



Instructions for Use

Great White Robotic Stirrups 800-0342-R

Great White Robotic Stirrups with Fins 800-0342-RF

Replacement Pads

Premium Stirrup Boot Pads, Set 508-1354

Platinum Stirrup Boot Pads, Set 508-1415

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Device Initial Release: 1/25/2017



Manufacturer

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EC REP Authorized Representative

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GENERAL SPECIFICATIONS

Device Dimensions (maximum)

- *Height: 35.25" +/- 0.5" (90 cm +/- 1 cm)*
- *Width: 9" +/- 0.5" (23 cm +/- 1 cm)*
- *Depth: 14" +/- 0.5" (36 cm +/- 1 cm)*
- *Device Weight Per Stirrup: 10 +/- 0.5 lbs. (4.5 +/- .22 kg) (with pad)*
- *Range of Motion: 60° to -55° lithotomy range, -9° to 25° adduction to abduction*
- *Single-person installation*
- *Connects to seat section of surgical table*
- *Store stirrups on transport/storage dolly (P/N 800-0074-R sold separately)*

INTENDED USE

Great White Robotic Stirrups are a patient positioning accessory used in Gynecology, Urology, and laparoscopic procedures. They provide a safe system for positioning the legs up to 600 lb. (272 kg) patients in a variety of lithotomy/abduction positions. These are the only stirrups that have been designed specifically for use in robotic assisted procedures. Stirrups can be lowered approximately 25° lower than conventional stirrups.



800-0342-R



800-0342-RF

GENERAL INFORMATION

- Product not made with Natural Rubber Latex
- Device supports 600 lb. (272 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 $+86^{\circ}\text{F}$ (-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.

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.



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

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 Robotic Stirrups and Great White Robotic Stirrups with Fins provide a safe system for positioning the legs up to 600 lb. (272 kg) patients in a variety of lithotomy/abduction positions.

Other required products for use:

- 800-0338 SpringLoc Clamp
- 800-0338-EU SpringLoc Clamp
- 800-0338-JPN SpringLoc Clamp
- 800-0338-SWISS SpringLoc Clamp

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 600 lbs. (272 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.

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.



IFU-800-0342-R-RF REV 3.04

Basic UDI-DI: 081001460F0040DU

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To View Available Translations

Go to schuremed.com, select product, scroll down and click on "Instructions for Use".