SchureMed
452 Randolph St, Abington, MA 02351, USA

Great White Stirrups:

Platinum	800-0342-PL	Robotic	800-0342-R 800-0342-RF
Premium	800-0342-PR 800-0342-PRF	Maxima	800-0342-M
HD 1000	800-0364	Pediatric	800-0342-PUPS 800-0342-KIDS

Prior to using this or any other type of medical equipment with a patient, it is recommended that you read the Instructions For Use and familiarize yourself with the product.

- Please read and understand all warnings in this manual and on the device itself before using it with a patient.
- The ⚠ symbol is designed to alert users to important procedures or safety instructions regarding the use of this device.
- The techniques described in this manual are suggestions from the manufacturer. The attending physician retains the final responsibility for patient care with respect to this device.
- Check the device function before each use. Do not use this device if there are obvious signs of damage or functional issues. Consult manufacturer before reusing.
- This device should only be operated by trained personnel.
- All modifications, upgrades, or repairs must be carried out by an authorized specialist.
- Any serious incidents related to the device should be reported to the manufacturer and the national competent authority where the user is located.

NEVER EXCEED THE WEIGHT CAPACITY OR IMPROPERLY DISTRIBUTE THE LOAD ON THE OPERATING ROOM TABLE.

Symbol	Description	Reference
	Manufacturer	EN ISO 15223-1
	Date of manufacture	EN ISO 15223-1
	Authorized Representative in the European Community	EN ISO 15223-1
	Authorized Representative in Switzerland	EN ISO 15223-1
	Authorized Representative in UK	EN ISO 15223-1
	Importer	EN ISO 15223-1
	Serial Number	EN ISO 15223-1
	Warning	IEC 60601-1
	Medical Device	MDR 2017/745
	Unique Device Identifier	EN ISO 15223-1
	CE Marking	MDR 2017/745
	Use-By Date	EN ISO 15223-1
	Batch Code	EN ISO 15223-1
	Manufacturer's Reference Number	EN ISO 15223-1

Indication for Use:

Great White Stirrups are used in a variety of surgical procedures including, but not limited to gynecology, urology, laparoscopy, colorectal, general, and robotic surgery. These devices are capable of being used with a broad patient population as deemed appropriate by medical professionals within hospitals and surgery centers

Intended Use:

Great White Stirrups are a patient positioning accessory used, but are not limited to, gynecology, urology, laparoscopic, general and robotic procedures. They provide a safe system for positioning the legs of patients in a variety of lithotomy/abduction positions. The intended users of these devices are medical professionals within hospitals, Doctors' offices, and surgery centers.

Intended User: Surgeons, Nurses, Doctors, Physicians and/or Healthcare professionals involved in the intended procedure utilizing the device. All staff using or preparing the intended product should be properly trained and familiar with the positioning device before use.

Intended Populations: This device is intended to be used with patients that do not exceed the weight in the safe working load field specified in the product specification section.

Residual Risk:

This product complies with relevant performance, safety standards. However, misuse, device damage, function or mechanical hazards may not be completely excluded. End users are responsible for ensuring device is securely attached and will operate in a safe manner.

Safety Considerations:

