AXiiiS®

STEREOTACTIC MINIFRAME

MONTERIS® MEDICAL

Instructions for Use

AXiiiS®

STEREOTACTIC MINIFRAME

AND ACCESSORIES

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® Stereotactic Miniframe Overview

The AXiiiS Stereotactic Miniframe is a single-use, skull-mounted trajectory guide. The AXiiiS can be manipulated to provide a wide range of trajectories into the head. An Image-Guided Surgery (IGS) system loaded with preoperative image data is typically used to navigate the AXiiiS to the intended trajectory. Once the desired trajectory is obtained, the AXiiiS joints are locked to provide a stable and rigid platform for neurosurgical device or instrument delivery.

AXiiiS has three telescoping legs connected to a center ball joint. Each of the legs is attached to the patient's skull with one self-tapping titanium bone screw. By adjusting the height of each leg, and the alignment of the center ball, various trajectories can be obtained.

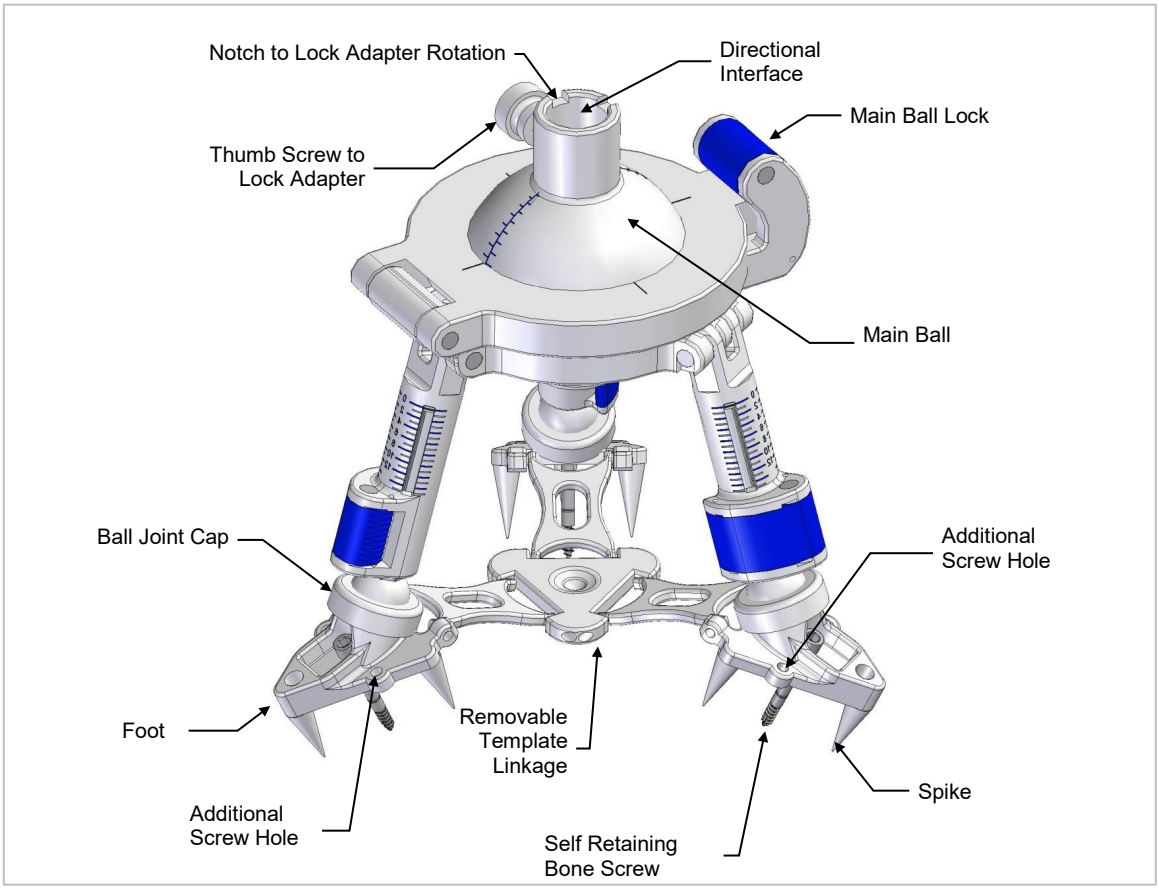


Figure 1: Diagram of AXiiiS illustrating the device's main functional parts.

Each leg is uniquely numbered and has linear graduation marks. Once the intended trajectory is defined the graduation settings on the legs and main ball can be recorded and confirmed for subsequent procedures.

A removable template linkage is provided to ensure proper spacing and orientation of the feet prior to attaching them to the head.

Multiple device adapters are available to interface with the Directional Interface on the Main Ball. These adapters lock securely to the center ball and provide guidance for various diameter instruments or devices.

1.1.1 Additional Device Details

- Each foot has one primary location for the bone screw to pass through and connect to the patient's head. If the primary screw fails, there are two empty holes for additional bone screws. The feet also have three spikes which will be pressed through the scalp to engage the skull surface.

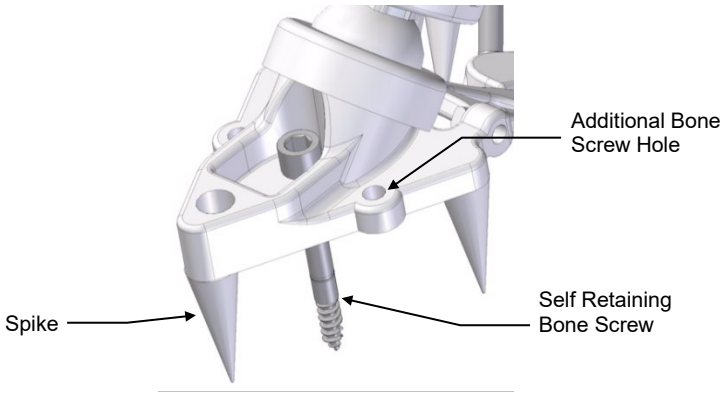


Figure 2: Detail of AXiiiS Foot.

- The feet are connected together by a template linkage which keeps them positioned properly. The template pieces are hinged at either end which allows the feet to tilt and align with the skull surface.
- The telescoping legs can be locked at any position by a cam lever lock located on the upper leg portion. They are connected to the feet by a ball joint which allows the leg to be manipulated in any direction.

