



452 Randolph St, Abington, MA 02351, USA



SchureLoc XPS

800-0280



Prior to using this or any other type of medical equipment with a patient, it is recommended that you read the Instructions For Use and familiarize yourself with the product.

- Please read and understand all warnings in this manual and on the device itself before using it with a patient.
- The  symbol is designed to alert users to important procedures or safety instructions regarding the use of this device.
- The techniques described in this manual are suggestions from the manufacturer. The attending physician retains the final responsibility for patient care with respect to this device.
- Check the device function before each use. Do not use this device if there are obvious signs of damage or functional issues. Consult manufacturer before reusing.
- This device should only be operated by trained personnel.
- All modifications, upgrades, or repairs must be carried out by an authorized specialist.
- Any serious incidents related to the device should be reported to the manufacturer and the national competent authority where the user is located.



**NEVER EXCEED THE WEIGHT CAPACITY OR IMPROPERLY
DISTRIBUTE THE LOAD ON THE OPERATING ROOM TABLE.**

Symbol	Description	Reference
	Manufacturer	EN ISO 15223-1
	Date of manufacture	EN ISO 15223-1
	Authorized Representative in the European Community	EN ISO 15223-1
	Authorized Representative in Switzerland	EN ISO 15223-1
	Authorized Representative in UK	EN ISO 15223-1
	Importer	EN ISO 15223-1
	Serial Number	EN ISO 15223-1
	Warning	IEC 60601-1
	Medical Device	MDR 2017/745
	Unique Device Identifier	EN ISO 15223-1
	CE Marking	MDR 2017/745
	Use-By Date	EN ISO 15223-1
	Batch Code	EN ISO 15223-1
	Manufacturer's Reference Number	EN ISO 15223-1

Indication for Use:

The SchureLoc XPS is used in a variety of surgical procedures. This device is capable of being used with a broad patient population as deemed appropriate by medical professionals within hospitals and surgery centers

Intended Use:

The intended use of the SchureLoc XPS is to securely hold a patient or surgical instrument during surgical procedures. The intended users of this device are medical professionals within hospitals and surgery centers.

Intended User: Surgeons, Nurses, Doctors, Physicians and/or Healthcare professionals involved in the intended procedure utilizing the device. All staff using or preparing the intended product should be properly trained and familiar with the positioning device before use.

Intended Populations: This device is intended to be used with patients that do not exceed the weight in the safe working load field specified in the product specification section.

Residual Risk:

This product complies with relevant performance, safety standards. However, misuse, device damage, function or mechanical hazards cannot be completely excluded. End users are responsible for ensuring device is securely attached and will operate in a safe manner.

Safety Considerations:

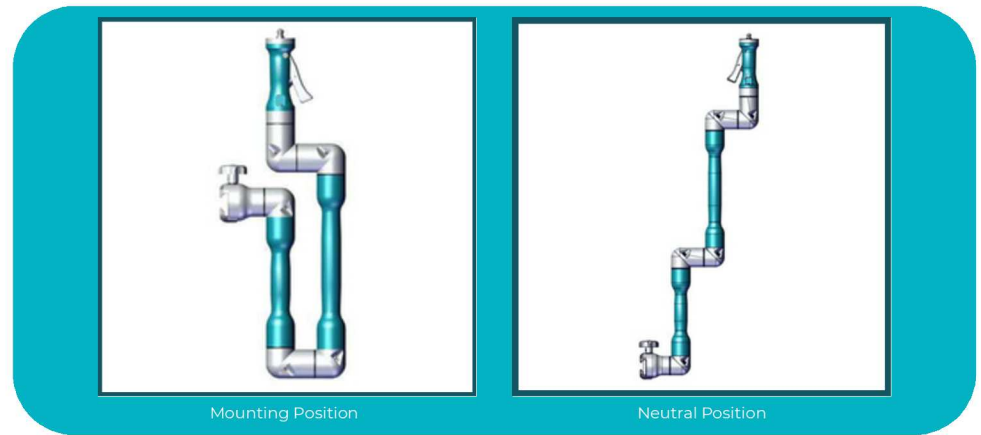
DO NOT USE IF THE PRODUCT SHOWS VISIBLE DAMAGE OR SIGNS OF IMPROPER FUNCTIONING.

