SchureMed

SchureFoot

SchureFoot, Lexan	800-0011
SchureFoot, Carbon Fiber	800-0408

Prior to using this or any other type of medical equipment with a patient, it is recommended that you read the Instructions For Use and familiarize yourself with the product.

- Please read and understand all warnings in this manual and on the device itself before using it with a patient.
- The ⚠ symbol is designed to alert users to important procedures or safety instructions regarding the use of this device.
- The techniques described in this manual are suggestions from the manufacturer. The attending physician retains the final responsibility for patient care with respect to this device.
- Check the device function before each use. Do not use this device if there are obvious signs of damage or functional issues. Consult manufacturer before reusing.
- This device should only be operated by trained personnel.
- All modifications, upgrades, or repairs must be carried out by an authorized specialist.
- Any serious incidents related to the device should be reported to the manufacturer and the national competent authority where the user is located.

NEVER EXCEED THE WEIGHT CAPACITY OR IMPROPERLY DISTRIBUTE THE LOAD ON THE OPERATING ROOM TABLE.

Symbol	Description	Reference
	Manufacturer	EN ISO 15223-1
	Date of manufacture	EN ISO 15223-1
	Authorized Representative in the European Community	EN ISO 15223-1
	Authorized Representative in Switzerland	EN ISO 15223-1
	Authorized Representative in UK	EN ISO 15223-1
	Importer	EN ISO 15223-1
	Serial Number	EN ISO 15223-1
	Warning	IEC 60601-1
	Medical Device	MDR 2017/745
	Unique Device Identifier	EN ISO 15223-1
	CE Marking	MDR 2017/745
	Use-By Date	EN ISO 15223-1
	Batch Code	EN ISO 15223-1
	Manufacturer's Reference Number	EN ISO 15223-1

Indication for Use:

The SchureFoot is used in a variety of surgical procedures. This device is capable of being used with a broad patient population as deemed appropriate by medical professionals within hospitals and surgery centers.

Intended Use:

The intended use of the SchureFoot is to hold the patient's foot firmly in place.

Intended User: Surgeons, Nurses, Doctors, Physicians and/or Healthcare professionals involved in the intended procedure utilizing the device. All staff using or preparing the intended product should be properly trained and familiar with the positioning device before use.

Intended Populations: This device is intended to be used with patients that do not exceed the weight specified in the general information section.

Residual Risk:

This product complies with relevant performance, safety standards. However, misuse, device damage, function or mechanical hazards cannot be completely excluded. End users are responsible for ensuring device is securely attached and will operate in a safe manner.

Safety Considerations:

DO NOT USE IF THE PRODUCT SHOWS VISIBLE DAMAGE OR SIGNS OF IMPROPER FUNCTIONING.

Equipment Misuse:

Do not use the product if package is damaged. All modifications, upgrades, or repairs must be performed by a SchureMed authorized specialist.

Safe Disposal:

End users should adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories.

Before clinical use, users should become familiar with the device's features, operation, and attachment procedures. Verify proper device function, positioning, and secure attachment prior to patient use.

Hazard resulting from incorrect use. Strictly follow instructions for your Operating Table system.

Set Up and Use of SchureFoot:

1. Attach the SchureSocket XL to the surgical table side rail at the appropriate location based on the planned procedure, patient positioning requirements, and desired SchureFoot placement.
2. Slide disposable pad #508-0111 (sold separately) onto SchureFoot tube.
3. Insert SchureFoot mounting post into socket.
4. Once patient is on surgical table, slide SchureFoot along rail to achieve desired position for leg.
5. Turn socket handle clockwise securing SchureFoot in desired position.

To prevent patient or operator injury from inadvertent device movement, securely tighten accessory clamp.

6. Prep and drape in usual method.
7. After completing procedure, discard the SchureFoot disposable pad. Clean using instructions in the cleaning and disinfection section.

Component Overview:
SchureFoot is used in a variety of surgical procedures, including but not limited to arthroscopic and arthroplasty procedures.

Replacement Pads
508-0111 Schurefoot Disposable Pads

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
- 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.
- 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)
- Device supports 600 lb. (272 kg) proportional patient load (6'4" (193 cm) tall patient per 99% human body model)
- SchureFoot may be utilized on any appropriate section of the surgical table as required to support the intended procedure, patient positioning needs, and desired clinical application.
- Requires a socket to attach to surgical table

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

Device Dimensions	
Length	12” +/- 0.5” (31 cm +/- 1 cm)
Diameter	2” +/- 0.5” (5 cm +/- 1 cm) (with pad 2 3/4” (7 cm))
Height	16” +/- 0.5” (41 cm +/- 1 cm)
Device Weight	2 +/- 0.5 lbs. (.9 +/- .22 kg)

Cleaning and Disinfection:

- **Clean the device after each use as directed.**
- **Do not submerge the device in liquid.**
- **Use caution in areas where liquid can get into the mechanism.**
- **Do not clean the device with bleach or products that contain bleach.**

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

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

Follow facility policies and applicable perioperative guidelines for cleaning, disinfection, inspection, and maintenance of reusable patient positioning devices.

Hand Cleaning

- Scrub each piece with a soft, plastic scrub brush and a recommended cleaning solution (see above)
- Rinse all parts thoroughly to remove any chemical residue
- Wipe each part completely dry with a clean, lint-free cloth

Washer Cleaning

- Put through washer/decontaminator according to manufacturer's instruction (Select cycle that does not included lubrication)
- Prepare for sterilization (device must be cleaned before sterilization)
- See sterilization instructions below

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.

Manufacturing Information