

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

### Atlas™ Flex Arms

AA-2000	AA-2000-D	AA-2000-S	AA-2001	AA-2001-D	AA-2001-S
AA-2006	AA-2020	AA-2060	AA-2080		

### Atlas™ Flex Arm Systems

AA-2010	AA-2010-D	AA-2010-S	AA-2012		
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### AXS Quick Connection Accessories

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

### AXS Posts

AA-2002	AA-2003	AA-2004			
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### AXS Table Clamps

AA-0200	AA-0202	AA-0204	AA-0210		
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#### 1. Introduction

You have purchased a product which was manufactured to the highest standards, in the United States. We are confident this product will meet your expectations.

#### 2. Intended Use

This product is used to hold and position instruments and other devices. It must only be used by trained medical personnel capable of judging and controlling any danger to patients.

**The product will be delivered non sterile.** Prior to the initial use and each following use, the product has to be cleaned, disinfected, and sterilized as well as checked for visible irregularities and malfunctioning according to the instructions given in this instruction for use. **THE RAIL CLAMPS ARE NOT INSULATED. DO NOT USE THE SYSTEM WHEN GROUNDING A PATIENT IS UNACCEPTABLE !**

#### 3. Product Description and Use

##### 3.1 Fixed Table Clamps

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.



##### 3.2 Rotatable Table Clamps

Provides an attachment point to the operating table rail. Accepts and holds the column of the AXS Posts 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 Posts into column opening, adjust the column to the desired angle, and tighten the column clamping knob when the arm is in the desired position.



#### 3.3. 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 chuck until fully seated (rotate to clock flats on shaft with inside square).
3. Let the collar spring forward and turn counter clockwise 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 hex shaft into the chuck until fully seated (rotate to clock flats on shaft with inside hex).
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:

1. Make sure the tight twist hex or square collar is in its unlocked position
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.*



#### 3.4. 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.
2. Slide mounting clamp onto desired post.
3. Turn mounting clamp knob clockwise to tighten Atlas™ Flex Arm into place.



To use Atlas™ Flex Arm:

1. Turn tension knob (orange) clockwise to tighten beads into desired position.
2. Turn tension knob counterclockwise to loosen beads.

#### 3.5. Atlas™ Flex Arm Systems

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-brackets fit over the rail, then tighten to secure.
2. To loosen, reverse step above.



To manipulate flex arm on the Atlas™ Flex Arm System:

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

#### 3.6 AXS Posts

##### 3.6.1. Straight Ball Joint Post

Accepts and holds the mounting clamp on the Atlas™ Flex Arm body. Attach to chosen rail clamp; please reference sections 3.1 & 3.2.

##### 3.6.2. Straight Ball Joint Post with Fixed Table Clamp

Provides an attachment point to the operating table rail. It accepts and holds the mounting clamp on the Atlas™ Flex Arm body.

To attach to the rail:

1. Open rail clamping knob 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.



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

#### 4. Inspection Before Use

All AXS products should be inspected throughout their lifetime to ensure proper function and performance. If product does not pass the 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 tighten and hold end effectors 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 System Only: The attached table clamp on the Atlas™ Flex Arm System 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 in and out of the quick connect distal end.
3. Clamp Screw on Quick Connect Accessory should be able to tighten and hold end effectors in place.

##### AXS Posts

1. Visually inspect instruments for damage or cracks.
2. Turning central tightening knob clockwise and 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.

## 5. Cleaning Instructions

### CAUTION:

- Only Cleaning and Sterilization procedures as indicated in this IFU should be used for Cleaning and Sterilization.
- 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.
- 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

### 5.1 Manual Cleaning

Preparing arm for manual cleaning:

Turn tightening knob clockwise to tighten ball joint prior to placing arm in ultrasonic cleaner.

### 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 an 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 solution prepared from Step 3.
5. While still submerged, remove any visible contamination and debris 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. For flex arms, turn the tightening knob counter-clockwise to loosen the internal cable to enable movement of the surgical arm beads to allow fluid to flow between each link.
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.

### 5.2 Automated Cleaning Instructions

**CAUTION:** Use only washer/disinfector machines that have been validated in accordance with ISO 15883. **AUTOMATED CLEANING IS NOT SUITABLE FOR ATLAS™ FLEX ARMS OR 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/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 the 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

## 6. Sterilization Instructions

Pre-sterilization Instructions:

- For instruments with moving parts, lubricate joints with a steam-permeable, water soluble instrument lubricant prior to sterilization.
- Central knob of AXS Post must be opened for sterilization. Instruments should be sterilized by standard cycles using steam with the procedures listed below.
- **Instruments should be sterilized in the opened or unlocked position.**

Recommended minimal sterilization parameters:

	Sterilize Temperature	Sterilize Time	Dry Time
<b>Gravity</b>	121°C (250°F)	30 minutes	30-minute
<b>Prevacuum (us)</b>	132°C (270°F)	4 minutes	30-minute
<b>Prevacuum (EU)</b>	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 temperatures and sterilization times.

## 7. 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.

## 8. Warning/Precautions:



1. **CAUTION:** US Federal law restricts this device to sale by or on the order of a physician.
2. Product is intended to be used by trained surgeons.
3. AXS products are for use only with other AXS products and may not be used with other manufacturer's products.
4. End of life is normally determined by wear and damage due to use.
5. 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.
6. To maintain intended clamping capacity of the table rail clamp, do not tighten the table rail clamping knob when the AXS post column is not fully installed.
7. Adjusting any Flex Arm's position without loosening tension knob will cause cable wear.
8. Acute bending of any Flex Arms will cause cable damage/wear.
9. **DO NOT FORCE ANY KNOBS PAST STOP.**

## 9. Warranty

Axcess Surgical Innovations, LLC products are warranted to be free from defects in material and workman ship 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, Axcess Surgical will, at its sole discretion, either repair or replace the defective product at no charge. This limited warranty is null and void if an Axcess Surgical product is repaired or modified in any way by any party that is not explicitly Axcess Surgical authorized. Axcess Surgical Innovations, LLC shall not be held responsible for consequential or indirect damage arising from the sale or use of any product.



REF

Description / Beskrivelse / Beschrijving / Description / Beschreibung / Descrizione / Descrição / Descripción:



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