

# **Instructions for Use**

REF

Patient Restraint Strap, 96"L 800-0057

REF

**Bariatric Restraint Straps with Pad 800-0119** 

Accessory (sold separately)
Restraint Strap Mounting Hook 512-0039

### **INTENDED USE**

Intended use is to stabilize patient positioning for various surgical procedures on operating room table. The intended users of this device are medical professionals within hospitals and surgery centers.

### **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.

## Attachment and Set Up

- 1. Place pad over patient's abdomen area.
- 2. Place strap(s) over pad and secure to surgical table side rails by looping them around side rails or by using Mounting Hooks (sold separately).
- 3. If mounting hooks are used, simply loop straps through mounting hook(s.)
- 4. Adjust and tighten by lifting buckles and pulling strap(s) securely.

## **Removal Instructions**

1. Loosen straps by lifting buckles and removing hooks (if used).

#### **GENERAL SPECIFICATIONS**

Device Dimensions (maximum)

	800-0057	800-0119
Strap Length	96" +/- 0.5" (243.8 cm +/- 1 cm)	132" +/- 0.5" (353 cm +/- 1 cm)
Strap Width	2" +/- 0.5" (5.1 cm +/- 1 cm)	2" +/- 0.5" (5.1 cm +/- 1 cm)
Pad Length	18" +/- 0.5" (46.7 cm +/- 1 cm)	30" +/- 0.5" (76.2 cm +/- 1 cm)
Pad Width	5" +/- 0.5" (12.7 cm +/- 1 cm)	12" +/- 0.5" (30.5 cm +/- 1 cm)
Device Weight	1.8 + - 0.5 lbs. (1 +22 kg)	5.5 +/- 0.5 lbs. (2.5 +/22 kg)



### **COMPONENT OVERVIEW**

Restraint Straps are a surgical table accessory that stabilizes patient positioning for various surgical procedures on operating room table.

### Accessory (sold separately)

Restraint Strap Mounting Hook 512-0039

#### **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)
- Clean with hospital grade disinfectant

#### 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!**

Hazard resulting from incorrect use. Strictly follow Instructions for Use with your surgical table system.



### WARNING!

Take care as pinching of the skin may occur when opening and closing strap buckles.



## **WARNING!**

Do not use equipment if worn, damaged, or if pieces are missing.

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.

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#### **WARNING!**

Adhere to standards for blood-borne pathogens from the Occupational Safety and Health Administration. Use recommended protective clothing, gloves, masks and eve 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	
3	Manufacturer	
₩	Date of manufacture	
EC REP	Authorized Representative in the European Community	
CH REP	Authorized Representative in the Swiss	
	Importer	
SN	Serial Number	
<u>^</u>	Warning	
MD	Medical Device	
UDI	Unique Device Identifier	
CE	CE Marking	



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