Equipment Misuse:

Do not use the product if package is damaged. All modifications, upgrades, or repairs must be performed by a SchureMed authorized specialist.

Safe Disposal:

End users should adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories.



System Setup:

1. Place articulating arm in mounting position.
2. Verify mounting knob is facing upward and in loose unlocked position.
3. Place clamp on accessory rail of surgical table.
4. Tighten clamp by turning mounting knob clockwise.



To prevent patient or operator injury from inadvertent device movement, securely tighten integrated clamp.

Draping the SchureLoc XPS:

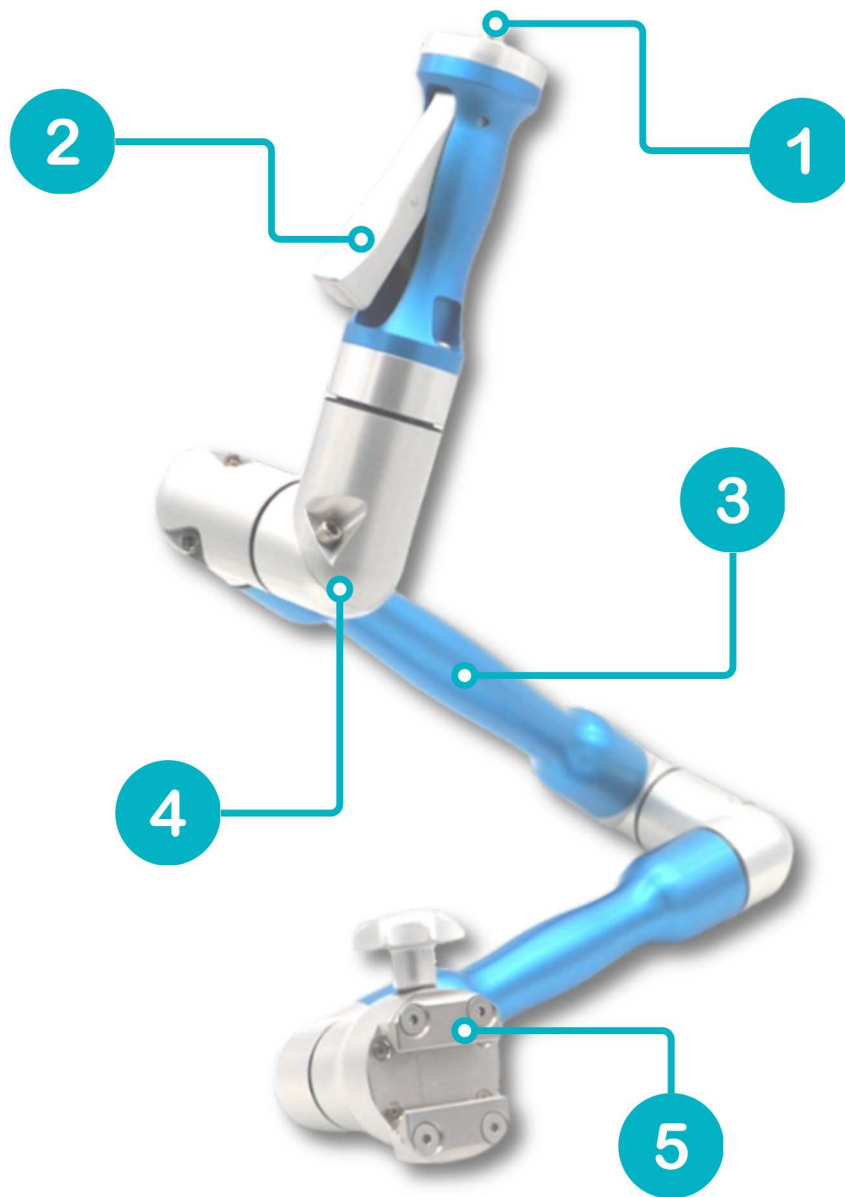
1. With the SchureLoc in neutral position, tape drape to sterilized SchureLoc adaptor so that half the tape is on drape and remainder is on adaptor.
2. Attach Adaptor to articulating arm. Twist to lock fully into place..
3. Pull drape down over Adaptor and to accessory rail to completely cover Articulating Arm.
4. Attach chosen SchureLoc accessory to the adaptor and rotate slightly so it is properly attached.

Adjusting SchureLoc XPS:

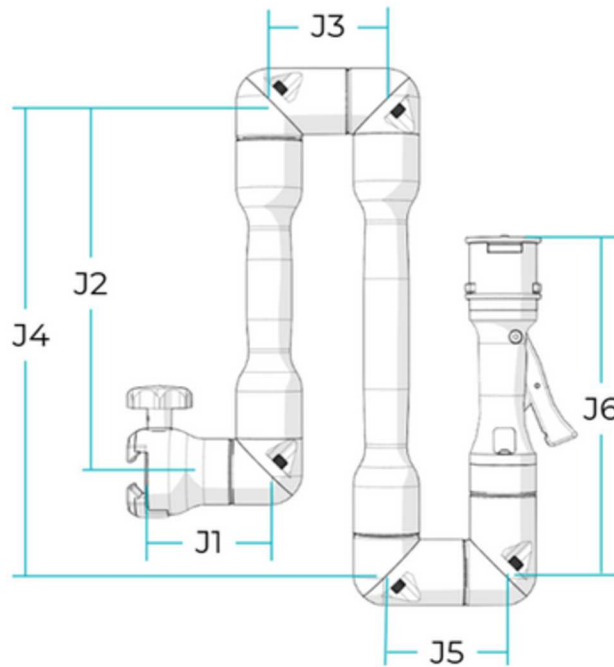
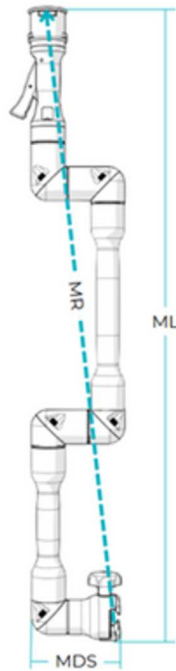
1. Squeeze Trigger as far as it will go and hold it. All swivel joints are released, and SchureLoc can move freely.
2. Swivel articulating arm to the desired position
3. Release Trigger and SchureLoc swivel joints will be locked

Device Removal:

1. Loosen clamp by turning mounting knob counter clockwise.
2. Move articulating arm in an upward motion to remove from accessory rail
3. Remove product from accessory rail, clean and store



- 1 Accessory Adapter Connection
- 2 Joint Release Trigger
- 3 Aluminum Grip Arms
- 4 Articulating Joints
- 5 Integrated Universal Rail Clamp



Device Dimensions	SchureLoc XPS (800-0280)
Max Length (ML)	36" +/-0.5" (91.4cm +/- 1cm)
Max Reach (MR)	37" +/-0.5" (94cm +/- 1cm)
Minimum Distance from Side Rail (MDS)	5" +/-0.5" (12.7cm +/- 1cm)
Joint 1 (J1)	3.6" +/-0.5" (9cm +/- 1cm)
Joint 2 (J2)	11" +/-0.5" (27.9cm +/- 1cm)
Joint 3 (J3)	3.5" +/-0.5" (8.9cm +/- 1cm)
Joint 4 (J4)	14" +/-0.5" (35.6cm +/- 1cm)
Joint 5 (J5)	3.5" +/-0.5" (8.9cm +/- 1cm)
Joint 6 (J6)	10" +/-0.5" (25.4cm +/- 1cm)
Net Weight, Arm Only	8 +/- 0.5 lbs. (3.6 +/- .22 kg)
Net Weight with Adapter	10 +/- 0.5 lbs. (4.5 +/- .22 kg)
Range of Motion	360° rotation at each joint

Storage Specifications	Description
Storage Temperature	-20° F to 140° F (-29° C to +60° C)
Storage Relative Humidity Range	15% to 85%
Operating Temperature	This device is intended to be used in a controlled Operating Room environment.
Operating Relative Humidity Range	

Cleaning and Disinfection:



- **Clean the device after each use as directed.**
- **Do not submerge the device in liquid.**
- **Use caution in areas where liquid can get into the mechanism.**
- **Do not clean the device with bleach or products that contain bleach.**

Wipes:

- Do not use wipes that contain greater than 2% sodium hypochlorite.
- Wipes may contain benzalkonium chloride (up to 0.6% conc.), didecyl dimethyl ammonium chloride (up to 0.6% conc.) and may also contain polyhexamethylene biguanide (up to 0.6% conc.).

