



Instructions for Use

REF Universal Rail Clamp 800-0085

INTENDED USE

Intended use is to hold surgical accessories on surgical table. The intended users of this device are medical professionals within hospitals and surgery centers.



INSTRUCTIONS

Become familiar with patient positioning device's features before use with patient. Always practice use on a nurse, physician or appropriate volunteer prior to using clinically.

Universal Rail Clamp is spring-loaded - attaches anywhere along surgical table side rail. Attaches to all surgical table side rails that are 3/8"W x 1-1/8"H (.95 cm x 3 cm). Clamp accepts any round mounting posts up to 5/8" (1.6 cm) in diameter and rectangular mounting posts up to 1" x 3/8" (2.5 cm x .95 cm).

Attaching to Side Rail

1. Attach clamp on rail
2. Turn clamp handle clockwise to lock securely

Detaching from Side Rail

1. Turn clamp handle counter-clockwise to unlock and remove from rail

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

- Length: 3" +/- 0.5" (8 cm +/- 1 cm) (Handle Collapsed),
5.5" +/- 0.5" (14 cm +/- 1 cm) (Handle Extended)
- Width: 2" +/- 0.5" (5 cm +/- 1 cm)
- Depth: 4" +/- 0.5" (10 cm +/- 1 cm)
- Device Weight: 1 +/- 0.5 lbs. (.45 kg +/- .22 kg)
- Attaches to rail of surgical table at any point on rail
- Single-person installation
- Holds accessory equipment up to 5/8" (1.6 cm) diameter and 1" x 3/8" (2.5 cm x .95 cm) flat mounting post

COMPONENT OVERVIEW

Universal Rail Clamp is a surgical table clamp attaching to all United States rails. Its function is to hold surgical accessories on a surgical table.

Side rail dimensions below:

US: 0.374" x 1.122" (9.5 mm x 28.5 mm)

GENERAL INFORMATION

- *Product not made with Natural Rubber Latex*
- *Device supports 350 lb. (159 kg) proportional patient load (6'4" (193 cm) tall patient per 99% human body model)*
- *Product warranty covers product from manufacturing defects for period of 2 years*
- *If damaged in shipping, call Customer Service at (888) 724-8763 or (781) 982-7000 to obtain Return Material Authorization number. For product warranty issues, contact Customer Service.*
- *CE marked medical device according to MDR (EU) 2017/745*
- *Product is maintenance-free, check product condition before next use*
- *Life of device is 5 years under normal use*
- *Store device between -4°F to +86°F (-20°C to 30°C)*

DISPOSAL

- **General** - *Prevent infection by cleaning and disinfecting product before disposal*
- **Packaging** - *Dispose packaging material via household waste according to national requirements*
- *SchureMed accepts back used or retired products - or dispose of product in accordance with national requirements*



PRODUCT USE WARNINGS

WARNING!

Maximum load should not exceed appropriate proportion of a patient weighing 350 lbs. (159 kg). Use care with low-maximum load capacity surgical tables that accessory rails are not overloaded.



WARNING! *Do not reuse device if there are obvious signs of damage or functional issues. Consult manufacturer before reusing.*

CLEANING RECOMMENDATION

Follow current Association of periOperative Registered Nurses Journal Guidelines for proper cleaning and disinfection procedures.



WARNING!

Adhere to standards for blood-borne pathogens from Occupational Safety and Health Administration. Use recommended protective clothing, gloves, masks and eye protection to clean accessory.

CAUTION

Strictly read/follow manufacturer's directions for cleaning fluids. DO NOT use cleaners containing phenolics.

1. Remove major contaminants from accessory with disposable materials. Follow appropriate bio-hazard waste disposal procedures.
2. Apply cleaning fluid liberally to entire accessory and wipe with clean, lint-free cloth until all moisture and cleaning fluid is removed from accessory
3. Let accessory dry

USER NOTICE












Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

UDI Basic UDI-DI: 081005737F0017KW

eIFU Language Versions

To download and print the Instructions for Use, please go to <http://www.schuremed.com/schuremed-eifu>.

Symbol Glossary

Symbol	Title	Symbol Description
	Manufacturer	Indicates the medical device manufacturer.
	Authorized Representative in the European Community	Indicates the authorized representative in the european community.
	Use-by Date	Indicates the date after which the medical device is not to be used.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue or Item Number	Indicates the manufacturer's catalogue or item number so that the medical device can be identified.
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Medical Device	Indicates the item is a medical device.
	Unique Device Identifier	Indicates a barcode as containing unique device identifier information.
	CE Marking	European Conformity.
	Single Patient Use	Indicates the item is a single patient use medical device.



Manufacturer

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