



CLEARPOINT®
NEURO

SmartFrame® Scalp Mount Base

INSTRUCTIONS FOR USE

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I. Intended Use

The Scalp-Mount Base is an accessory to the ClearPoint® System to assist in providing 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 System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion. The system is intended for use only with 1.5 and 3.0 Tesla MRI scanners.

Warning: The ClearPoint Neuro ClearPoint System ALONE should not be used to guide a deep brain stimulation (DBS) electrode into a specific brain target such as the subthalamic nucleus. Final placement of DBS electrodes requires physiological recordings to confirm that they are located in the correct brain target and functioning as intended. The ClearPoint Neuro ClearPoint System is not designed or intended to be used for physiological recording of brain activity. The safety and effectiveness of using the ClearPoint Neuro ClearPoint System ALONE for final placement of DBS electrodes has not been studied.

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 Neuro ClearPoint User's Guide.

II. Device Description

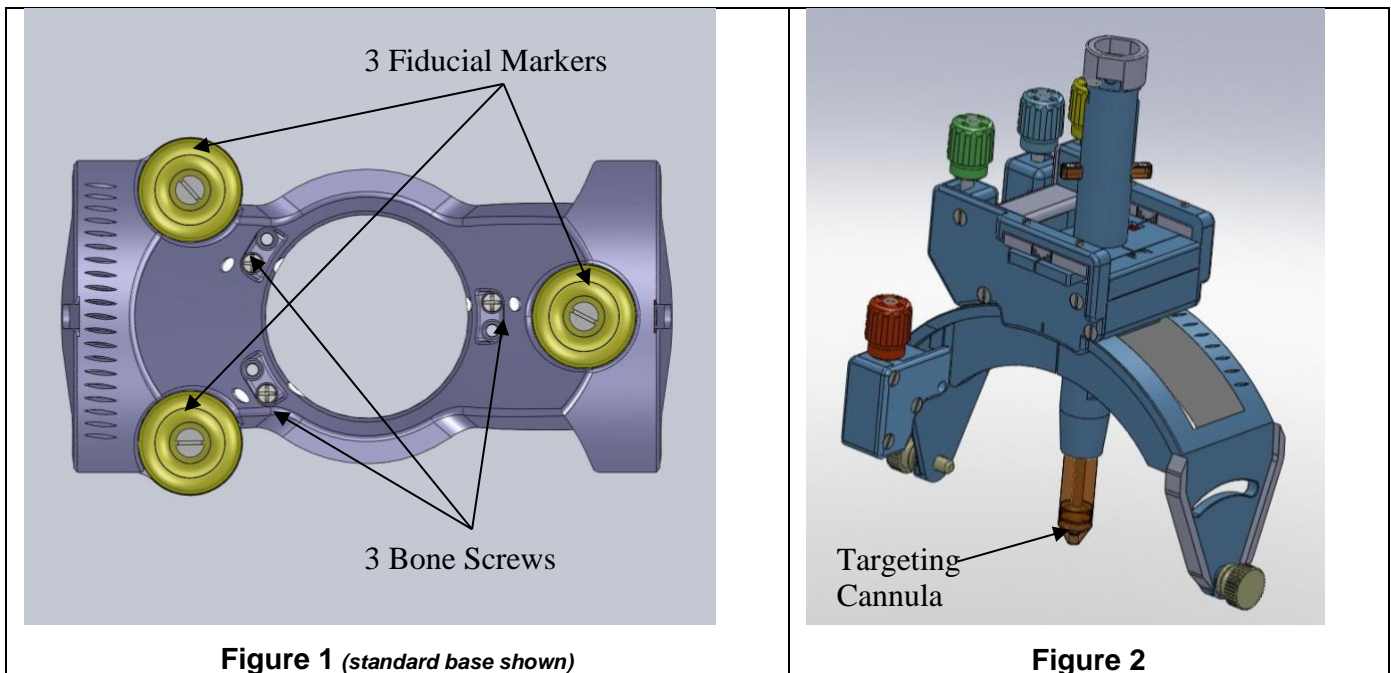
Package Contents:

NGS-SM- 01: **SmartFrame® Scalp Mount Base**
Centering Tool, Scalp-Mount Base Assembly, Self-Tapping Screws (6),
Scalp-Mount Dock

Associated Devices:

NGS--SF-01-11:	SmartFrame® MRI-Guided Trajectory Frame Centering Tool, Base Assembly, MRI Stereotactic Frame, Dock, Device Lock, Large Device Lock, Screwdriver, Self-Tapping Screws (6), and Roll Lock Screw w/washer
NGS-TE-01:	SmartFrame® Thumb Wheel Extension Set Thumb Wheel Extension Set
NGS-AK-01-11:	SmartFrame® Accessory Kit Stylet, Peel-Away Sheath, Ruler, Depth Stop, 15 GA Guide Tube, 18 GA Guide Tube
NGS-SG-01-11:	SMARTGrid® MR Planning Grid Marking Grid and Marking Tool
NGS-PD-02-L:	MR Neuro Procedure Drape Tapered MR Neuro Procedure Drape Tapered, Marker Pen, Track Ball Cover
NGS-PD-03-L:	MR Neuro Procedure Drape Tapered w/Extension MR Neuro Procedure Drape Tapered w/Extension, Marker Pen, Track Ball Cover
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, Track Ball Cover, Cable Cover
NGS-HD-01:	SmartTwist MR Hand Drill Hand Drill
NGS-DB-45:	SmartTip MR Drill Kit, 4.5-mm 4.5-mm Drill Bit, 3.4 mm Drill Bit, Lancet, Depth Stop (2), Ruler

The Scalp-Mount Base is designed to be attached to the patient’s skull through the scalp using three (3) pre-loaded bone screws. It is manufactured completely of plastic, except for the titanium bone screws, support pins, and the fiducial marker fluid. A Scalp Mount Centering Tool is provided in the package to aid in the relative positioning of the Scalp Mount Base to the desired entry point. The Base has three (3) fiducial markers that are visible to Magnetic Resonance Imaging (MRI) that are used to define the three-dimensional position and orientation of the Base. **See Figure 1.**



The Tower (**see Figure 2**) attaches to the Scalp-Mount Base. The Tower, also completely made of plastic, is designed to provide multi-directional orientation adjustments to the Targeting Cannula, which is housed in the center of the Tower. The Targeting Cannula has a distal fluid filled sphere and a proximal fluid filled column that are both MRI visible. The Targeting Cannula also has a central lumen through which a Peel-Away Sheath and Stylet or other suitable devices can be placed and oriented. The Tower, when attached to the Scalp Mount Base, provides adjustments in the roll, pitch, X, and Y directions by turning the appropriate thumb wheels. **See Figure 3.**

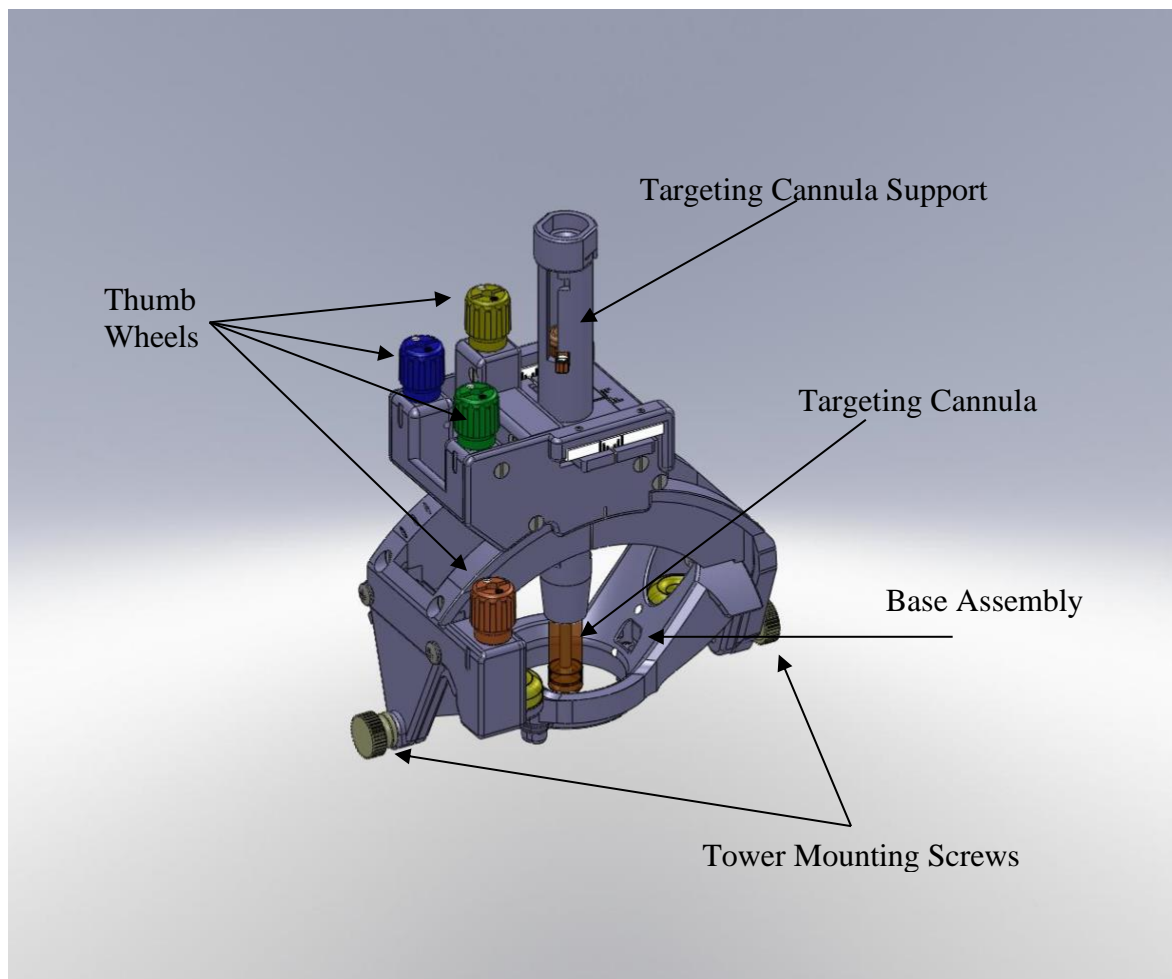


Figure 3: SmartFrame Assembly

The adjustments can be made by directly turning the thumb wheels or by using the Thumbwheel Extension Set. The Thumb Wheel Extensions can be attached to the SmartFrame and utilized to rotate the thumb wheels while the patient is inside of the MR scanner bore. See SmartFrame IFU for complete instructions on using the SmartFrame and the Thumb Wheel Extensions.

III. General Warnings and Precautions

The device is intended for single-use-only and is provided sterile. Do not re-sterilize.

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:** Verify scanner is within calibration prior to scanning.
- Warning:** All tools and ancillary equipment and devices must be MR compatible when performing scanning. When labeling is un-clear, assume the device is not compatible. Always follow the manufacturer's instructions.
- 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.
- Caution:** It is recommended that additional sterile product be available for use.
- Caution:** The ClearPoint Neuro SmartFrame system is designed to reach a target less than (<) 12 cm from the surface of the skull.
- Caution:** The planned trajectory must allow for a 30 cm long device to be placed into the top of the assembled SmartFrame to prevent interfering with the bore of the MRI machine.
- Caution:** This device is to be used only by physicians trained by ClearPoint Neuro personnel.
- Caution:** The compatibility of neurological instruments and devices should be evaluated before use with the ClearPoint Neuro SmartFrame System.

General Precautions

- Handle all components using standard hospital sterile practices.
- Minimize any forces applied directly to the SmartFrame.
- The following disposable components are MR Conditional: Scalp-Mount Base and Scalp-Mount Centering Tool.

1.5T & 3T Environment Compatibility:

Non-clinical testing has demonstrated the ClearPoint 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 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 Scalp-Mount Base is packaged with a double sterile barrier; a CSR-Wrapped device is placed inside a sealed mylar/Tyvek pouch; or a component inside a sealed Tyvek pouch inside another sealed Tyvek pouch.

Warning: Do not use the Scalp-Mount Base or any of the components if the packaging is damaged.

1. The Patient's head shall be prepared just prior to surgery using standard sterile techniques.
2. The patient's head is positioned outside the scanner at the head (superior) 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 the appropriate ClearPoint Neuro MR Neuro Procedure Drape following the Instructions for Use (IFU).
5. The Scalp Mount Base is to be used with components provided in the Scalp Mount Base Kit. Use the other components as directed in these IFU and the SmartFrame Kit IFU.

