SchureMed

452 Randolph St, Abington, MA 02351, USA

STEALTH

SCHUREMED ORTHOPAEDICS

Stealth Armboard	800-0406
Stealth-Steris	800-0406-ST

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 Union	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:

The Stealth is used in a variety of surgical procedures. This device is capable of being used with a broad patient population as deemed appropriate by medical professionals within hospitals and surgery centers

Intended Use:

The intended use of the Stealth is to position a patient's arm during surgical procedures.

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 a 500 lb. (227kg) proportional patient load (6'4" (193 cm) tall patient per 99% human body model).

Residual Risk:

This product complies with relevant performance, safety standards. However, misuse, device damage, function or mechanical hazards cannot 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.

System Setup:

1. Prior to placing the Stealth on the table, the patient should be examined and assessed for any pre-existing conditions that might prohibit the safe use of the equipment.
2. Drop the SchureSocket XL P/N 800-0134 on accessory rail.
3. Insert the bar of the Stealth into the SchureSocket XL and adjust to the desired height. Tighten the clamp by turning the knob clockwise. Ensure the Stealth is securely fastened and does not come out of the clamp or off the rail before use.
4. Lightly pull the trigger and adjust the tilt and pitch of the armboard.

To prevent patient or operator injury from inadvertent device movement, securely tighten accessory clamp.

Positioning the Patient:

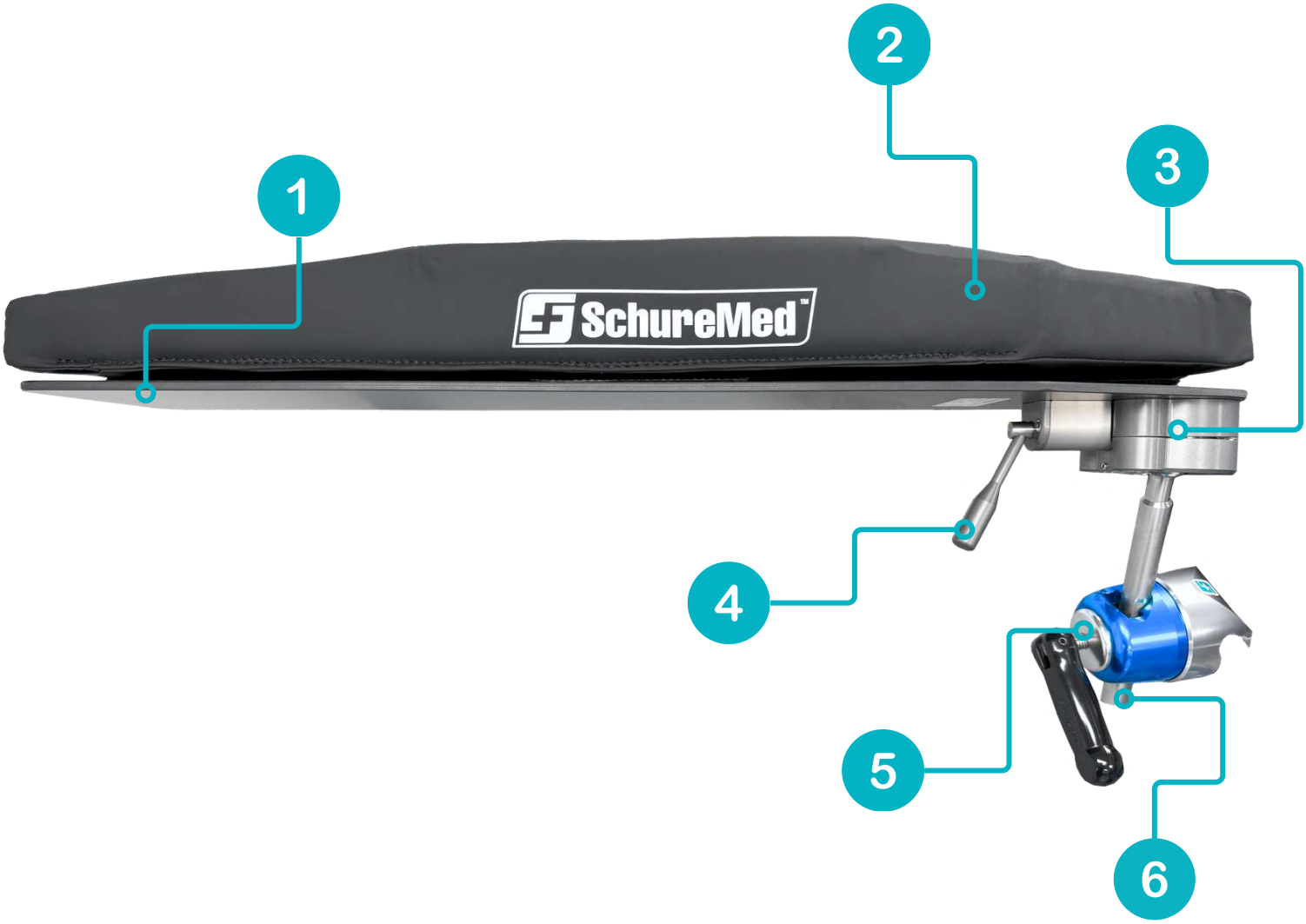
1. Gently position that patients arm onto the armboard, then secure their arm to the armboard using SchureStrap.
2. To achieve appropriate height position, loosen the SchureSocket XL. Adjust the height of the armboard to desired position and re-tighten clamp.
3. To achieve appropriate position, pull the trigger, adjust to desired position and release to lock.
4. Ensure patient is positioned on surgical table in accordance with procedure and surgeon requirements.