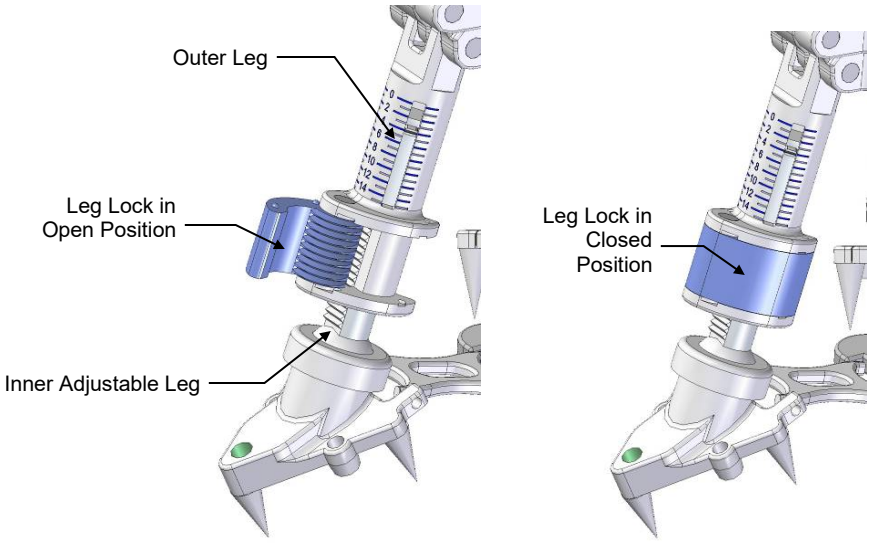


Figure 3: Detailed view of AXiiiS leg adjustment functions.

- The Main Ball provides a directional connection for an array of adapters. It is allowed to rotate in any direction, and is locked by a cam lever in any orientation.
- There are multiple MRI visible markers within the AXiiiS body, as shown in the images below. These markers can be used to visualize position of various AXiiiS components in MR images.

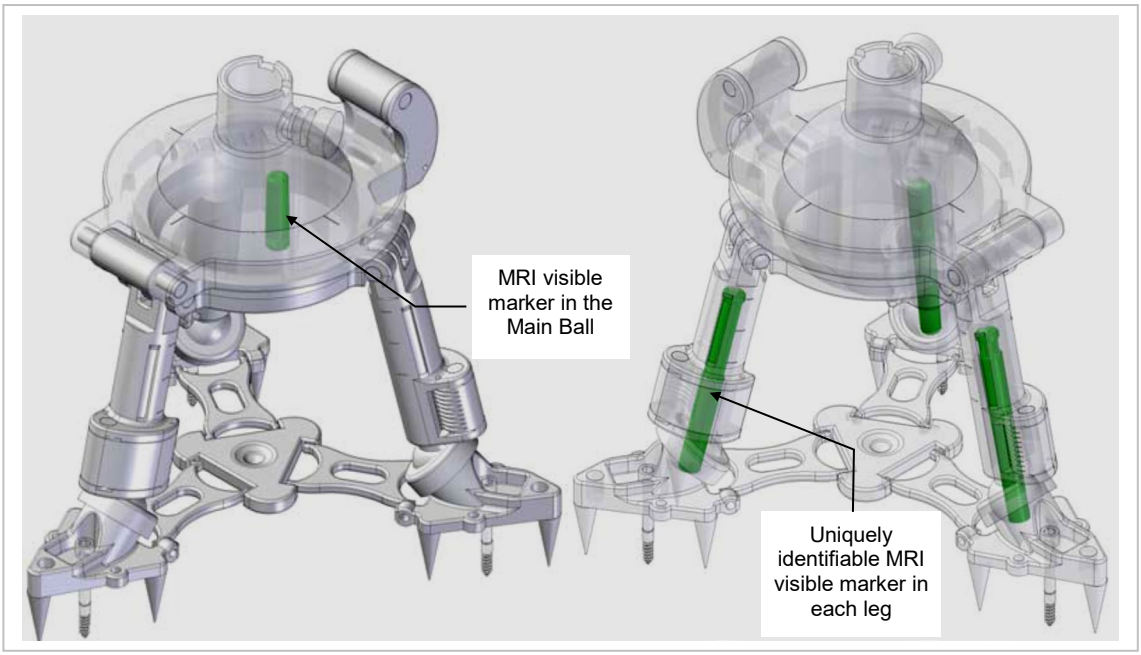


Figure 4: MR Visible Markers Imbedded in the AXiiiS Main Ball (left) and Legs (right).

1.1.2 Trajectory Angle Limits

The following patient specific circumstances limit the effective trajectory angle (including AXiiiS feet position on skull surface, extreme Main Ball angles and burr hole size) and should be considered in the procedure planning stage.

For no pre-drilled entry point:

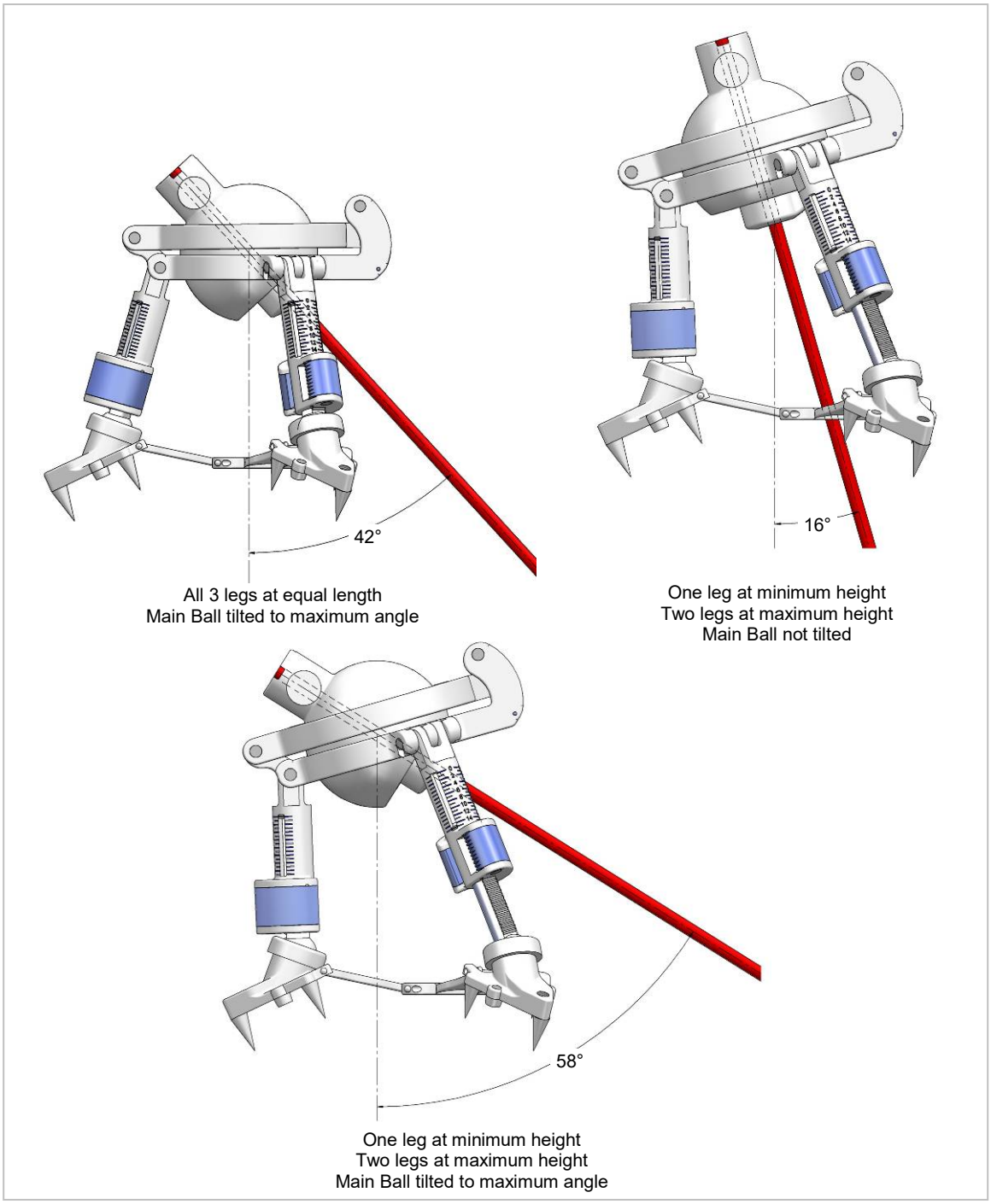


Figure 5: Adjustability when there is not a pre-drilled access in skull.

For pre-drilled burr holes:

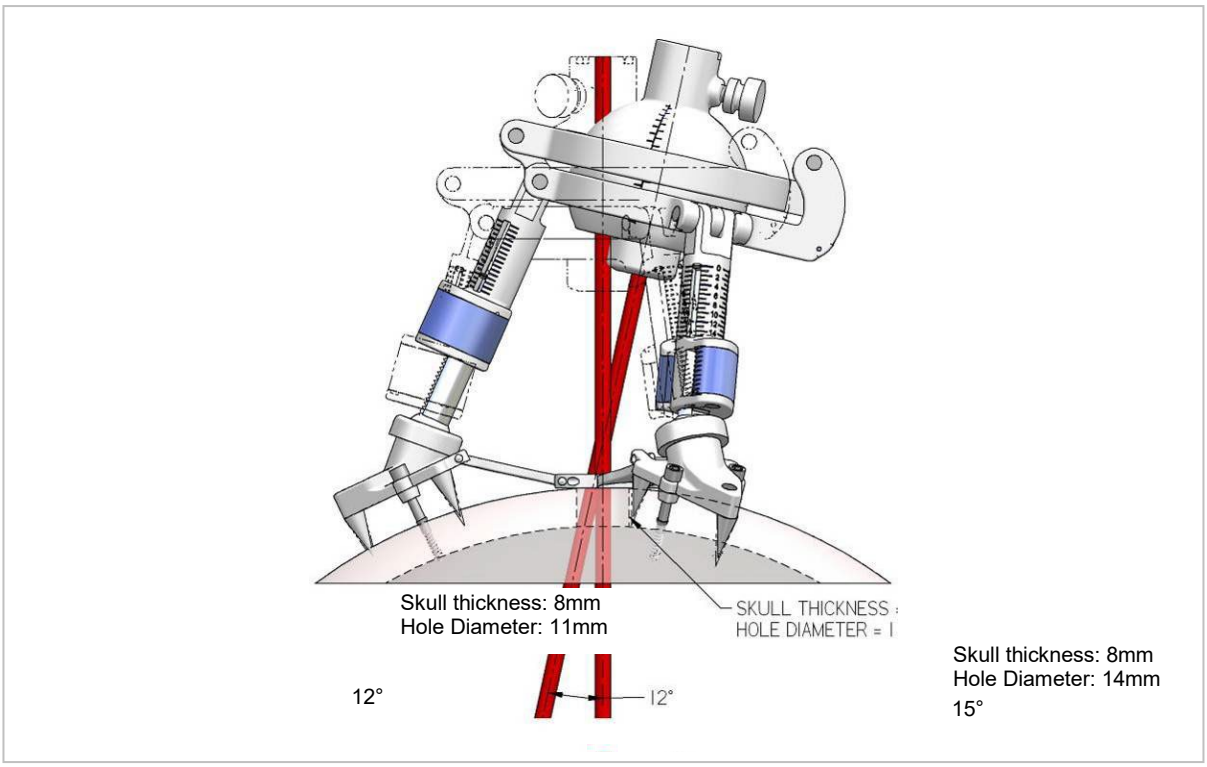


Figure 6: Adjustability for 11 mm (left) and 14 mm (right) Pre-Drilled Holes through Skull

1.2 Disposable Instrument Adapters

MR 1.5/3.0 T

Single-use, plastic Instrument Adapters (right) are available as an accessory to the AXiiiS device and are used as reducing tubes for the AXiiiS Directional Interface to allow trajectory guidance of smaller diameter Neurosurgical instruments or devices. Three sterile adapters with different internal diameters (1.9, 2.2 and 2.6 mm) are provided in a peel pouch.

