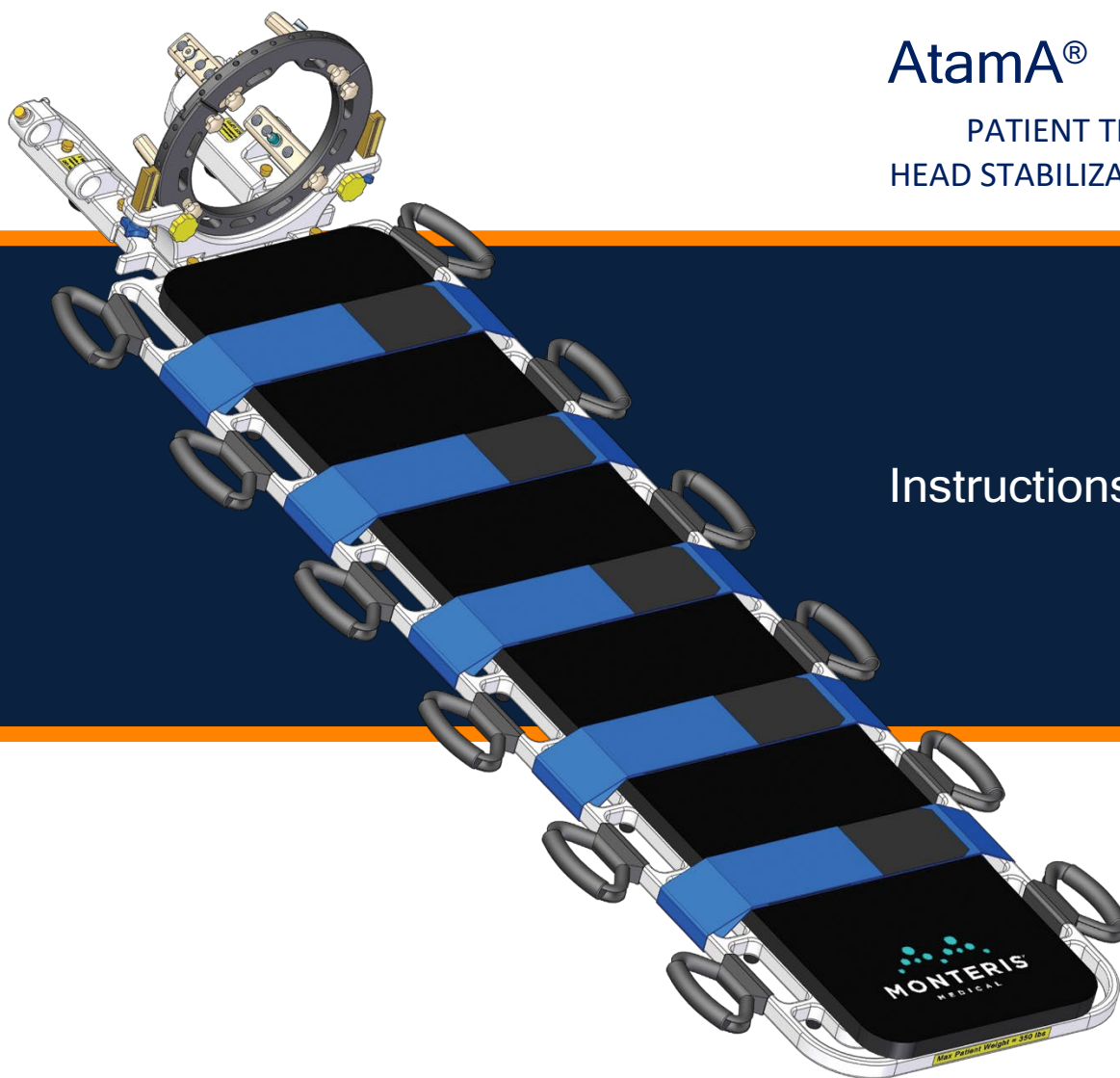




AtamA[®] System

PATIENT TRANSFER AND
HEAD STABILIZATION SYSTEM

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.

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1. System Description

The AtamA® System is a patient transfer and head stabilization system for the MRI (Figure 1). It is comprised of two subsystems:

- (i) Patient Transfer Board
- (ii) Head Stabilization System

These two subsystems are designed to work in unison to meet the varied needs of surgeons performing neurosurgical procedures utilizing MRI.

The head stabilization subsystem can also be used for other neurosurgical procedures requiring the patient's head to be stabilized or fixed.

The AtamA® System allows a streamlined workflow for procedures requiring the patient to undergo MRI examination before, during, or after neurosurgical procedures. The AtamA System maintains patient head fixation while providing a convenient, safe and effective method of moving the patient from an OR table to transport gurney to MRI couch without the need to unpin and re-pin the patient.

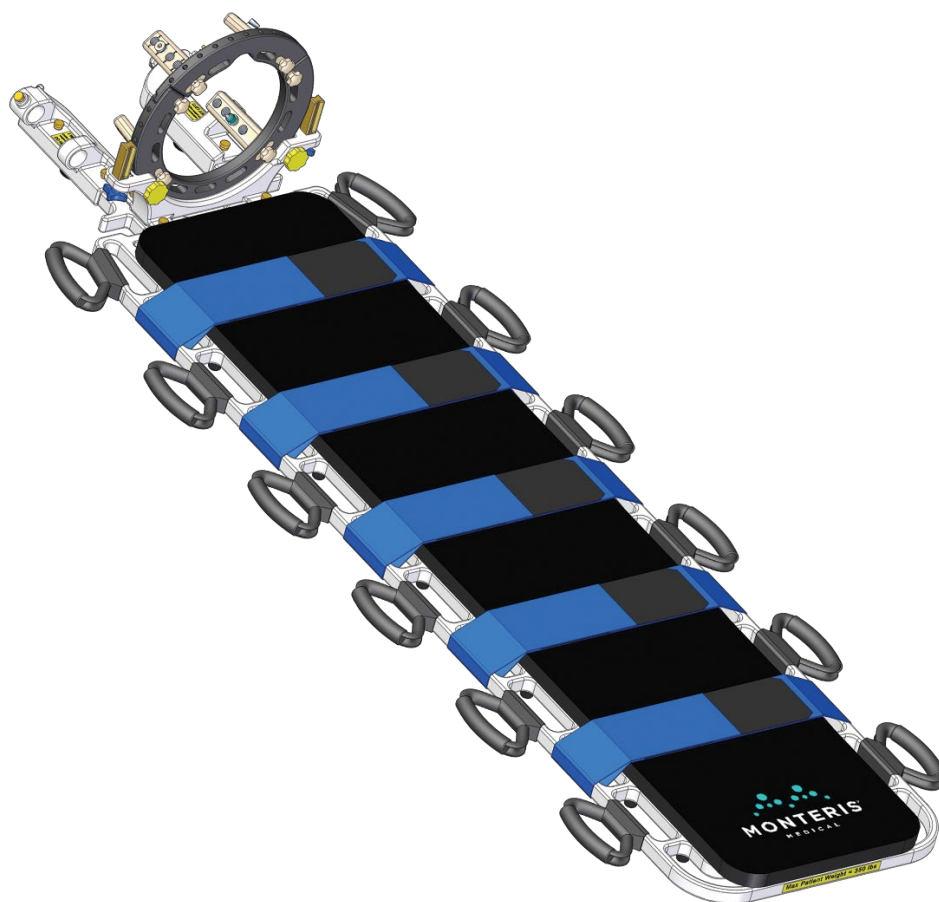


Figure 1. Illustration of AtamA System

The summary of the AtamA System Catalog Numbers is shown in Table 1.
 Required accessories which are not included with AtamA are listed in Table 2.

Table 1. AtamA System Catalog Numbers

Catalog #	Description	Compatible Systems	Safety
ATB002	Patient Board	IMRIS (any type*) GE (any type*) Siemens (Symphony, Avanto, Trio, Espree, Verio, Prisma)	 1.5 / 3.0 T
ATB002-R	Patient Board (Refurbished)		
ATB002-IM	Patient Board for IMRIS	IMRIS	
ATB002-2	Patient Board for Philips Ingenia	Philips (Ingenia & Achieva)	
ATB002-IG-R	Patient Board for Philips Ingenia (Refurbished)		
ATB002-AS	Patient Board for Siemens Aera or Skyra	Siemens (Aera, Skyra, Sola, Vida)	
ATB002-AS-R	Patient Board for Siemens Aera or Skyra (Refurbished)		
ATF102	Head Fixation Ring Subsystem (2 piece)	Philips (Achieva)	
ATF102-R	Head Fixation Ring Subsystem (2 piece) (Refurbished)		
ATF103	Head Fixation Ring Subsystem (3 piece)	Siemens (any type*) IMRIS (any type*) GE (any type*) Philips (Ingenia ONLY)	
ATF103-R	Head Fixation Ring Subsystem (3 piece) (Refurbished)		
ATS002	Rolling Utility Stand	Any System	
ATS002-R	Rolling Utility Stand (Refurbished)	Any System	
ASA001	Starburst Adapter	Any System	

** See IFU supplement (80575) for list of compatible MRI models*

Table 2. Accessories Required for use with the AtamA System

DORO® Disposable Skull Pins, Titanium, Adult (MRI Conditional) Order from Pro Med Instruments: 877.225.4086	Item-No. 3006-20 (box of 12 sterile packs - 3 pins each)
Standard Sterile Drapes	Each hospital will determine the appropriate sterile draping scheme based on standard practices. Typically, a combination of commonly available clear, plastic bag drapes such as “Snap Covers” or Isolation Drapes are used to maintain the sterile field.

