Instructions for Use

REF **SchureFoot, Stainless Steel 800-0062**

Replacement Pads
SchureFoot Disposable Pads 508-0111

INTENDED USE
Intended use is to hold patient's foot firmly in place during knee replacement surgery. 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.

Set Up and Use of SchureFoot
- *Attach Schure Socket XL (sold separately) to surgical table side rail near end of torso section, on side of operative knee*
- *Slide disposable pad #508-0111 (sold separately) onto SchureFoot tube*
- *Insert SchureFoot mounting post into socket*
- *Once patient is on surgical table, slide SchureFoot along rail to achieve desired position for knee*
- *Turn socket handle clockwise securing SchureFoot in desired position*
- *Prep and drape in usual method*
- *After completing procedure, discard the SchureFoot disposable pad. Spray SchureFoot with hospital-approved disinfectant and wipe clean*

GENERAL SPECIFICATIONS
Device Dimensions (maximum)
- *Length: 12" +/- 0.5" (31 cm +/- 1 cm)*
- *Height: 18" +/- 0.5" (46 cm +/- 1 cm)*
- *Diameter: 2" +/- 0.5" (5 cm +/- 1 cm) (with pad 2 3/4" (7 cm))*
- *Device Weight: 2 +/- 0.5 lbs. (.9 +/- .22 kg)*
- *Operates on leg section of surgical table*
- *Requires a socket to attach to surgical table*

COMPONENT OVERVIEW
SchureFoot, Stainless Steel is a knee positioning device used in knee replacement surgery.

Replacement Pads
508-0111 SchureFoot Disposable Pads, 12/cs

Other required products for use**: **800-0134 Schure Socket XL
***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!
Hazard resulting 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.*

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 the 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: 081001460F0042DY

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)
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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