1.3 Disposable MRI Trajectory Wand

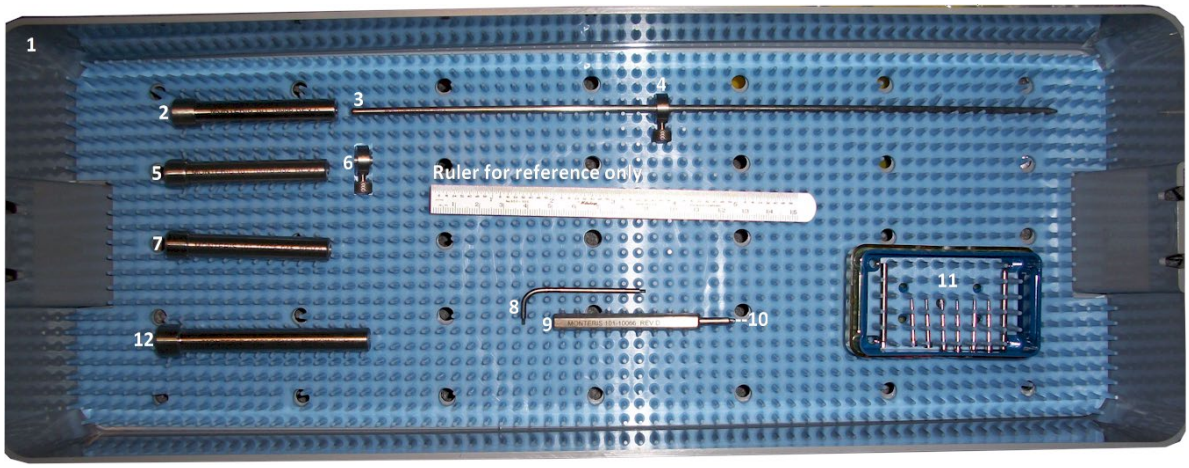
MR 1.5/3.0 T

A single-use, MRI-visible plastic stem (below) is available as an accessory to the AXiiiS and is used to assess the established trajectory of the AXiiiS device prior to device or instrument delivery. A single sterile MR Trajectory Wand is provided in a peel pouch.

1.4 Accessory Toolkit

MR

A set of non-ferrous, reusable stainless steel instruments (below) are available. The set includes instrument adapters (ID sizes: 3.2, 4.5, 4.8, 6.0 mm), IGS pointer probe adapters (for Medtronic, BrainLAB and Stryker IGS), a screw driver blade interface for a power driver, a test probe with depth stop and a sterilization tray. These instruments have not been tested for conditional MRI status and should be considered MRI unsafe.



MR 1.5/3.0 T

Additional AXiiiS attachment, titanium bone screws (#11 image above) are provided in a smaller sterilization tray. The screws are disposable and 1.5T or 3.0T MRI Conditional.

1.5 Catalogue Numbers

Table 1: AXiiiS and Monteris AXiiiS Accessories Catalog Numbers.

Cat Number	Description		MRI Status
AX300-01 (120000)	AXiiiS Trajectory Guide (1) Titanium Bone Screws (3) Screw Driver (1) Instructions for Use (1)		 1.5/3.0 T
MW300-01 (120003)	Accessory MRI Visible Wand		 1.5/3.0 T
IA300-01 (120021)	Accessory Instrument Adapters: 1.9 mm guide 2.2 mm guide 2.6 mm guide		 1.5/3.0 T
AXT100	**Part Numbers:** 10912 20422 20418-032 20418-045 20418-048 20418-060 20416 20423 20424 20425 10913	**AXiiiS Accessory Toolkit includes:** Sterilization Tray 3.2 mm Test Probe 3.2mm Instrument Adapter, includes: - 3.2mm Depth Stop with Thumbscrew 4.5mm Instrument Adapter, includes: - 4.5mm Depth Stop with Thumbscrew 4.8 mm Instrument Adapter 6.0 mm Instrument Adapter, includes: - 6.0 mm Depth Stop with Thumbscrew Screwdriver Blade for Power Driver, includes: - Screwdriver Blade Hex Wrench **IGS Pointer Adapters for:** - BrainLAB Standard Pointer Probe - Medtronic Stealth Navigus Probe - Stryker Short Pointer Small sterilization tray to retain screws	
	20417	15 AXiiiS Attachment Screws	 1.5/3.0 T

2 Indications for Use

The Monteris Medical AXiiiS Stereotactic Miniframe is intended to provide stereotactic guidance, placement and fixation for the operation of instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and(or) perioperative MR or CT imaging. These procedures include laser coagulation, biopsies, catheter placement and electrode implant procedures.

3 Contraindications

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

4 Warnings, Cautions, and General Safety Requirements

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

4.1 Warning and 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 (eg. 1.5 / 3.0 T)		
	**MRI Safe** - the item poses NO known hazards in ALL MR environments.		
	High Voltage present. Electrical hazard. Authorized personnel only.		
	Caution followed by text message.		
	Consult instructions for use.		
	Keep away from sunlight.		
	Manufacturer		
	Equipotentiality		Protective earth
	Serial Number		Batch code
	Do not re-sterilize		Do not reuse

4.2 AXiiiS Stereotactic Miniframe, Accessory Instrument Adapter and Accessory MRI Trajectory Wand Warnings and Cautions

WARNING:

- Perform systematic validation of the image-guided surgery (IGS) system used in conjunction with the AXiiiS 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.
- Assess the boney skull anatomy prior to AXiiiS foot attachment. Use caution when attaching AXiiiS feet to previously resected bone flaps or to diseased or damaged bone.
- The spikes and bone screws protruding from the bottom of each foot of the AXiiiS are very sharp and will easily puncture/penetrate surgical gloves. Exercise due caution when handling the AXiiiS outside of its protective trays.

CAUTION:

- Exercise caution if using accessories not qualified by Monteris Medical with this equipment. Failure to do so may result in improper performance and/or damage to the equipment with the potential to cause harm.
- Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised or the contents damaged, DO NOT USE and contact your Monteris Medical representative.
- For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death.
- Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

CAUTION cont'd:

- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- Ensure that all bone screws are properly tightened.
- Do not attempt to use the AXiiiS before thoroughly reading the Instructions for Use and Directions for Use section. For future reference, keep this document in a convenient, easily accessible place.
- Avoid insertion of bone screws into skull sutures.
- Injection of local anesthesia at AXiiiS feet scalp locations may prevent the foot spikes from fully seating on skull surface.