Device Removal:

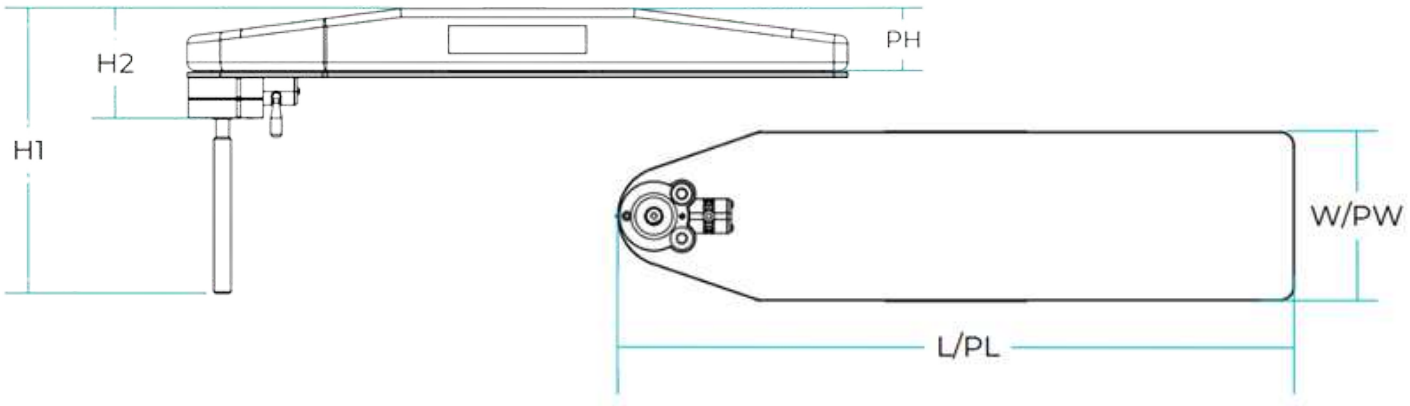
1. Loosen clamp and remove the armboard by sliding the bar out of the clamp.
2. Remove clamp from side rail.
3. If available, place armboard and clamp on a storage cart or storage shelf to prevent damage.

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.



1. Radiolucent Carbon Fiber Armboard Platform
2. Contoured Ergonomic Pad
3. Ball joint housing
4. Ball Joint Release Trigger
5. SchureSocket XL
6. Height Adjustment Bar



Device Dimensions	STEALTH (800-0406)
Height Extended (H1)	10.3” +/-0.5” (26.2cm +/- 1cm)
Height/ w/o Extension	4” +/-0.5” (2.5cm +/- 1cm)
Width / Pad Width (W/PW)	6” +/-0.5” (15.2cm +/- 1cm)
Length / Pad Length (L/PL)	24” +/-0.5” (61cm +/- 1cm)
Pad Height (PH)	2.25” +/-0.5” (5.7cm +/- 1cm)

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	

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 armboard 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

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).

EU Authorized Representative

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Manufacturing Information

SchureMed
452 Randolph Street,
Abington, MA 02351 USA
Toll Free (888) 724-8763
Ph (781) 982-7000
orders@schuremed.com

UK Authorized Representative

Emergo Consulting (UK) Limited
Compass House, Vision Park Histon
c/o Cr360 - UL International
Cambridge CB24 9BZ
England, United Kingdom

EU & Swiss Importer

MedEnvoy Global B.V.
Prinses Margrietplantsoen
33 - Suite 123
2595 AM The Hague
The Netherlands

CH Authorized Representative

MedEnvoy Switzerland AG
Gotthardstrasse 28
6302 Zug
Switzerland