MONTERIS AXIIIS-CMB & ACCESSORIES

Catalog Numbers: CMB022, CMB022-AA, CMB022-UP,
CMB033, CMB033-AA, CMB033-UP, CMB-CW, CMB-LK

INSTRUCTIONS FOR USE

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

Carefully read all instructions prior to use. Observe all contraindications, warnings and cautions noted in these directions. Failure to do so may result in patient complications.

Table of Contents

1 Device Description

1.1 AXiiiS-CMB

The AXiiiS-CMB assembly (Figure 1) is a disposable, rigid skull fixation device designed to provide a stable platform to deliver neurosurgical devices or instruments.

The AXiiiS-CMB has an outer diameter (OD) of 4.5 mm and its inner diameter (ID) can accept and provide guidance for an instrument or device with an OD of 3.3 mm.

It is provided in a non-sterile plastic pouch which includes two brass #6-32 thumbscrews as well as a Collar Adapter and two additional #8-32 brass thumbscrews for optional attachment of the NeuroBlate® Robotic Probe Driver.

Refer to the NeuroBlate® System Instructions for Use (IFU) for use of the AXiiiS-CMB with the NeuroBlate® Robotic Probe Driver.

A 4.5 mm diameter twist drill is not included but is required to create an on-trajectory opening in the skull to accept the AXiiiS-CMB.

Figure 1: AXiiiS-CMB Assembly Components

1.2 Accessories and Adapters

The AXiiiS-CMB Host and Insert Adapters (Figure 2) are stainless steel bushings designed to enable on-trajectory deployment of the AXiiiS-CMB into the skull. The adapters allow the use of various stereotactic frames or image-guided surgery (IGS) articulated arm systems to place the AXiiiS-CMB along an intended trajectory.

The Host and Insert Adapters are required for the on-trajectory deployment of the AXiiiS-CMB and are sold separately. They are provided non-sterile in a plastic pouch and can be re-used for an indefinite number of uses.

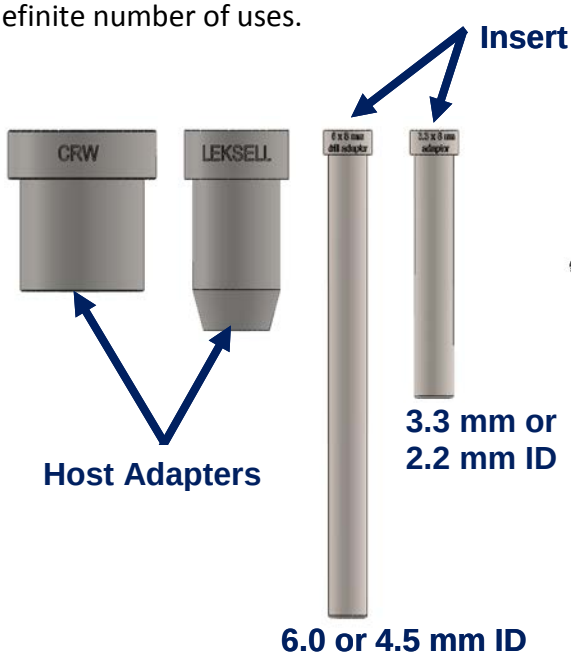


Figure 2: Accessory Adapter Components Unassembled

Figure 3: Insert Adapters as Assembled with CRW and Leksell Host Adapters

The Host Adapters are configured into kits (see Table 1) which contain the necessary components to utilize a specific stereotactic frame.

For a stereotactic frame, the proper Host Adapter is inserted into the respective frame's Instrument Guide. The Host Adapter can receive the two Insert Adapters as shown in Figure 3.

For an IGS articulated arm, only the two Insert Adapters are required.

Additional AXiiiS-CMB accessories (Figure 4) are required are required for on-trajectory deployment into the skull. There are two different accessory kits for the 2.2 mm and 3.3 mm AXiiiS-CMB. These kits both include an Insert Adapter which accepts a 4.5 mm instrument such as a drill bit, a 4.5 mm outer diameter (OD) Clearance Mandrel to assess for complete skull trephination, a Stereotactic Driver and T-Handle which attaches to the driver. The Stereotactic Driver shaft has the same 8 mm OD as the Insert Adapters allowing for trajectory guidance through the Host Adapters or articulated arm systems during deployment of the AXiiiS-CMB into the skull. The tip of the Stereotactic Driver differs in OD depending on the internal diameter (ID) of the AXiiiS-CMB it is intended to be used with. A 2.2 or 3.3 mm Alignment Mandrel and 3.3 mm ID Host Adapter are also provided in the respective kits. A titanium MRI Removal Tool is also included to allow removal of the MiniBolt within the MRI environment.

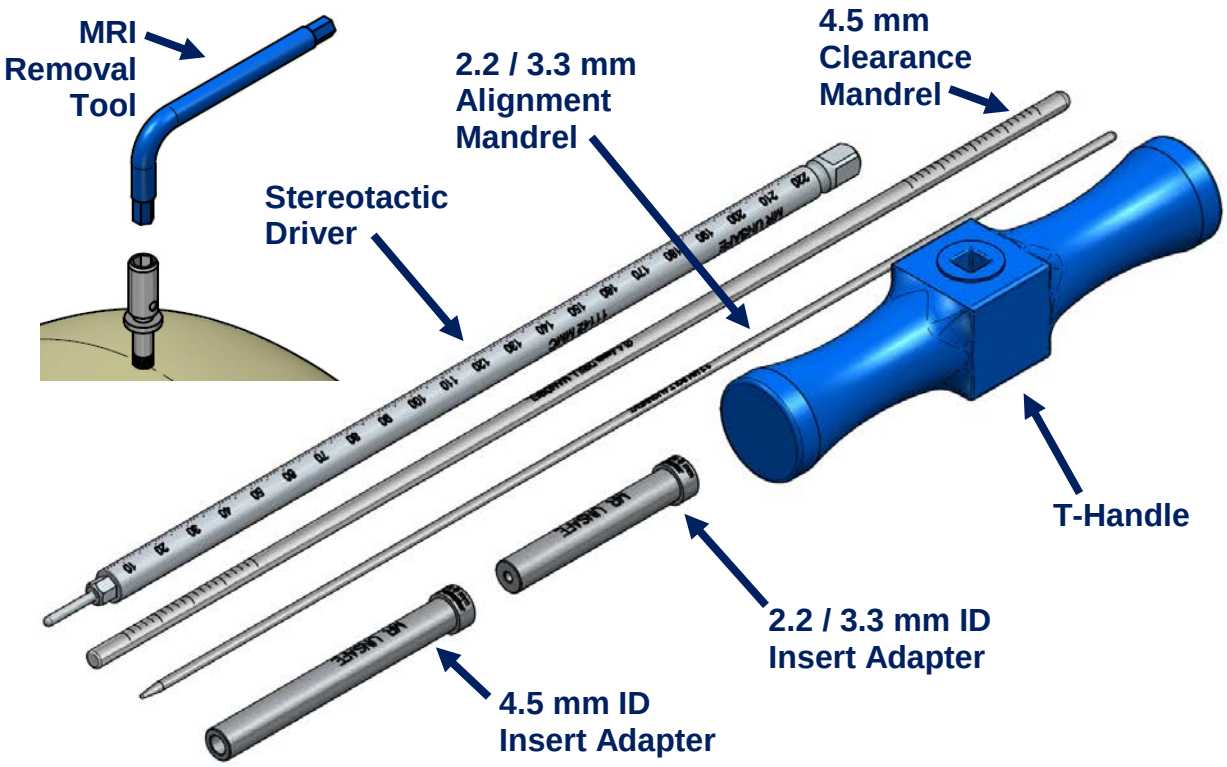


Figure 4: AXiiiS-CMB Accessories

1.3 Catalogue Numbers

Table 1: AXiiiS-CMB and Accessories Catalog Numbers

Cat Number	Description	MRI Status
CMB033	**3.3 AXiiiS-CMB Assembly includes:** • 4.5 mm OD Stem Bolt for 3.3 mm Instrument • #6-32 Thumbscrews - for AXiiiS-CMB (qty. 2) • Collar Adapter - for NeuroBlate® Robotic Probe Driver • #8-32 Thumbscrews - for Collar Adapter (qty. 2) • 3.3 mm AXiiiS-CMB Plug	 1.5/3.0 T
CMB033-AA	**3.3 Monteris AXiiiS-CMB Accessory Kit, Includes:** • T-Handle and 3.3 mm Stereotactic Driver • Insert Adapter for 4.5 mm Instrument • Insert Adapter for 3.3 mm Alignment Mandrel	
	• 4.5 mm Clearance Mandrel • 3.3 mm Alignment Mandrel • MR Safe Removal Tool	 1.5/3.0 T
CMB033-UP	**3.3 mm Accessories Upgrade Kit, Includes:** • 3.3 mm Stereotactic Driver • Insert Adapter for 3.3 mm Alignment Mandrel	
	• 3.3 mm Alignment Mandrel	
CMB022	**2.2 AXiiiS-CMB Assembly includes:** • 4.5 mm OD Stem Bolt for 2.2 mm Instrument • Collar Adapter - for NeuroBlate® Robotic Probe Driver • #8-32 Brass Thumbscrews - for Collar Adapter (qty. 2) • 2.2 mm AXiiiS-CMB Plug	 1.5/3.0 T
CMB022-AA	**2.2 Monteris AXiiiS-CMB Accessory Kit, Includes:** • T-Handle and 2.2 mm Stereotactic Driver • Insert Adapter for 4.5 mm Instrument • Insert Adapter for 2.2 mm Alignment Mandrel	
	• 4.5 mm Clearance Mandrel • 2.2 mm Alignment Mandrel • MR Safe Removal Tool	 1.5/3.0 T
CMB022-UP	**2.2 mm Accessories Upgrade Kit, Includes:** • 2.2 mm Stereotactic Driver • Insert Adapter for 2.2 mm Alignment Mandrel	
	• 2.2 mm Alignment Mandrel	
CMB-CW	**Accessory Host Adapter for CRW Stereotactic Frame includes:** • Host Adapter for CRW Instrument Guide • #6-32 Thumb Screw	
CMB-LK	**Accessory Host Adapter for Leksell Stereotactic Frame includes:** • Host Adapter for Leksell Instrument Guide • #6-32 Thumb Screw	

2 Indications for Use

The AXiiiS-CMB is a disposable device intended to provide placement and skull fixation of neurosurgical instruments or devices with an outer diameter (OD) of 3.3 or 2.2 mm.

3 Contraindications

None

4 Warnings, Cautions, and General Safety Requirements

The following are warnings, cautions, and safety requirements that apply to the AXiiiS-CMB assembly and accessories; consult the device specific instructions for all devices used in conjunction with the AXiiiS-CMB for warnings specific to those devices.

4.1 Identification Labels

Symbols displayed on Monteris products or in their documentation are:

	**MRI Unsafe** - item is **NOT** MRI compatible and is known to pose a hazard in MR environments. This equipment should not be taken into the MRI room within the 5 Gauss perimeter line.
	**MR Conditional** - the item poses NO known hazards in a specified MRI Environment (e.g. 1.5 / 3.0 T)
	Caution followed by text message.
	Consult instructions for use (IFU).
	Do not use if package is damaged.
	Manufacturer
	Product Model Number/ Designation or Part Number
	Product Lot number

4.2 Warnings and Cautions

WARNING:

- The AXiiiS-CMB and accessories are to be used only by trained physicians.
- Perform systematic validation of the image-guided surgery (IGS) system used in conjunction with the AXiiiS-CMB according to the IGS system manufacturer guidelines to ensure system accuracy and efficacy. Error magnitudes can vary for different IGS systems. If the IGS system is not validated prior to performing the surgical procedure, there is a greater potential for trajectory and depth error.
- Image-guided surgery (IGS) system compatibility and accessories – Verify the compatibility of the image-guided surgery (IGS) system and accessories before use with the AXiiiS-CMB.
- Assess the boney skull anatomy for previously resected bone flaps or diseased or damaged bone prior to AXiiiS-CMB attachment and use caution if attaching to these areas.
- With the exception of the Alignment Mandrel and Clearance Mandrel, the rest of the AXiiiS-CMB Accessories have not been evaluated for MR compatibility. They are therefore considered MR Unsafe and should not be subjected to MRI.

CAUTION:

- Exercise caution if using accessories not supplied by Monteris Medical. Failure to do so may result in improper performance and/or damage to the device with the potential to cause harm.
- Do not attempt to use the AXiiiS-CMB before thoroughly reading the Instructions for Use.

5 MRI Conditional Status

5.1 AXiiiS-CMB Assembly

1.5 / 3.0T

Non-clinical testing has demonstrated that the AXiiiS-CMB components are **MR Conditional.** The following guidelines should be followed:

- Static magnetic field of 1.5/3.0 Tesla
- Scan in “Normal Operating Mode” only with a maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg.
- Use only whole body transmitting coils, no local transmitting coils are allowed, local receiving coils can be used.

5.2 AXiiiS-CMB Accessories

See component list for specific component MR designations in Table 1.

The Stereotactic Driver, T-Handel for the Stereotactic Driver and Insert Adapters in the Accessory Kits should be considered MRI unsafe.

