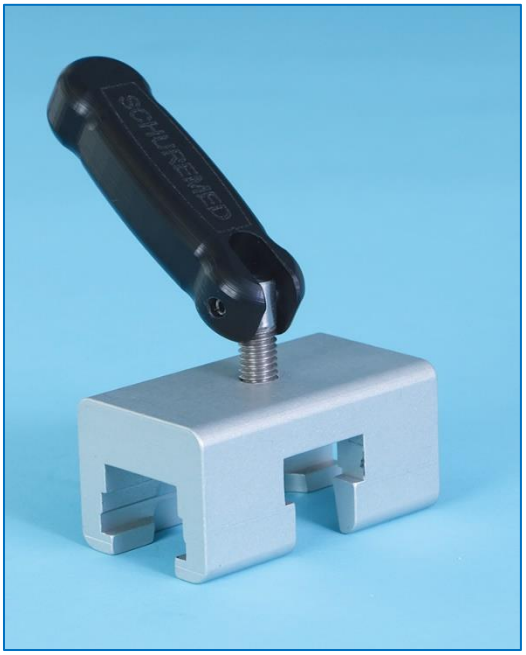
Instructions for Use



REF **Simple Clamp 800-0228**

REF **Simple Clamp (EU) 800-0228-EU**

REF **Simple Clamp (UK) 800-0228-UK**

REF **Simple Clamp (DEN) 800-0228-DEN**

REF **Simple Clamp (JPN) 800-0228-JPN**

REF **Simple Clamp (SWISS) 800-0228-SWISS**

INTENDED USE
Intended use is to hold surgical accessories with 1" x 3/8" (2.5 cm x .95 cm) flat mounting post vertically anywhere along table side rail or a 1" x 1/4" (2.5 cm x .64 cm) horizontally mounting blades. 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 on a nurse, physician or appropriate volunteer prior to using clinically.

Attaching to Side Rail

1. *Snap Simple Clamp on surgical table side rail*
2. *Place flat bar of accessory into mounting hole*
3. *Secure clamp by turning handle clockwise to lock position*

Detaching from Side Rail

1. *Unlock clamp by turning the handle counterclockwise and remove mounting bar*
2. *Lift simple clamp off surgical table side rail*

GENERAL SPECIFICATIONS
Device Dimensions (maximum)

- *Length: 3" +/- 0.5" (8 cm +/- 1 cm)*
- *Width: 1.75" +/- 0.5" (4 cm +/- 1 cm)*
- *Depth: 1.375"+/- 0.5" (4 cm +/- 1 cm)*
- *Device Weight: 1 +/- 0.5 lbs. (.45 kg +/- .22 kg)*
- *Attaches to rail of a surgical table at any point on rail*
- *Single person installation*
- *Holds accessory equipment with 1" x 3/8" (2.5 cm x .95 cm) flat mounting posts*

IFU-800-0228 REV 3.05
Latest Revision: 2022-01

COMPONENT OVERVIEW
Simple Clamp is a surgical table clamp that attaches to all rails. Its function is to hold surgical accessories on a surgical table.

See side rail dimensions below:
***US**: 0.374" x 1.122" (9.5 mm x 28.5 mm) PN# 800-0228*
***Denyer**: 0.236" x 1.496" (6 mm x 38 mm) PN# 800-0228-DEN*
***Europe**: 0.394" x 0.984" (10 mm x 25 mm) PN# 800-0228-EU*
***Eschmann (UK)**: 0.236" x 1.260" (6 mm x 32 mm) PN# 800-0228-UK*
***Japan**: 0.354" x 1.260" (9 mm x 32 mm) PN# 800-0228-JPN*
***Swiss**: 0.394" x 1.181" (10 mm x 30 mm) PN# 800-0228-SWISS*

GENERAL INFORMATION
- *Product not made with Natural Rubber Latex*
- *Device supports 720 lb. (327 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 720 lb. (327 kg). Use care with low-maximum load capacity surgical tables that accessory rails are not overloaded.*

WARNING!
Hazards result from incorrect use. Strictly follow Instructions for Use with your Operating Table system.

***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.

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: 081001460F0051DZ

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.
EC REP	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.
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalogue or Item Number	Indicates the manufacturer's catalogue or item number so that the medical device can be identified.
SN	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.
MD	Medical Device	Indicates the item is a medical device.
UDI	Unique Device Identifier	Indicates a barcode as containing unique device identifier information.
CE	CE Marking	European Conformity.
	Single Patient Use	Indicates the item is a single patient use medical device.

Manufacturer

SchureMed (081001460)
452 Randolph Street, Abington, MA 02351 USA
Toll Free (888) 724-8763 | **Ph** (781) 982-7000 | **Fax** (781) 982-7001 | **orders@schuremed.com**

CE MD

EC REP **Authorized Representative**

Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands