



Instructions for Use

REF Lateral Braces 800-0042

Replacement Pads

Lateral Brace Round Pad 508-0115

Lateral Brace Rectangle Pad 508-0116

INTENDED USE

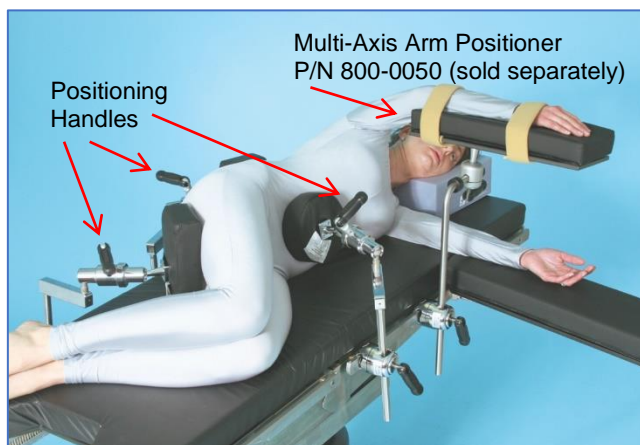
Intended use is to provide secure and comfortable positioning for total hip replacement and any other procedure requiring total lateral stability. The intended users of this device are medical professionals within hospitals and surgery centers.

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.




Basic UDI-DI: 081001460F0058EF

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)

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