1.5 / 3.0T

Non-clinical testing has demonstrated that the Clearance Mandrel, Alignment Mandrel and MRI Removal Tool in the Accessory Kits are **MR Conditional.** For the accessories with an MRI status of "MR Conditional", the following guidelines should be followed:

- Static magnetic field of 1.5/3.0 Tesla
- Scan in “Normal Operating Mode” only with a maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg.
- Use only whole body transmitting coils, no local transmitting coils are allowed, local receiving coils can be used.

6 Directions for Use

6.1 Sterilization

Thoroughly clean and steam sterilize the AXiiiS-CMB and accessories prior to use following institution's Central Supply SOP for steam sterilization. General guidelines are provided in Section 8 below.

WARNING: To prevent loss of attachment stability in bone, do not reuse the AXiiiS-CMB as patient injury may result.

6.2 Trajectory Alignment and Attachment to Skull

Refer to the stereotactic or IGS system manufacturer's IFU for trajectory alignment.

- Use the appropriate surgical planning software for the stereotactic or IGS arm system used to guide the AXiiiS-CMB's trajectory to determine target and entry locations on previously loaded MRI and or CT scans per manufacturer's IFU.

WARNING: To prevent patient injury, assess the skull anatomy prior to attachment. Use caution when attaching to resection bone flaps or to diseased or damaged bone. Ensure a minimum skull thickness of 5 mm exists at the at the AXiiiS-CMB attachment point.

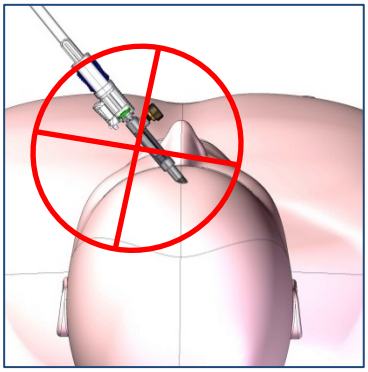
- Assess the desired trajectory for proper stack-up clearance of devices placed by the AXiiiS-CMB within the MRI bore.

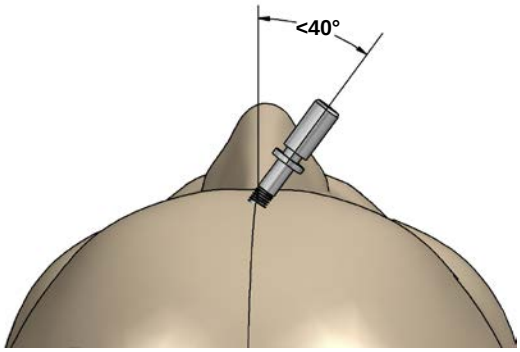
WARNING: To prevent potential patient injury, avoid trajectories ~ 90˚ (perpendicular) to the MRI bore which can lead to collisions with devices placed by the AXiiiS-CMB.

- Perform surgical prep as well as sterile draping of patient head per standard hospital practice.
- Examine skull for previously installed cranial plating, mesh or cranial hardware.

WARNING: Do not affix the AXiiiS-CMB over previously installed cranial plating, mesh or other cranial hardware to avoid patient injury.

- Follow the stereotactic or IGS system manufacture's guidelines for establishing the desired trajectory with the device used to deploy the AXiiiS-CMB.





WARNING: To ensure proper attachment of the AXiiiS-CMB to the skull and to avoid patient injury, do not exceed 40° away from perpendicular to the skull as shown in the images above.

- Identify and mark the planned entry point on the scalp which intersects the optimal surgical trajectory to the predetermined target in the brain.
- Ensure adequate clearance for the AXiiiS-CMB exists between the aiming device and the head to allow placement.
- Create a scalp incision at the desired entry location.
- Create a 4.5 mm diameter twist drill hole in the skull oriented along the desired trajectory through the 4.5 mm Insert Adapter.
  Note: A non-skiving 4.5 mm twist-drill is recommended for initial trephination of the outer table of the skull. Final, complete trephination though the inner table of the skull should be completed using a drill bit that has a flatter or less aggressive (pointed) flute design at the drill tip.

CAUTION: Incomplete drilling of the twist drill hole through both tables of the skull can interfere with stable anchoring of the AXiiiS-CMB or interference with placement of the intended instrument or device.