5 MRI Conditional Status

5.1 AXiiiS Stereotactic Miniframe, Instrument Adapters, MRI Trajectory Wand and Additional AXiiiS Bone Screws

Non-clinical testing has demonstrated the AXiiiS Stereotactic Miniframe, titanium bone screws, Instrument Adapters, and MRI Wand are **MR Conditional**. They can be used under the following conditions:

- 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 Accessory Toolkit

The Accessory Toolkit and its instrument components have not been tested for conditional MRI status and should be considered MRI unsafe.

The additional AXiiiS bone screws included in the Toolkit are **1.5 or 3.0 T MR Conditional**.

6 Directions for Use

6.1 Package Inspection & Accessory Toolkit Sterilization

Before opening the AXiiiS Stereotactic Miniframe, MR Trajectory Wand or Instrument Adapter package, inspect it for damage. If damage is evident and the sterile barrier may have been compromised, return the package to Monteris Medical and DO NOT USE.

Steam sterilize the Accessory Toolkit following institution's Central Supply SOP for steam sterilization. General guidelines are provided in Section 9.2 below.

6.2 Mount AXiiiS to Patient

Attachment of the AXiiiS is recommended with the linkage template in place (attached) and the leg cam levers locked in the manufacturer's preset position, unless the standard configuration forces any one of the feet to be attached at an undesirable point on the skull.

WARNING: Assess the boney skull anatomy prior to AXiiiS foot attachment. Use caution when attaching AXiiiS feet to previously resected bone flaps or to diseased or damaged bone.

- Use the surgical planning software included in the IGS system to determine target and entry locations on previously loaded MRI and or CT scans per manufacturer's IFU.
- Identify and mark the planned entry point on the scalp which intersects the optimal surgical trajectory to the predetermined target in the brain.
- Perform surgical prep to include entry and foot attachment points as well as sterile draping of patient head per standard hospital practice.
- Determine optimal positions for attachment of AXiiiS feet.
- If NOT using AXiiiS as a drill guide to create a twist-drill hole created on-trajectory, create the desired opening in the skull.

If using a perforator or burr device to create an opening in the skull:
- Incise scalp at the desired entry point
- Ensure incision is large enough to accommodate the size of hole to be created
- Create the desired opening in the skull before attaching the AXiiiS

NOTE: It is recommended to attach the AXiiiS feet such that the entry point is centered equally between the feet provided that suitable bone for attachment exists at these points.

- Although the AXiiiS attachment screws may be used in a self-tapping manner, there are circumstances when pilot-hole drilling may be preferred.

CAUTION: Circumstances such as age, gender, lifestyle (athletic, lifetime physical labor, etc.) and prior cranial accession in the region of screw placement can result in harder skull bones, as may the proximity of prior surgical implants. If there is a concern that such conditions exist, nominal (1 mm) pilot holes should be drilled. Pilot holes are strongly recommended for patients with dense cortical bone or abnormally hard skull surfaces.

- Examine skull for previously installed cranial plating, mesh or cranial hardware.
- Evaluate the patient for evidence of abnormally hard skull.
- Position the AXiiiS over the head such that the middle of the template linkage is centered over the identified entry location or created burr hole.
- If complicating circumstances exist, it is recommended that pilot holes be drilled for each of the screws (see optional recommendation below).

WARNING: Do not affix feet over previously installed cranial plating, mesh or other cranial hardware.

CAUTION: Avoid insertion of bone screws into skull sutures.

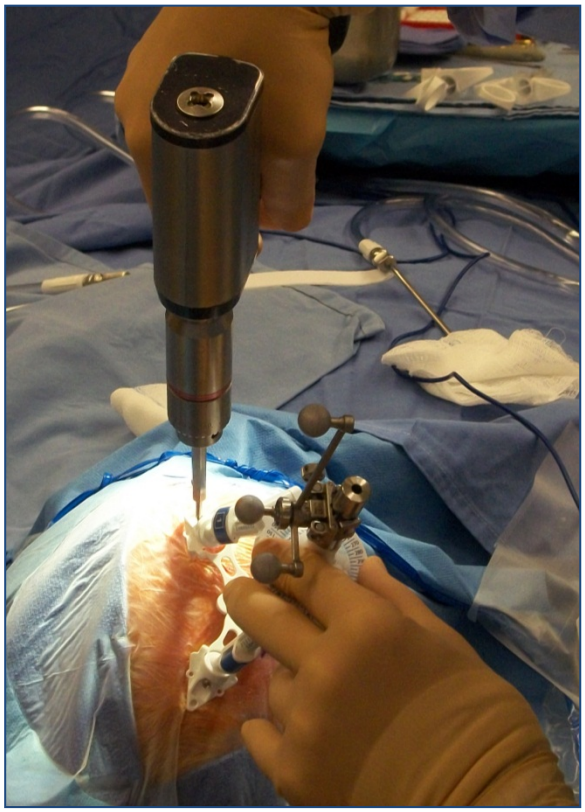
CAUTION: Injection of local anesthesia at AXiiiS feet scalp attachment point may prevent the foot spikes from fully seating on skull surface.

Optional: To make pilot holes for AXiiiS screw attachment, remove the bone screws packaged with the AXiiiS from the center hole of each AXiiiS foot using aseptic technique.

- For each of the three (3) AXiiiS feet respectively:
  - Position the AXiiiS on the head centered on the desired entry point.
  - Firmly press each foot's three spikes through the scalp.
  - Ensure each spike engages the skull surface.

Optional pilot-hole creation in the skull surface:
- Attach a 1mm diameter twist drill or router bit to a powered driver.
- Drill pilot holes into the skull surface through the desired screw hole(s) for each foot.
- Reinsert the attachment bone screw into the desired screw hole(s) for each foot.

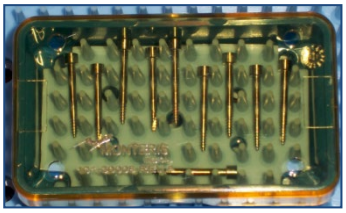
- Chuck the screw driver blade from the Accessory Toolkit into a power driver
- While holding the foot in place, carefully drive the bone screw(s) into the skull using the powered driver and driver blade to start and partially seat each screw.
- Use the disposable manual screwdriver that is supplied in the AXiiiS sterile tray to complete full seating of each screw alternately advancing each bone screw 2 - 3 quarter turns until all screws are fully seated.
- Check the stability of attachment of each foot before proceeding.
- Remove the template linkage from AXiiiS by gently twisting the linkages away from the feet.



WARNING: Exercise due care to not over-tighten the bone screws to prevent stripping of the bone channel at attachment. Use only enough force to assure stable attachment of the feet.

- If additional attachment bone screws are needed, utilize the screws in the small sterilization tray provided with the Accessory Toolkit (image right).

MR
1.5/3.0 T

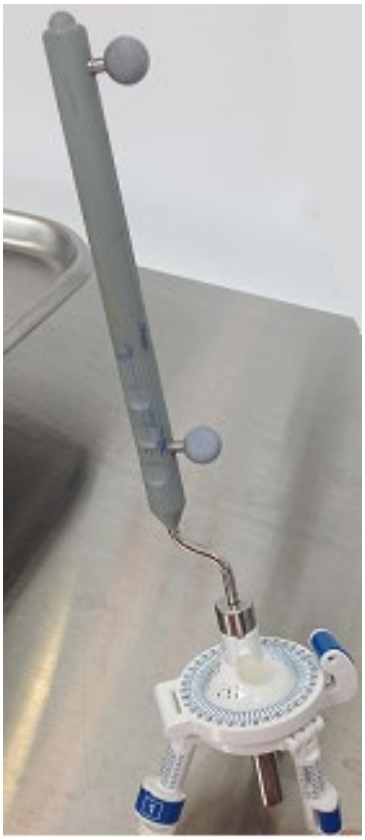


6.3 AXiiiS Trajectory Alignment with IGS System

Recommended Alignment Method with IGS Standard Pointer Probe

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

Note: It is recommended to set an entry and target point during IGS pre-planning. The IGS Probes-Eye-View or Guidance View is recommended for trajectory alignment.



1. Insert the appropriate IGS Adapter for the IGS system's standard pointer probe into the AXiiiS Directional Interface.
2. Tighten the Directional Interface thumbscrew.
3. Insert the IGS pointer probe into the adapter to visualize the trajectory and anatomy from the pre-operative scan on the navigation system (see image right).
4. Unlock the AXiiiS main ball lock to enable trajectory manipulation.
5. Manually adjust the main ball until alignment to the intended entry point is achieved.
6. Lock the main ball lock.
7. Unlock all 3 AXiiiS leg locks and manually adjust the leg heights until alignment to the intended target is achieved.
8. Lock all three leg locks.
9. Assess alignment on IGS workstation and repeat steps 4 - 8 until alignment along the intended trajectory is achieved.
10. Evaluate established trajectory and ensure no further adjustments to the ball or legs are required.

Optional IGS Tracking Tool and MR Trajectory Wand Set Up

- Attach an IGS system universal tracking device, such as the BrainLAB StarLink tracking system, to the MRI Trajectory Wand as shown in Figure 7.1.

Calibrate the universal tracking device and IGS alignment tool assembly for navigation with the IGS system per the manufacturer's IFU.

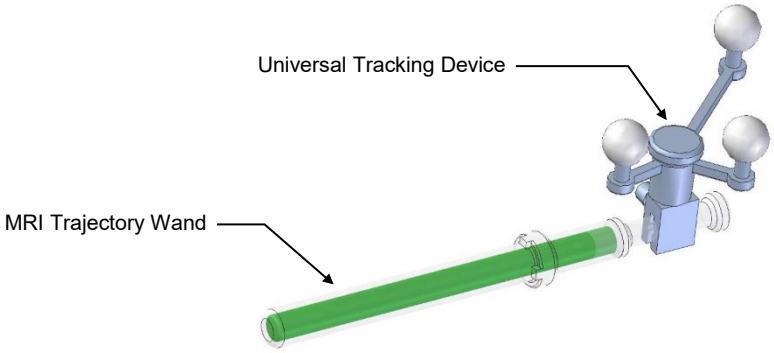


Figure 7.1: Illustration of IGS Universal Tracking Device attached to MRI Trajectory Wand.

- Insert the calibrated IGS tracking device - MRI Wand assembly into AXiiiS trajectory guide directional interface (Figure 7.2).
- Tighten adapter thumb screw.

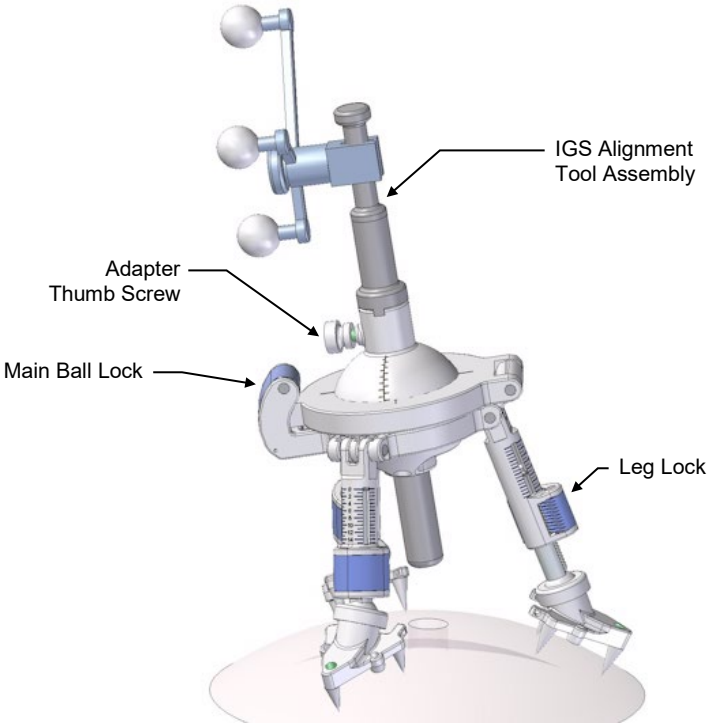


Figure 7.2: Illustration of the MRI Wand (with IGS Tracking) attached to the AXiiiS.

6.4 Engage AXiiiS Locking Cams

- Once aligned, close all the leg locks to fix the set trajectory.
- Record the positions of each of the legs, the main ball, and the frame containing the main ball for confirmatory use later in procedures.

NOTE: If resistance is felt when attempting to close the leg lock, slightly adjust the leg in or out to ensure the leg lock and lock teeth interface properly.