B. Determine and Mark the Access Hole Location using the SMARTGrid

1. Carefully read all cautions and warnings provided in the SMARTGrid IFU.
2. Position and secure patient in an appropriate head fixation frame and appropriate imaging coils to achieve desired image quality and provide access to procedure site.
3. Install a sterile MR Neuro Procedure Drape and attach the incise tape portion of the drape to the patient's head.
4. Remove paper back from the Marking Grid.
5. Affix sticky side of Marking Grid onto the patient's head (over the incise tape portion of the drape), centered at the approximate location for the access hole.
6. Determine location on SmartGrid® to mark skull per instructions from CLEARPOINT workstation (alpha-numeric coordinates).
7. Peel off top fluid filled layer of SMARTGrid while firmly holding the lower layer in position.
8. Using the Marking Tool and the coordinates provided, mark location on the scalp, entering through one of the holes provided on the Grid. The Marking Tool should be twisted/rotated several times using sufficient pressure to reach and mark the skull.

Caution: Only use minimum force required to reach the skull. This is only meant to provide surgeon a landmark, not to penetrate patient's skull.

9. As an alternative method of marking the access hole entry point, the Drill Kit Lancet may be used to make a stab incision through one of the holes in on the Grid.

Warning: Do not perform an MRI scan while the Drill Kit Lancet is contacting tissue or being held by the user. Serious burns could result if scanning while the Drill Kit Lancet is in contact with tissue.

10. Peel off the remaining bottom layer of SMARTGrid.

C. Mounting the Scalp Mount Base

1. The Scalp Mount Base has four adjustable height support pins and three self-tapping bone screws, as shown in Figures 4. The support pins have sharp tips, as shown in Figure 5. They have small protective tubes covering them. Remove the tubes before proceeding.

