Instructions for Use

REF Knee Crutches 800-0041

Replacement Pads
Knee Crutch Pads 508-0154

INTENDED USE

Intended use is to hold patient's legs during short or long gynecologic, urological or laparoscopic procedures. The intended users of this device are medical professionals within hospitals and surgery centers.

GENERAL INFORMATION

- *Product not made with Natural Rubber Latex*
- *Device supports 350 lb. (159 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)*

INSTRUCTIONS

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

Attaching Knee Crutches to Surgical Table

1. *Place patient on surgical table.*
2. *Place Schure Socket XL clamps P/N 800-0134 (sold separately) onto surgical table side rails adjacent to patient hips.*
3. *Put mounting post into clamps and turn clamp handles clockwise to tighten.*

Adjusting Knee Crutches

1. *Adjust vertically from 12" (31 cm) to 19" (48 cm) and have a floating brace to provide precise positioning. Adjust height and lock by turning adjustment to the right.*
2. *Lock Knee Crutch by twisting ergonomic handle.*

Detaching Knee Crutches from Surgical Table

1. *Turn Schure Socket XL handle counterclockwise to loosen and remove stirrup from socket.*

GENERAL SPECIFICATIONS
Device Dimensions (maximum)

- *Extended Length: 44" +/- .5 (112 cm +/- 1 cm)*
- *Extended Collapsed: 28" +/- .5" (71 cm +/- 1 cm)*
- *Width: 17" +/- .5" (43 cm +/- 1 cm)*
- *Depth: 10.5" +/- .5" (27 cm +/- 1 cm)*
- *Device Weight Per Stirrup: 5 +/- 0.5 lbs. (2.2 +/- .22 kg)*
- *Connects to surgical table side rails*
- *Single-person installation*
- *Knee Crutches has 5/8" (1.6 cm) mounting post which attaches with 800-0134 Schure Socket XL (sold separately)*

COMPONENT OVERVIEW
Knee Crutches are a surgical leg holding device that attaches to surgical table side rails with Schure Socket XL clamps. Device may be used primarily for urology, GYN and GYN laparoscopy as well as for procedures requiring dual site exposures.

Replacement Pads
508-0154 Knee Crutch Pads, pr

Other required products for use: 800-0134 Schure Socket XL, 2 each (sold separately)

See side rail dimensions below:
***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*

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 350 lbs. (159 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 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!
Surgical table load capacities may be less. Never overload surgical table. Device is intended for mounting on surgical table side rail only.

WARNING! *Do not raise thigh closer to torso than 90° as patient may experience nerve damage.*

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 the 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: 081001460F0057ED

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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CE MD

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