

Instructions for Use

REF Lateral Positioners 800-0043

REF Lateral Braces 800-0042

Replacement Pad

Lateral Positioner Pad 508-0156

Lateral Brace Round Pad 508-0115

Lateral Brace Rectangle Pad 508-0116

INTENDED USE

Intended use is to provide secure and comfortable positioning for total hip replacement and any other procedure requiring total lateral stability. The intended users of this device are medical professionals within hospitals and surgery centers.

INSTRUCTIONS

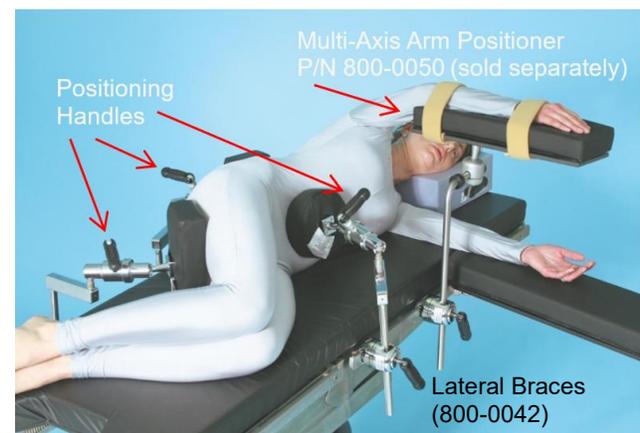
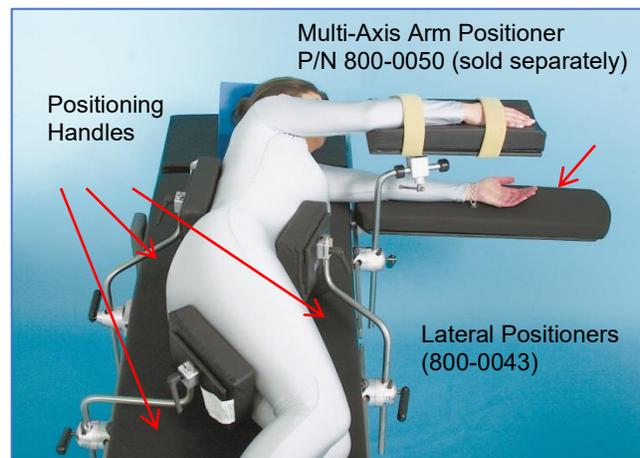
Become familiar with patient positioning device's features before use with patient. Always practice use on a nurse, physician or appropriate volunteer prior to using clinically.

Set Up and Use of Lateral Braces or Positioners

1. Insert three (3) mounting posts into clamps and turn clamp handles clockwise to tighten
2. Insert two (2) pads on patient back side and one (1) pad on patient front side and tighten positioning handles
3. With patient on table, unlock positioning handles, move to desired positions and tighten to lock
4. To position in lateral, prone, neuro and park bench positions, adjust the Schure Socket XL P/N 800-0134 (sold separately)

Detaching Lateral Braces or Positioners from Surgical Table

1. Turn positioning handles counterclockwise to loosen each lateral brace
2. Remove from clamps



GENERAL SPECIFICATIONS

Lateral Positioners (800-0043) Dimensions (maximum):

- *Length per Positioner: 13.12" +/- 0.5" (33 cm x 1 cm)*
- *Width per Positioner: 5.17" +/- 0.5" (13 cm +/- 1 cm)*
- *Height per Positioner: 20.59" +/- 0.5" (52 cm +/- 1 cm)*
- *Device Weight per Positioner: 3 +/- 0.5 lbs. (1.36 +/- .22 kg)*
- *5/8" (1.56 cm) diameter mounting post inserts into socket*
- *Single-person installation*

Lateral Braces (800-0042) Dimensions (maximum):

- *Length Brace-Rectangle & Circle: 14.5 +/- 0.5" (37 cm +/- 1 cm)*
- *Width per Brace-Rectangle & Circle: 9.56" +/- 0.5" (24 cm +/- 1 cm)*
- *Height per Brace-Rectangle & Circle: 21.75" +/- 0.5" (55 cm x 1 cm)*
- *Device Weight per Brace: 12 +/- 0.5 lbs. (5.4 +/- .22 kg)*
- *5/8" (1.56 cm) diameter mounting post inserts into socket*
- *Single-person installation*

COMPONENT OVERVIEW

Lateral Braces and Positioners are surgical table accessories which provide secure and comfortable positioning for total hip replacement and any other procedure requiring total lateral stability.

Replacement Pads:

508-0156 Lateral Positioner Pad

508-0115 Lateral Brace Round Replacement Pad

508-0116 Lateral Brace Rectangle Replacement Pad

Other required product for use: 800-0134 Schure Socket XL (sold separately)

US: 0.374" x 1.122" (9.5 mm x 28.5 mm) PN# 800-0134

Denyer: 0.236" x 1.496" (6 mm x 38 mm) PN# 800-0134-DEN

Europe: 0.394" x 0.984" (10 mm x 25 mm) PN# 800-0134-EU

Eschmann (UK): 0.236" x 1.260" (6 mm x 32 mm) PN# 800-0134-UK

Japan: 0.354" x 1.260" (9 mm x 32 mm) PN# 800-0134-JPN

Swiss: 0.394" x 1.181" (10 mm x 30 mm) PN# 800-0134-SWISS

GENERAL INFORMATION

- *Product not made with Natural Rubber Latex*
- *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!

Hazards result from incorrect use. Strictly follow Instructions for Use for your Operating Table system.



WARNING!

Do not reuse device if there are obvious signs of damage or functional issues. Consult manufacturer before reusing.

CLEANING RECOMMENDATION

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



WARNING!

Adhere to standards for blood-borne pathogens from 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.

eIFU Language Versions

To download and print the Instructions for Use, please go to www.schuremed.com

Symbol Glossary

Symbol	Title
	Manufacturer
	Date of manufacture
	Authorized Representative in the European Community
	Authorized Representative in the Swiss
	Importer

REF	Catalogue Number
SN	Serial Number
	Warning
MD	Medical Device
UDI	Unique Device Identifier
	CE Marking
	Single Patient Use



SchureMed (081001460)

452 Randolph Street, Abington, MA 02351 USA

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