NOTE: Once the final trajectory is established and all AXiiiS locks are engaged, reset the planned entry point established by the IGS system to evaluate the actual instrument path through brain tissue using probes eye or trajectory views.

6.5 Perform Intended Neurosurgical Procedure

NOTE: If it is desired to assess the set trajectory using MRI imaging prior to delivering a device into the brain, refer to section **7 MRI Trajectory Confirmation**.

- If not done previously, create the necessary access hole through the skull with a twist drill along the established trajectory.
    - Create a stab incision at the desired skin entry location.
    - Insert the appropriately sized Instrument Adapter for the twist drill bit used to create the access hole in the skull.
    - Using a depth stop on the shaft of the twist drill bit to control penetration, drill through the skull taking care to use the depth stop to prevent the drill from penetrating the dura.
- Insert the 3.2mm Test Probe Adapter into the AXiiiS directional interface.
- Pass the Test Probe through the adapter to the skull surface to assess if desired clearance has been achieved to pass the intended device or instrument through the skull access hole.

Remove the IGS Adapter (or MRI Wand if used) from the AXiiis Stereotactic Miniframe by loosening the adapter thumb screw and sliding the assembly out of the Directional Interface.

- Insert the appropriately sized Instrument Adapter into the directional interface.
- Tighten the adapter thumb screw.

- To set a depth-stop on the instrument to be delivered (a biopsy needle will be used as an example):
    - Touch the tip of the calibrated assembly or standard IGS pointer probe to the proximal surface of the inserted instrument adapter.
    - Record distance to target as displayed on IGS per manufacturers IFU.
    - Use the recorded depth to set the depth-stop measured from the distal end of the biopsy needle (or biopsy window) to the bottom of the depth-stop.

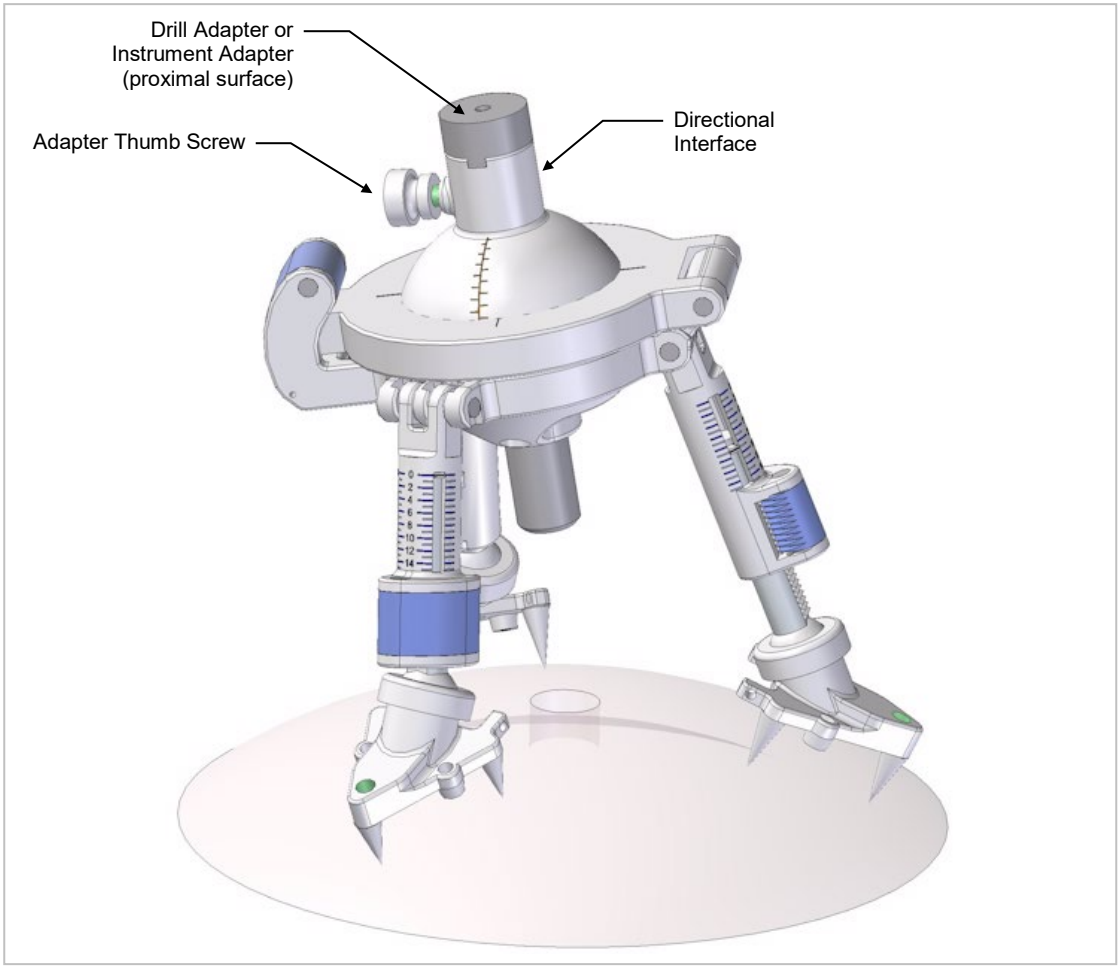


Figure 8: Illustration of the mounting of an accessory Instrument Adapter to the AXiiiS.

- Deliver the biopsy needle (or instrument/device) to the intended target.

NOTE: It is recommended that the user attach a universal tracking instrument such as the BrainLAB StarLink to the biopsy needle (or delivered instrument) and calibrate per the IGS manufacturer's IFU to track the tip of instrument as it is delivered to the intended target.

6.6 AXiiiS Disassembly

- If performing MRI confirmation of established trajectory (e.g. for a NeuroBlate® System procedure), continue to **MRI Trajectory Confirmation** (below) prior to device removal.
- Once intended neurosurgical procedure is complete, remove any instruments or devices (such as the biopsy needle) from the Directional Interface.
- Use the AXiiiS disposable screwdriver to remove all bone screws securing AXiiiS feet to the skull.
- Lift AXiiiS off the skull.
- Cover twist drill hole or burr hole per standard neurosurgical practice.
- Suture wounds in the scalp under the AXiiiS feet, per standard neurosurgical practice.

7 MRI Trajectory Confirmation

The set trajectory of the AXiiiS can be evaluated prior to delivery of the intended instrument.

