2. While still submerged, remove visible soil by scrubbing with a soft nylon bristle brush for a minimum of 4 minutes until no visible soil is observed.
3. Rinse with flowing, cold deionized water (18.5°C to 20.2°C) for a minimum of 30 seconds for each instrument.
4. Load instruments into washer/disinfector in accordance with the manufacturer's instructions.
5. Arrange instruments with curved surfaces and cannulations facing downward to prevent pooling of water.
6. Operate that washer/disinfector cycle according to the manufacturer's instructions.

Recommended minimal washer/disinfector parameters:

	Temperature	Time
Heated Wash	60°C (140°F)	2 minutes
Heated Tap Water Rinse	60°C (140°F)	20 seconds
Heated Deionized Water Rinse	82°C (180°F)	1 minutes
Forced Air Drying	116°C (240°F)	9 minutes

9.3 Sterilization Instructions

A. Note

1. For instruments with moving parts, lubricate joints with a steam-permeable, water soluble instrument lubricant prior to sterilization.
2. Instruments should be sterilized in the opened or unlocked position. Central knob of any Atlas™ Rigid Arm must be opened for sterilization.

B. Preparation for Sterilization

Note: Use only FDA cleared CSR Sterilization Wrap for component packaging. Only use wrappers validated for use in double simultaneous wrapping.

1. Each instrument should be wrapped in two layers of FDA Cleared CSR Wrap using the simultaneous double wrapping equal fold technique.
2. Chemical indicator tape should be used to secure packaging and for labeling the contents. Note: Chemical Indicator Tape will change color or display diagonal stripes when exposed to temperatures of 121°C (250°F).

Instruments should be sterilized by standard cycles using steam with the parameters listed below:

	Sterilize Temperature	Sterilize Time	Dry Time
Gravity	121°C (250°F)	30 minutes	30-minute
Prevacuum (US)	132°C (270°F)	4 minutes	30-minute
Pre vacuum (EU)	134°C (273°F)	3 minutes	30-minute

CAUTION: Autoclave temperatures should not surpass 137°C (280°F), as the handle, insulation or other non-metallic parts may be affected. The steam autoclave manufacturer may be contacted to confirm appropriate temperature and sterilization times.

10. Warranty

Axcess Surgical Innovations products are warranted to be free from defects in material and workmanship when used under normal condition for its intended purpose for 5 years from invoice date. Any product that proves to be defective during this period, AXS will, at its sole discretion, either repair or replace the defective product at no charge. This limited warranty is null and void if AXS product is repaired or modified in any way by any party that is not explicitly AXS authorized. AXS shall not be held responsible for consequential or indirect damage arising from the sale of any product.

11. Complaint Handling/ Reporting

Any adverse event involving AXS products should be reported to AXS and the country specific regulatory authorities immediately. To report an event to AXS:
Call: 650-563-9106 (USA) or
Email: sales@axcesssurgical.com

12. Maintenance

Axcess Surgical recommends that instruments be sent to Axcess Surgical for preventive maintenance every 2-3 years to maximize instrument longevity.
Preventive maintenance includes:

1. Replacement of wear parts
2. Instrument adjustment

Contact Axcess at info@axcesssurgical.com to learn more about enrolling into the maintenance program.

13. Explanation of Symbols

REF	Reference number		Manufacturer
LOT	Batch Code	EC REP	Authorized Representative in the European Community
QTY	Product Quantity	NON STERILE	Product Supplied Non-Sterile
CE	Compliant with European Medical Device Regulation	MD	Indicates product is a Medical Device
	Date of Manufacture		

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Atlas™ Rigid Arms System

INSTRUCTIONS FOR USE

This instruction for use is only applicable for the medical instruments listed below.

Rigid Arms

AA-0100	AA-0101	AA-0103	AA-0104	AA-0105	AA-0106
AA-0107	AA-0108	AA-0109	AA-0111	AA-0113	AA-0145
AA-0150	AA-0151	AA-0156	AA-0157	AA-0158	AA-0159
AA-0180	AA-0300	AA-0301	AA-0303	AA-0309	AA-0350
AA-0351	AA-0400	AA-0401	AA-0409	AA-0413	AA-0450
AA-0451	AA-0453	AA-0458	AA-0459	AA-0461	AA-0471
AA-0480	AA-0483	AA-0500	AA-0501	AA-0505	AA-0509
AA-0511	AA-0513	AA-0553			

Quick Connection Accessories

AA-0120	AA-0125	AA-0130	AA-0135	AA-2040	AA-2041
AA-2050	AA-2051	AA-2053			

Table Clamps

AA-0200	AA-0202	AA-0204	AA-0210	AA-0212	

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1. **Introduction**
AXS Rigid Arms and accessories are operating table accessories. The Arms are available with Columns in straight or angled configurations.

2. **Intended Use**
AXS Rigid Arms and accessories are intended to hold and position retractors or other instruments during a surgical procedure.

3. **Contraindications**
This product is not intended for use except as indicated.

4. **Warnings**
5.1 US Federal law restricts this device to sale by or on the order of a physician.
5.2 The product must only be used by trained medical personnel capable of judging and controlling danger to patients.
5.3 The products will be delivered non sterile. Prior to the initial use, and each following use, the products must be cleaned and sterilized as well as checked for visible irregularities and malfunctions according to the instructions given in this Instructions for Use.
5.4 AXS products are for use only with other AXS products and may not be used with other manufacturer's products.
5.5 End of life is normally determined by wear and damage due to use.
5.6 Use of this instrument for any purpose, or in any manner other than those described here may cause instrument damage or failure which could result in serious patient injury or death. If needed, all AXS metal products or fragments thereof can be located by means of an X-Ray.
5.7 To maintain intended clamping capacity of the table rail clamp (AA-0200), do not tighten the table rail clamping knob when the Atlas™ Rigid Arm column is not fully installed.
5.8 DO NOT FORCE ANY KNOB PAST STOP.
5.9 **THE RAIL CLAMPS ARE NOT INSULATED. DO NOT USE THE SYSTEM WHEN GROUNDING A PATIENT IS UNACCEPTABLE!**

5. **Possible Adverse Effects**
Delayed surgical procedure.

6. **Storage**
Instruments should be stored in a clean and dry area. Inspect each instrument prior to use for functionality and damage. When necessary, dispose of products in accordance with national regulations and approved hospital practices for surgical instrument disposal.

7. **Product Description and Use**

7.1 Fixed AXS Table Clamp
Provides an attachment point to the operating table rail. Accepts and holds the column of the Atlas™ Rigid Arm in position.

To attach to the rail:
1. Open rail clamping knob until the L-brackets fit over the rail, then tighten to secure.
2. Insert column of the Atlas™ Rigid Arm into column opening and tighten the column clamping knob when arm is in desired position.

7.2 Rotatable AXS Table Clamp
Provides an attachment point to the operating table rail. Accepts and holds the column of the Atlas™ Rigid Arm in position and allows for full range of rotation.

To attach to the rail:
1. Open the rail clamping knob until the L-brackets fit over the rail, then tighten to secure.
2. Insert the column of the Atlas™ Rigid Arm into column opening, adjust the column to the desired angle, and tighten the column clamping knob when the arm is in the desired position.

7.3 AXS Quick Connection Accessories
Provides a fast connection point for accessories to the distal end of the Atlas™ Rigid Arm. Depending on customer preference, Atlas™ Rigid Arm can come with the following quick connect chucks:
A. Squared Shaft Quick Connect
B. Hex Shaft Quick Connect
C. Tight Twist Hex Shaft Quick Connect
D. Tight Twist Square Shaft Quick Connect

These quick connect chucks are not interchangeable and can only be used with the appropriate AXS Quick Connection Shaft.

To attach the square shaft quick connect accessories:
1. Turn collar clockwise and pull back.
2. Insert the accessory shaft into the chuck until fully seated (rotate to clock flats on shaft with inside square).
3. Let the collar spring forward and turn counterclockwise to lock. Check to see that the shaft is secured, and the collar is in locked position.
To unlock, reverse the above steps.

To attach the hex shaft quick connect accessories:
1. Push the sliding collar forward.
2. Insert the accessory shaft into the chuck until fully seated (rotate to clock flats on shaft with inside).
3. Pull the collar back to lock. Check to see that shaft is secured and the collar is in locked position.
To unlock, reverse the above steps.

To attach to tight twist hex or square shaft quick connect accessories:
1. Twist collar counterclockwise.
2. Insert the accessory shaft into chuck until fully seated (rotate to clock flats on shaft with inside).
3. Twist the collar clockwise to lock the quick connect accessory into place. Check to see that the shaft is secured and the collar is in locked position.
To unlock, reverse the above steps.

7.4 Atlas™ Rigid Arm
Provides five point positioning of the attached accessories into the surgical field. Attaches to either a Straight or L-Column.