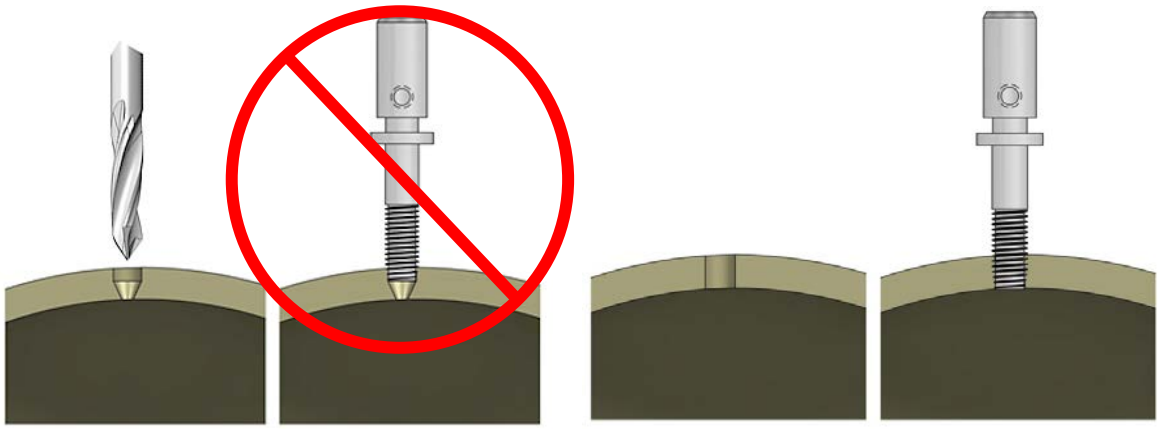


Figure 5: Incomplete Drilling with a Pointed Drill Bit (left); Complete Drilling (right)

- Insert the flat, non-beveled end of the 4.5 mm Clearance Mandrel through the 4.5 mm Insert Adapter and extend through the created twist drill hole to the Dura (Figure 6).
- Ensure a clear path for placement of the AXiiiS-CMB created through both the outer and inner tables.
- If there is any noted resistance in passing the Clearance Mandrel through the skull to the Dura, complete the drilling process or use a cutting instrument to de-burr the inner skull table.

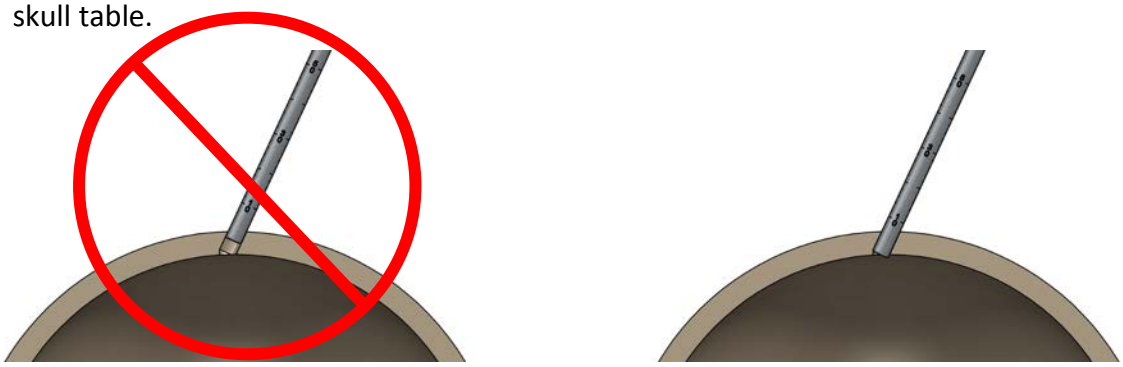


Figure 6: Incomplete Drilling (left); Clearance Mandrel with Complete Drilling (right)

- Insert the Stereotactic Driver shaft into the T-Handle while depressing the button located on the flat surface at the end of the silver banded side of the handle (Figure 7).
- Insert the Stereotactic Driver into the appropriate Host Adapter or directly into the IGS aiming device and into the proximal end of the AXiiiS-CMB (Figure 7).