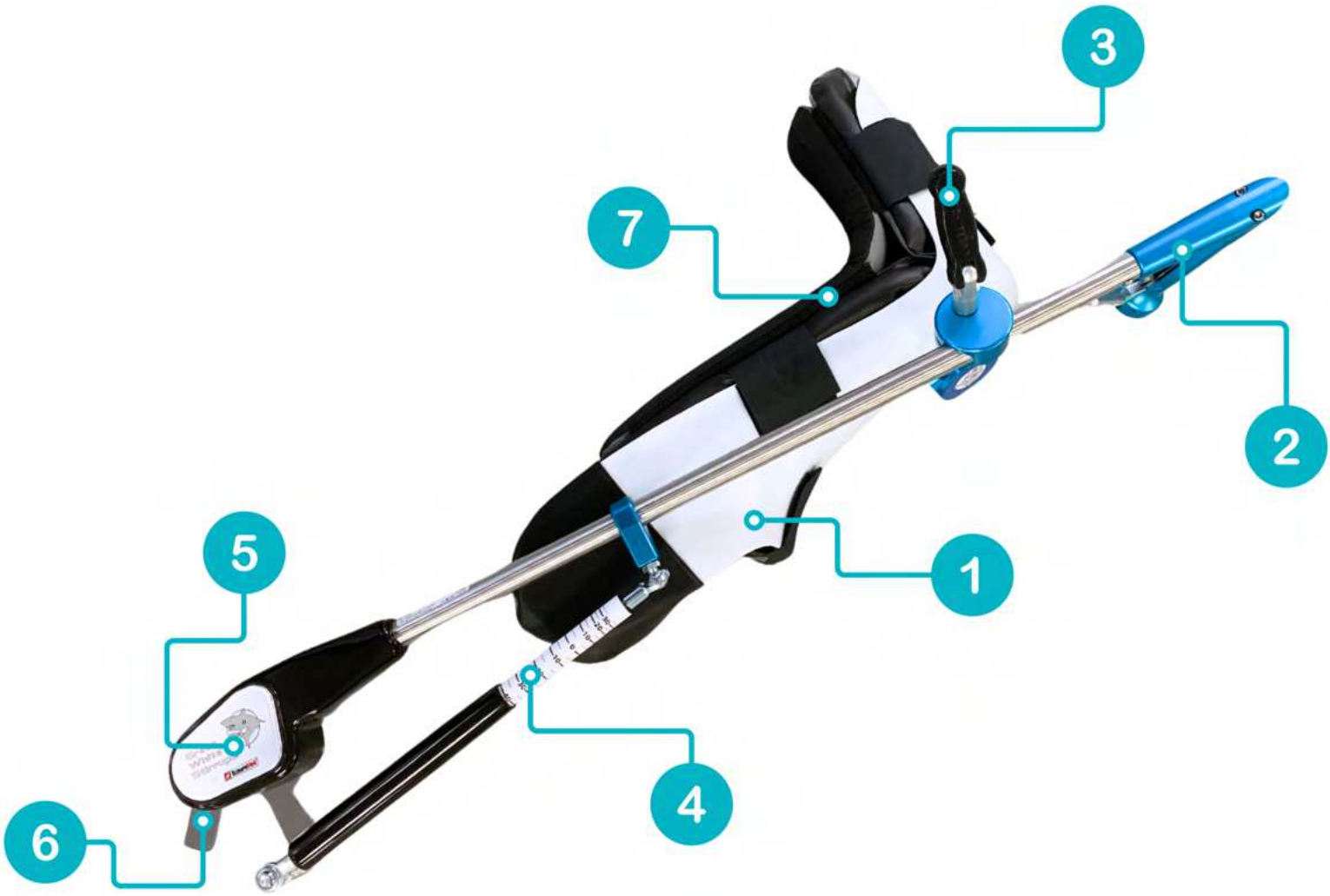
DO NOT USE IF THE PRODUCT SHOWS VISIBLE DAMAGE OR SIGNS OF IMPROPER FUNCTIONING.

Equipment Misuse:

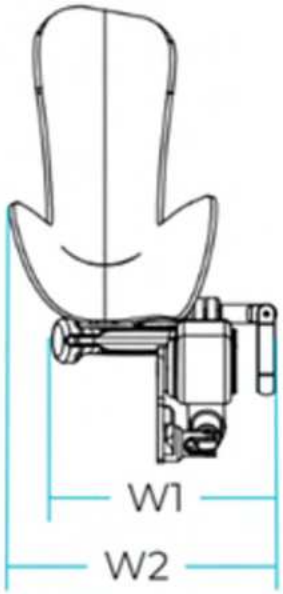
Do not use the product if package is damaged. All modifications, upgrades, or repairs must be performed by a SchureMed authorized specialist.