To position and lock in place:
1. Support the distal end with one hand and loosen the central tightening knob by turning counterclockwise.
2. Position the attached accessory as needed and turn knob clockwise to lock in place. Check to see that Atlas™ Rigid Arm is secure enough to hold position.
To loosen, reverse the above steps.

CAUTION: When loosening, do not force knob past stop.

8. **Inspection Before Use**
All AXS products should be inspected througout its lifetime to ensure proper function and performance. If product does not pass inspection, do not use. Send product back to AXS for repair immediately.

Atlas™ Rigid Arm
1. Visually inspect instruments for damage or cracks.
2. Check to make sure that arm becomes rigid at all three joints by turning central tightening knob clockwise.
3. Insert arm column into table clamp, turn column clamping knob clockwise and ensure that it hold securely.
4. Check quick connect distal end to make sure the collar locks and unlocks accessory securely.

AXS Quick Connection Accessories
1. Visually inspect instruments for damage or cracks.
2. Quick Connect Shaft should freely engage and disengage in and out of the quick connect distal end.
3. Clamp Screw on Quick Connect Accessory should be able to open and close fully without moving on its own.

AXS Table Clamps
1. Visually inspect instruments for damage or cracks.
2. L-brackets on AXS Table Clamp should clamp securely to table rail.
3. Insert Atlas™ Rigid Arm into column opening, turn central tightening knob clockwise and make sure the post is held securely inside the column opening.

9. **Cleaning and Sterilization Instructions**

CAUTION:
1. Only Cleaning and Sterilization Procedures as indicated in this IFU should be used for Cleaning and Sterilization.
2. The color of AXS's aluminum instruments may vary due to the anodizing process or alloy used. Shading or loss of color may also occur after sterilization. This is not a defect in the instruments or material and will not affect the performance of your high quality AXS instrument.
3. Automated cleaning is not suitable for instruments with long lumens, ball joints, or stainless-steel cables (e.g. suction tubes, surgical arms, and flexible surgical arms). Such instruments should only undergo a manual cleaning prior to sterilization.

Supplies and Equipment Needed:
- Ultrasonic Cleaner (Sonicator)
- FDA Cleared CSR Wrap
- pH Neutral Cleaner such as Prolystica manufactured by Steris Corp. or equivalent
- 3-1000 MILTEX Instrument Cleaning Brush, Nylon Bristles or equivalent (available from Integra Miltex)
- Chemical Indicator Tape

9.1 Manual Cleaning
Preparing arm for manual cleaning: turn central tightening knob clockwise to tighten ball joint prior to placing arm in ultrasonic cleaner.

A. Manual Cleaning Instructions
1. Rinse each instrument individually with a steady stream of tap water (16.9°C to 18.9°C) until gross contaminants are removed. Depending on the complexity of the device, this process should take approximately 1-2 minutes.
2. Place each instrument into an ultrasonic cleaner containing enzymatic, pH neutral detergent solution and warm tap water (25°C to 35°C) prepared according to the detergent manufacturer's instructions and sonicate for 10 minutes.
3. Prepare a wash solution using an enzymatic, pH neutral detergent with tap water (25°C to 35°C) using the concentration recommended by the detergent manufacturer.
4. Transfer each instrument to the manual wash container and fully immerse in the cleaning or wash solution prepared in Step 3.
5. While still submerged, any visible contamination and debris should be removed by scrubbing each instrument with a soft nylon bristle brush until visibly clean, paying particular attention to hard to clean areas such as crevices and joints. This process should take approximately 1-2 minutes.
6. Rinse with cold, flowing, deionized water (17°C to 21°C) for 30-60 seconds until no visible soil remains.
7. Dry each instrument using clean, absorbent, low lint wipes to remove excess rinse water.

B. Automated Cleaning

CAUTION: Use only washer/disinfector machines that have been validated in accordance with ISO 15883. AUTOMATED CLEANING IS NOT SUITABLE FOR ATLAS™ RIGID ARMS. AUTOMATED CLEANING IS ONLY SUITABLE FOR AXS TABLE CLAMPS AND AXS QUICK CONNECT ACCESSORIES.

1. Perform pre-cleaning to remove gross contaminants as follows:
   a. Prepare a wash solution using an enzyme pH neutral detergent, in a wash container with tap water (27°C to 33°C) using the minimum concentration recommended by the detergent manufacturer.
   b. Submerge and soak in wash solution for a minimum of 1 minute.

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