SchureMed

452 Randolph St, Abington, MA 02351, USA

SpringLoc Clamp

SpringLoc Clamp 800-0127

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
EC REP	Authorized Representative in the European Community	EN ISO 15223-1
CH REP	Authorized Representative in Switzerland	EN ISO 15223-1
UK REP	Authorized Representative in UK	EN ISO 15223-1
	Importer	EN ISO 15223-1
SN	Serial Number	EN ISO 15223-1
	Warning	IEC 60601-1
MD	Medical Device	MDR 2017/745
UDI	Unique Device Identifier	EN ISO 15223-1
CE	CE Marking	MDR 2017/745
	Use-By Date	EN ISO 15223-1
LOT	Batch Code	EN ISO 15223-1
REF	Manufacturer's Reference Number	EN ISO 15223-1

Indication for Use:

The SpringLoc Clamp is an O.R. table clamp that will attach to surgical table side rails. This clamp is primarily used in conjunction with our Great White Stirrups.

Intended Use:

The intended use is to hold O.R. accessories on an O.R. table. This clamp is primarily used in conjunction with SchureMed's Great White Stirrups.

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.

Instructions:

It is recommended that with this patient positioning device that you should become familiar with its features operation. You should always practice its use on a nurse, physician or appropriate volunteer prior to using it clinically.

The SpringLoc clamp is spring-loaded and attaches to the O.R. table side rail anywhere along the rail. It accepts a 1" x 1/4" flat bar mounting post. Holds all accessories in the vertical position.

The maximum load placed on the product may not exceed the appropriate proportion of a patient weighing 800 lbs. Restrictions result from the permissible overall load, among other things, of accessory rails when using operating tables with a low maximum load capacity. Be absolutely sure to follow the instructions for use for your Operating Table system.

Attaching to the Side Rail:

1. Snap clamp anywhere on the side rail with the SchureMed logo facing up.
2. Secure clamp by turning the handle clockwise to the lock position.

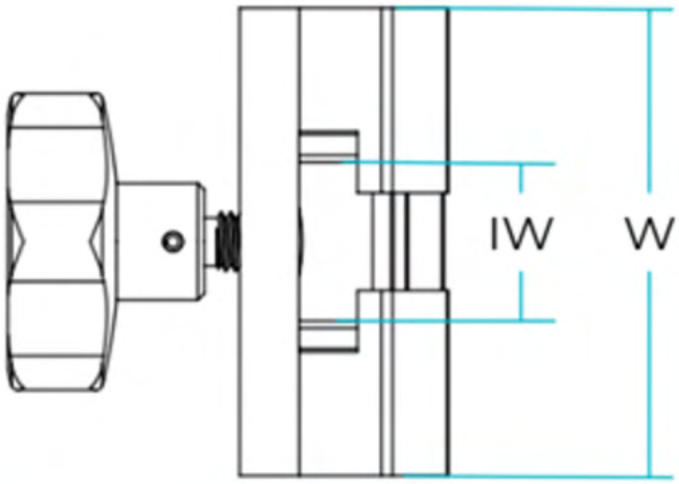
Removal from the Side Rail:

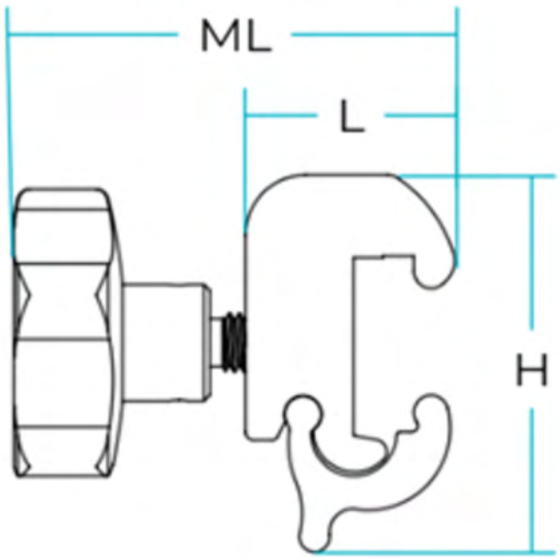
1. Unlock the clamp by turning the handle counterclockwise and remove accessory.
2. Lift the pull to release lever to remove from the side rail.

Hazard resulting from incorrect use. Be absolutely sure to follow the instructions for use for your Operating Table system.

Device Maintenance:

1. Make sure that all labels can be read. Replace labels as necessary. Use an alcohol wipe to remove any adhesive residue.
2. Contact SchureMed or an authorized SchureMed Certified Distributor if you need to repair or replace the device.





Device Dimensions	US
Clamp Length (L)	1.31" +/-0.5" (3.33cm +/- 1cm)
Clamp Height (H)	2.42" +/-0.5" (6.15cm +/- 1cm)
Clamp Width (W)	3.00" +/-0.5" (7.62cm +/- 1cm)
Max Length (ML)	2.80" +/-0.5" (7.11cm +/- 1cm)
Inner Width (IW)	1.02" +/-0.5" (2.59cm +/- 1cm)

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.

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.

Compliance with Medical Device Regulations

CE 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

EC REP

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Manufacturing Information

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