

INSTRUCTION FOR USE

3.3 Quick Connect Chucks

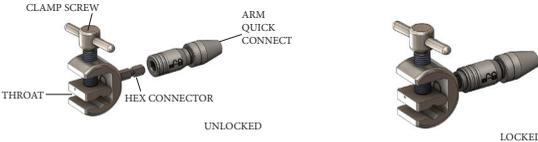
Provides a fast connection point for accessories to the distal end of Accessory Arm. Depending on customer preference, accessory attachments can come with either a square quick connect shaft or a hex quick connect shaft. These connection shafts are not interchangeable and can only be used with the appropriate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

3.3.1 To attach square shaft quick connect accessories:



1. Turn collar clockwise and pull back.
2. Insert accessory 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. Check to see that shaft is secured and collar is in locked position. To unlock: Reverse above steps.

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. Check to see that shaft is secured and collar is in locked position. To unlock: Reverse above steps.

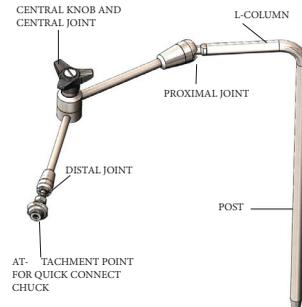
3.4 Accessory Arm

Provides three point positioning of the attached accessories into the surgical field. Attaches to either Straight or L-Column.

To position and lock in place:

1. Hold distal end with one hand and loosen central knob by turning counter clockwise.
2. Position attached accessory as needed and turn knob clockwise to lock in place.

Check to see that accessory arm is secure enough to hold position. To loosen, reverse the above steps.



INSTRUCTION FOR USE

4. Inspection before use:

1. Check entire assembly for damage.
2. Hold arm assembly at column and tighten central tightening knob clockwise.
3. Check to make sure that arm is rigid at all three joints.
4. Insert column into rail clamp, tighten column tightening lever and make sure that it holds securely.

5. Cleaning and Sterilization

5.1 Manual Cleaning Instructions for Surgical Arms

- 1) Articulating Arms: Turn tightening knob clockwise to tighten ball joint prior to placing arm in ultrasonic cleaner.
- 2) Place surgical arm into ultrasonic with enzymatic cleaner prepared using the minimum concentration recommended by the detergent manufacturer and warm tap water with a temperature ranging from 25°C to 35°C for a minimum of 10 minutes.
- 3) Completely submerge surgical arm in enzymatic cleaner prepared using warm tap water (25°C to 35°C) for manual cleaning with appropriately-sized soft nylon bristle brush for a minimum for 2 minutes
- 4) Rinse surgical arm for up to 1 minute with flowing deionized water.
- 5) Manually dry surgical arm using clean, absorbent, low-lint wipes to remove excess water.

Inspection before use:

Articulating Arms

- 1) Inspect entire assembly for damage.
- 2) Hold arm assembly at column and tighten central tightening knob clockwise.
- 3) Check to make sure that arm is rigid at all three joints.
- 4) Insert column into rail clamp, tighten column tightening lever and make sure that it holds securely.

5.2 Sterilization

Arm should be sterilized in the open or unlocked position. This product has been sterilization validated according to AANSI / AAMI / ISO 17665.

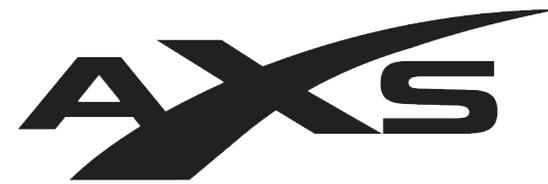
The following steam sterilization cycles have been validated with these minimum parameters:

Gravity: 30 minutes at 121°C/250°F with 30-minute dry time
Prevacuum: 4 minutes at 132°C/270°F with 30-minute dry time

After sterilization, allow for a minimum of 2 hours of ambient cooling

6. Storage

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



INSTRUCTION FOR USE

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 surgeons.

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 for these instruments. End of life is normally determined by wear and damage due to use.

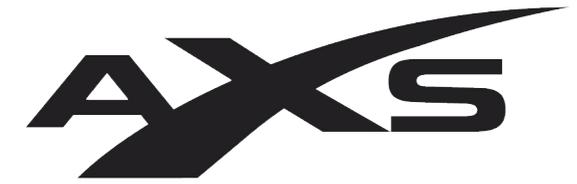
5. Use of this instrument for any purpose, or in any manner other than those described here may cause instrument damage or failure which could result in serious patient injury or death. If needed, all AXS metal products or fragments thereof can be located by means of an X-Ray.