Sprays:

When using a spray do not spray the device directly. Spray a clean cloth then wipe the device to clean.

- Sprays may contain up to 2% sodium hypochlorite.
- Sprays may contain up to .2% benzalkonium chloride and up to 0.2% didecyl dimethyl ammonium chloride (quaternary ammonium chloride solution (QACs) and may also contain polyhexamethylene biguanide (up to 0.6% conc.).
- Sprays may contain up to 2% hydrogen peroxide.

Steam Sterilization:

- Wrap using envelope method or accepted wrap method at your facility.
- Follow your hospital or facility's policy on steam sterilization procedures

Read the cleaning product's directions and follow the instructions on the label. Use caution in areas where fluid migration may occur.

Wipe device with a clean, dry cloth. Be sure that the product is dry prior to reinstalling and storage to avoid damage.

CAUTION: Damage may result if product is cleaned with caustic chemicals or harsh abrasives

ATTENTION: If any SchureMed product is damaged or does not function normally, discontinue use and contact SchureMed or an authorized SchureMed Certified Distributor.

Compatible Products and Cleaning:

Accessory Description	Product Number	Cleaning Instructions
SchureLoc XPS Adapter	790-0039	Steam
SchureLoc XPS Disposable Sterile Kit	800-0281	
SchureLoc XPS Forearm Attachment	790-0040	Steam
SchureLoc XPS TKR Positioner	790-0077	Steam
SchureLoc XPS Elbow/Ankle Positioner	790-0075	Wipe/Spray
SchureLoc XPS Armboard	790-0056	Wipe/Spray
SchureLoc XPS Counter Traction Post	790-0057	Wipe/Spray
SchureLoc XPS Finger Trap	790-0058	Steam
SchureLoc XPS Femoral Hook Holder	790-0101	Steam
SchureLoc XPS Retractor Holder	790-0103	Steam

Accessory Instructions:

790-0058 Finger Trap:

1. Articulate Schure Loc™ XPS to desired position
2. Slide the finger trap pads outwards
3. Position the patient's hand on the finger trap system
4. Slide the pads between the patient's fingers



790-0101 Femoral Hook Holder:

1. Articulate Schure Loc™ XPS to desired position
2. Loop your femoral hook of choice unto the femoral hook holder
3. Fine adjustments can be made by turning the knob counter clockwise to elevate, and clockwise to lower, insert and position the hook

790-0077 TKR Positioner:

1. Drape surgical table
2. Articulate Schure Loc™ XPS to desired position, TKR boot must be resting on table
3. Line boot with our sterile TKR Boot Liner #800-0146 (sold separately 12/cs)
4. Insert foot into boot, secure foot by wrapping sterile coban



790-0103 Retractor Holder:

1. Articulate Schure Loc™ XPS to desired position
2. Place the retractor of your choice into the retractor holder and fasten tightly by turning the knob clockwise.
3. To remove the retractor, simply turn the knob counterclockwise until the vice around the retractor releases.

790-0057 Counter Traction Post:

1. Articulate Schure Loc™ XPS to desired position, wrap patient's arm around post with elbow pointing up.
2. Articulate Schure Loc™ XPS to desired position, rest patient bottom foot on post



Accessory Instructions:

790-0056 Armboard:



1. Place patient's arm in center of pad, attach strap to velcro strap on bottom of armboard and wrap it around arm and attach strap to velcro strap on the bottom of board.

790-0075 Elbow/Ankle Positioner:

1. Articulate Schure Loc™ XPS to desired position, wrap patient's arm inside cradle with elbow pointing up
2. Articulate Schure Loc™ XPS to desired position, rest patient foot in cradle



Compliance with Medical Device Regulations



These products are non-invasive, Class I Medical Devices and are CE-marked according to AnnexVIII, Rule 1, of the Medical Device Regulations (REGULATION (EU) 2017/745).

EC Authorized Representative



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