**Instruction for use:**

**Flexible Holding Arm and Accessories**

This instruction for use is only applicable for the medical instruments and/or accessories listed below.

**Flexible Holding Arm and Accessories**

- **Flexible Arms**
- **Flexible Arm Systems**
  - AA-2010/2010-D/2010-S/2012/2012-D/2012-S
- **Articulating Accessory Arm Columns**
- **Quick Connect Chucks**
  - AA-0120/0125/0130/0135/2040/2041/2050/2051/2053/2060/2065/2070/2075/2080/2090

### 1. Introduction

**Contact Information**

- www.axcesssurgical.com
- sales@axcesssurgical.com
- orders@axcesssurgical.com
- info@axcesssurgical.com
- p: 650.563.9231

Customer Service Information:

- info@axcesssurgical.com
- Fax: 650-563-9143
- Tel: 650-563-9106
- Half Moon Bay, CA 94019 USA

Axcess Surgical Innovations

- 141 California Ave, Suite 102
- Half Moon Bay, CA 94019 USA

Manufacturing Contact Information:

- Tel: 650-563-9066
- Fax: 650-563-9143
- info@axcesssurgical.com

### 2. Intended use:

This product is used to hold and position instruments, endoscopes, 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 and each following use, the product must cleaned, disinfected, and sterilized as well as checked for visible irregularities and malfunctioning according to the instructions given in this manual.

**The Rail Clamps are not insulated! DO NOT USE the system when grounding the patient is NOT ACCEPTABLE.**

### 3. Product description and use

#### 3.1 Fixed Rail/Table Clamps

Provides an attachment point to the operating table rail. Accepts and holds the column of the accessory arm in position.

1. Open rail clamping knob until L-brackets fit over the rail, then tighten column clamping knob when arm is in desired position.

#### 3.2 Rotatable Rail/Table Clamps

Provides an attachment point to the operating table rail. Accepts and holds the column of the accessory arm in position and allows for full range of rotation.

1. Open rail clamping knob until L-brackets fit over the rail, then tighten to secure.
2. Insert column of the accessory arm into column opening, and tighten column clamping knob when arm is in desired position.

#### 3.3 Quick Connect Chucks

Provides a fast connection point for accessories to the distal end of Articulated Arm. Depending on customer preference, accessory attachments can come with either a square quick connect shaft or a hex quick connect shaft. These connection shafts are not interchangeable and can only be used with the appropriate quick connect chuck.

- **3.3.1 To attach square shaft quick connect accessories:**
  1. Turn collar clockwise and pull back.
  2. Insert accessory hex shaft into chuck until fully seated (rotate to clock flats on shaft with inside square).
  3. Let collar spring forward and turn counter clockwise to lock.

- **3.3.2 To attach hex shaft quick connect accessories:**
  1. Push sliding collar forward.
  2. Insert accessory hex shaft into chuck until fully seated (rotate to clock flats on shaft with inside hex).
  3. Pull collar back to lock.

**3.4 Articulating Accessory Arm Column**

#### 3.4.1 Table Clamped Ball Joint Arm

Provides an attachment point to the operating table rail. It accepts and holds the mounting clamp on the flex arm body.

To attach Table Clamped Ball Joint Arm to the table rail:

1. Open Rail Clamping Knob until the top bracket will fit over the rail, then tighten to secure.
2. Insert collar clockwise and pull back.
3. Pull collar back to lock.

**3.4.2 Joint Arm to the table rail:**

1. Open Rail Clamping Knob until the top bracket will fit over the rail, then tighten to secure.
2. Insert collar back to lock.
3. Pull collar back to lock.

**3.4.3 Joint Arm to the table rail:**

1. Open Rail Clamping Knob until the top bracket will fit over the rail, then tighten to secure.
2. Insert collar back to lock.
3. Pull collar back to lock.
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3.5 Flexible Arms

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

To use flexible arm:
1. Turn tension knob (orange) clockwise to tighten beads into desired position.
2. Turn tension knob counterclockwise to loosen beads.

