Instructions for Use

REF **Great White HD 1000**
Stirrup Boot System
800-0364

Replacement Boots & Pads

Premium Boots/Pads	**800-0364-BS**
Platinum Boots/Pads	**800-0364-BM**
Maxima Boots/Pads	**800-0364-BL**

Replacement Pads Only

Platinum Stirrup Boot Pads, Set
508-1415

Premium Stirrup Boot Pads, Set
508-1354

Maxima Stirrup Boot Pads, Set
508-1502

INTENDED USE

Great White HD 1000 Stirrups are a patient positioning accessory used in gynecology, urology, and laparoscopic procedures. They provide a safe system for positioning the legs of up to 1,000 lb. (454 kg) patients in a variety of lithotomy/abduction positions. Interchangeable boots allow the user to perform different procedures without switching stirrup. The intended users of this device are medical professionals within hospitals and surgery centers.

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

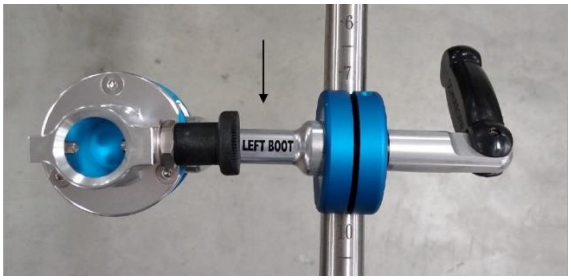
- *Height: 40.25" +/- 0.5" (102 cm +/- 1 cm)*
- *Width: 9" +/- 0.5" (23 cm +/- 1 cm)*
- *Depth: 14" +/- 0.5" (36 cm +/- 1 cm)*
- *Connects to the seat section of the surgical table*
- *Range of Motion: -25° to 75° lithotomy range, -9° to 25° adduction to abduction*
- *Single-person installation*
- *Device Weight Per Stirrup:*
  14.7 +/- 0.5 lbs. (6.7 +/- .22 kg) (with Maxima pads)
  14 +/- 0.5 lbs. (6 +/- .22 kg) (with Platinum pads)
  13.7 +/- 0.5 lbs. (6.2 +/- .22 kg) (with Premium pads)
  10.5 +/- 0.5 lbs. (5 +/- .22 kg) (without Boot)
- *Store stirrups on transport/storage dolly (P/N 800-0074-S sold separately)*

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.

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*

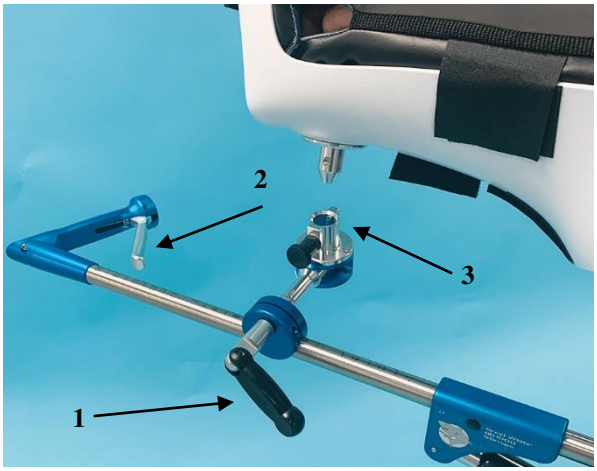
2. *Prior to placing device into SpringLoc Clamp, identify patient's left and right side of stirrup indicated on shaft of boot connector*



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 the accessory clamp and the boot clamp.

5. *Select appropriate boot for procedures. Boot label will identify left or right boot, insert boot into connector (label on Step 2 will identify appropriate connector)*	  
6. *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.*	
7. *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.* 8. *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 to the right through-out full range of motion, reducing risk of superficial nerve injury.*	 *1. Boot Clamp.* *2. Trigger Handle* *3. Free-Floating Boot Pivot*

TAKE DOWN

1. *Remove boot by pulling and holding plunger with one hand, using your other hand support bottom of boot, once supported–lift boot until plug is free from connection. Repeat procedure to remove other boot.*
2. *Loosen clamps and remove stirrups by lifting them out of clamps*
3. *Remove accessory clamps from side rails*

COMPONENT OVERVIEW

Great White HD 1000 Stirrup Boot System provides a safe system for positioning the legs of up to 1,000 lb. (454 kg) patients in a variety of lithotomy/abduction positions.

Replacement Boots & Pads

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800-0364-BM Platinum Boots/Pads
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508-1502 Maxima Stirrup Boot Pads, Set

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)

GENERAL INFORMATION

- *This product is not made with Natural Rubber Latex*
- *This device supports a 1,000 lb. (454 kg) proportional patient load (6'4" (193 cm) tall patient per 99% human body model)*
- *Product warranty covers the product from manufacturing defects for a period of 2 years*
- *If damaged in shipping, please call Customer Service at (888) 724-8763 or (781) 982-7000 to obtain a Return Material Authorization number. For product warranty issues also contact Customer Service.*
- *CE marked medical device according to MDR (EU) 2017/745*
- *Life of device is 5 years under normal use*
- *Storage of device shall be between -4°F to +86°F (-20°C to 30°C)*

DISPOSAL

- *General - Used products or parts may be contaminated. To prevent potential infection, please clean and disinfect the product prior to disposing*
- *Packaging - Packaging material can be disposed of via household waste in accordance with national requirement*
- *SchureMed will take back used product or no longer in service. Product can also be disposed in accordance with national requirement*

PRODUCT USE WARNINGS

WARNING! *Maximum load should not exceed appropriate proportion of a patient weighing 1,000 lbs.* (454 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! *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. The device is intended for mounting on the side of a rail of a surgical table only.*

WARNING! *You should always practice on a nurse, physician or a volunteer prior to use clinically.*

WARNING! *Improper cleaning and disinfection can cause property damage! Perform visual and functional inspections after each cleaning and disinfection process.*

MAINTENANCE

There is no specific maintenance required. Please check stirrups before every procedure to ensure it is operating as designed.

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: 081001460F0075EF

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.
	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)
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CE MD

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