



Instructions for Use

REF SchureFoot, Lexan 800-0011

Replacement Pads

SchureFoot Disposable Pads, 12/cs 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 socket 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: 16" +/- 0.5" (41 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, Lexan 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 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: 081005737F0029L5

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

SchureMed (081001460)

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Authorized Representative

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