SchureMed

452 Randolph St, Abington, MA 02351, USA

ÓTIMO

Otimo	800-0398
Otimo Extended	800-0398-EX

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
EC REP	Authorized Representative in the European Community	EN ISO 15223-1
CH REP	Authorized Representative in Switzerland	EN ISO 15223-1
UK REP	Authorized Representative in UK	EN ISO 15223-1
	Importer	EN ISO 15223-1
SN	Serial Number	EN ISO 15223-1
	Warning	IEC 60601-1
MD	Medical Device	MDR 2017/745
UDI	Unique Device Identifier	EN ISO 15223-1
CE	CE Marking	MDR 2017/745
	Use-By Date	EN ISO 15223-1
LOT	Batch Code	EN ISO 15223-1
REF	Manufacturer's Reference Number	EN ISO 15223-1

Indication for Use:

The Ótimo is used in a variety of surgical procedures. 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:

The intended use of the Ótimo is to position a patient's arm during surgical procedures. The intended users of this device are medical professionals within hospitals 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 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 Ótimo 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. Place the Ótimo on the accessory rail and tighten the integrated rail clamp.
3. For the Ótimo Extended, drop the SchureSocket XL P/N 800-0134 on accessory rail. Slide the bar into the SchureSocket XL and adjust to the desired height. Tighten the clamp by turning the knob clockwise. Ensure the Ótimo is securely fastened and does not come out of the clamp or off the rail before use.
4. Hold the articulating arm with one hand while you turn the knob counter clockwise to release the joints and adjust the Ótimo to the desired position.
5. Once the Ótimo is in the desired position, turn the knob clockwise to lock the joints in place.

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 Ótimo, then secure their arm to the Ótimo using SchureStrap.
2. To achieve appropriate height position with the Ótimo Extended, loosen the SchureSocket XL. Adjust the height of the Ótimo to desired position and re-tighten clamp.
3. To achieve appropriate position, loosen the knob, adjust to desired position and tighten the knob.
4. Ensure patient is positioned on surgical table in accordance with procedure and surgeon requirements.

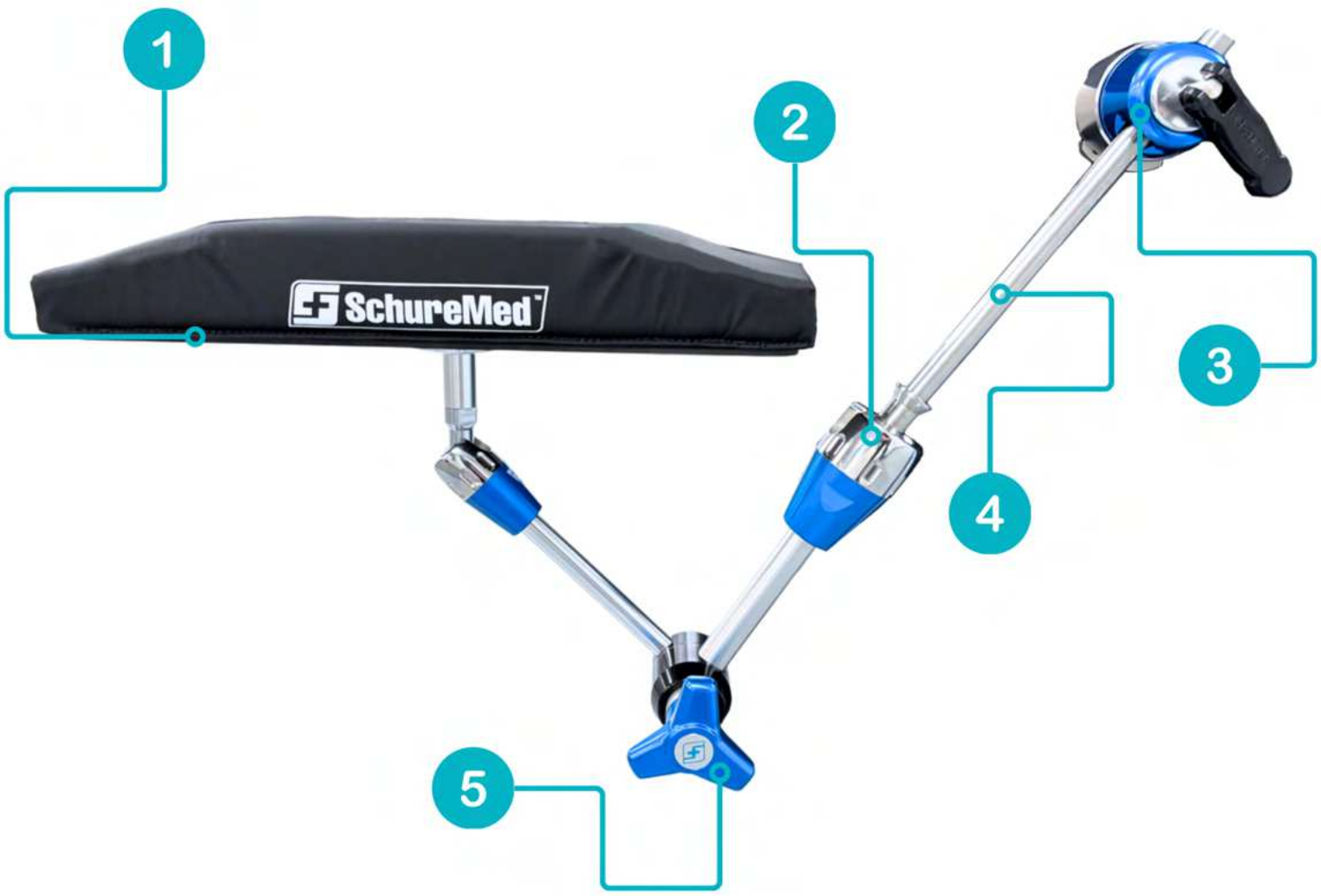
Device Removal:

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

Device Maintenance:

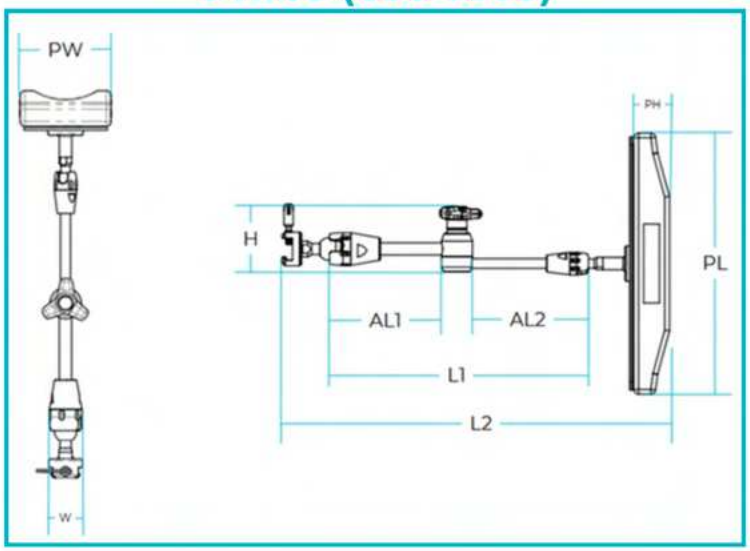
1. Make sure that all labels can be read. Replace labels as necessary. Use an alcohol wipe to remove any adhesive residue.
2. Contact SchureMed or an authorized SchureMed Certified Distributor if you need to repair or replace the device.

1. Radiolucent Carbon Fiber Armboard Platform
2. Ball joint housing
3. Ball Joint Release Knob
4. Integrated Rail Clamp

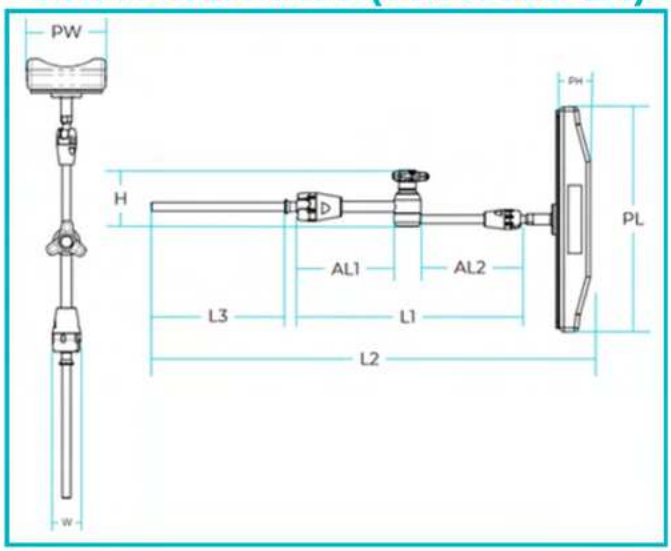


1. Radiolucent Carbon Fiber Armboard Platform
2. Ball joint housing
3. SchureSocket XL
4. Height Adjustment Bar
5. Ball Joint Release Knob

ÓTIMO (800-0398)



ÓTIMO Extended (800-0398-EX)



Device Dimensions	ÓTIMO (800-0398)	ÓTIMO Extended (800-0398-EX)
Combined Arm Length (L1)	16.4" +/- 0.5" (41.7cm +/- 1cm)	16.4" +/-0.5" (41.7cm +/- 1cm)
Total Length (L2)	24.5" +/- 0.5" (62.2cm +/- 1cm)	32.2" +/-0.5" (81.8cm +/- 1cm)
Extender Length (L3)	N/A	9.8" +/-0.5" (24.9cm +/- 1cm)
Arm 1 Length (AL1)	7.1" +/- 0.5" (18cm +/- 1cm)	7.1" +/-0.5" (18cm +/- 1cm)
Arm 2 Length (AL2)	7.2" +/- 0.5" (18cm +/- 1cm)	7.2" +/-0.5" (18cm +/- 1cm)
Height (H)	4.1" +/- 0.5" (10.4cm +/- 1cm)	4.1" +/-0.5" (10.4cm +/- 1cm)
Width (W)	2" +/- 0.5" (5cm +/- 1cm)	2" +/-0.5" (5cm +/- 1cm)
Pad Length (PL)	16.5" +/- 0.5" (41.9cm +/- 1cm)	16.5" +/-0.5" (41.9cm +/- 1cm)
Pad Height (PH)	2.25" +/- 0.5" (5.7cm +/- 1cm)	2.25" +/-0.5" (5.7cm +/- 1cm)
Pad Width (PW)	5.75" +/- 0.5" (14.6cm +/- 1cm)	5.75" +/-0.5" (14.6cm +/- 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

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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Manufacturing Information

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UK REP

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CH Authorized Representative

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