1.1. PATIENT HEAD STABILIZATION SUBSYSTEM

The Patient Head Stabilization subsystem has three major components (Figure 2. Lifting/Transporting a Patient with Four People):

- **Head Fixation Ring (HFR)** multiple piece ring with interchangeable Standard and Extended front sections providing three to six point skull fixation
- **Cradle** to maintain the position of the HFR
- Patient **Board** for the efficient transport of the patient while maintaining stability and spatial registration of the patient.

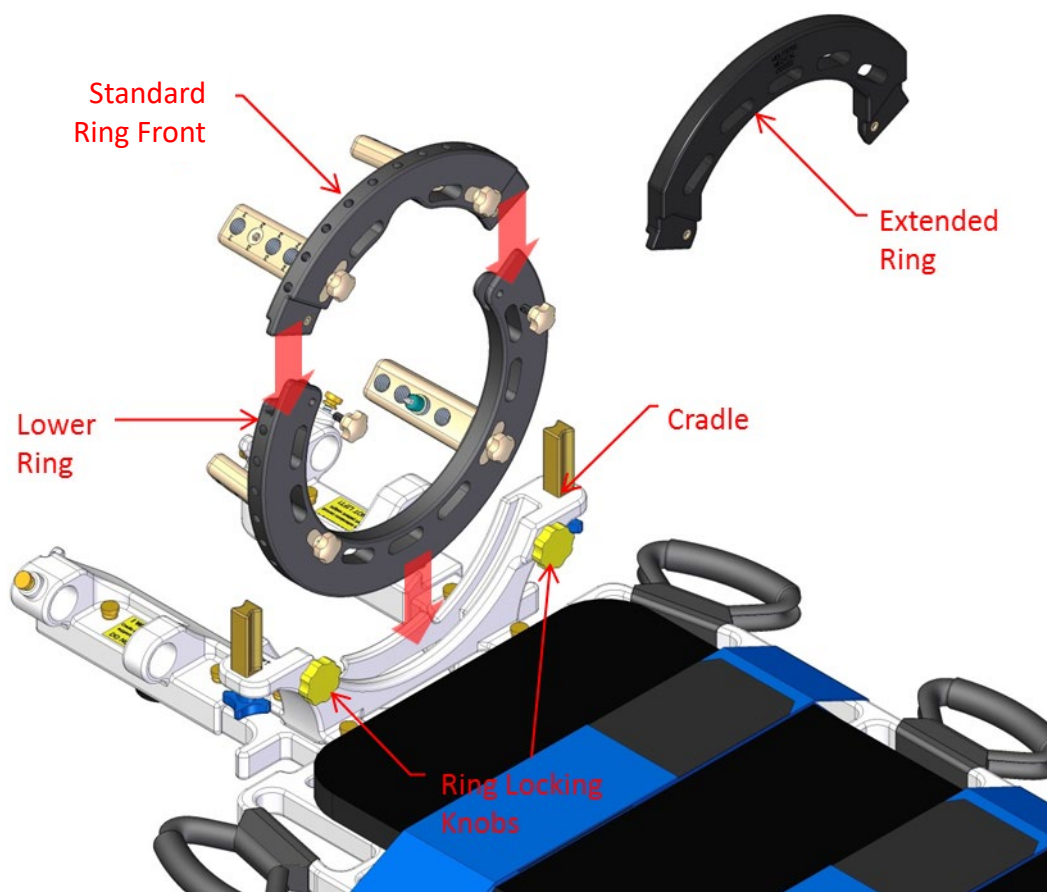


Figure 2. Detail of the Head Stabilization Subsystem (Patient Board and HFR)

The Head Fixation Ring fits into a groove in the Cradle allowing the ring to rotate freely (see Figure 2. Lifting/Transporting a Patient with Four People). The ring is locked in place by two Locking Knobs located on the patient side of Cradle. These knobs apply friction to outer surface of the ring to lock it into position. Once the patient's head is fixed (pinned), the ring can be rotated within the cradle and locked into place to provide the desired head position for the procedure. No tools are required to rotate or lock the Ring.

1.2. HEAD FIXATION RING (HFR)

The HFR posts (Figure) can be inserted into any of the cutouts in the ring. The ring can be configured to use 3 to 6 point fixation.

Each post provides 4 location options for inserting the pin holder and disposable, MRI compatible skull pin. Varying lengths of pin holders provide accommodation for a range of patient head sizes. An extra-long pin holder length is provided with the Split Head Fixation Ring assembly.

A convenient Storage Tray (Figure) holds all of the HFR components.

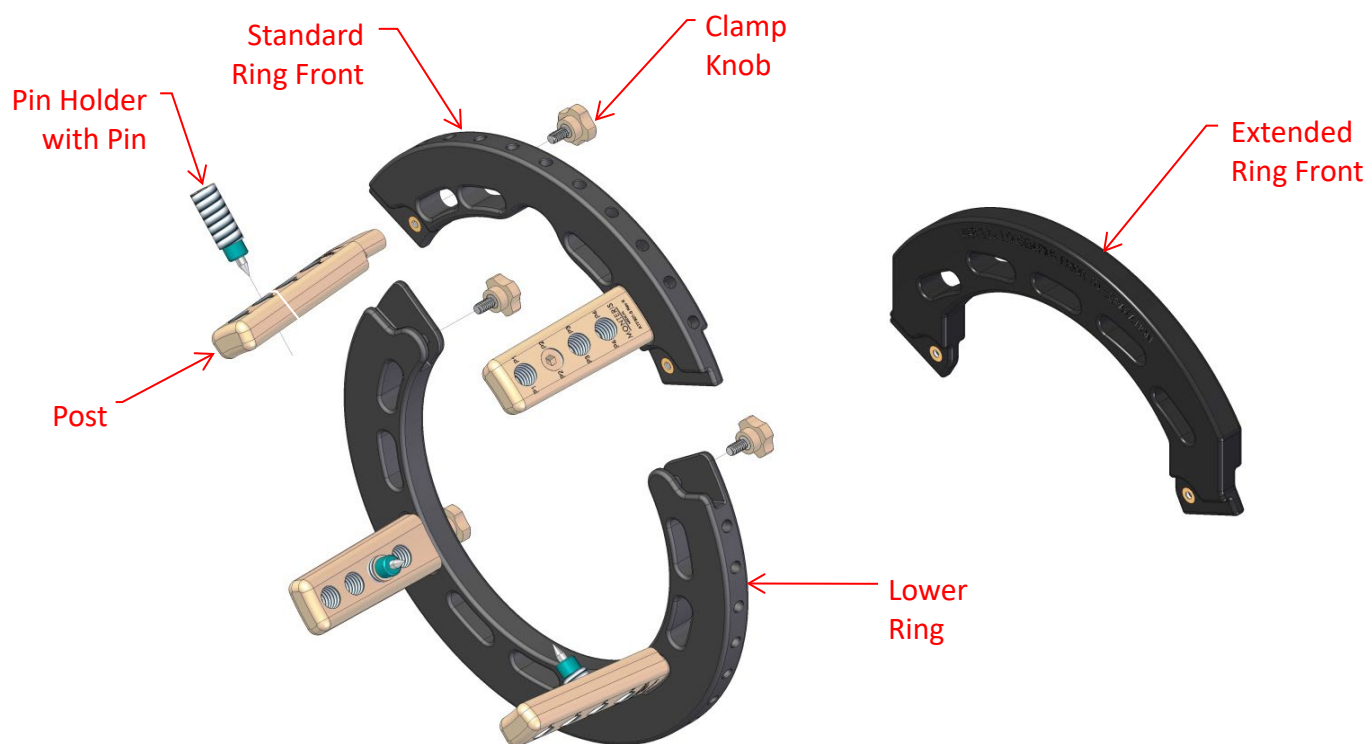


Figure 3. Detail of the Split Head Fixation Ring (HFR)

Note: The individual components shown can be replaced if lost or damaged. Contact your Monteris Medical representative for details.