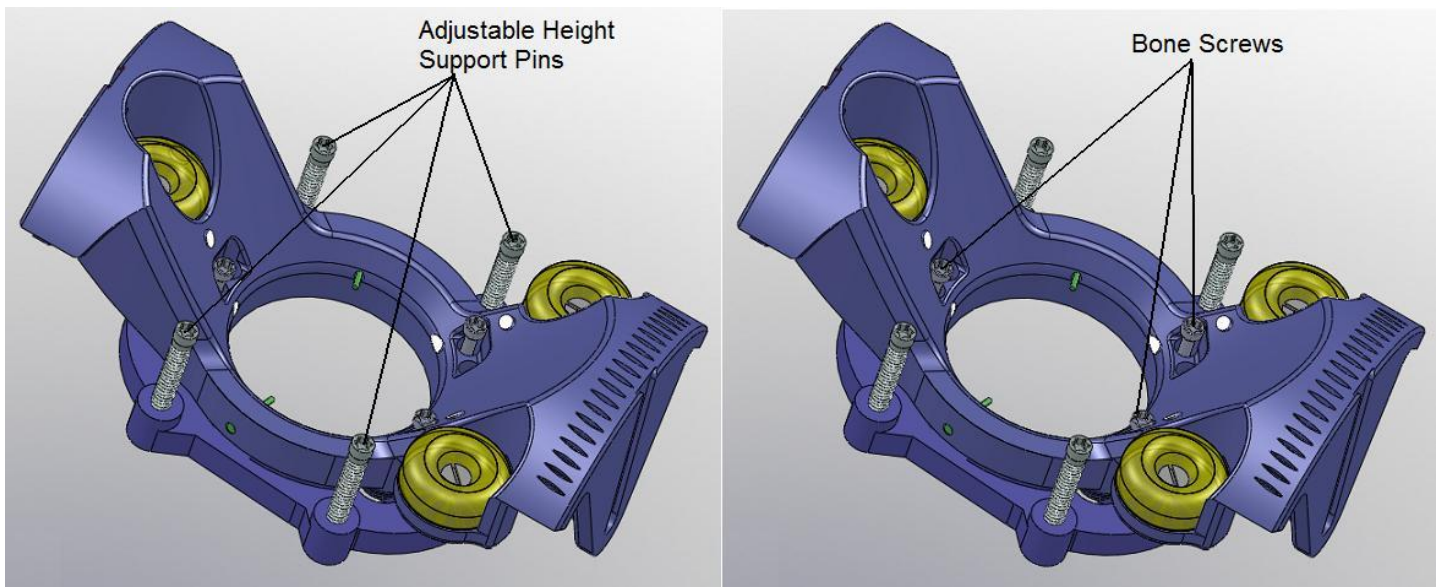


Figure 4

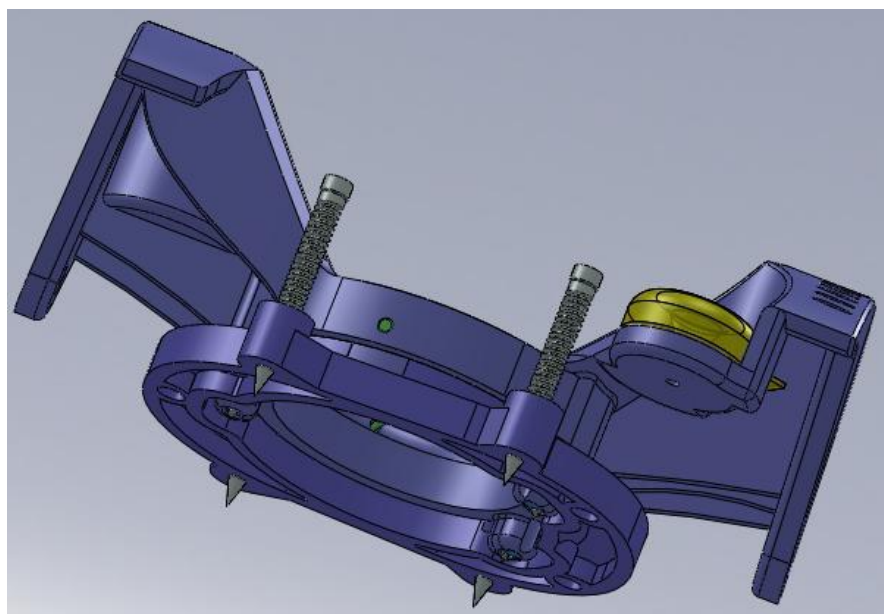


Figure 5

2. The Scalp-Mount Centering Tool has “cross-hairs” visible at the bottom of the tool when looking down the Tool’s center, as shown in Figure 6.

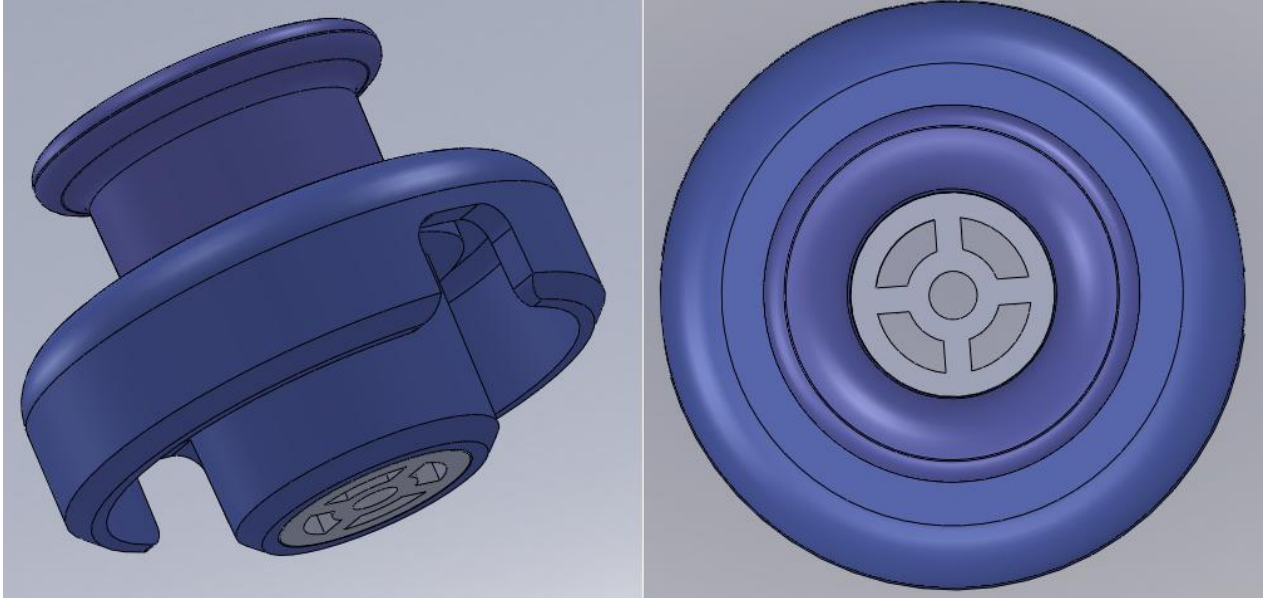


Figure 6

3. Insert the Centering Tool into the Scalp Mount Base so that it is held in place by the small silicone “fingers” that protrude inside the Base (see Figure 7).