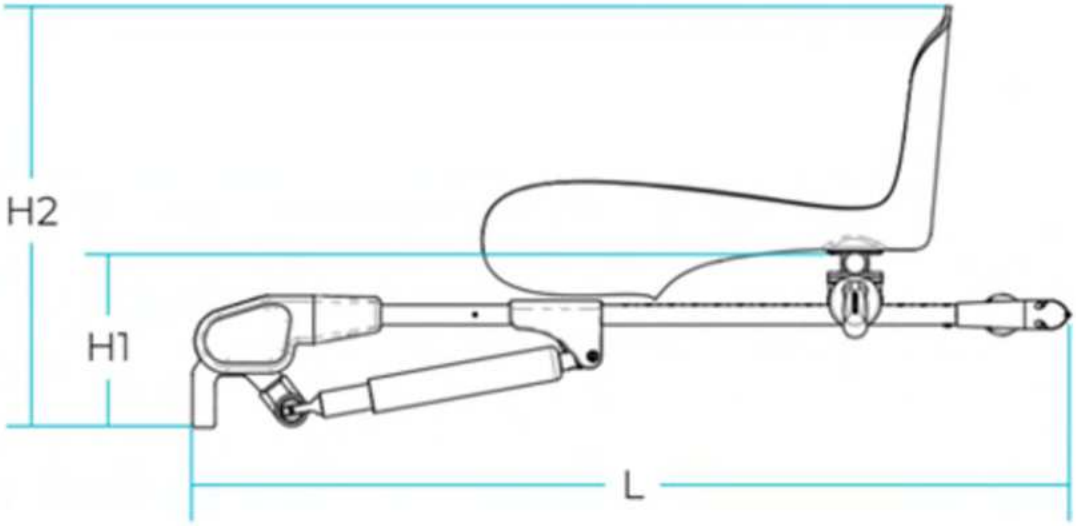
Safe Disposal:

End users should adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories.



1. Boot
2. Lithotomy Adjustment Trigger
3. Boot Control Handle
4. Locking Gas Spring with Lithotomy Indicator
5. Ball Joint
6. Stirrup Blade
7. Boot Pad





Device Dimensions	HD1000	Platinum	Premium	Maxima	Robotic	Pediatric PUPS	Pediatric KIDS
Stirrup Length (L)	38.2" +/- 0.5" (97cm +/- 1cm)	38.2" +/- 0.5" (97cm +/- 1cm)	38.2" +/- 0.5" (97cm +/- 1cm)	38.2" +/- 0.5" (97cm +/- 1cm)	34" +/- 0.5" (86.4cm +/- 1cm)	34" +/- 0.5" (86.4cm +/- 1cm)	34" +/- 0.5" (86.4cm +/- 1cm)
Stirrup Height w/o Boot (H1)	7.9" +/- 0.5" (20cm +/- 1cm)	7.9" +/- 0.5" (20cm +/- 1cm)	7.9" +/- 0.5" (20cm +/- 1cm)	7.9" +/- 0.5" (20cm +/- 1cm)	7.9" +/- 0.5" (20cm +/- 1cm)	7.9" +/- 0.5" (20cm +/- 1cm)	7.9" +/- 0.5" (20cm +/- 1cm)
Stirrup Height w/ Boot (H2)	18.7" +/- 0.5" (47.5cm +/- 1cm)	17.5" +/- 0.5" (44.5cm +/- 1cm)	17.5" +/- 0.5" (44.5cm +/- 1cm)	17.5" +/- 0.5" (44.5cm +/- 1cm)	17.5" +/- 0.5" (44.5cm +/- 1cm)	13.5" +/- 0.5" (34.3cm +/- 1cm)	15" +/- 0.5" (38cm +/- 1cm)
Stirrup Width w/o Boot (W1)	9" +/- 0.5" (22.8cm +/- 1cm)	9" +/- 0.5" (22.8cm +/- 1cm)	9" +/- 0.5" (22.8cm +/- 1cm)	9" +/- 0.5" (22.8cm +/- 1cm)	9" +/- 0.5" (22.8cm +/- 1cm)	9" +/- 0.5" (22.8cm +/- 1cm)	9" +/- 0.5" (22.8cm +/- 1cm)
Stirrup Width w/ Boot (W2)	10.7" +/- 0.5" (27.1cm +/- 1cm)	10.7" +/- 0.5" (27.1cm +/- 1cm)	10.7" +/- 0.5" (27.1cm +/- 1cm)	10.7" +/- 0.5" (27.1cm +/- 1cm)	10.7" +/- 0.5" (27.1cm +/- 1cm)	10.7" +/- 0.5" (27.1cm +/- 1cm)	10.7" +/- 0.5" (27.1cm +/- 1cm)
Device Weight	Range from 21lbs (9.5kg) to 29.4lbs (13.3kg)	22lbs (10kg)	22lbs (10kg)	24lbs (11kg)	20lbs (9kg)	16lbs (7.26kg)	16lbs (7.26kg)
Patient Weight Capacity	1,000lbs (454kg)	600lbs (272kg)	400lbs (181kg)	800lbs (383kg)	600lbs (272kg)	160lbs (73kg)	250lbs (113kg)