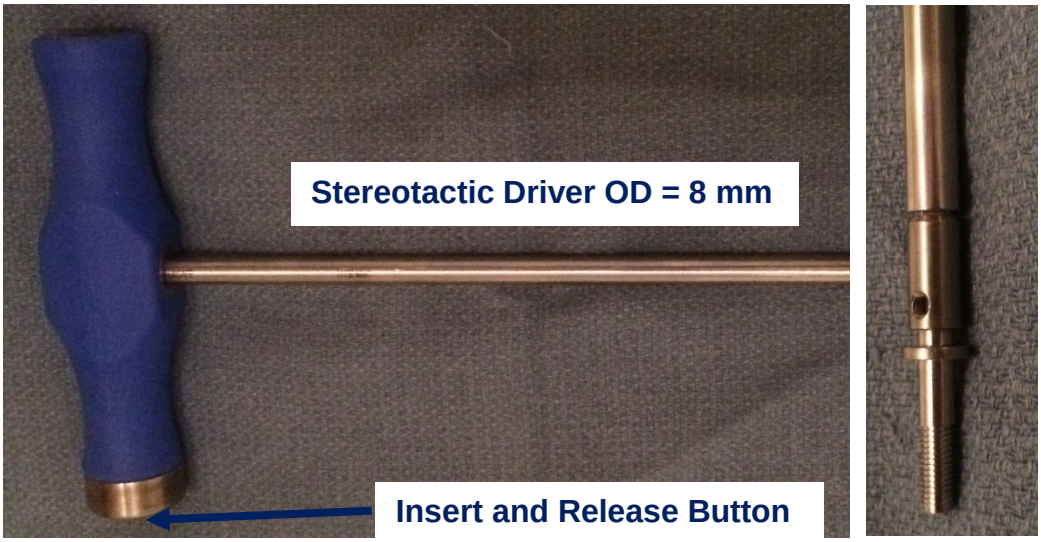
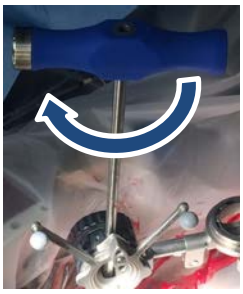


Figure 7: T-Handle and Stereotactic Driver (left); Driver Inserted into AXiiiS-CMB (right)

- Thread the AXiiiS-CMB into the skull opening.
- Rotate the Stereotactic Driver clockwise until the AXiiiS-CMB is fully seated and engaged to the skull inner table - 10 full turns will place the threads 8 mm into the skull (see Table 2).
- Manually check the stability of attachment into the skull before proceeding.



WARNING: Exercise care, over-tightening the AXiiiS-CMB may cause stripping of the bone channel at attachment. Use only enough force to assure stable attachment.

- Remove the Stereotactic Driver from the AXiiiS-CMB.
- Insert the Bolt Plug into the AXiiiS-CMB if desired to temporarily close plug the open channel to the brain (image right).
- Perform the intended neurosurgical procedure.

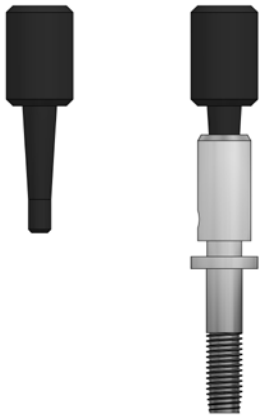


Table 2: Chart to Calculate AXiiiS-CMB Depth in Skull Based on Number of 360° Driver Turns

Number of Turns	Depth Into Skull
4	3.2mm
5	4.0mm
6	4.8mm
7	5.6mm
8	6.4mm
9	7.2mm
10	8.0mm
11	8.8mm
12	9.6mm
13	10.4mm
14	11.2mm
15	12.0mm

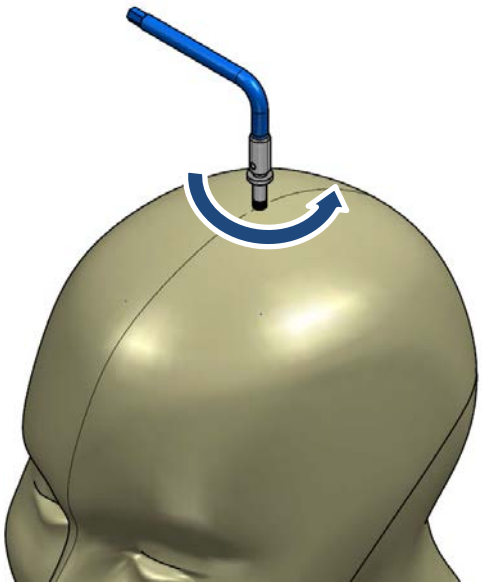
- See section 6.3 for measurements of the AXiiiS-CMB and accessories to determine proper depth settings for the delivered instrument or device.

Refer to the stereotactic or IGS system manufacturer's IFU to properly calculate delivered instrument or device depth to the intended target.

- See section 6.4 if performing a NeuroBlate® System Procedure.

