

Instructions for Use

REF

Pediatric Lithotomy Stirrups - PUPS 800-0233



Pediatric Lithotomy Stirrups - KIDS 800-0234

Replacement Pads

PUPS Boot Pads 508-1295 KIDS Boot Pads 508-1296

INTENDED USE

Intended use is to hold patient's legs during short or long gynecologic, urological and laparoscopic procedures. The intended users of this device are medical professionals within hospitals and surgery centers.



GENERAL INFORMATION

- Product not made with Natural Rubber Latex
- Device supports 350 lb. (159 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)

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

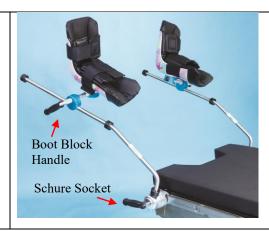
- Length: 26.5" +/- 0.5" (67 cm +/- 1 cm)
- Width: 6" +/- 0.5" (15 cm +/- 1 cm)
- Depth: 2.5" +/- 0.5" (6 cm +/- 1 cm) (with pad)
- Device Weight Per Stirrup: 5.25 +/- 0.5 lbs. (2.3 +/- .22 kg)
- Attaches to surgical table rail at any point on rail
- Single-person installation

INSTRUCTIONS

Become familiar with features of patient positioning device before use with patient. Always practice use on a nurse, physician or appropriate volunteer prior to using clinically.

Attaching PUPS and KIDS Pediatric Lithotomy Stirrups to Surgical Table

- 1. Put PUPS and KIDS Pediatric Lithotomy Stirrups mounting posts into Schure Sockets (sold separately) and turn Schure Socket handles clockwise to tighten.
- 2. Put patient's legs into boots and fasten with hook and loop fastener straps.



Adjusting PUPS and KIDS Pediatric Lithotomy Stirrups

1. Turn boot block handles counterclockwise to loosen and adjust up or down to desired position. Turn boot block handles clockwise to tighten.

Detaching PUPS and KIDS Pediatric Lithotomy Stirrups from Surgical Table

1. Turn Schure Socket handles counterclockwise to loosen and pull stirrups from sockets.

COMPONENT OVERVIEW

PUPS and KIDS Pediatric Lithotomy Stirrups are a surgical table accessory that aids in positioning of legs for gynecological, urological and laparoscopic procedures.

Replacement Pads

508-1295 PUPS Boot Pads

508-1296 KIDS Boot Pads

Other required products for use:

800-0006 Schure Socket, 2 each (sold separately)

See side rail dimensions below:

US: 0.374" x 1.122" (9.5 mm x 28.5 mm) PN# 800-0006

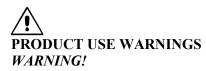
Denyer: 0.236" x 1.496" (6 mm x 38 mm) PN# 800-0006-DEN **Europe**: 0.394" x 0.984" (10 mm x 25 mm) PN# 800-0006-EU

Eschmann (UK): 0.236" x 1.260" (6 mm x 32 mm) PN# 800-0006-UK

Japan: 0.354" x 1.260" (9 mm x 32 mm) PN# 800-0006-JPN Swiss: 0.394" x 1.118" (10 mm x 30 mm) PN# 800-0006-SWISS

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



Maximum load should not exceed appropriate proportion of a patient weighing 350 lbs. (159 kg). Use care with low-maximum load capacity surgical tables that accessory rails are not overloaded.



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.



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 biohazard 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: 081001460F0013DR

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.
À	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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