7.1 Transfer to MRI

- Insert MRI Trajectory Wand into the AXiiiS Directional Interface using aseptic technique.
- Tighten the AXiiiS adapter thumb screw.
- Create a sterile barrier around the AXiiiS device using aseptic technique per institutional protocol.
    - A sterile, drawstring-style bag drape can be used.
    - The bag can be placed over AXiiiS and secured around the AXiiiS feet.
- Transfer patient to MRI while taking precautions to maintain the sterile barriers around AXiiiS.

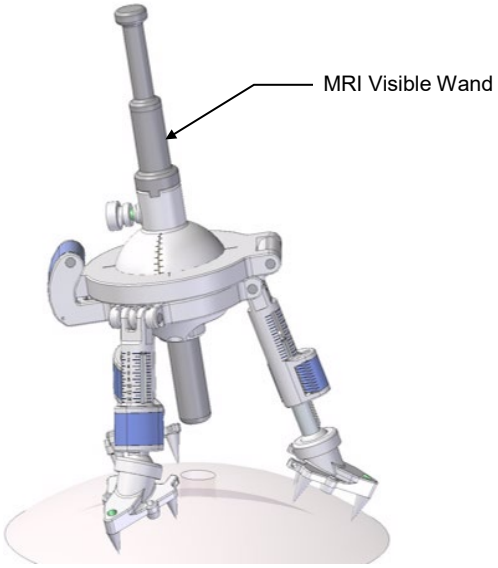


Figure 7: Illustration of MRI Trajectory Wand mounted in the AXiiiS.

7.2 Confirm Trajectory

Refer to the IGS system IFU or NeuroBlate System IFU for recommended imaging protocols.

- Acquire MRI imaging to include the intended target area and entire length of MRI Trajectory Wand.
- Input the acquired MRI images into the IGS system planning or NeuroBlate System software per the manufacturer's IFU.
- Visually confirm the established AXiiiS trajectory (denoted by the high signal intensity of the MRI Trajectory Wand displayed on the acquired MR images) by comparing its orientation to the intended target with the intended trajectory displayed on the planning system.
- Remove the Wand from the AXiiiS by loosening the adapter thumb screw and gently withdrawing the Wand.

If performing a NeuroBlate® System procedure, refer to the NeuroBlate System Software IFU for specific instructions to confirm trajectory.

7.3 Perform MRI-Guided Neurosurgical Procedure

If performing a NeuroBlate® System procedure, refer to the NeuroBlate System Software IFU for specific instructions to confirm trajectory.

- Insert the appropriate sized instrument adapter into the AXiiiS directional interface and tighten the adapter thumb screw.
- A depth stop may be set on the instrument by using the previously recorded "depth to target" to measure from the distal end of the instrument to the bottom of the depth stop.
- Deliver the instrument to target using MRI imaging to monitor its progress through brain tissue.

8 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.

9 Inspection, cleaning, disinfection, sterilization

9.1 AXiiiS Stereotactic Miniframe and Disposable Accessories

- Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised or the contents damaged, DO NOT USE and contact your Monteris Medical representative.

- For single use only.

- Do not reuse, reprocess or re-sterilize.

9.2 AXiiiS Accessory Toolkit

- Prior to use, sterilize the AXiiiS Accessory Toolkit. The following parameters have been validated for effective sterilization using moist heat:
    - 4 minute, 132° C prevacuum cycle, 30 minute dry time
    - 18 minute, 134° C prevacuum cycle, 30 minute dry time

WARNING: Proper sterilization of the AXiiiS Accessories must be done prior to each use to prevent patient injury.

- After use, the AXiiiS Accessory Toolkit components should be cleaned using either a manual or automated washer-disinfector process that is equivalent to or exceeds the following validated parameters:

Manual Cleaning:

Step	Parameters
Point of Use	Wipe or rinse gross soil from device surfaces with a damp cloth or water.
Transport	Place instruments in a protective container to minimize damage during transport. Keep surfaces moist using a foam or gel designed for transport and holding of surgical devices. Minimize transport and holding time before cleaning.
Rinse	Rinse devices to remove visible soil from surfaces using cold or warm potable water (19° to 30° C) for at least 1 minute or until visible soil is removed.
Wash	Immerse devices in warm prepared neutral or alkaline detergent solution using the recommended dose and temperature as labeled by the detergent manufacturer. With devices fully immersed, brush the exterior surfaces with a soft nylon-bristled brush for a minimum of 30 seconds. Using a suitable lumen/cannula brush (bristle diameter slightly larger than the inner diameter of the lumen), brush the lumen of the device in up and down and twisting motions for a minimum of 30 seconds.
Rinse	Rinse the devices with warm (20° C to 30°C) purified water for at least 30 seconds or until visible signs of detergent have been removed.

Automated Processing

Description	Selection
Point of Use	Wipe or rinse gross soil from device surfaces with a damp cloth or water
Transport	Place instruments in a protective container to minimize damage during transport. Keep surfaces moist using a foam or gel designed for transport and holding of surgical devices. Minimize transport and holding time before cleaning.
Pre-Wash	
Number of rinses	1
Water	Cold Tap Water (CTW)
Duration	00:15 (mm:ss)
Wash	
Duration	02:00 (mm:ss)
Dose and Temperature	Within alkaline or neutral detergent manufacturer's recommended range
Rinse	
Number of Rinses	1
Duration	00:15 (mm:ss)
Temperature	43.3 °C (110.0 °F)
Thermal Rinse	
Duration	01:00 (mm:ss)
Temperature	82.2 °C (180.0 °F) (equipment not capable of performing a thermal disinfection rinse, should incorporate an additional hot water rinse of at least 1 minute)
Drying	
Duration	Within equipment manufacturer's recommended range

10 Operating Conditions

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

11 Storage Conditions

- Temperature: 10°C (50°F) to 40°C (104°F)
- Relative Humidity: < 60%
- Not in direct sunlight

12 Contact Information

12.1 Distributed by:

Monteris Medical Corp.
14755 27th Ave. North
Suite C
Plymouth, MN 55447
(763) 253-4711 / (866) 799-7655
reporting@monteris.com

12.2 Manufactured by:

Monteris Medical Corp.
14755 27th Ave. North
Suite C
Plymouth, MN 55447
(763) 253-4711 / (866) 799-7655
www.monteris.com