Instructions for Use

REF **Lateral Braces 800-0042**

Replacement Pads
Lateral Brace Round Pad 508-0115
Lateral Brace Rectangle Pad 508-0116

INTENDED USE

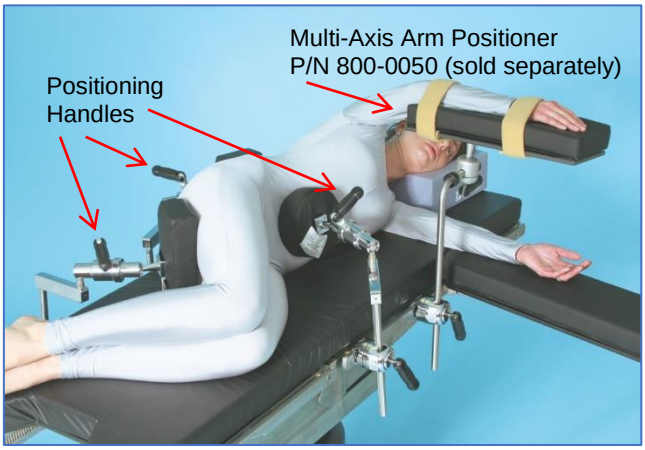
Intended use is to provide secure and comfortable positioning for total hip replacement and any other procedure requiring total lateral stability. The intended users of this device are medical professionals within hospitals and surgery centers.

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

1. *Insert three (3) mounting posts into clamps and turn clamp handles clockwise to tighten*
2. *Insert two (2) rectangular pads on patient back side and one (1) round 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 from Surgical Table

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

GENERAL SPECIFICATIONS

Device Dimensions (maximum):

- *Length per Brace-Rectangle & Circle: 23" +/- 0.5" (58 cm x 1 cm)*
- *Width per Rectangle Brace: 9.5" +/- 0.5" (24 cm +/- 1 cm)*
- *Width per Circle Brace: 7" +/- 0.5" (18 cm +/- 1 cm)*
- *Depth per Brace: 8" +/- 0.5" (20 cm +/- 1 cm)*

- *Device Weight per Brace: 3.6 +/- 0.5 lbs. (2 +/- .22 kg)*
- *5/8" (1.56 cm) diameter mounting post inserts into socket*
- *Single-person installation*

COMPONENT OVERVIEW
Lateral Braces are a surgical table accessory which provides secure and comfortable positioning for total hip replacement and any other procedure requiring total lateral stability.

Replacement Pads:
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*
- *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.*
- *Product is maintenance-free, check product condition before next use*
- *CE marked medical device according to MDR (EU) 2017/745*
- *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!
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.

UDI Basic UDI-DI: 081001460F0058EF

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

Manufacturer
SchureMed (081001460)
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Toll Free (888) 724-8763 | **Ph** (781) 982-7000 | **Fax** (781) 982-7001 | **orders@schuremed.com**

CE MD

EC REP **Authorized Representative**
Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands