

Instructions for Use

REF Great White Premium Stirrups 800-0342-PR^{SEP}

REF Great White Premium Stirrups with Fins
800-0342-PRF

Replacement Pads

Premium Stirrup Boot Pads, Set 508-1354

Platinum Stirrup Boot Pads, Set 508-1415

INTENDED USE

Great White Premium Stirrups are a patient positioning accessory used in gynecology, urology, and laparoscopic procedures. They provide a safe system for positioning the legs up to 400 lb. (181 kg) patients in a variety of lithotomy/abduction positions. The intended users of this device are medical professionals within hospitals and surgery centers.

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

- Height: 40.25" +/- 0.5" (102 cm +/- 1 cm)
- Width: 9" +/- 0.5" (23 cm +/- 1 cm)
- Depth: 14" +/- 0.5" (36 cm +/- 1 cm)
- Device Weight Per Stirrup: 11 +/- 0.5 lbs. (5 +/- .22 kg) (with pad)
- Connects to seat section of surgical table
- Single-person installation
- Range of Motion: -30° to 75° lithotomy range, -9° to 25° adduction to abduction
- Store stirrups on transport/storage dolly (P/N 800-0074-S sold separately)

GENERAL INFORMATION

- Product not made with Natural Rubber Latex
- Device supports 400 lb. (181 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
- Life of device is 5 years under normal use
- Store device between -4°F to +86°F (-20°C to 30°C)



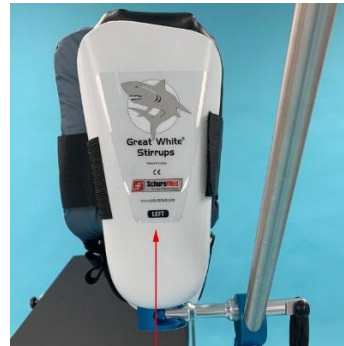
INSTRUCTIONS

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.

INSTRUCTIONS

1. Attach SpringLoc Clamps P/N 800-0338 on accessory rails in same location on opposite sides of surgical table at patient's hip joints.

2. Prior to placing device into SpringLoc Clamp, identify patient's left and right side stirrup indicated on boot label.



3. Insert stirrup blades into clamps. Tighten clamps by turning handle to the right.



4. Ensure patient is positioned on surgical table in accordance with procedure and surgeon requirements.
WARNING!! To prevent patient or operator injury from inadvertent stirrup movement, securely tighten accessory clamp and boot clamp.



Step 5



Step 6



Step 7

(1) Trigger Handle (2) Free Floating Boot Pivot (3) Boot Clamp

5. Support patient's leg by grasping heel in one hand and underside of knee with other hand. Gently flex knees and transfer leg into boot, then secure boot straps.

6. To achieve appropriate leg/foot position, loosen boot clamp. Adjust boot to desired position and re-tighten clamp. Ensure patient's heels are securely seated in boot heels.
7. To achieve appropriate lithotomy and abduction positions, squeeze trigger, adjust to desired position and release to lock.

Note: Free-floating boot is designed to rotate about pivot shown above through-out the full range of motion, reducing risk of superficial nerve injury.

TAKE DOWN

1. Loosen clamps and remove stirrups by lifting them out of clamps
2. Remove accessory clamps from side rails

COMPONENT OVERVIEW

Great White Premium Stirrups and Great White Premium Stirrups with Fins provide a safe system for positioning the legs up to 400 lb. (181 kg) patients in a variety of lithotomy/abduction positions.

Other required products for use:

- 800-0338** SpringLoc Clamp (US)
- 800-0338-EU** SpringLoc Clamp (EU)
- 800-0338-JPN** SpringLoc Clamp (JPN)
- 800-0338-SWISS** SpringLoc Clamp (SWISS)

Replacement Pads:

- 508-1354** Premium Stirrup Boot Pads, Set
- 508-1415** Platinum Stirrup Boot Pads, Set

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 400 lbs. (181 kg). Use care with low-maximum load capacity surgical tables that accessory rails are not overloaded.



WARNING! Hazards result from incorrect use. Strictly follow instructions for use with your Operating Table system.



WARNING! Surgical table load capacities may be less. Never overload a surgical table. Device is intended for mounting on side of a rail of a surgical table only.



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 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: 081001460F0040DU

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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