock and Lock Assembly onto the SmartFrame OR Tower

Note: It may be necessary to pinch the center of the Lock and Dock Assembly to flare out the Dock elements with black paint and facilitate easier attachment to the Cap.

f. Set the insertion Depth on the instrument following the instructions in **Section F** (Measuring out Instrument Insertion Depth).

Warning: The depth measurements are based on mandatory usage of the Device Lock & Dock Assembly. Do not insert an instrument without having correctly placed the Device Lock & Dock Assembly onto the SmartFrame OR Tower. Inserting an instrument without the Dock and Lock attached to the SmartFrame OR Tower may cause a deeper than intended insertion, and harm to the patient.

g. Insert the instrument into the Device Lock & Dock Assembly through the Device Guide until the distal face of the Depth Stop sits flush with the proximal face of the Device Lock. Tighten the white set screw of the Device Lock (see Figure 35).

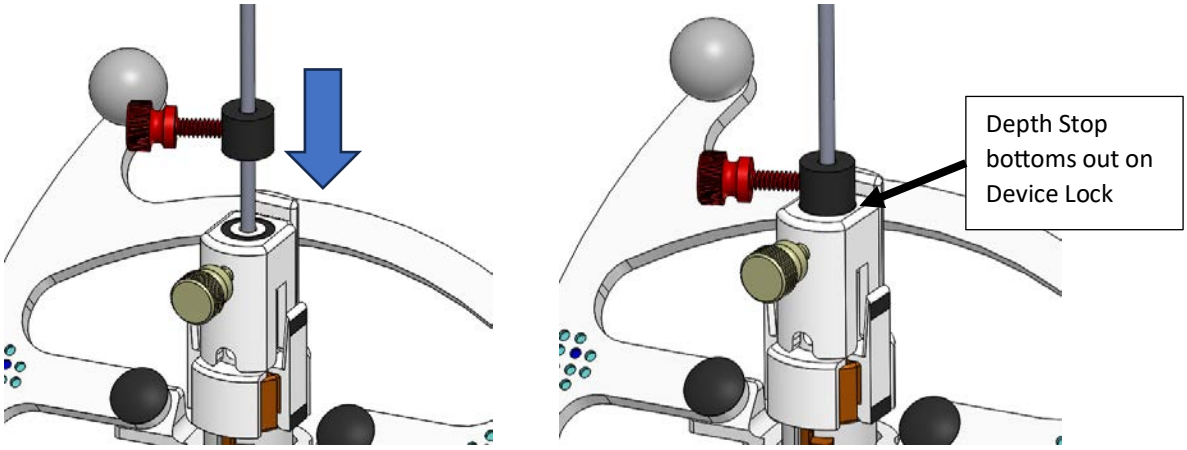


Figure 35: Direct Insertion of an Instrument

h. Perform the procedure as intended.

L. System Removal

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

1. Remove the SmartFrame OR Tower's Roll Lock Screws and set aside.
2. Carefully loosen the Tower Mounting Screws on the SmartFrame OR Tower to remove the Tower from the Base. If completing a bilateral procedure and the tower will be reused for a second side, it can be placed on the second side Base now after re-zeroing the green and yellow knobs X/Y knobs. To complete the second side of a bilateral procedure, repeat all appropriate steps starting at "Attaching the SmartFrame OR Tower".
3. Remove the Base from the skull by unscrewing the bone screws.
4. **Complete the Procedure**
   a. If not already complete, complete the procedure per the device manufacturer's IFU and standard medical practices.
   b. Appropriately dispose of the device.

      Note: Safe disposal of the device: The device shall be treated as biohazardous materials and shall be disposed of accordingly per hospital policy.

M. Storage and Technical Specifications

1. **Storage**
   a. Store in a cool dry place.
2. **Technical Specifications**
   a. **SmartFrame OR System Accuracy**

Table 6: Error Table for Performance Validation: Cranial S8 System with Bone Screw Fiducial Registration, SmartFrame OR Hardware, and PIVOT Technique			
Error Component	**Mean**	**Standard Deviation**	**99% Confidence Interval (upper bound)**
Positional Error (mm)	1.36	0.86	1.57
Trajectory Angle Error (°)	0.67	0.46	0.92

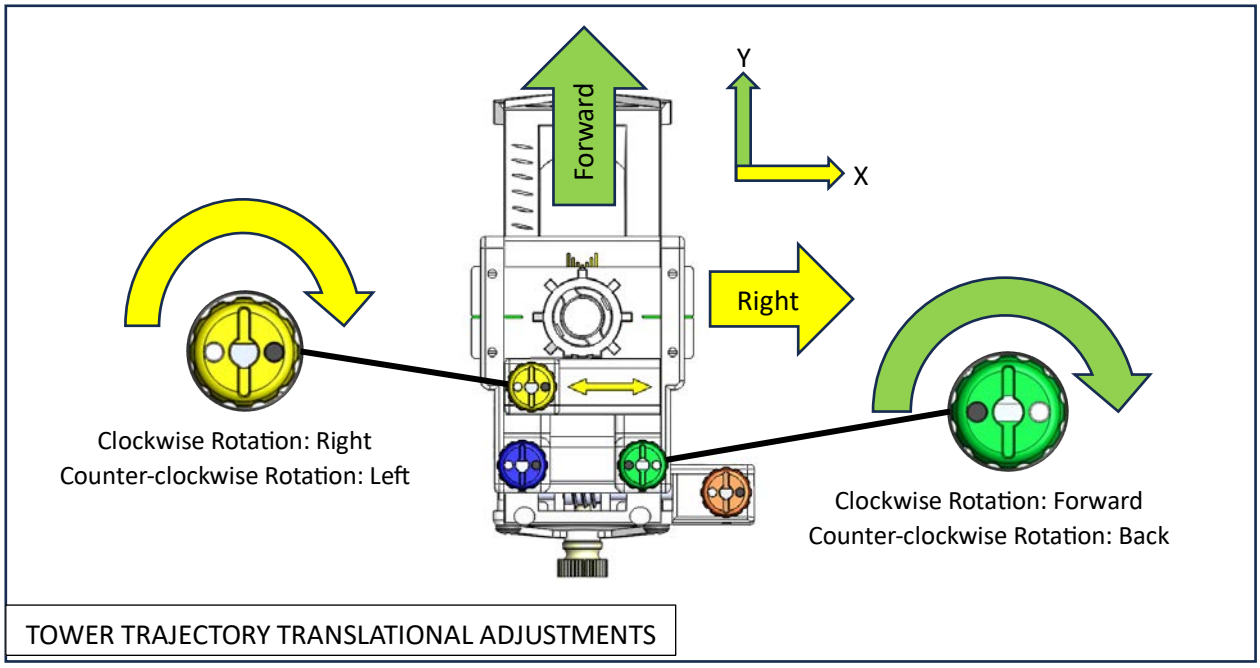
Note: Measurement tools used in accuracy testing were found to add up to a 0.25 mm differential to results. To represent worst case of this measurement error, this 0.25 mm has been added to the results in Table 1.

   b. **Pivot Point of the SmartFrame OR Tower to Top of Device Lock Height:**
      i. 145.0mm
   c. **Instrument Sizes and Appropriate Device or Drill Guides**

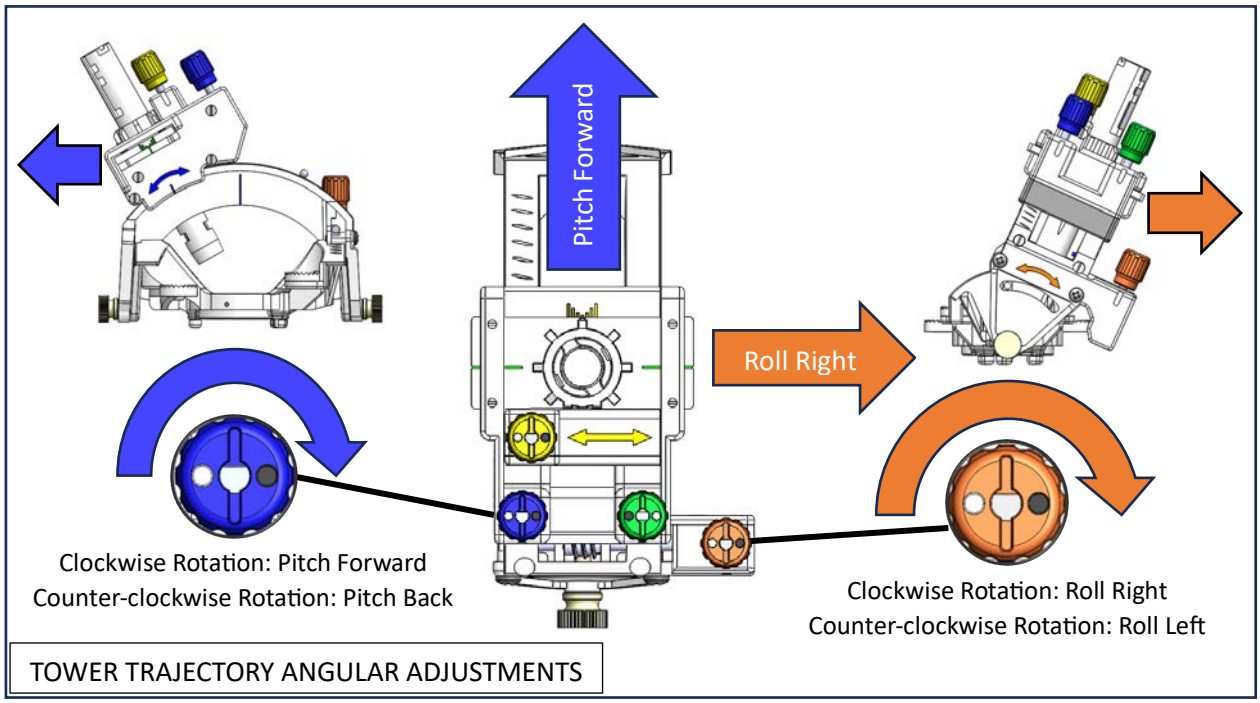
Table 7: SmartFrame OR Device Guide Table			
Guide Catalog Number	**Description**	**Guide Inner Diameter (mm)**	**Instrument Size (mm)**
NGS-SFOR-XG-01	SmartFrame OR Device Guide, 2.1mm	2.15	1.9 – 2.1
NGS-SFOR-DG-07	SmartFrame OR Drill Guide, 3.4mm	3.58	3.2 – 3.4
	SmartFrame OR Drill Guide, 4.5mm	4.65	4.3 – 4.5
NGS-SFOR-DG-06	SmartFrame OR Drill Guide, 5.4mm	.56	5.2 – 5.4

d. **Range of Movement**

Table 8: SmartFrame OR Tower Adjustments			
Orientation	**Travel**	**Travel per 1 Rotation of Thumb Wheel**	**Thumb Wheel Color**
Roll	± 26°	4°	**Orange**
Pitch	± 33°	4°	**Blue**
X	± 2.5 mm	1 mm	**Yellow**
Y	± 2.5 mm	1 mm	**Green**



TOWER TRAJECTORY TRANSLATIONAL ADJUSTMENTS



TOWER TRAJECTORY ANGULAR ADJUSTMENTS

Explanation of symbols on product or package labeling - Refer to the appropriate product for symbols that apply.

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

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