Instructions for Use

REF Great White Maxima Stirrups 800-0342-M

Replacement Pads
Bariatric Stirrup Boot Pads, Set 508-1502

INTENDED USE

Great White Maxima 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 800 lb. (363 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: 40.5" +/- 0.5" (102 cm +/- 1 cm)*
- *Width: 12" +/- 0.5" (31 cm +/- 1 cm)*
- *Depth: 18" +/- 0.5" (46 cm +/- 1 cm)*
- *Device Weight Per Stirrup: 12 +/- 0.5 lbs. (5.4 +/- .22 kg) (with pad)*
- *Range of Motion: -30° to 75° 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-S sold separately)*

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GENERAL INFORMATION

- *Product not made with Natural Rubber Latex*
- *Device supports 800 lb. (363 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)*

IFU-800-0342-M REV 3.03
Latest Revision: 2022-01

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) 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 Maxima Stirrups provide a safe system for positioning the legs of up to 800 lb. (363 kg) patients in a variety of lithotomy/abduction positions.

Replacement Pads

508-1502 Bariatric Stirrup Boot Pads, Set

Other required products for use:

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

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 800 lbs. (363 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. 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.

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.
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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Toll Free (888) 724-8763 | **Ph** (781) 982-7000 | **Fax** (781) 982-7001 | **orders@schuremed.com**

CE MD

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