Storage Specifications	Description
Storage Temperature	-20° F to 140° F (-29° C to +60° C)
Storage Relative Humidity Range	15% to 85%
Operating Temperature	This device is intended to be used in a controlled Operating Room environment.
Operating Relative Humidity Range	

SchureMed™ Surgical Stirrup Comparison Chart

	PRODUCT	Patient Weight Limit	Protective Fin Design	Lift Mechanism	Lithotomy Adjustment (From Sterile Field)	Lithotomy Range (From Sterile Field)	Abduction Adjustment (From Sterile Field)	Abduction Range (From Sterile Field)	Lithotomy Indicator
	Great White® HD 1000 Stirrups #800-0364	1,000 lbs. (454 kg)	✓	✓	Yes, All Positions In Range	+75°, -25° External Rotation 20°	Yes, All Positions In Range	+25°, -9°	✓ (on rod)
	Great White® Maxima Stirrups #800-0342-M	800 lbs. (363 kg)	✓	✓	Yes, All Positions In Range	+75°, -30° External Rotation 20°	Yes, All Positions In Range	+25°, -9°	✓ (on rod)
	Great White® Platinum Stirrups #800-0342-PL	600 lbs. (272 kg)	✓	✓	Yes, All Positions In Range	+75°, -30° External Rotation 20°	Yes, All Positions In Range	+25°, -9°	✓ (on rod)
	Great White® Robotic Stirrups #800-0342-RF	600 lbs. (272 kg)	✓	✓	Yes, All Positions In Range	+60°, -55° External Rotation 20°	Yes, All Positions In Range	+25°, -9°	✓ (on rod)
	Great White® Premium Stirrups #800-0342-PR	400 lbs. (181 kg)	X	✓	Yes, All Positions In Range	+75°, -30° External Rotation 20°	Yes, All Positions In Range	+25°, -9°	✓ (on rod)
	Lithotomy Stirrups #800-0049	350 lbs. (159 kg)	✓	X	X	N/A	N/A	N/A	N/A
	Candy Cane Stirrups #800-0012	350 lbs. (159 kg)	✓	X	X	N/A	N/A	N/A	N/A
PEDIATRIC	**Pediatric E-Z Lift Stirrups** #800-0342-PUPS #800-0342-KIDS	PUPS: 160 lbs. (73 kg) KIDS: 250 lbs. (113 kg)	X	✓	Yes, All Positions In Range	+75°, -30° External Rotation 20°	Yes, All Positions In Range	+25°, -9°	✓
PEDIATRIC	**Pediatric Lithotomy Stirrups** #800-0233-PUPS #800-0234-KIDS	PUPS: 160 lbs. (73 kg) KIDS: 250 lbs. (113 kg)	X	X	X	N/A	N/A	N/A	N/A

Compatible Product Table:

Accessory Description	Product Number	Compatible Products
Stirrup Clamp	800-0396	800-0364, 800-0342-M, 800-0342-PL, 800-0342-RF, 800-0342-PR, 800-0342-PUPS, 800-0342-KIDS
Wall Rack	800-0284	800-0364, 800-0342-M, 800-0342-PL, 800-0342-RF, 800-0342-PR, 800-0342-PUPS, 800-0342-KIDS
Platinum Boot Pads	508-1415	800-0364, 800-0342-PL, 800-0342-RF
Premium Boot Pads	508-1354	800-0364, 800-0342-RF, 800-0342-PR
Bariatric Boot Pads	508-1502	800-0364, 800-0342-M
PUPS Boot Pads	508-1295	800-0342-PUPS
KIDS Boot Pads	508-1296	800-0342-KIDS
HD1000 Replacement Platinum Boot	800-0364-PL	800-0364
HD1000 Replacement Premium Boot	800-0364-PR	800-0364
HD1000 Replacement Bariatric Boot	800-0364-M	800-0364

System Setup:

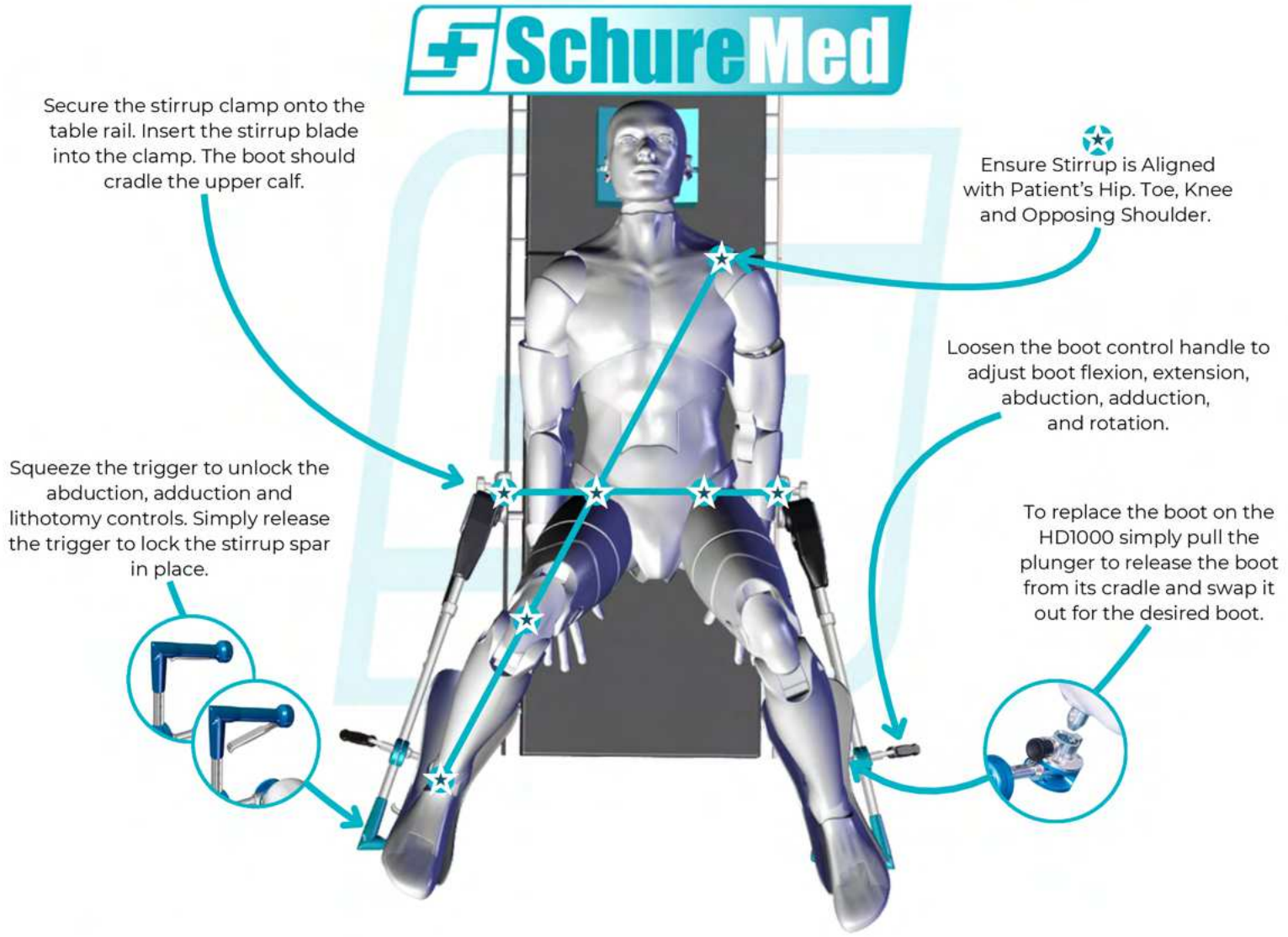
1. Prior to placing the Stirrups on the table, the patient should be examined and assessed for any pre-existing conditions that might prohibit the safe use of lithotomy positioning equipment.
2. Drop the Stirrup Clamps P/N 800-0396 on accessory rails in same location on opposite sides of surgical table at patient's hip joints.
3. Prior to placing device into Stirrup Clamp, identify patient's left and right side stirrup indicated on boot label. The longer lateral fin of each stirrup boot should be positioned on the lateral side of the patient leg.
4. Insert the blade of the stirrup fully into the table clamp. Tighten the clamp by turning the knob clockwise. Ensure the stirrup is securely fastened and does not come out of the clamp or off the rail before use.
5. Loosen the boot adjustment clamp, to slide boot along support rod until the calf portion of the boot is located near the patient's calf. Tighten the boot adjustment clamp on the boot securely such that boot cannot be moved up or down the spar. Repeat for the opposite stirrup.
6. Position stirrups to be level with the table by turning the handle while moving the stirrups into place.