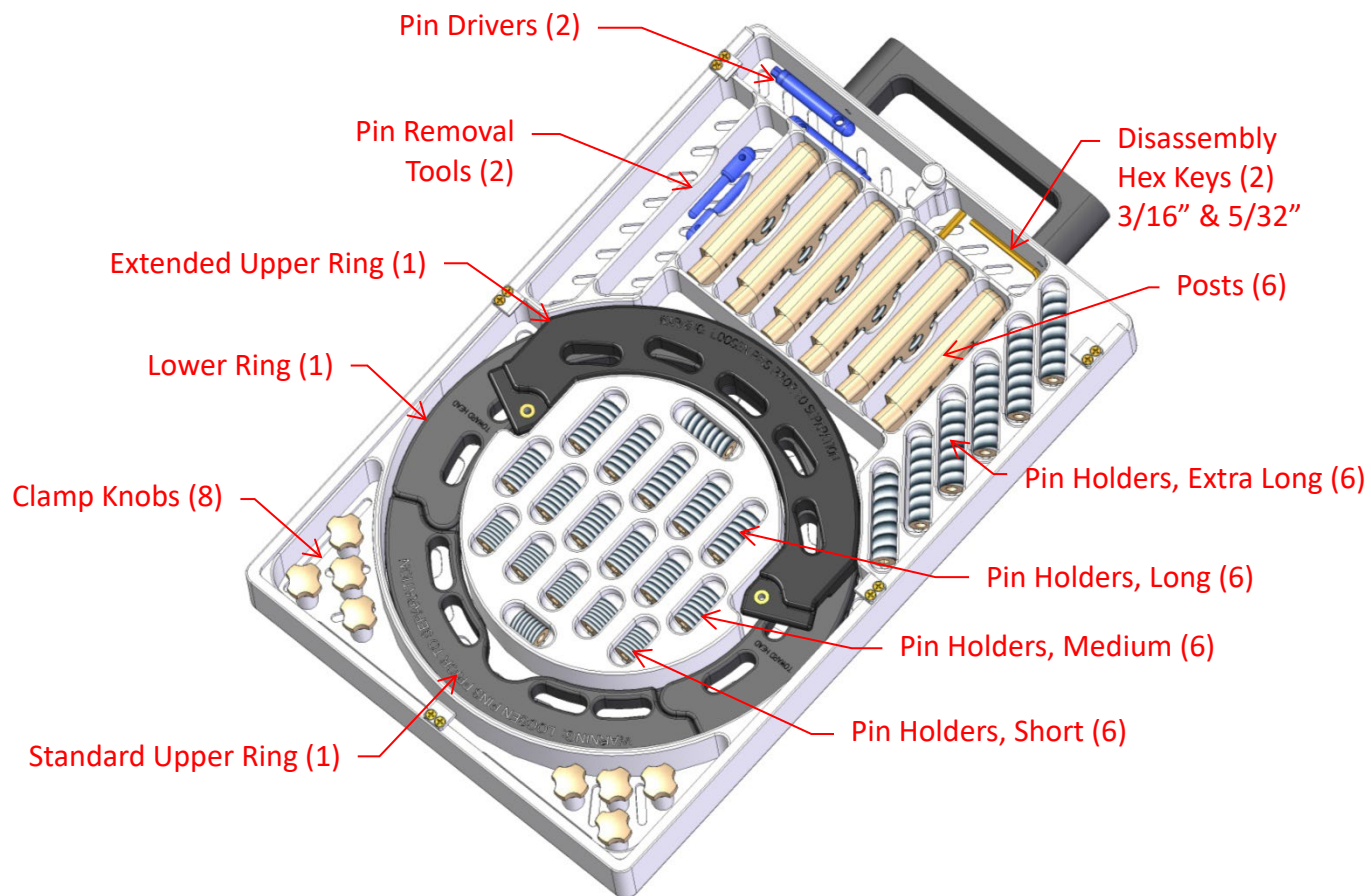


Figure 4. Storage Tray with Split Head Fixation Ring (HFR) Components

1.3. THE PATIENT BOARD

The Patient Board (Figure) has a patient load capacity of 350 pounds. It has 12 lifting handles to assist patient transfer and 5 straps to secure the patient. A Patient Pad is attached with Velcro to the top of the Board.

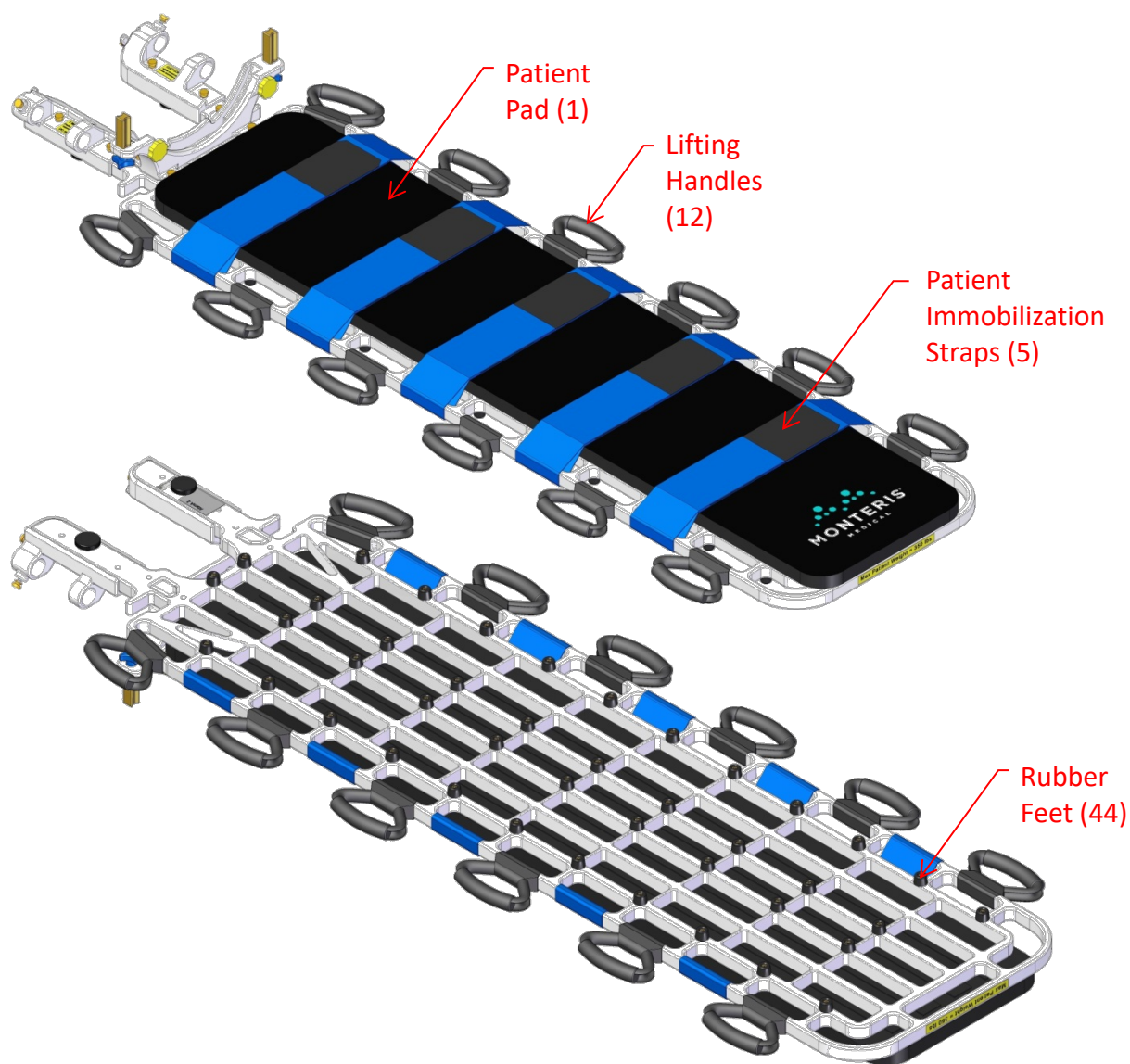


Figure 5. Details of the Patient Board

The Head Fixation Ring attaches to the Cradle, maintaining its relative position to the patient's head when the patient is transported. The Cradle provides 2 universal attachment posts (clamping locations) for an IGS system reference array (Figure). These posts are removable and are held in place with a large blue thumbscrew.



See the specific IGS system Instructions for Use for proper utilization of the reference array for image-guided procedures.

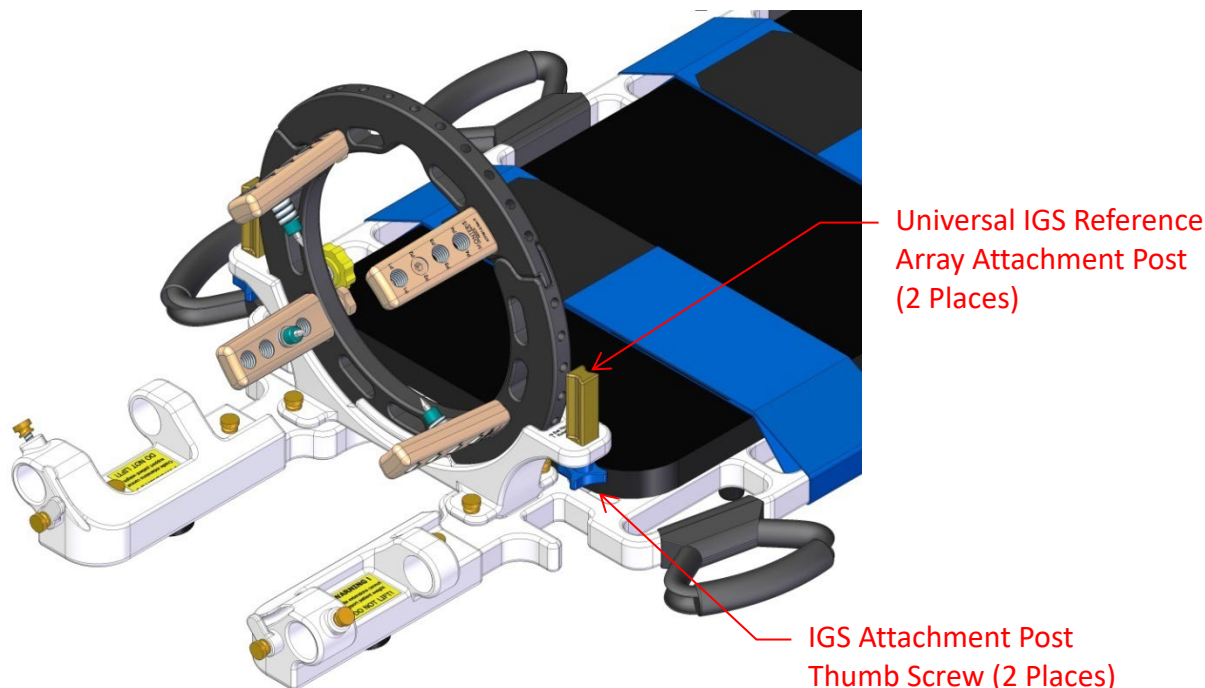


Figure 6. Reference Array Attachment



The Starburst Adapter is an aluminum plate with a standard starburst fitting which attaches to the Patient Board via two brass thumbscrews. It facilitates attachment of ancillary equipment such as image-guided navigation hardware that use standard starburst connections. The Starburst Adapter is not intended to be used in the MRI environment.

