

Instructions for Use

REF

Leg Prepper 800-0013

Replacement Part
Leg Prepper Pad and Cover 790-0074

INTENDED USE

Intended use is to hold patient's leg comfortably during prepping procedure. 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.



- 1. Snap Schure Socket XL P/N 800-0134 (sold separately) onto the rail
- 2. Insert mounting post into socket lock tight

Detaching Leg Prepper from Surgical Table

1. Turn clamp handle counterclockwise to loosen Leg Prepper and remove

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

- Length: 36.5" +/- 0.5" (93 cm x 1 cm)
- Width: 12" +/- 0.5" (31 cm +/- 1 cm)
- Depth: 2" +/- 0.5" (5 cm +/- 1 cm)
- Device Weight: 4 +/- 0.5 lbs. (1.8 +/- .22 kg)
- 5/8" (1.56 cm) diameter mounting post inserts into socket
- Single-person installation
- Twist lock/Release Handle

COMPONENT OVERVIEW

Leg Prepper is a surgical table accessory. Padded horseshoe design holds patient's leg comfortably during prepping procedure.

Replacement Part

790-0074 Leg Prepper Pad and Cover

Other required product for use:

800-0134 Schure Socket XL (sold separately)

US: 0.374" x 1.122" (9.5 mm x 28.5 mm) PN# 800-0134

Denyer: 0.236" x 1.496" (6 mm x 38 mm) PN# 800-0134-DEN Europe: 0.394" x 0.984" (10 mm x 25 mm) PN# 800-0134-EU

Eschmann (UK): 0.236" x 1.260" (6 mm x 32 mm) PN# 800-0134-UK

Japan: 0.354" x 1.260" (9 mm x 32 mm) PN# 800-0134-JPN Swiss: 0.394" x 1.181" (10 mm x 30 mm) PN# 800-0134-SWISS

GENERAL INFORMATION

- Product not made with Natural Rubber Latex
- Device supports 500 lb. (227 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 500 lbs. (227 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 for your Operating Table system.



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



WARNING!

Surgical table load capacities may be less. Never overload a surgical table. Device is intended for mounting on side of surgical table rail only.

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.

Basic UDI-DI: 081001460F0014DT

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.
23	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.
\triangle	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.
2	Single Patient Use	Indicates the item is a single patient use medical device.



Manufacturer

SchureMed (081001460)

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EC REP Authorized Representative

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