To prevent patient or operator injury from inadvertent stirrup movement, securely tighten accessory clamp and boot clamp.

Positioning the Patient:

1. 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.
2. 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.
3. To achieve appropriate lithotomy and abduction positions, squeeze trigger, adjust to desired position and release to lock.
4. Ensure patient is positioned on surgical table in accordance with procedure and surgeon requirements.

Additional positioning devices should be used when using the stirrup in Trendelenburg or reverse Trendelenburg



Device Removal:

1. Loosen clamps and remove stirrups by lifting them out of the clamps.
2. Remove stirrup clamps from side rails.
3. If available, place stirrups and clamps on the storage cart or storage shelf to prevent damage.

Device Maintenance:

1. Make sure that all labels can be read. Replace labels as necessary. Use an alcohol wipe to remove any adhesive residue.
2. Contact SchureMed or an authorized SchureMed Certified Distributor if you need to repair or replace the device.

Cleaning and Disinfection:

- **Clean the device after each use as directed.**
- **Do not submerge the device in liquid.**
- **Use caution in areas where liquid can get into the mechanism.**
- **Position the stirrup parallel to the floor when cleaning to prevent fluids from migrating into product mechanics.**
- **Do not clean the device with bleach or products that contain bleach.**

Wipes:

- Do not use wipes that contain greater than 2% sodium hypochlorite.
- Wipes may contain benzalkonium chloride (up to 0.6% conc.), didecyl dimethyl ammonium chloride (up to 0.6% conc.) and may also contain polyhexamethylene biguanide (up to 0.6% conc.).

Sprays:

When using a spray do not spray the device directly. Spray a clean cloth then wipe the device to clean.

- Sprays may contain up to 2% sodium hypochlorite.
- Sprays may contain up to .2% benzalkonium chloride and up to 0.2% didecyl dimethyl ammonium chloride (quaternary ammonium chloride solution (QACs) and may also contain polyhexamethylene biguanide (up to 0.6% conc.).
- Sprays may contain up to 2% hydrogen peroxide.

Read the cleaning product's directions and follow the instructions on the label. Use caution in areas where fluid migration may occur.

Wipe device with a clean, dry cloth. Be sure that the product is dry prior to reinstalling and storage to avoid damage.

CAUTION: Damage may result if product is cleaned with caustic chemicals or harsh abrasives

ATTENTION: If any SchureMed product is damaged or does not function normally, discontinue use and contact SchureMed or an authorized SchureMed Certified Distributor.

Compliance with Medical Device Regulations

CE

These products are non-invasive, Class I Medical Devices and are CE-marked according to AnnexVIII, Rule 1, of the Medical Device Regulations (REGULATION (EU) 2017/745).

EC Authorized Representative

EC REP

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