

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

A. Preparing the Flex Arm for manual cleaning:

1. Turn the main orange knob counterclockwise to loosen and relax the cable.
2. While holding the cable and bead section of the arm in a loop, rotate the clamp housing counterclockwise to loosen and create a space between the housing and the first bead.
3. Clean and sterilize, with in between beads, steam or other sterilizing media can enter into the internal space of the flex arm.

B. 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.

9.2. Automated Cleaning Instructions

CAUTION: Use only washer/disinfecter machines that have been validated in accordance with ISO 15883. AUTOMATED CLEANING IS NOT SUITABLE FOR ATLAS™ FLEX ARMS, ATLAS™ FLEX ARM SYSTEM, OR AXS POST. 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.
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/disinfecter 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/disinfecter cycle according to the manufacturer's instructions.

Recommended minimal washer/disinfecter 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 AXS Post 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.

9.4. Retightening the Flex Arm for use:

1. Lubricate threads of tensioning knob with water soluble lubricant.
2. Turn the orange main knob counterclockwise until it stops.
3. While holding the cable and bead section of the arm in a loop, rotate the clamp housing section clockwise until the gap is closed and there is slight resistance.
4. To tighten the arm, turn the orange knob clockwise until firm. Flex arm may sag with excessive load attached to accessory quick connector.

11. Warranty

Access 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.

12. 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@accessurgical.com

13. Maintenance

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

1. Replacement of wear parts
2. Instrument adjustment

Contact Access at info@accessurgical.com to learn more about enrolling into the maintenance program.

14. Explanation of Symbols

	Reference number		Manufacturer
	Batch Code		Authorized Representative in the European Community
	Product Quantity		Product Supplied Non-Sterile
	Compliant with European Medical Device Regulation		Indicates product is a Medical Device
	Date of Manufacture		



Atlas™ Flex Arms System

INSTRUCTIONS FOR USE

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

Flex Arms

AA-2000	AA-2001	AA-2001-S	AA-2006	AA-2010	AA-2010-DS
AA-2010-S	AA-2012	AA-2020	AA-2060		

Posts

AA-2002	AA-2004				
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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 Flex Arms and accessories are operating table accessories.

2. Intended Use

AXS Flex 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 of 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 clamping knob when the AXS Post column is not fully installed.
- 5.8 Adjusting any Flex Arm's position without loosening tension knob may cause cable wear.
- 5.9 Acute bending of any Flex Arms will cause cable damage/wear.
- 5.10 **DO NOT FORCE ANY KNOB PAST STOP.**
- 5.11 **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 AXS Posts 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 AXS Post 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 AXS Post 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 AXS Post 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™ Flex Arm. Depending on customer preference, Atlas™ Flex 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 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.

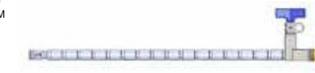


7.4 Atlas™ Flex Arms

Provides numerous positions for surgery with flexible beads while diminishing hand-held retraction.

To mount Atlas™ Flex Arm:

1. Turn mounting clamp knob (blue) counterclockwise until clamp is loose.
2. Slide mounting clamp onto a compatible post (see section 7.6).
3. Turn mounting clamp knob clockwise to tighten Atlas™ Flex Arm into place.



To use Atlas™ Flex Arm:

1. Hold distal end and adjust into position. Turn tension knob (orange) clockwise to tighten beads until position is held.
2. Turn tension knob counterclockwise to loosen beads.

7.5 Atlas™ Flex Arm with Fixed Table Clamp

All-in one structure that features a Flex Arm with an integrated Table Clamp.

To attach to the rail:

1. Open rail clamping knob until L-bracket fits over the rail, then tighten to secure.
2. To loosen, reverse step above



To manipulate flex arm on the Atlas™ Flex Arm with Fixed Table Clamp:

1. Turn tension tightening knob clockwise to tighten beads into desired position.
2. Turn tension tightening knob counterclockwise to loosen beads.

7.6 AXS Posts

7.6.1 Straight Ball Joint Post

Used as a mount/platform for the Atlas™ Flex Arm. Attach to OR Table via chosen table clamp; reference sections 7.1 & 7.2.

7.6.2 Straight Ball Joint Post with Fixed Table Clamp

Used as a mount/platform for the the Atlas™ Flex Arm. Directly attaches to OR Table Rail. It accepts and holds the mounting clamp on the Atlas™ Flex Arm body.

To attach to the rail:

1. Open rail clamp by rotating knob counter-clockwise until L-brackets fit over the rail, then tighten to secure.
2. Hold the distal end with one hand and loosen the central tightening knob by turning counter-clockwise.
3. Slide mounting clamp of Atlas™ Flex Arms onto post, and tighten mounting clamp knob and central tightening knob when arm is in desired position.



Adjust post position as needed by loosening the central black knob and tightening it back into place when desired position is reached.

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

8. Inspection Before Use

All AXS products should be inspected prior to each use throughout lifetime of product to ensure proper function and performance. If product does not pass inspection, do not use. Send product back to AXS for repair immediately.

Atlas™ Flex Arms

1. Visually inspect instruments for damage or cracks.
2. Orange knob should be able to adjust and tighten flex arm section so that end-effectors may be held in place.
3. Loosen flex arm and check cable between links for fraying or broken wires. Normal use will eventually wear out the steel tensioning cable.
4. Insert Atlas™ Flex Arm onto post, turn the blue knob clockwise and ensure that the flex arm holds securely on the post.
5. Check quick connect distal end to make sure it locks and unlocks accessory securely.
6. Atlas™ Flex Arm with Fixed Table Clamp: the attached table clamp on the Atlas™ Flex Arm should clamp securely to the table rail.

AXS Quick Connection Accessories

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

AXS Posts

1. Visually inspect instruments for damage or cracks.
2. Turning central tightening knob clockwise make sure ball joint is rigid.
3. For posts with attached Table Clamps: make sure L-bracket clamps securely to table rail.

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 AXS Post 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 Titanium and 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.