To mount flexible arm:
1. Mounting clamp knob (blue) clockwise.
2. Slide mounting clamp into desired post.

Note: when loosening, do not force black knob past the stop.

To attach instrument holders/endoscopes to flexible arm please reference section 3.3.

3.6 Flexible Arm Systems

All-in-one structure with an integrated table clamp.

To manipulate flexible arm:
1. Turn tension "TIGHTEN" knob clockwise to tighten beads into desired position.
2. Turn tension "TIGHTEN" knob counterclockwise to loosen beads.

To attach instrument holders/endoscopes to flexible arm please reference section 3.3.

4. Inspection Before Use

Product should be inspected throughout its lifetime to ensure proper function and performance. Table clamping ball joint arm should clamp securely to table rail; the flex arm main knob should be able to tighten and hold end effectors in place. Quick connect should freely engage and disengage by sliding the outer sleeve. When loosened, check for fraying. Normal use will eventually diminishing hand-held retraction.

5. Cleaning and Sterilization

5.1 Preparing the Arm:
1. Lubricate threads of tensioning knob with water soluble lubricant.
2. Turn the main orange knob counter-clockwise into desired position.
3. While holding the cable and bead section of the arm in a loop, rotate the clamp housing counter-clockwise to loosen and create a space between the housing and the first bead.
4. Clean and sterilize, with in between beads, steam or other sterilizing media can enter into the internal space of the flex arm.

5.2 Manual and Automatic Cleaning Instructions

Flex arm and associated rail mounts and quick connect should be cleaned and sterilized before each use. Do not disassemble the flex arm, ball joint arm or endoscope holders. Parts are not designed to be disassembled. Loosen as per steps in this manual for sterilization. Allow space in between beads for cleaning solution and sterilization agents.

1. Prepare an enzymatic detergent (3m) in a water bath (approximately 3000ml at 27°C to 33°C).
2. Submerge and soak instruments in detergent solution for 1-2 minutes.
3. Brush the device with a nylon-bristled brush while submerged in the cleaning solution (3 to 4 minutes) until no visible soil can be seen.
4. Rinse instruments in cold deionized water for 30 seconds per instrument.
5. Load instruments into an appropriate basket and place in an automatic washer/disinfector.

Note: Flex arms are ONLY cleaned manually.

Use cleaning parameters below for automatic wash:
1. Heated wash (140°F/60°C) for 2 minutes using concentrated enzymatic detergent.
2. Rinse with hot tap water (140°F/60°C) for 20 seconds.
3. Thermal Rinse- Heated Deionized (DI) water for 1 minute.
4. Drying cycle set on High (240°F/116°C) for 9 minutes.

5.3 Sterilization Instructions

Devices should be sterilized in the open and unsealed packages. This please reference section 3.3. When mounted table clamp please reference section 3.4.

4. Mounting clamp knob to the table rail.

5.4 Retightening the arm for use.
1. Turn the main orange knob counter-clockwise until it stops.
2. Turn the orange knob counterclockwise until it stops.

6. Storage

Instruments should be stored in a clean and dry area. Please examine instrument prior to use for functionality and damage. Dispose of at end of life in accordance with national regulations and approved hospital practices for surgical instrumentation disposal.

7. 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 medical professional.
3. AXS products are for use only with other AXS products and may not be used with other manufacturer’s products.
4. Normal repeated use has minimal effect on these instruments. 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. Adjusting flex arms position without loosening tension knob will cause cable wear.
7. Acute flex arm bending will cause cable damage/wear.

8. Warranty

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

For more information on products in this IFU please contact:
info@axcesssurgical.com

Customer Service Information
P: 650.563.9231
sales@axcesssurgical.com
www.axcesssurgical.com

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AXCESS SURGICAL INNOVATIONS
141 California Ave, Suite 102
Half Moon Bay, CA 94019 USA

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