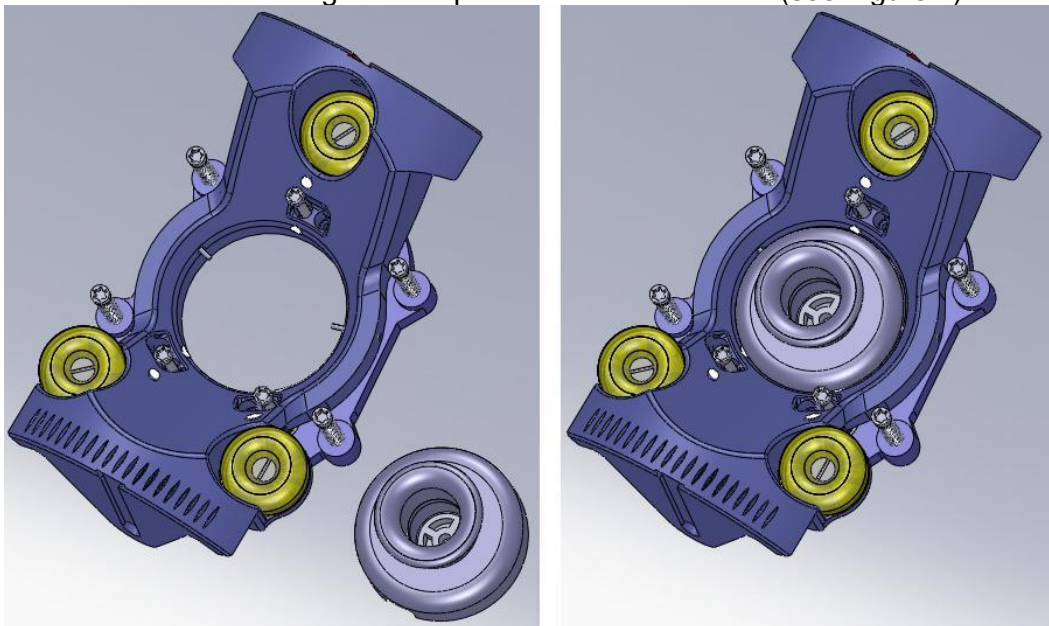


Figure 7

4. Use the Cross-Hairs to position the center of the Base over the mark made in the scalp in Step B.

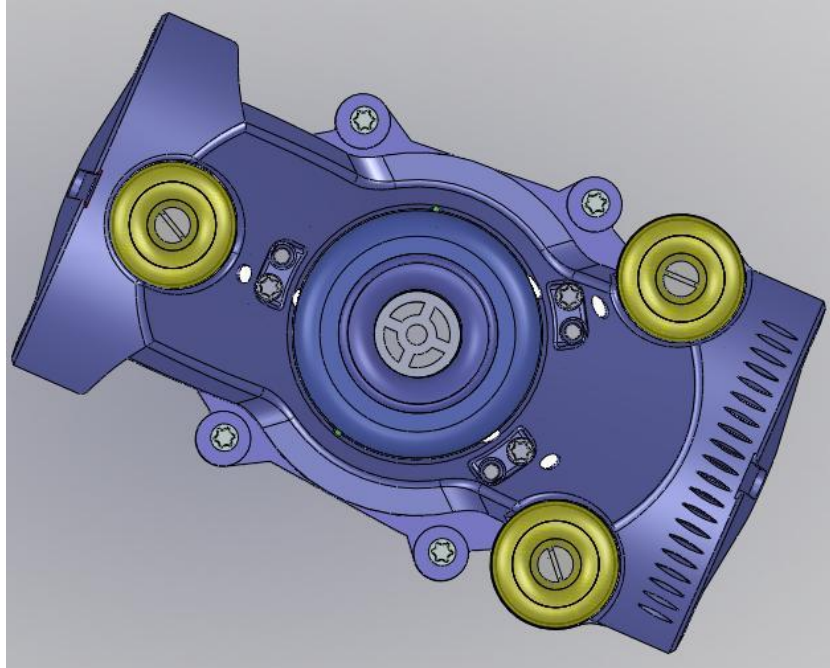


Figure 8

5. Once the Base is in position, begin securing the Bone Screws to the skull through the scalp. Using the screw driver supplied in the SmartFrame Kit, mount the Scalp-Mount Base with the three (3) pre-mounted self-tapping screws to the skull.