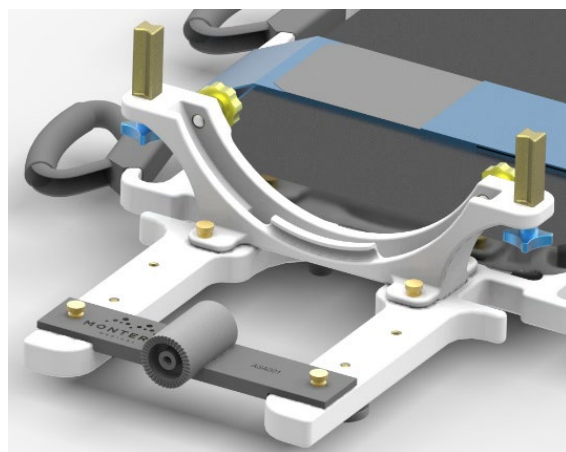


Figure 7. Starburst Adapter Attached to Patient Board

2. Indications for Use

The intended use of the AtamA System (comprised of two major subsystems: a head stabilization system and a patient transfer board), is for stabilizing the patient's head during neurosurgical procedures and imaging.

The patient head-stabilizing apparatus can also be used for other neurosurgical procedures requiring the patient's head to be stabilized or fixed.

3. Contraindications

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

Observe all contraindications for MRI scanning of patients.

4. Warnings, Cautions, and General Safety Requirements



The following are warnings, cautions, and safety requirements that apply to the AtamA System; consult the device specific instructions for all devices used in conjunction with the AtamA System 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.
 1.5 T / 3.0 T	MR Conditional - the item has been demonstrated to pose no known hazards in a 1.5T or 3.0T MR environments as described in Section 4.4 of the Instructions for Use.
	MRI Safe - the item poses NO known hazards in ALL MR environments.
	Caution/Warning followed by text message.
	Refer to instructions
	Consult instructions for use.
	Keep away from sunlight.
	Non-reusable
	Non-sterile
	Rx Only
	Do not use if package is damaged.
	Date of manufacture
	Manufacturer

REF	Product Model Number/ Catalog Number
LOT	Product Lot number
	No Latex
UDI	Unique device identifier

4.2. WARNINGS



WARNING:

- Do not attempt to use the AtamA System before thoroughly reading *Instructions for Use*.
- The physician must decide which type of head fixation is appropriate, what clamping force is required and which MRI conditional or safe skull pins to use. Refer to the commercially available MRI compatible Skull Pins' Instructions for Use, e.g., Pro Med Instruments DORO® Disposable Skull Pins.
- Failure to properly position the Skull Pins may cause injury to the patient. Avoid using pins near the frontal sinus, temporal fossa, blood vessels or nerves. Refer to the commercially available Skull Pins' Instructions for Use, e.g., Pro Med Instruments DORO® Disposable Skull Pins.
- Use extreme caution during transport and movement of the board when the patient is secured by skull pins. At least one person should be assigned to monitor and protect the patient.
- Failure to remove all magnetic materials associated with the patient or the IGS Reference Array affixed to the AtamA System may result in damage to the MRI system, damage to the AtamA System, interference with MR data, and possible injury or death to the patient or operators. Ensure that all ancillary magnetic materials are removed prior to locating the AtamA System within the MRI magnetic field.
- To disassemble and remove the front section of the Ring while the head is fixed, any Pin Holders in the front section **MUST** be removed to prevent patient injury.

4.3. CAUTIONS



CAUTION:

- Exercise caution when using accessories not qualified by Monteris Medical with this equipment. Failure to do so may result in improper performance, damage to the equipment, or injury to patient or user.
 - The Aluminum Pin Driver, the Aluminum Pin Removal Tool and the Beryllium Copper Disassembly Allen Wrench components of the Head Fixation Kit must be removed from the scanner bore before MRI scanning.
 - Skull pins are 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 of skull pins may create a risk of contamination 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.
 - After use, dispose skull pins and packaging in accordance with hospital, administrative and/or local government policy.
-



4.4. MRI COMPATIBILITY: MRI CONDITIONAL STATUS

With the exception of the Starburst Adapter, testing has demonstrated the AtamA System is **MR Conditional** in compatibility. It can be used under the following conditions:

- Static magnetic field of:
 - 1.5 or 3.0 Tesla
- Scan in “Normal Operating Mode” only with a maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg.
- The AtamA System is compatible with multiple 1.5 T or 3.0T MRI equipment. Please contact your Monteris Representative for facility specific MRI equipment compatibility or refer to the Instructions for Use Supplement (80575 – Compatible MRI Systems Supplement) at www.Monteris.com.



1.5 T / 3.0 T



WARNING: The Starburst Adapter should be removed prior to placing the AtamA System into the MRI environment to avoid injury or MRI damage.

5. Head Fixation



The physician must decide on the type of fixation and the clamping force required, based on the thickness of the skull and the bone structure. Refer to the commercially available Skull Pins' Instructions for Use, e.g., Pro Med Instruments DORO® Disposable Skull Pins.

Head fixation is accomplished using a three to six-point arrangement of post/pin holder/pin combinations. The pins are tightened/loosened by turning the pin holders mounted in threaded holes in the posts, using the torque limiting driver.



Failure to properly position the skull pins may cause serious injury to the patient. Avoid the frontal sinus, temporal fossa, blood vessels or nerves.



Skull Pins are 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.

6. Workflow Directions for Use

6.1. OUTLINE OF ATAMA SYSTEM WORKFLOW STEPS

1. Device Set-Up
2. Patient Head Fixation
 - a. Anesthetized Patient
 - b. Awake Patient
3. Surgical Prep and Initial Operating Room Procedures
 - a. Prep of entry area
 - b. Establish local sterile field: Draping
 - c. Initial Operating Room Procedures, such as:
 - i. Setting Stereotactic Trajectory
 - ii. Stereotactic Biopsy
4. Prepare for Transport.
5. Perform procedure: MRI series, Stereotactic Procedure, NeuroBlate™ procedures, fMRI.
6. Reverse (steps 4 thru 1) to finish.

6.2. DEVICE SET-UP

1. Place the Board with Cradle attached on the operating room table or MR procedure table.
2. Cover the Cradle inner surface with a fluid-proof drape to prevent contamination of the Cradle during the subsequent steps of Head Fixation and Patient Prep.

6.2.1. SPECIAL INSTRUCTIONS FOR IMRIS SET-UP

1. Ensure the IMRIS semi-circular head rest is inserted into the head end of the IMRIS table.
2. Place the Patient Board with Cradle on the IMRIS table.
3. Slide the Patient Board forward or back to ensure the patient head will be centered at BO within the MRI scanner. Figure shows the approximate position of the board on the IMRIS table.
4. Use the additional Velcro straps supplied with the IMRIS table to secure the Board to the OR table.

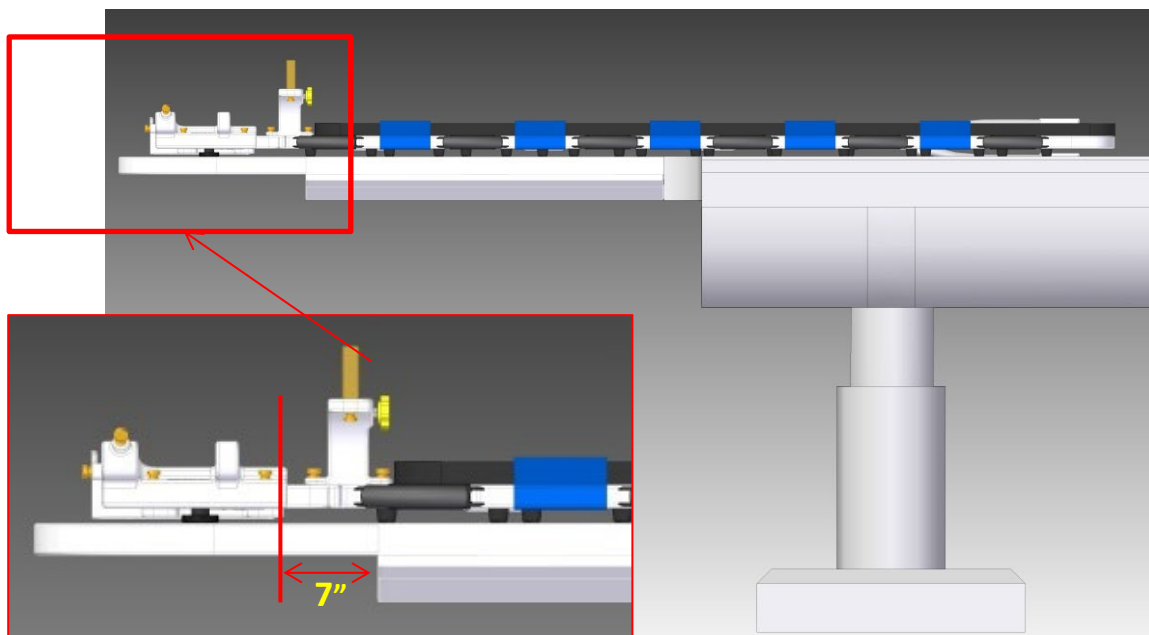


Figure 8. Position of Patient Board on the IMRIS Surgical Table



CAUTION: Do not cantilever (raise) the head end of the IMRIS table once the Patient Board has been positioned to avoid changing the desired board placement.

6.2.2. SPECIAL INSTRUCTIONS FOR SIEMENS AERA / SKYRA SET-UP

1. Remove any table mounted RF coils from the MRI table (including the spine coil).
2. Place both Riser parts (large body Riser and small foot Riser) into the MRI table.

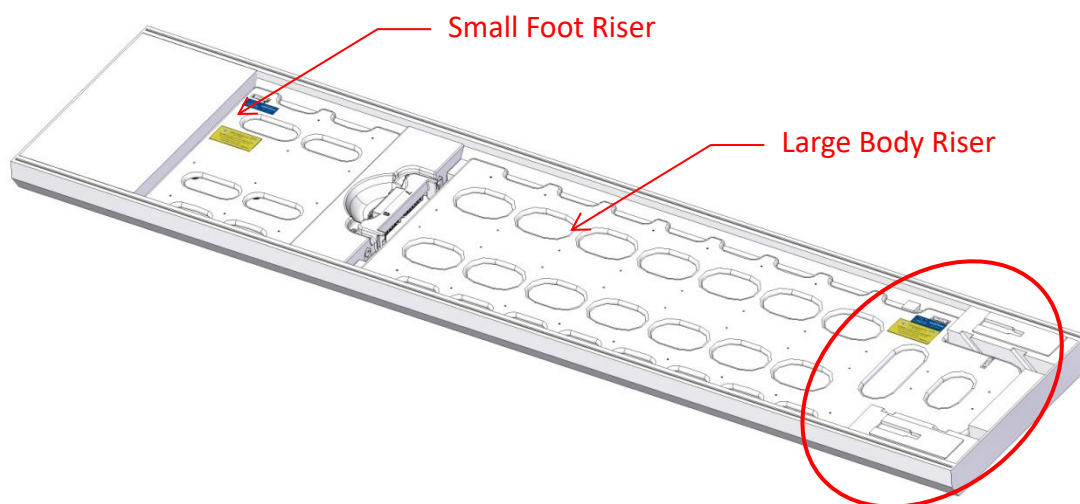


Figure 9. Risers for AtamA Board in Siemens Aera / Skyra Table

3. Place the Patient Board with Cradle on the Risers in the MRI table. Ensure that the foot end of the Board is approximately 1" away from the bottom of the MRI table. This ensures adequate clearance at the head end.

Align Bottom of Patient Board ~1" from Bottom of MRI table as shown

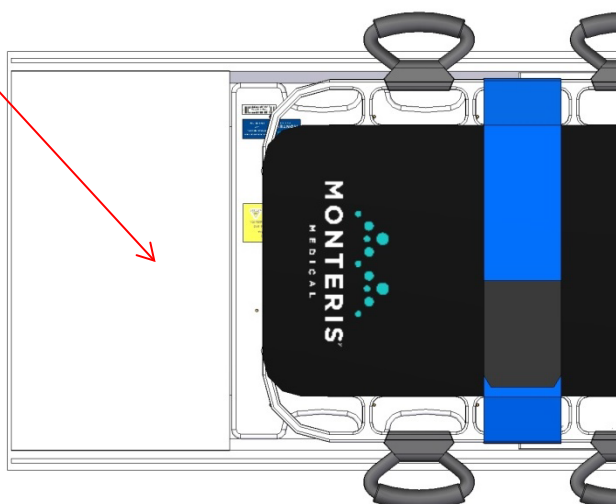


Figure 10. Alignment of AtamA Patient Board on Siemens Aera / Skyra MRI Table

6.2.3. SPECIAL INSTRUCTIONS FOR PHILIPS INGENIA SET-UP

Place Patient Board onto the MRI table. Note, the bottom part of the Board is narrow to fit into the narrow section of the MRI table.

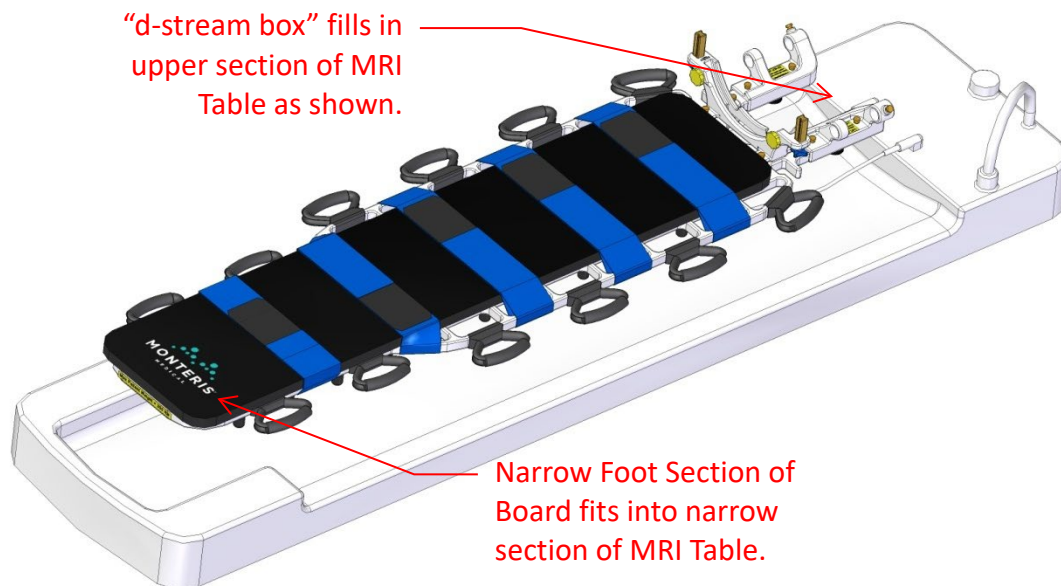


Figure 11. Fit of AtamA Patient Board on Philips Ingenia MRI Table

6.2.4. OPTIONAL: INSTRUCTIONS FOR STARBURST ADAPTER

Remove each of the Interface Platform (IP) Arm Interfaces from the Patient Board by removing the two thumbscrews (Figure 12)

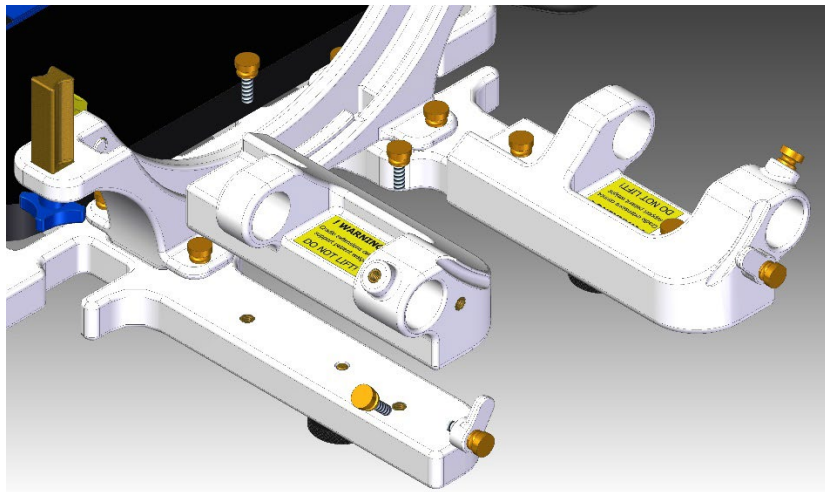


Figure 12. Remove the IP Arm Interfaces

1. Attach the Starburst Adapter to the forked head end side of the Patient Board using the two Knurled Head Thumb Screws threaded into the top screw receptacles located on each fork of the Patient Board (Figure 13).

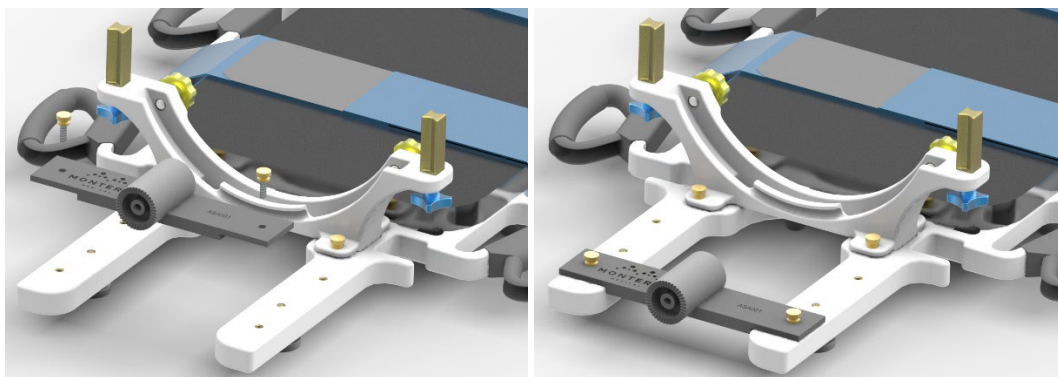


Figure 13. Attach the Starburst Adapter to the Patient Board

2. Attach the desired ancillary devices to the Starburst and secure with the ancillary device's attachment screw.
3. When use of ancillary devices and Starburst Adapter is complete, remove the Starburst adapter and reattach the IP Arm Interfaces.



WARNING: The Starburst Adapter must be removed prior to placing the AtamA System into the MRI environment to avoid injury or MRI damage.

6.3. HEAD FIXATION OF THE ANESTHETIZED PATIENT

1. The awake patient is placed onto the Board, which is positioned on the OR table; use a rolled towel or other padding to temporarily cushion the patient's head.
2. Administer anesthesia.
3. Attach two Posts to the Ring (Lower Ring if using the Split Head Fixation) section with one to three slots separation; finger-tighten the Clamp Knobs.



WARNING: Post / Pin Location Considerations:

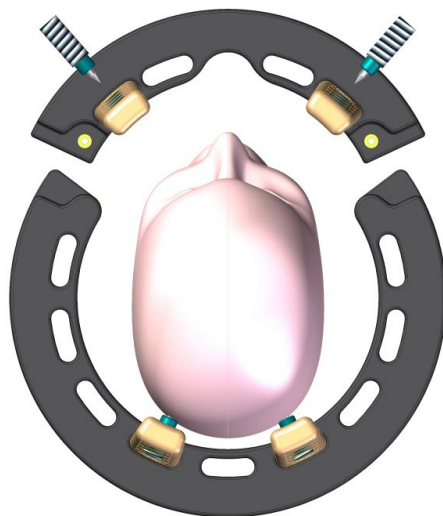
1. Be certain that pins are inserted into regions of the skull with adequate strength and integrity (avoid prior surgical defects or thin regions).
 2. If applicable, account for skull anchor mounting location / entry point.
 3. Avoid placing pins adjacent to the treatment target site as the Pins may affect MRI images.
-
4. Gently lift the head and shoulders and place the Lower Ring Section with the Posts under the head (the Posts should be on the posterior skull).
 5. Gently lower the patient's head and shoulders towards the Board. Remove the temporary cushion material from Step 1.
 6. Place the Ring in the Cradle and tighten the two Ring Locking Knobs to fix the Ring in the Cradle.
 7. Attach one Short Pin Holder in the desired position on each post and insert a sterile commercially available MRI compatible Skull Pin (e.g., Pro Med Instruments DORO® Disposable Skull Pins) in each Pin Holder.
 8. Lower the patient's head towards the ring and onto the two pins (Figure a). Assess if the Standard Front section of the ring will accommodate the size of the patient's head (Figure a). If not, use the Extended Front section.



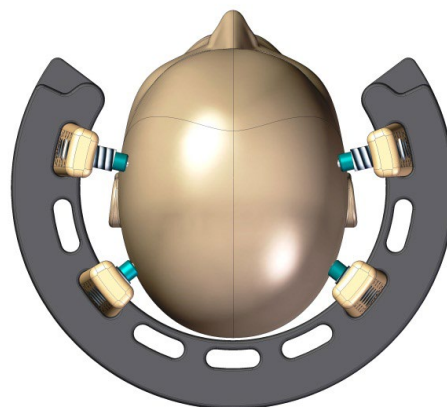
WARNING: To prevent patient injury, do not attach the front ring section with fixation pins in place.



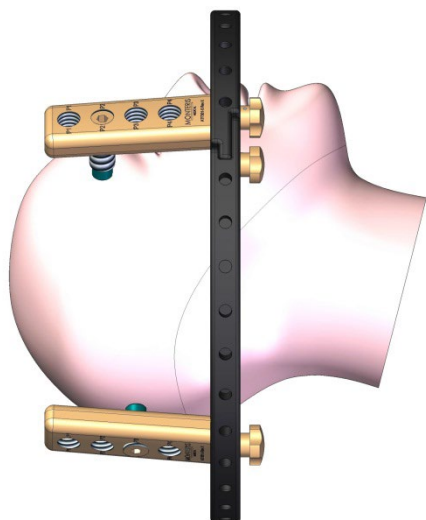
CAUTION: Account for the stereotactic skull bolt mounting location when positioning head in ring and when selecting Post / Pin locations.



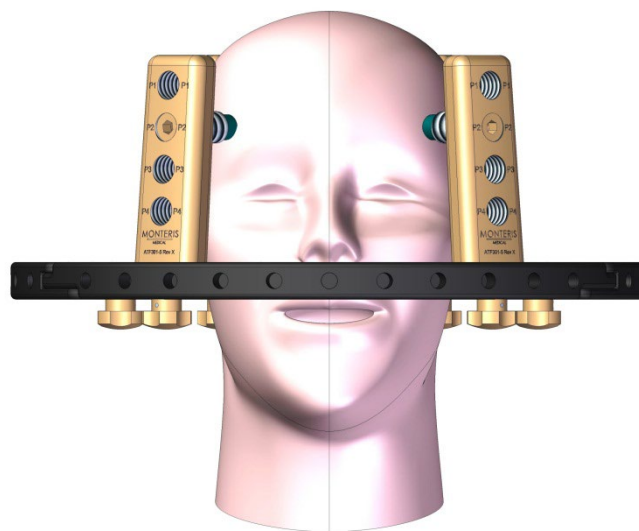
a. Pinning With Front Section



b. Alternative Pinning Without Front Section



c. Side View



d. Front (top down) View

Figure 14. Split Head Fixation Ring Attachment

a. Placing the head onto the lower ring section followed by front attachment

b. Alternative pinning without the front ring section

c/d. Proper alignment of Split Head Fixation Ring with attached front

9. If using Figure a scenario, attach the front ring section, insert the two Clamp Knobs and locate the desired pin positions on the patient's skull.



WARNING: If using pinning scenario shown in Figure b, DO NOT tighten posterior Pin Holders after the anterior Pin Holders have been engaged to the skull to prevent patient injury.

10. Insert the desired number of Posts into the appropriate ring slots and lock in place with Clamp Knobs.

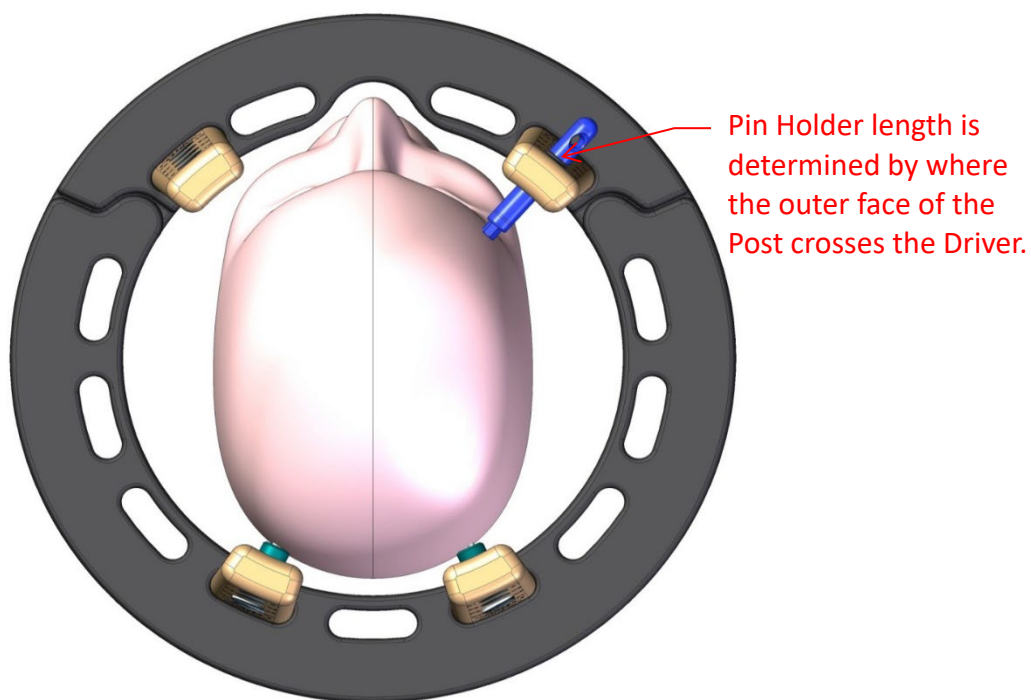


Figure 15. Pin Holder size selection using Torque Limiting Driver

11. Insert the Torque Limiting Driver through each desired hole in the Post (hex end first) until the Driver touches the patient's head (Figure). Determine the length of each Pin Holder required, based on driver gradation seen at the outer face of the Post (Figure).

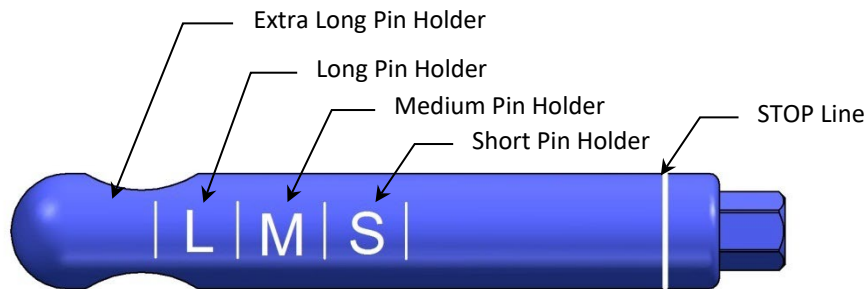


Figure 16. Torque Limiting Driver – Pin Holder size selection gradation

12. Insert Pins into the appropriately sized Pin Holders. While maintaining sterility and protecting sleeves on each pin, press pins into the Pin Holders.

13. Carefully thread each Pin Holder/Pin assembly through the appropriate hole in the Posts, using fingers. Follow with the Torque Limiting Driver, until the pins protrude slightly from the patient side of the Posts.
14. Prepare targeted areas of the patient's head for fixation using routine procedures.
15. Carefully remove the sterile-protectant sleeves from the pins.



CAUTION! The points of skull pins are very sharp. Injury to operator or patient can occur unless care is exercised.

16. With an assistant holding the patient's head, gently and carefully tighten each Pin Holder / Pin using the Torque Limiting Driver. The Driver prevents over tightening of the Pins. When tightening Pins, stop turning when "STOP" line on Driver reaches the outer face of the Post (Figure). If more force is required, remove Pin Holder and replace with a longer one. If the pins extend too far, remove the pin/pin holder and, replace Pin Holder with a shorter one. Use a new disposable skull pin.



WARNING: Do not use the Pin Removal Tool when tightening the pins. This may cause excessive force and may result in damage to the Head Fixation components or patient injury.

17. Carefully inspect patient fixation in relation to intended treatment entry point (or foot attachment locations for AXiiiS[®]).
18. Determine if the patient's head needs to be rotated for correct position for the neurosurgical procedure. If so, carefully loosen the Ring Locking Knobs. With an assistant coordinating movement of the patient's torso, slowly rotate the patient's head and body (with the Ring rotating in the Cradle) to the desired position. Support the patient's body with padding as necessary and engage the Ring Locking Knobs to lock the Ring in place.



WARNING: Loosen Pin Holders in Front Section prior to separating the Front and Back Ring Sections to prevent patient injury.



CAUTION: Prepare the Pin Sites as necessary for the specific patient's intended operating room technique.



WARNING: Extreme care must be exercised during transport and movement of the Patient Board while a head-pinned patient is attached. At least one person should be dedicated to monitoring and protecting the patient (especially the neck and skull base areas).

6.4. NEUROBLATE® SYSTEM INTERFACE PLATFORM ATTACHMENT

The AtamA System provides locking thumbscrews for the NeuroBlate® System Interface Platform (Figure).

To mount the Interface Platform, slide the two IP Arms into the IP Arm Interface holes at the head end of the AtamA Board (Figure).

To disengage, loosen the locking thumbscrews above each IP Arm Interface and slide the IP Arms out of the Arm Interface holes.

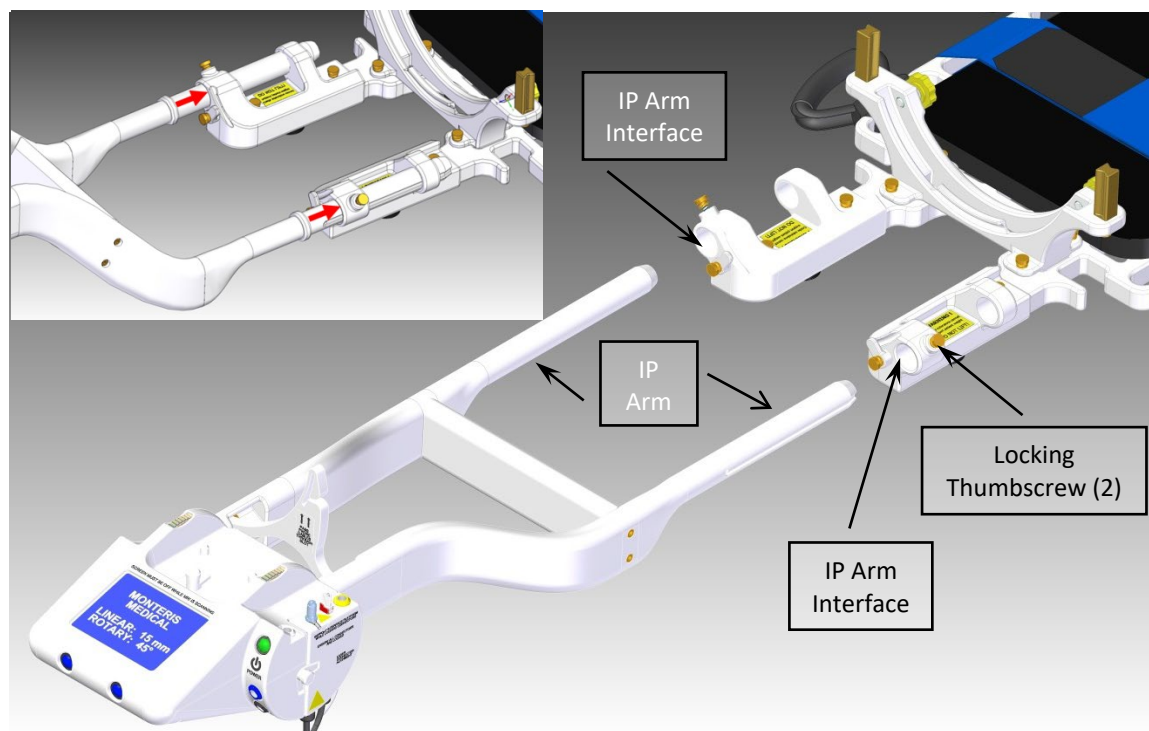


Figure 17. Detail of Monteris NeuroBlate™ System Interface Platform Attachment

Note for GE MRI Use: during NeuroBlate System Laser Delivery Probe insertion, the user may need to disengage the IP locking thumbscrews and slide the IP arms out away from the patient (red arrows Figure).

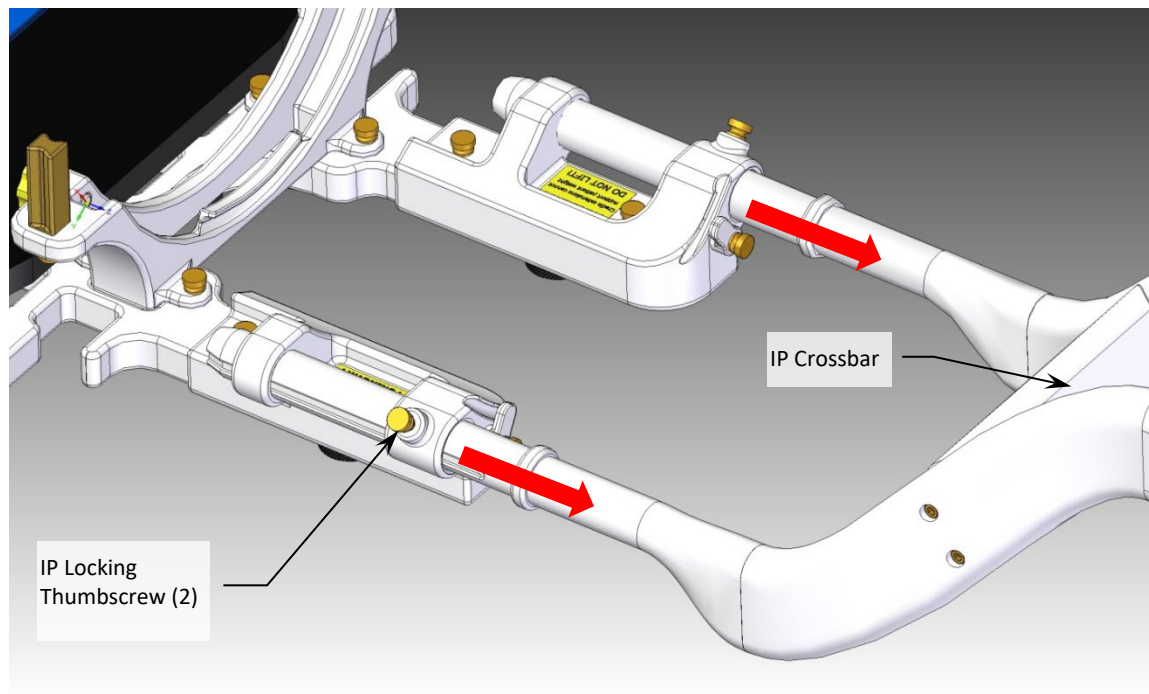


Figure 18. Detail of Monteris NeuroBlate™ Interface Platform Attachment.

7. Patient Lifting and Transport Instructions

Consult Figure 19 and Figure 20 for proper and Figure 21 for improper lifting positions. Depending on the patient weight, a minimum of four (4) people are required to move the patient when secured to the AtamA System. For heavier patients, it is recommended that six (6) people move the patient.

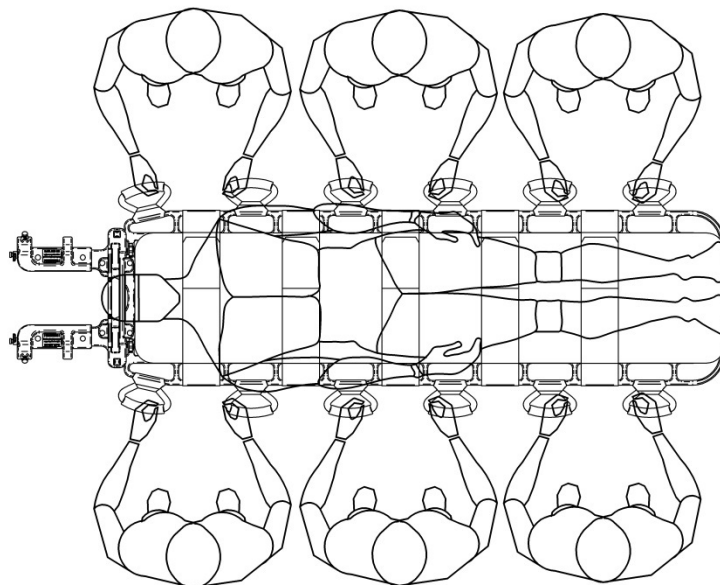


Figure 19. Lifting/Transporting a Patient with Six People

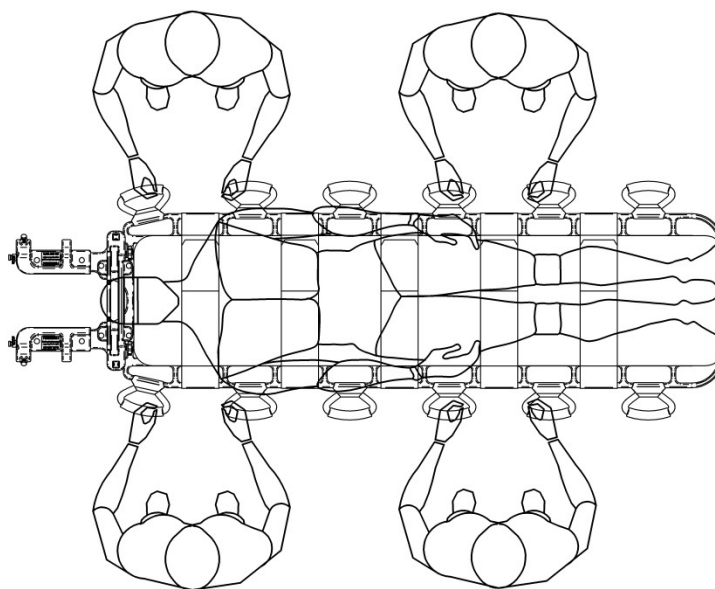


Figure 2. Lifting/Transporting a Patient with Four People

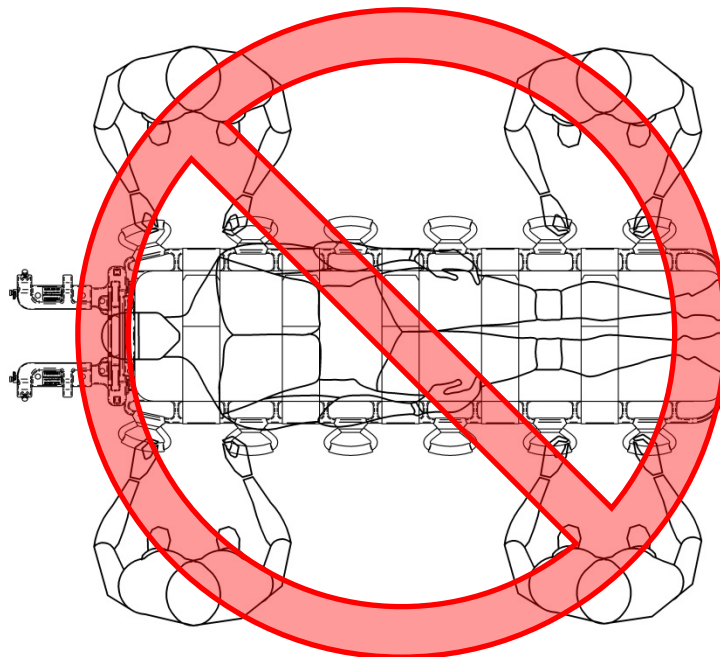


Figure 3. INCORRECT Location of People for Four Person lift.

8. Disassembly and Cleaning

8.1. *DISASSEMBLY*

After the procedure is completed and the patient is removed from the Atama System, disassemble the System into the following subassemblies:

- Patient Board, Pad and Risers (if applicable)
 - Cradle (Figure - left)
 - IP Arm Supports (Figure - right)
- Head Fixation (including Ring, Posts, Clamp Knobs and Pin Holders)

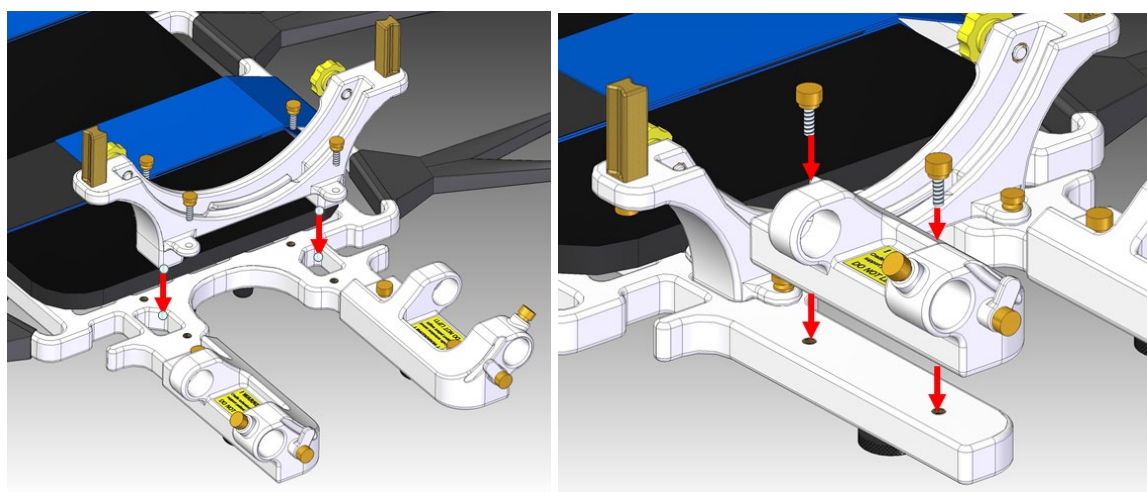


Figure 22. Disassembly of Cradle and IP Arm Supports for Cleaning

8.2. *ATAMA CLEANING GUIDELINES: SUGGESTED MATERIALS*

GOJO [®] Scrubbing Wipes	Gojo	6380-04
Steris Coverage [®] Plus Germicidal Wipes	Steris	1608-WC
Conflkt Detergent Disinfectant	Decon Labs	4101
Steris Prolystica [®] Neutral Detergent	Steris	1C07-T6WR
Steris Resert [®] HLD Disinfectant-Chemosterilant	Steris	

8.3. ATAMA CLEANING GUIDELINES

Head Fixation Parts:

1. Collect AtamA Ring, Posts, Knobs, and Pin Holders – WARNING the pins are sharp. Dispose pins in approved Sharps containers. Use Germicidal Wipes to remove the bulk of any soiled material. Place parts in the utility box. Let sit for at least 3 minutes.
2. Remove any residual adhesive using the Gojo Scrubbing wipes, rinse with water, and return the parts to the utility box.
3. All obvious contaminants or foreign material must be removed before proceeding.
4. Add 0.5 ounce of Prolystica[®] Neutral Detergent to Gray Tray, followed by 2 gallons of warm-to-hot tap water. Allow the parts to soak for 1 to 5 hours. Drain detergent solution and rinse parts with tap water. Dry the AtamA parts with paper towels or a soft cloth and return to storage tray.

Board Components:

1. Use Germicidal Wipes to remove excess soil and to fully cover the Patient Board, Cradle, IP Arm Supports and Risers (if applicable) with a film of the Germicidal liquid. Allow to sit for at least three minutes. Wipe with dry paper towels.
2. Clean the patient-supporting part of the board with Germicidal Wipes.
3. If excessive soiling of any surface of the board occurred, use paper towels saturated with the *Conflikt* Disinfecting Detergent to clean. In particular, pay attention to potential contamination of joints and crevices. Allow disinfecting liquid film to remain for 3-5 minutes. Rinse with tap water dampened paper towels, followed by dry paper towels. If required, the board may be disassembled for cleaning access of contaminated areas.

NOTE: The Head Fixation parts and the Board (without straps and pads) can be disinfected using Steris Resert[®] HLD Disinfectant-Chemosterilant according to the manufacturer's instructions for manual processing.

NOTE: The Head Fixation components, Cradle, IP Arm Supports and assorted thumbscrews can be disinfected using an automated wash apparatus according to the manufacturer's instructions for manual processing.

9. Storage and Rolling Utility Stand

Carefully inspect the system prior to use for any damage or contamination.

The AtamA System subassemblies listed in section 8.1 should be stored together on the Rolling Utility Stand as shown in Figure . Avoid locations that may introduce magnetic items.

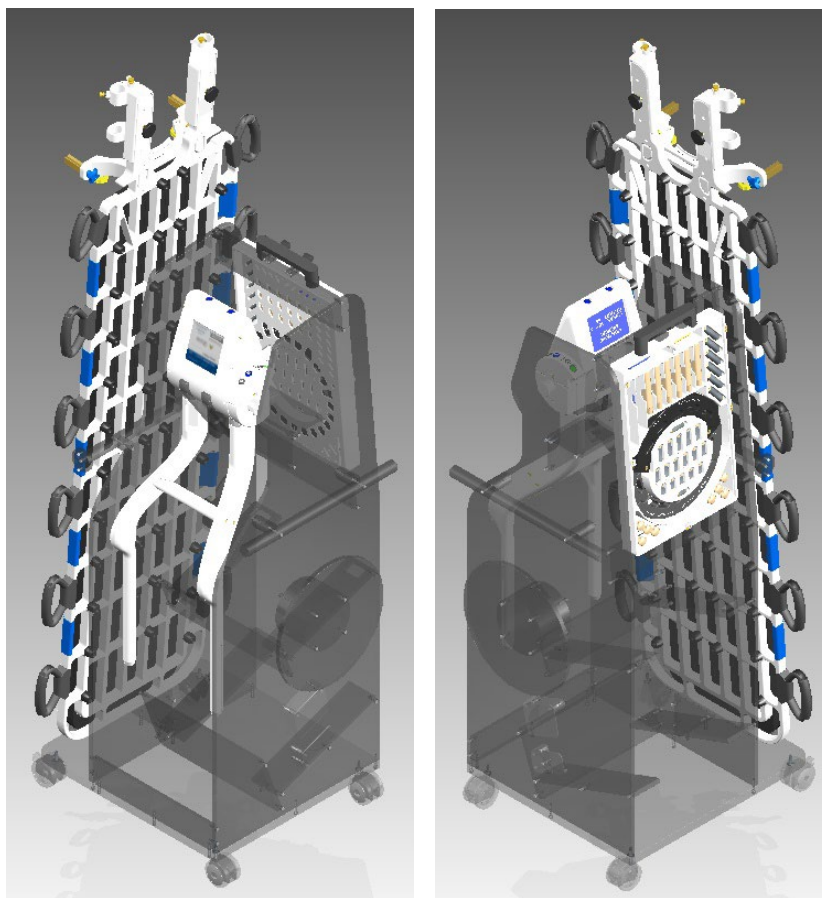


Figure 23. Utility Stand in Different Views

10. Troubleshooting

Contact Monteris Customer Support for specific trouble shooting tips:

Monteris Toll Free Customer Support:

1-866-799-7655

Callers may choose between being connected directly to a Technical Services Representative, leaving a message requesting service, or be connected to the Monteris Medical operator.

Monteris Email Reporting System:

reporting@monteris.com

Contact Monteris Medical via email to request service, make product improvement suggestions, report system issues or register complaints.

11. Operating Conditions

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



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

13. Contact Information

13.1. DISTRIBUTOR/REP CONTACT:

Monteris Medical Corporation
131 Cheshire Lane
Suite 100,
Minnetonka, MN 55305
(763) 253-4711 / (866) 799-7655
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13.2. MANUFACTURED BY:

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