

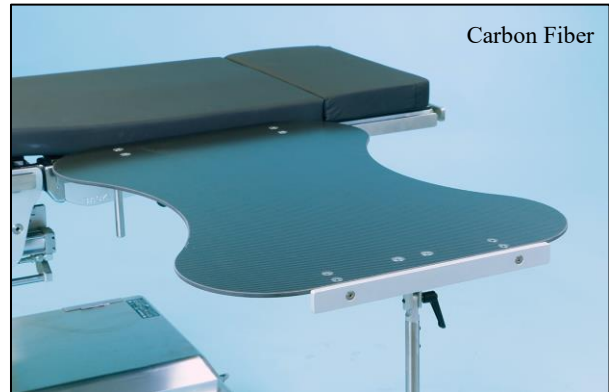


Instructions for Use

REF Hourglass Procedure Table w/Leg,
Phenolic 800-0026-HG-P

REF Hourglass Procedure Table w/Leg,
Carbon Fiber 800-0026-HG-CF

Replacement Pad
Hourglass Deluxe Foam Pad 508-0106



INTENDED USE

Its function is to hold a patient's arm during surgery. The intended users of this device are medical professionals within hospitals and surgery centers.

GENERAL SPECIFICATIONS

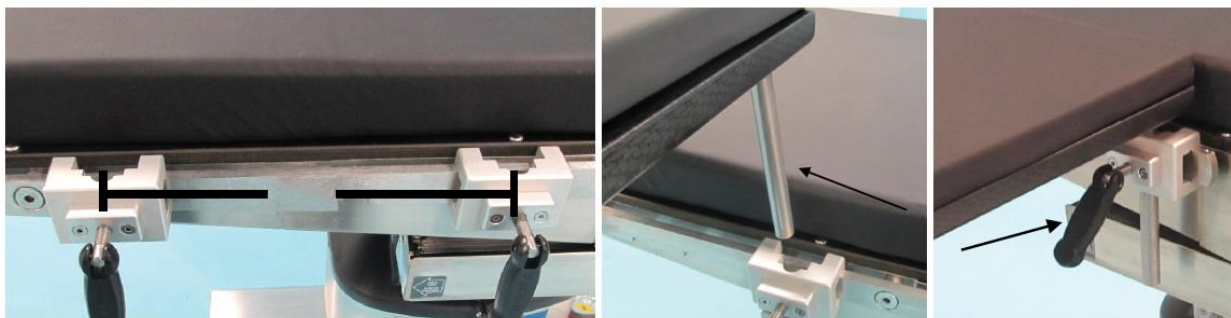
Device Dimensions (maximum)

- Length: 32" +/- 0.5" (81 cm +/- 1 cm)
- Width: 15" +/- 0.5" Middle (38 cm +/- 1 cm)
- Width: 23" +/- 0.5" Ends (58 cm +/- 1 cm)
- Depth: 23" +/- 0.5" (58 cm +/- 1 cm)
- Phenolic Device Weight: 18 +/- 0.5 lbs. (8.1 +/- .22 kg)
- Carbon Fiber Device Weight: 15 +/- 0.5 lbs. (6.8 +/- .22 kg)
- Attaches to rail of surgical table at any point on the rail using two rail clamps
- Single-person installation
- Clean with hospital grade disinfectant

INSTRUCTIONS FOR USE

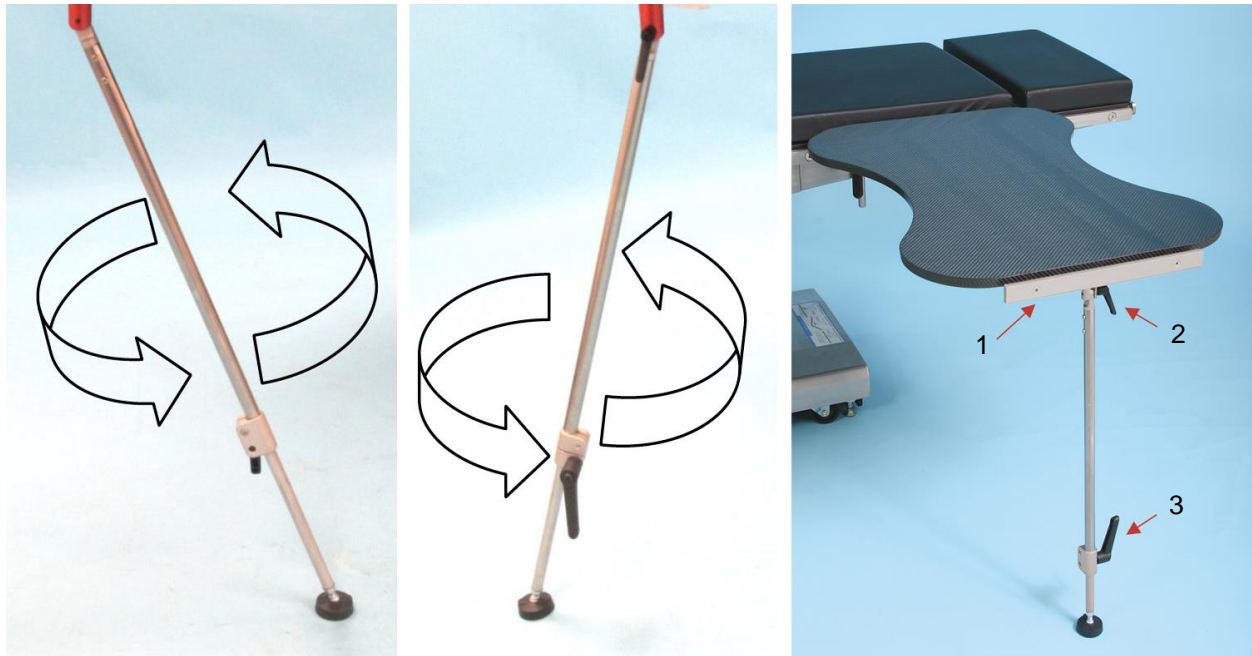
Become familiar with the features of patient positioning device before use with a patient. Always practice use on a nurse, physician or appropriate volunteer prior to using clinically.

Attaching Procedure Table to Surgical Table



1. Attach clamps (sold separately) to side rail and place them approximately 1' (31 cm) apart (as shown)
2. Insert mounting rods into clamps
3. Adjust procedure table so that it is level with surgical table pad. Secure table to accessory rail using clamp locking knobs
4. Includes 1" (3 cm) pressure management pad

Adjusting Table Leg



(1) End Rail • (2) Adjustable Swivel Leg Locking Handle • (3) Adjustable Height Locking Handle

1. Swivel leg in 360° to obtain unlimited C-arm axis (See above)
2. Loosen Adjustable Leg Handle (3) and extend leg until it sits firmly against floor then lock handle tight by turning it to the right
3. End rail accommodates traction attachments

COMPONENT OVERVIEW

Hourglass Procedure Table w/Leg, Phenolic or Carbon Fiber, are surgical table extensions that attach to all rails.

Replacement Pad

508-0106 Hourglass Deluxe Foam Pad

Two Clamps Required: Choose Universal Clamp for US or Deluxe Rail Clamp for Outside US

US – Universal Rail Clamp

- US: 0.374" x 1.122" (9.5 mm x 28.5 mm) PN# 800-0085

Outside US – Deluxe Rail Clamp

- Denyer: 0.236" x 1.496" (6 mm x 38 mm) PN# 800-0248-DEN
- Europe: 0.394" x 0.984" (10 mm x 25 mm) PN# 800-0248-EU
- Eschmann (UK): 0.236" x 1.260" (6 mm x 32 mm) PN# 800-0248-UK

- *Japan: 0.354" x 1.260" (9 mm x 32 mm) PN# 800-0248-JPN*
- *Swiss: 0.394" x 1.181" (10 mm x 30 mm) PN# 800-0248-SWISS*

GENERAL INFORMATION

- *Product not made with Natural Rubber Latex*
- *Device supports 500 lb. (227 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*
- *Product is maintenance-free, check product condition before next use*
- *Life of device is 5 years under normal use*
- *Store device between -4°F to +86°F (-20°C to 30°C)*

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 500 lbs. (227 kg). Use care with low-maximum load capacity surgical tables that accessory rails are not overloaded.



WARNING!

Hazard resulting 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!

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

CLEANING RECOMMENDATION

Follow current Association of periOperative Registered Nurses Journal Guidelines for proper cleaning and disinfection procedures.

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: 800-0026-HG-P – 081005737F0022KP

UDI Basic UDI-DI: 800-0026-HG-CF – 081005737F0023KR

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.
	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.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue or Item Number	Indicates the manufacturer's catalogue or item number so that the medical device can be identified.
	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.
	Medical Device	Indicates the item is a medical device.
	Unique Device Identifier	Indicates a barcode as containing unique device identifier information.
	CE Marking	European Conformity.
	Single Patient Use	Indicates the item is a single patient use medical device.



Manufacturer

SchureMed (081001460)

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Authorized Representative

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