BI-LATERAL PREPPER DSC-800-0236

Equipment Purpose

Intended use is to hold lower extremities during prepping procedure. 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 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)*

INSTRUCTIONS

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

Attaching Bi-Lateral Prepper to Surgical Table

1. *Attach Schure Socket XL P/N 800-0134 (sold separately) onto side rail*
2. *Insert mounting post into socket and lock tight*
3. *Unlock horseshoe cradles by turning handles counterclockwise and move to desired positions, turn handle clockwise to lock*

Detaching Bi-Lateral Prepper from Surgical Table

1. *Turn clamp handle counterclockwise to loosen and remove*

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

- *Length: 19" +/- 0.5" (48 cm +/- 1 cm) (between stops)*
- *Height: 34" +/- 0.5" (86 cm +/- 1 cm)*
- *Width: 4" +/- 0.5" (10 cm +/- 1 cm) (horseshoe cradle pads)*
- *Device Weight: 8.5 +/- 0.5 lbs. (3.8 +/- .22 kg)*
- *5/8" (1.6 cm) diameter mounting post insert into socket*
- *Single-person installation*
- *Twist lock/Release Handle*

COMPONENT OVERVIEW

Bi-Lateral Prepper is a surgical table accessory that is used to hold lower extremities during prepping procedure.

Replacement Pad
508-0159 Universal Prepper 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*

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!
Surgical table load capacities may be less. Never overload a surgical table. The device is intended for mounting on the side of a rail of a surgical table only.

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.

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.