6. DO NOT FORCE PAST STOP WHEN OPENING.

8. Warranty

Access Surgical Innovations, LLC 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, Access Surgical will, at its sole discretion, either repair or replace the defective product at no charge. This limited warranty is null and void if a Access Surgical product is repaired or modified in any way by any party that is not explicitly Access Surgical authorized. Access 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 contact:
info@accesssurgical.com



INSTRUCTION FOR USE

REF

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

Quantity / Antal / Hoeveelheid / Quantité / Menge / Quantità / Quantidade / Cantidad: 1



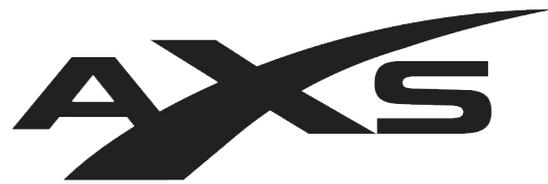
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Half Moon Bay, CA 94019 USA

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THE NETHERLANDS





INSTRUCTION FOR USE

Instruction for use for:

Accessory Holding Arm

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4. Inspection Before Use

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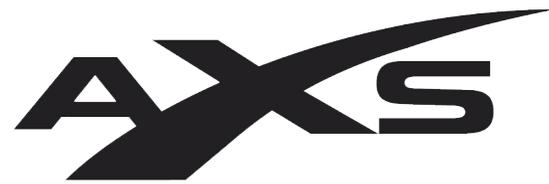
5.1 Manual Cleaning

5.2 Sterilization

6. Storage

7. Warning

8. Warranty



INSTRUCTION FOR USE

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

Accessory Holding Arm

Accessory Arm with Quick Connect

AA-0100/0101/0109

AA-0150/0151/0159

AA-0300/0301/0309

AA-0350/0351/0359

AA-0400/0401/0409

AA-0450/0451/0459/0460/0470

AA-0500/0501/0509

AA-0550/0551/553/0559

Accessory Arm with Instrument "C" Clamp

AA-0104/0153/0303/0353/0403/0453/0503/0553

Accessory Arm with Rack Clamp

AA-0105/0155/0305/0355/0405/0455/0505/0555

Accessory Arm with Stainless Steel Endoscope

AA-0107/0157/0307/0357/0407/0457/0507/0557

Accessory Arm with Plastic Endoscope

AA-0108/0158/0308/0358/0408/0458/0508/0558

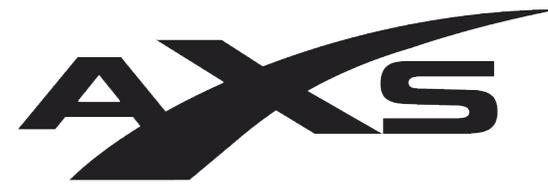
Quick Connection Chucks

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

NA-0002/0004/0006/0012/0014/0016

Table/Rail Clamps

AA-0200/0202/0204/0210



INSTRUCTION FOR USE

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.

1.1 For more Information please contact:

Access Surgical Innovations

141 California Ave, Suite 102

Half Moon Bay, CA 94019 USA

Manufacturing Contact Information

Tel: 650-563-9106

Fax: 650-563-9143

Customer Service Information

p: 650.563.9231

info@accesssurgical.com

orders@accesssurgical.com

sales@accesssurgical.com

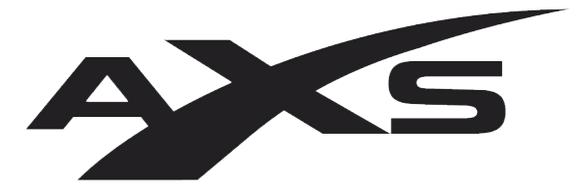
www.accesssurgical.com

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 has to be 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.

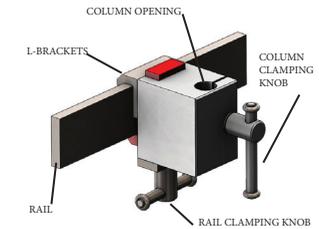


INSTRUCTION FOR USE

3. Product Description and Use

3.1 Fixed Rail/Table Clamps

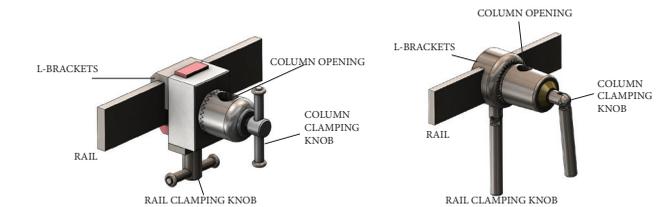
Provides an attachment point to the operating table rail. Accepts and holds the column of the accessory arm in position. To attach to the rail:



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.

3.2 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.



- To attach to the rail:
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, adjust column to desired angle, and tighten column clamping knob when arm is in desired position.