At the end of the procedure, remove the AXiiiS-CMB using the Stereotactic Driver and T-handle outside of the MRI environment.

If is necessary to remove the AXiiiS-CMB inside the MRI environment, use the MRI Safe Removal Tool image right).



6.3 AXiiiS-CMB and Accessory Adapter Dimensions (mm's)

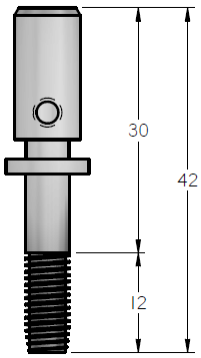


Figure 8: Measurements of the AXiiiS-CMB

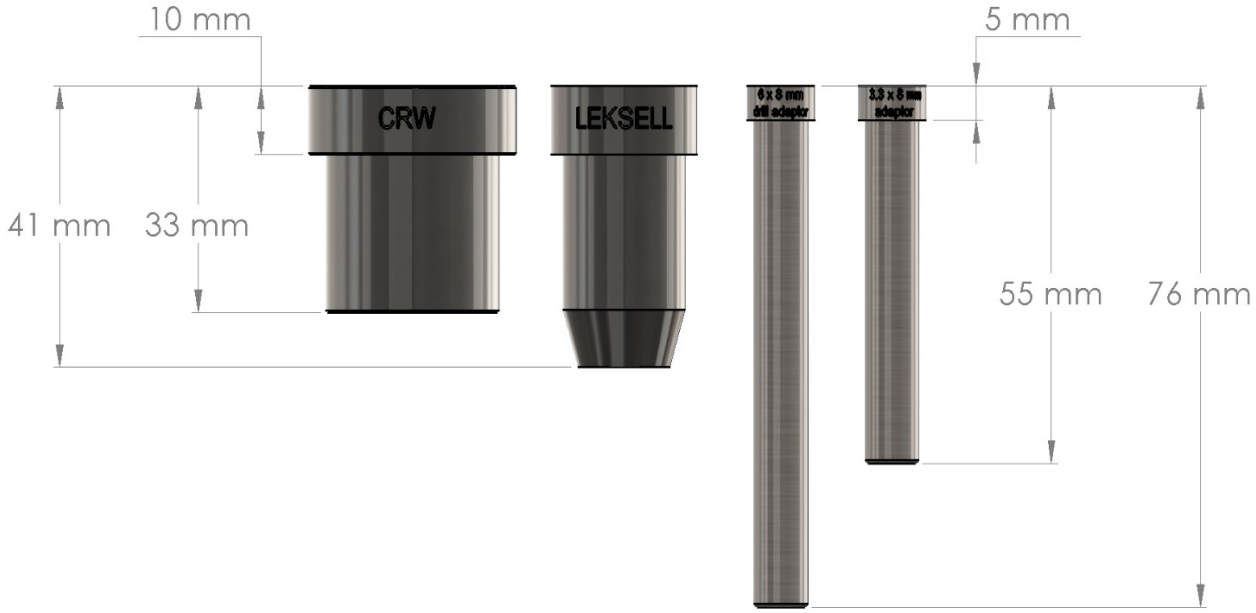


Figure 9: Measurements of the Host Adapters and Insert Adapters

6.4 Using AXiiiS-CMB for NeuroBlate® System Procedures

Refer to the NeuroBlate® System's Instructions for Use to determine appropriate depth settings for delivery of a laser probe via the AXiiiS-CMB.

Note: If thermal imaging is required at depths less than 23 mm for 1.5 T and 28 mm for 3.0 T from the inner table of the skull, user should acquire the thermal gradient echo sequence and assess for MRI artifact prior to delivering laser energy.

WARNING: MRI artifact can extend as much as 23 mm for 1.5 T and 28 mm for 3.0 T away from distal end of the AXiiiS-CMB (inner table of the skull) into brain tissue. If thermal imaging at depths less than this is required, user should proceed with extreme caution to ensure safe laser energy delivery. The amount of thermal data pixel dropout at shallow depths should be evaluated prior to laser energy delivery. To prevent patient injury, the user should not deliver laser energy into tissue that cannot be properly evaluated with thermal imaging.

- MR imaging should be used to confirm any linear instrument adjustments after initial delivery into the brain.
- To attach the NeuroBlate Robotic Probe Driver Follower to the AXiiiS-CMB, insert the Follower stem into the Locking Collar

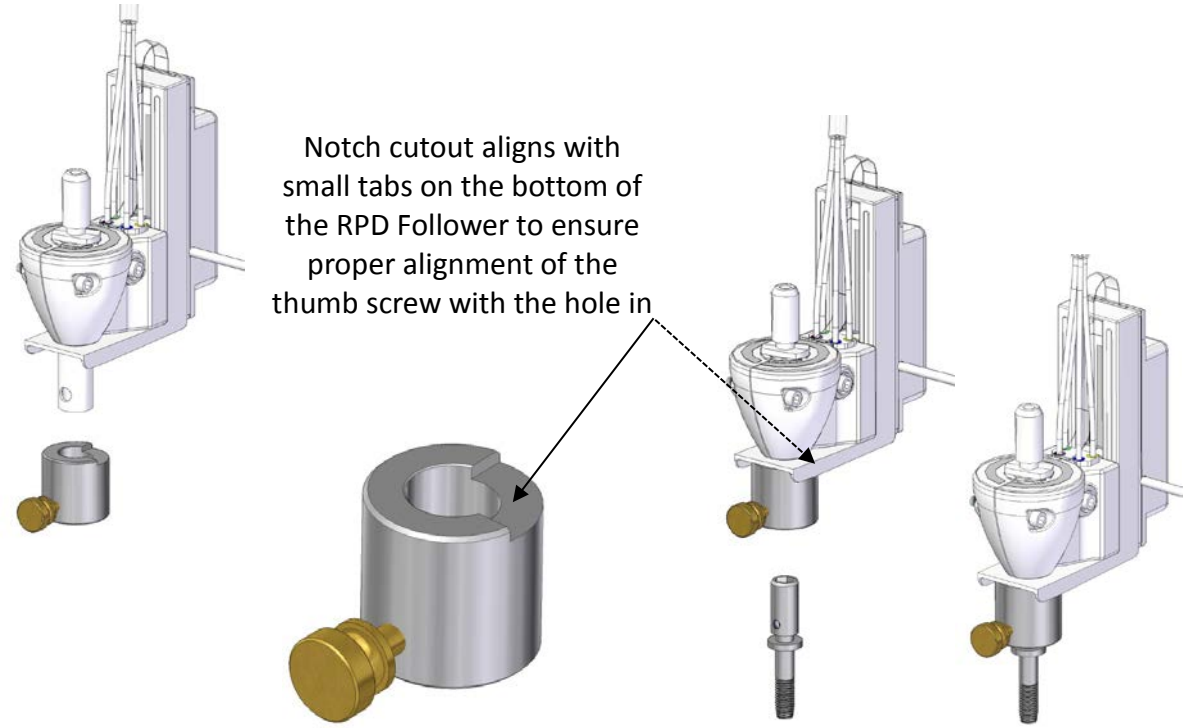


Figure 10: Attaching the RPD to the AXiiiS-CMB

7 Troubleshooting

Contact Monteris Customer Support for specific trouble shooting tips:

- **Monteris Toll Free Customer Support:** **1-866-799-7655**
  Callers may choose to be connected directly to a Technical Services Representative, to leave a message requesting service or product sales, or be connected to the Monteris Medical operator.
- **Monteris Email Reporting System:** reporting@monteris.com
  Contact Monteris via email to request service, make product improvement suggestions, report system issues or register complaints.

8 Inspection, Cleaning, Disinfection, Sterilization

- Prior to use, steam sterilize the AXiiiS-CMB and AXiiiS-CMB Accessories per institution's Central Supply SOP for titanium, brass and stainless steel instruments.

WARNING: Proper sterilization of the AXiiiS-CMB assembly and accessories must be done prior to each use to prevent patient injury.

- After use, thoroughly clean the AXiiiS-CMB Accessory components per institution's Central Supply SOP for titanium, brass and stainless steel instruments.

WARNING: To prevent patient injury **do not** reuse the AXiiiS-CMB.

9 Operating Conditions

- Temperature: 15°C (59°F) to 30°C (86°F)
- Relative Humidity: < 70%

10 Storage Conditions

- Temperature: 10°C (50°F) to 40°C (104°F)
- Relative Humidity: < 60%

11 Contact Information

11.1 Distributed by:

Monteris Medical Corp.
14755 27th Ave N
Suite C
Plymouth, MN 55447
(763) 253-4710 / (866) 799-7655
reporting@monteris.com

11.2 Manufactured by:

Monteris Medical Corp.
14755 27th Ave N
Suite C
Plymouth, MN 55447
(763) 253-4710 / (866) 799-7655
www.monteris.com