Note: In the event a replacement screw is required for securing the Scalp-Mount Base, additional screws (3) have been provided in the Scalp-Mount Base packaging.

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

Caution: Only ClearPoint Neuro-provided screws should be used for securing the Scalp-Mount Base.
6. Secure the three bone screws into the skull. 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.
7. 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.
8. Repeatedly check the security of the Base during this operation. Once the Base is secure, proceed to the next step.

Note: 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

9. Remove the Scalp-Mount Centering Tool if used.
10. The SmartFrame is ready to be mounted to the Base.
11. Refer to the SmartFrame IFU for mounting the Tower.
12. When creating an access hole using the SmartFrame and Scalp Mount Base, the pitch-roll and X-Y adjustments must be made prior to creating the access hole. DO NOT create the access hole prior to making pitch-roll and X-Y adjustments.
13. Refer to the IFU for the SmartFrame for complete instructions on making trajectory adjustments using the SmartFrame and Thumb Wheel Extension.
14. Perform a scan and alignment check before creating the access hole to confirm that the path and accuracy to target are as desired.

Caution: When performing the scan and alignment check, make sure no metallic devices are inserted into the SmartFrame Targeting Cannula prior to scanning.
15. After confirming that the path and alignment are acceptable, use the Roll Lock Screw provided with the SmartFrame to lock the ATF Tower into position. See the SmartFrame IFU for complete instructions on securing the Tower to the Base.
16. A Scalp Mount Dock is provided in the Scalp Mount Base packaging. The dock may be attached to the top of the SmartFrame. If using SmartTip MR Drill Kit, the Scalp Mount Dock may be used to provide a surface for the Depth Stop to seat against during Drilling procedures.
17. Insert the Drill Bit into the SmartTwist MR Hand Drill, and then slide the Depth Stop over the Drill Bit. See the SmartTwist MR Hand Drill IFU for complete instructions on inserting and securing the Drill Bit into the Drill.
18. Insert the Drill Bit carefully into the Targeting Cannula until the Drill Bit Tip is in the desired position.
19. Secure the Depth Stop at the desired height above the Dock or Tower. See the SmartTwist MR Hand Drill IFU for complete instructions on securing the Depth Stop to the Drill Bit.
20. Use the SmartTwist MR Hand Drill to create the access hole as desired. See the SmartTwist MR Hand Drill IFU for complete instructions on using the Hand Drill and Drill Bit.
21. Remove the Hand Drill and Drill Bit from the Targeting Cannula.

22. Remove the Scalp Mount Dock from the Targeting Cannula.
23. Perform a confirmatory scan to ensure proper alignment of Targeting Cannula to target.
24. Refer to the SmartFrame Instructions for Use for complete instructions on inserting and guiding instruments to the desired target.

D. Removing the Scalp Mount Base

1. Remove the ATF tower from the Base as instructed in the SmartFrame IFU.
2. Using the screw driver supplied with the SmartFrame, unscrew the support pins so that the tips are out of the scalp.
3. Using the same screw driver, unscrew the three bone screws until they are also out of the scalp.
4. Gently pull the base away from the scalp.

E. Storage and Technical Specifications

Storage

- Store in a cool dry place

Technical Specifications

- **SmartFrame**











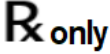



- **Device Accuracy**

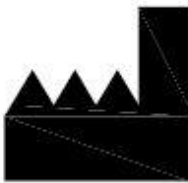
The device can guide a tool to the intended brain target with an error less than 1.5 mm.

- **Overall height (top of Device Lock) - 152.4 mm (6.00")**

- **Range of Movement**

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

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Consult instructions for use		MR Conditional
	Catalogue number		Keep away from sunlight
	Batch code		Keep Dry
	Use by date		Manufacturer
	Single use		Double sterile barrier
	Prescription device		Not made with natural rubber latex
	Sterilized using ethylene oxide		Do not use if the product sterilization barrier or its packaging is compromised



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