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

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table of Contents</td>
<td>2</td>
</tr>
<tr>
<td>1. System Description</td>
<td>3</td>
</tr>
<tr>
<td>1.1. Head Coil Subsystem</td>
<td>6</td>
</tr>
<tr>
<td>1.2. Stabilization Subsystem</td>
<td>8</td>
</tr>
<tr>
<td>2. Indications for Use</td>
<td>14</td>
</tr>
<tr>
<td>3. Contraindications</td>
<td>14</td>
</tr>
<tr>
<td>4. Warnings, Cautions, and General Safety Requirements</td>
<td>15</td>
</tr>
<tr>
<td>4.1. Warning and Identification Labels</td>
<td>15</td>
</tr>
<tr>
<td>4.2. Warnings</td>
<td>16</td>
</tr>
<tr>
<td>4.3. Cautions</td>
<td>17</td>
</tr>
<tr>
<td>4.4. MRI Compatibility: MRI Conditional Status</td>
<td>17</td>
</tr>
<tr>
<td>5. Head Fixation</td>
<td>18</td>
</tr>
<tr>
<td>6. Workflow Directions for Use</td>
<td>19</td>
</tr>
<tr>
<td>6.1. Outline of AtamA System Workflow Steps</td>
<td>19</td>
</tr>
<tr>
<td>6.2. Device Set-Up</td>
<td>19</td>
</tr>
<tr>
<td>6.3. Head Fixation of the Anesthetized Patient</td>
<td>20</td>
</tr>
<tr>
<td>6.4. Head Fixation - Awake Patient</td>
<td>23</td>
</tr>
<tr>
<td>6.5. Surgical Field Preparation</td>
<td>26</td>
</tr>
<tr>
<td>6.6. Attach Lower Head Coil to Cradle</td>
<td>26</td>
</tr>
<tr>
<td>6.7. Drape Lower Head Coil</td>
<td>27</td>
</tr>
<tr>
<td>6.8. Attach Upper Head Coil to Lower Head Coil</td>
<td>28</td>
</tr>
<tr>
<td>6.9. Connection of Monteris NeuroBlate™ system</td>
<td>28</td>
</tr>
<tr>
<td>7. Patient Lifting and Transport Instructions</td>
<td>29</td>
</tr>
<tr>
<td>8. Disassembly and Storage</td>
<td>30</td>
</tr>
<tr>
<td>8.1. Disassembly</td>
<td>30</td>
</tr>
<tr>
<td>8.2. Storage</td>
<td>30</td>
</tr>
<tr>
<td>9. Troubleshooting</td>
<td>31</td>
</tr>
<tr>
<td>10. Inspection, cleaning, and disinfection</td>
<td>31</td>
</tr>
<tr>
<td>10.2. AtamA™ Cleaning Guidelines</td>
<td>31</td>
</tr>
<tr>
<td>11. Operating Conditions</td>
<td>33</td>
</tr>
<tr>
<td>12. Storage Conditions</td>
<td>33</td>
</tr>
<tr>
<td>13. Contact Information</td>
<td>33</td>
</tr>
<tr>
<td>13.1. Distributor/rep contact:</td>
<td>33</td>
</tr>
<tr>
<td>13.2. Manufactured by:</td>
<td>33</td>
</tr>
</tbody>
</table>
1. System Description

The AtamA™ Head Coil and Stabilization System (AtamA System) is a combination MRI head coil and head stabilization system (Figure 1). It is comprised of two subsystems:

(i) MR head coil
(ii) patient stabilization system components.

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

Specifically, 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, shown over MRI table (not included).

The subsystems are comprised of the components listed in Table 1.

Required accessories which are not included with AtamA are listed in Table 2.
Table 1. AtamA System Components and Subsystems

<table>
<thead>
<tr>
<th>System Item</th>
<th>Cat #</th>
<th>Included</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Entire AtamA Systems with MRI Head Coil</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AtamA 1.5 Tesla System for Siemens or IMRIS MRI</td>
<td>AT151-SI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>AT151-IM</td>
<td></td>
</tr>
<tr>
<td>1.5 T Head Coil Subsystem</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Patient Board Subsystem</td>
<td>ATB001-SI or ATB001-IM</td>
<td></td>
</tr>
<tr>
<td>Patient Stabilization Subsystem</td>
<td>ATF001</td>
<td>✓</td>
</tr>
<tr>
<td>Rolling Utility Stand(s) for OR &amp; Diagnostic MRI</td>
<td>ATS101-1 &amp; ATS201-1 or ATS301-1</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>AtamA Head Coil Subsystem</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AtamA 1.5 Tesla Head Coil for Siemens or IMRIS MRI</td>
<td>Contact Monteris for Replacement Part Numbers</td>
<td></td>
</tr>
<tr>
<td>Extended Upper Coil</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Standard Upper Coil</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Lower Coil with Cable</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Coil Files on CD*</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Subsystems for Individual Sale</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Board for 1.5 or 3.0 Tesla Siemens or IMRIS MRI</td>
<td>ATB001-SI</td>
<td></td>
</tr>
<tr>
<td>Head Fixation Subsystem</td>
<td>ATV001</td>
<td></td>
</tr>
<tr>
<td>Rolling Utility Stand(s) for OR &amp; Diagnostic MRI</td>
<td>ATS101-1 &amp; ATS201-1 or ATS301-1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*CD* denotes compact disc.
<table>
<thead>
<tr>
<th>System Item</th>
<th>Cat #</th>
<th>Included</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Head Fixation Ring Subsystem Only</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Head Fixation Ring Subsystem</td>
<td>ATF001</td>
<td></td>
</tr>
<tr>
<td>Head Fixation Ring</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Posts (6)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Head Rest Pads (pair)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Pin Holders, long (6)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Pin Holders, medium (6)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Pin Holders, short (6)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Placement Strap</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Torque-Limiting Pin Driver (2)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>MR-Safe Pin Removal Tool (2)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Head Fixation Component Tray</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Disassembly Allen Key (3/16&quot;)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Disassembly Allen Key (5/32&quot;)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Patient Board Subsystem</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Board for 1.5 or 3.0 Tesla Siemens or IMRIS MRI</td>
<td>ATB001-SI</td>
<td></td>
</tr>
<tr>
<td>Patient Board for 1.5 or 3.0 Tesla Siemens or IMRIS MRI</td>
<td>ATB001-IM</td>
<td></td>
</tr>
<tr>
<td>Patient Board</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Cradle Assembly</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Lifting straps (12)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Patient Safety Restraints (5)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Patient pad</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

**Table 2. Accessories Required for use with the AtamA System**

<table>
<thead>
<tr>
<th>Description</th>
<th>Item-No. 3006-20</th>
</tr>
</thead>
<tbody>
<tr>
<td>DORO® Disposable Skull Pins, Titanium, Adult (MRI Compatible)</td>
<td></td>
</tr>
<tr>
<td>Order from <a href="#">pro med instruments</a>: 877.225.4086</td>
<td></td>
</tr>
<tr>
<td>Standard Sterile Drapes</td>
<td></td>
</tr>
<tr>
<td>- Each hospital will determine the appropriate sterile draping scheme based</td>
<td></td>
</tr>
<tr>
<td>on standard practices. Typically a combination of commonly available</td>
<td></td>
</tr>
<tr>
<td>clear, plastic bag and split drapes are used to maintain the sterile</td>
<td></td>
</tr>
<tr>
<td>field.</td>
<td></td>
</tr>
</tbody>
</table>
1.1. **HEAD COIL SUBSYSTEM**

The Head Coil subsystem (Figure 2) is a novel split-array multi-channel (8 channel) receive coil. It is comprised of a common Lower Coil, two interchangeable Upper Coils and the appropriate coil configuration data (“coil files”) for the selected MRI system.

![Illustration of the Head Coil Subsystem](image)

**Figure 2. Illustration of the Head Coil Subsystem (cable omitted for clarity)**

Openings in the two-part coil can be positioned to allow surgical access to any supratentorial skull location without repositioning the patient. This allows for expedient collection of high quality MR data and maintenance of spatial registration.
The Head Coil subsystem (Figure 2) comes with two interchangeable Upper Coils: 
**Standard** - for accommodating trajectories extending from the top of the patient head; 
**Extended** - for accommodating trajectories extending at an angle away from the top of the head.

The Upper Coils have four (4) alignment pins that insert into corresponding sockets in the Lower Coil, ensuring that the 6 electrical connectors will be properly aligned. The Lower Coil (Figure 3) carries the MRI connection cable.
1.2. **STABILIZATION SUBSYSTEM**

The Stabilization subsystem has three major components (Figure 4):

- **Head Fixation Ring** (HFR) providing three to five point skull fixation
- **Cradle** to maintain the position of the HFR and the Head Coil relative to each other and to the MRI system bore; Plunger Pins are used to lock the rotation of the ring
- **Patient Board** for the efficient transport of the patient while maintaining stability and spatial registration of the patient

![Figure 4. Detail of the Stabilization Subsystem](image)
1.2.1. Head Fixation Ring (HFR)

The HFR posts (Figure 5) can be inserted into any of the cutouts in the ring. The ring can be configured to use 3 to 5 point fixation, oriented at any angle. Two headrest pads are provided and can be applied over the posts to allow a padded position for the head during application of the pins.

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.

A convenient MR-safe Storage Tray (Figure 6) holds all of the HFR components. **Note:** The individual components shown can be replaced if lost or damaged. Contact your Monteris Medical representative for details.

---

**Figure 5.** Detail of the Head Fixation Ring (HFR), showing the Ring, Posts, Pin Holders, Head Rest Pads, Clamp Knobs, and Placement Strap.
1.2.2. Connection between HFR and Cradle

The Head Fixation Ring fits into a groove in the Cradle allowing the ring to rotate freely (see Figure 4). The ring is locked in place by 2 Plunger Pins located on either side of Cradle. These pins insert into holes around the outer perimeter 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.
1.2.3. The Patient Board

The Patient Board (board) (Figure 7) has a patient load capacity of 350 pounds. It has 12 lifting handles to assist patient transfer and four straps to secure the patient. The underside of the board is hollow with strengthening ribs. Padding attached to the top of the board is provided to improve patient comfort during longer procedures.

**Figure 7. Details of the 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 attachment locations for a standard IGS system reference array (Figure 8).

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

Figure 8. Reference Array Attachment
1.2.4. Coil to Cradle Connection

The Lower Coil has a raised ridge around each end which fits into grooves in the Cradle. The coil is rotated to align with the desired trajectory and then a set of locks (Figure 9) are engaged to prevent the coil from lifting or rotating.

*Figure 9. Board with Cradle showing Lower Coil attachment grooves and clamps*
2. Indications for Use

The intended use of the AtamA™ System (comprised of two major subsystems: a MR head coil apparatus and a patient stabilization apparatus), in conjunction with a magnetic resonance (MR) imaging system, is the collection of MR data and images of the human brain before, during, and at the end of brain surgery, in a standard operating room, diagnostic MRI rooms, or in a MR intra-operative room, while 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.

The head coil can also be used as a standard diagnostic head coil for diagnostic MR imaging.

When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

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:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="symbol.png" alt="MR Unsafe" /></td>
<td><strong>MRI Unsafe</strong> - 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.</td>
</tr>
<tr>
<td><img src="symbol.png" alt="MR Conditional" /></td>
<td><strong>MR Conditional</strong> - the item poses NO known hazards in a specified MRI Environment (e.g. 1.5 / 3.0 T)</td>
</tr>
<tr>
<td><img src="symbol.png" alt="MR Safe" /></td>
<td><strong>MRI Safe</strong> - the item poses NO known hazards in ALL MR environments.</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Caution" /></td>
<td>Caution followed by text message.</td>
</tr>
<tr>
<td><img src="symbol.png" alt="i" /></td>
<td>Consult instructions for use.</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Keep away from sunlight" /></td>
<td>Keep away from sunlight.</td>
</tr>
</tbody>
</table>
4.2. **WARNINGS**

**WARNING:**

- Do not attempt to use the AtamA System before thoroughly reading *Instructions for Use*. For future reference, keep this document in a convenient, accessible place.

- The physician must decide which type of head fixation is warranted and the clamping force required. Refer to the ProMed DORO® Disposable Skull Pins *Instructions for Use*.

- 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 ProMed DORO® Disposable Skull Pins Instructions for Use.

- 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. Assure that all magnetic materials are removed prior to locating the AtamA System within the MRI magnetic field.
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.

- 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**

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 Tesla for the Patient Stabilization Subsystem
  - 3.0 Tesla for the Patient Stabilization Subsystem
  - 1.5 Tesla for the 151-XX series of Head Coils.

- Scan in “Normal Operating Mode” only with a maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg.
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 pro med DORO® Disposable Skull Pins *Instructions for Use*.

Head fixation is accomplished using a three-point, four-point or five-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. Attach Coil Halves (draped/covered for contamination control).
6. Perform procedure: MRI series, Stereotactic Procedure, NeuroBlate™ procedures, fMRI.
7. 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 Board with Cradle on the IMRIS table.
3. The alignment tabs on the Board will automatically center the Board from side to side.
4. Slide the Board forward or back to align the Alignment Labels with the transition between the metal and plastic portions of the MRI table (Figure 10).

5. Secure the foot end of Board to table using the 2 sets of Velcro straps. Wrap each strap around the metal rail on the IMRIS table (Figure 10).

![Figure 10. IMRIS Surgical Table with AtamA Alignment Labels & Velcro Straps](image)

6. Secure the head end of the Board by passing the longer Velcro straps (one on each side, aligned with top patient strap) under the front plastic section of the table (Figure 10).

### 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 with one or two slots between them; finger-tighten the Clamp Knobs. Slide a Head Pad over each of these two posts. This will support the head during the pinning steps later.

4. When patient is anesthetized, gently lift the head and shoulders and place Ring with the Head Pads/Posts over the head (the Head Pads should be on the posterior skull).

5. Gently lower the patient head and shoulders towards the Board, keeping anesthesia and other equipment clear. Remove the temporary cushion material from Step 1. Engage the ring in the Cradle.

6. Insert the plunger pins to lock the Ring to the Cradle.
7. Gently adjust the patient’s position within the ring so that the Ring and patient’s head are in proper alignment (see Figure 11).

Figure 11. Proper alignment of Head Fixation Ring, Anesthetized Patient

8. If not already determined, locate the desired pin positions on the patient’s skull.
   NOTE: If applicable, account for AXiiiS® Stereotactic Miniframe (AXiiiS) mounting location when selecting Post / Pin locations.

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 AXiiiS mounting location / entry point.

3. Avoid placing pins adjacent to the treatment target site as the Pins may affect MRI images.

9. Insert the desired number of Posts into the appropriate Ring slots, and lock in place with Clamp Knobs.
10. Insert the Torque Limiting Driver through the each desired hole in the Post (hex end first) until the Driver touches the patient’s head (Figure 12). Determine the length of each Pin Holder required, based on driver gradation seen at the outer face of the Post (Figure 13).
11. Insert Pins into the appropriately sized Pin Holders. While maintaining sterility and protecting sleeves on each pin, press pins into the Pin Holders.

12. 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.

13. Prepare targeted areas of the patient’s head for fixation using routine procedures.

14. 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.

15. 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 13). If more force is required, remove Pin Holder and replace with a longer one. When the Pins are tight, ensure that they do not extend more than 2mm (~1.5 threads) beyond the outer face of the Post or they will interfere with the Head Coil. 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.

16. Carefully remove the Head Pads. Posts that supported the Head Pads may be removed or left in place.

17. Carefully inspect patient fixation in relation to intended treatment entry point (or foot attachment locations for AXiiS®).

18. Determine if the patient’s head needs to be rotated for correct position for the neurosurgical procedure. If so, carefully unlock the Ring plunger pins. 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 plunger pins to lock the Ring in place.

### 6.4. **Head Fixation - Awake Patient**

1. If not already determined, locate the desired pin positions on the patient’s skull.

⚠️ **WARNING:** be sure to only pin to regions of the skull with adequate strength and integrity (avoid prior surgical defects or thin regions).

2. Insert the desired number of Posts (from 3 to 5) into the appropriate Ring slots, and lock in place with Clamp Knobs.
3. Attach the Placement Straps to the Ring by inserting the hook-and-loop ends through appropriate open slots on the Ring, so that the Ring will be suspended in the correct orientation when placed on the patient.

4. With the patient sitting up, lower the Ring with attached Placement Strap over the patient’s head, adjusting the Placement Strap as necessary to achieve the appropriate alignment (see Figure 14).

![Front View](image)

**Figure 14. Proper alignment of Head Fixation Ring, Awake Patient**

5. Insert the Torque Limiting Driver through the desired hole in the Post (hex end first) until the tip of the Driver touches the patient’s head. Determine which length of Pin Holder to use based on driver gradations at the outer face of the Post. See Figures 15 and 16 for details.
Figure 15. Pin Holder size selection using Torque Limiting Driver

Figure 16. Torque Limiting Driver – size selection detail

6. Insert Pins into Pin Holders: keeping the sterility-protecting sleeves on the Pins in place, press the appropriate fixation pins into Pin Holders; one for each of the Posts being used.
7. Carefully thread a Pin Holder / Pin assembly through the appropriate hole in each of the Posts, using finger tightening first, followed by the Torque Limiting Driver, until the Pins protrude slightly from the inside (closest to patient) of the Post.

8. Anesthetize the local tissue (if appropriate) and prepare the areas of the patient’s head to receive the pins according to routine procedures.

9. Carefully remove the sterile-protectant sleeves from the pins.

⚠️ **CAUTION:** The pin points are very sharp; injury to operator or patient can occur unless care is exercised.

10. With an assistant holding the patient’s head, gently and carefully tighten the Pin Holders / Pins using the Torque Limiting Driver such that the patient’s head is stably fixed. The size of the Driver prevents over tightening of the Pins. When the Pins are tight, ensure that they do not extend more than 2mm (~1.5 threads) beyond the outer face of the Post. If they do, they will interfere with the Head Coil. Replace Pin Holder with shorter one if necessary. When tightening Pins, stop turning when “STOP” line on Driver reaches the outer face of the Post (Figure 16). If more force is still required, remove Pin Holder and replace with a longer one. Use a new disposable skull pin.

11. Patient is transferred onto the Board (which is on the OR table).

12. Gently lower the patient down towards the Board, keeping all IV lines and equipment clear, so that the Ring engages in the Cradle.

13. If rotation of the patient’s head is required, carefully unlock the Ring Plunger Pins (Figure 4). With an assistant moving the patient’s torso, slowly rotate the patient with the Ring in the Cradle to the desired position. Support the patient’s body with padding as necessary, and then engage the Ring plunger pins to lock the Ring in place.

### 6.5. **SURGICAL FIELD PREPARATION**

1. Prepare the surgical site as necessary for the procedures based on standard operating room techniques.

2. Establish the required sterile field using a draping technique compatible with subsequent placement of Head Coil.

### 6.6. **ATTACH LOWER HEAD COIL TO CRADLE**

1. Slide the Lower Head Coil between the Cradle and the HFR Posts/Head Rest. Raised ridges located on either end of the lower Coil fit into grooves in the Cradle. Make certain the ridges are fully inserted into the grooves (Figure 17).
2. Rotate the Lower Coil to the desired orientation.

3. Rotate the locking arms to the locked position to hold the Lower Head Coil in place.

4. Plug Head Coil cable into the MRI system.

   NOTE: For IMRIS set-up plug Head Coil cable into the corresponding socket attached to the Board. Plug extension into sockets located on the MRI. Secure cables with straps provided along the side of the Board.

   ![Figure 17. Attaching the Lower Head Coil to the Cradle](image)

   **WARNING:** Extreme care must be exercised during transport and movement of the 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).

---

**6.7. Drape Lower Head Coil**

Lay sterile drapes over the Lower Head Coil. Position the drapes to prevent the leakage of liquids or bodily fluids onto or into the Head Coil. Do not cover the electrical connectors with the drape.
6.8. **ATTACH UPPER HEAD COIL TO LOWER HEAD COIL**

Determine whether the standard or extended Upper Head Coil provides the optimum opening for the selected trajectory or procedure. Cover the selected Upper Coil with a disposable protective drape, making small cut-outs, as required, for the alignment pins and electrical connectors.

Attach the selected Upper Head Coil to the Lower Coil by aligning the alignment pins and electrical connectors and pressing the two halves together. Make certain that the electrical connectors are fully engaged.

6.9. **CONNECTION OF MONTERIS NEUROBLATE® SYSTEM**

The AtamA System provides a locking mount for the NeuroBlate® System Interface Platform. (Figure 18)

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 18).

Two persons are required to disengage the Interface Platform. To disengage, one person should press in both Locking Mechanism buttons located on either side of the cradle while a second person sides the IP Arms out of the Arm Interface holes.

![Figure 18. Detail of Monteris NeuroBlate™ Interface Platform attachment.](image-url)
7. Patient Lifting and Transport Instructions

Consult Figure 19 through Figure 21 for proper (and 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 6 People

Figure 20. Lifting/Transporting a Patient with Four (4) people
8. Disassembly and Storage

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 (including cradle)
- Head Fixation (including Ring, Posts, Knobs and Pin Holders)
- Lower Head Coil
- Upper Head Coil - standard
- Upper Head Coil - extended

8.2. STORAGE
The AtamA System subassemblies listed in section 8.1 should be stored together. Avoid locations that may introduce magnetic items.
9. 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.

10. Inspection, cleaning, and disinfection

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

### 10.1. ATAMA™ CLEANING GUIDELINE: SUGGESTED MATERIALS

<table>
<thead>
<tr>
<th>Material Description</th>
<th>Manufacturer</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOJO® Scrubbing Wipes</td>
<td>Gojo</td>
<td>6380-04</td>
</tr>
<tr>
<td>Steris Coverage® Plus Germicidal Wipes</td>
<td>Steris</td>
<td>1608-WC</td>
</tr>
<tr>
<td>Conflikt Detergent Disinfectant</td>
<td>Decon Labs</td>
<td>4101</td>
</tr>
<tr>
<td>Steris Prolystica® Neutral Detergent</td>
<td>Steris</td>
<td>1C07-T6WR</td>
</tr>
<tr>
<td>Steris Resert® HLD Disinfectant-Chemosterilant</td>
<td>Steris</td>
<td></td>
</tr>
<tr>
<td>Rubbermaid® 4 5/8 Gallon Bus/Utility Box</td>
<td>Rubbermaid</td>
<td>FG334900GRAY</td>
</tr>
<tr>
<td>20&quot;L x 15&quot;W x 5&quot;H</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 10.2. ATAMA™ CLEANING GUIDELINES

**Head Coil (including IMRIS Connection Box & Extension):**

**WARNING:** Do Not Sterilize! Protect Device from Fluids!

**WARNING:** Do Not Submerge! Do Not Spray to Clean!

1. Wipe each half of the head coil down with a Germicidal Wipe (use at least one for each half), and allow the halves to sit for at least three minutes (to allow for complete decontamination). Do not allow excess liquid make contact with the electrical connectors. Dry the head coil components with a soft cloth or paper towels.

2. Store the cleaned and disinfected head coil halves appropriately to prevent damage and contamination.
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:

1. Use Germicidal Wipes to remove excess soil and to fully cover the Cradle and head coil supporting regions of the Board 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. WARNING: the Coil halves ARE NOT compatible with sterilization procedures.
11. Operating Conditions

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

12. Storage Conditions

- 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 Inc.
100 - 78 Innovation Drive
Winnipeg, MB
Canada R3T 6C2
(204) 272-2220 / (866) 799-7655
reporting@monteris.com

13.2. MANUFACTURED BY:
Monteris Medical Inc.
100 - 78 Innovation Drive
Winnipeg, MB
Canada R3T 6C2
www.monteris.com