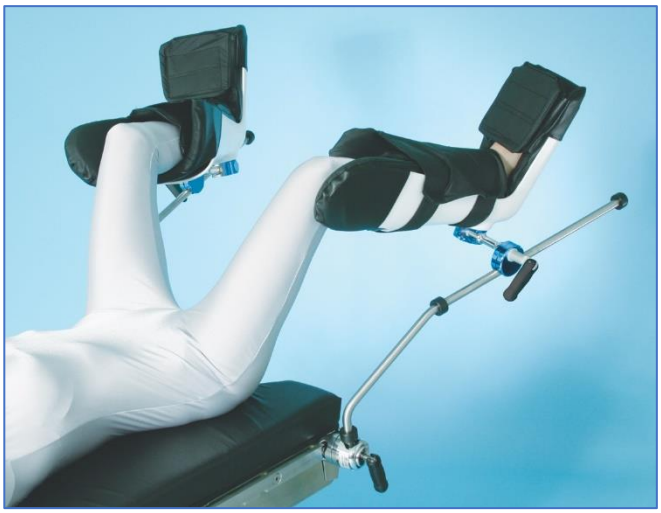
Instructions for Use



REF **Lithotomy Stirrups 800-0049**

Replacement Pads
Platinum Stirrup Boot Pads 508-1415

INTENDED USE

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

INSTRUCTIONS

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

Attaching Stirrups to Surgical Table

1. *Attach Schure Socket Clamps (sold separately) onto table side rails.*
2. *Insert Lithotomy Stirrup mounting posts into clamps. Turn Schure Socket handle clockwise to tighten.*
3. *Put patient's legs into boots and fasten with loop and hook straps.*

Adjusting Stirrups

1. *Turn boot block handles counterclockwise to loosen boot blocks. Adjust up or down to desired position. Turn boot block handle clockwise to tighten.*

Detaching Stirrups from Table

1. *Turn Schure Socket handle counterclockwise to loosen and pull stirrup from socket.*

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

- *Length 39" +/- 0.5" (99 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: 7.5 +/- 0.5 lbs. (3.4 +/- .22 kg)*
- *Attaches to rail of surgical table at any point on the rail*
- *Single-person installation*
- *Push Release Trigger*

COMPONENT OVERVIEW

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

Replacement Pads
508-1415 Platinum Stirrup Boot Pads, Set

Other required products for use:
800-0006 Schure Socket, 2 each (sold separately)

- ***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 1.181" (10 mm x 30 mm) PN# 800-0006-SWISS*

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)*

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 350 lbs. (159 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 with 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 procedure.

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: 081001460F0060E2

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)

CE MD

EC REP **Authorized Representative**
Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands