



## Instructions for Use

**REF** Nissen Straps 800-0055

**REF** Bariatric Nissen Straps 800-0118

### INTENDED USE

Intended use is to provide a safe system for positioning patients in reverse Trendelenburg. 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. *Attach Simple Clamps (sold separately) onto table side rails. Insert mounting posts into clamps and securely lock into place*
2. *Wrap Nissen Straps around patient's legs so pads face toward inner thighs*
3. *Attach clips on buckle sides to mounting post clips. Adjust by lifting buckles and pulling straps.*

### Removal Instructions

1. *Loosen straps by lifting buckles then remove clips*
2. *Loosen clamps and remove Nissen Straps by lifting them out of clamps*
3. *Remove clamps from side rails*

## GENERAL SPECIFICATIONS

*Device Dimensions (maximum)*

	<b>800-0055</b>	<b>800-0118</b>
<i>Strap Length</i>	<i>58" +/- 0.5" (147.3 cm +/- 1 cm)</i>	<i>74.5" +/- 0.5" (189.2 cm +/- 1 cm)</i>
<i>Strap Width</i>	<i>2" +/- 0.5" (5.1 cm +/- 1 cm)</i>	<i>2" +/- 0.5" (5.1 cm +/- 1 cm)</i>
<i>Pad Length</i>	<i>20" +/- 0.5" (50.8 cm +/- 1 cm)</i>	<i>31.5" +/- 0.5" (80 cm +/- 1 cm)</i>
<i>Pad Width</i>	<i>5" +/- 0.5" (12.7 cm +/- 1 cm)</i>	<i>6.75" +/- 0.5" (17.1 cm +/- 1 cm)</i>
<i>Device Weight (Single Nissen Strap)</i>	<i>1.4 +/- 0.5 lbs. (0.63 +/- .22 kg)</i>	<i>3.0 +/- 0.5 lbs. (1.4 +/- .22 kg)</i>

## COMPONENT OVERVIEW

Nissen Straps are a surgical table accessory that attaches to sides of a surgical table with an accessory clamp.

**Other required products for use:**

**(2) 800-0228 Simple Clamp** (sold separately)

**US:** 0.374" x 1.122" (9.5 mm x 28.5 mm) PN# 800-0228

**Denyer:** 0.236" x 1.496" (6 mm x 38 mm) PN# 800-0228-DEN

**Europe:** 0.394" x 0.984" (10 mm x 25 mm ) PN# 800-0228-EU

**Eschmann (UK):** 0.236" x 1.260" (6 mm x 32 mm) PN# 800-0228-UK

**Japan:** 0.354" x 1.260" (9 mm x 32 mm ) PN# 800-0228-JPN

**Swiss:** 0.394" x 1.181" (10 mm x 30 mm ) PN# 800-0228-SWISS

## 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*
- *Pads conform to Cal #117*

## 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!**

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



### **WARNING!**

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



### **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.**



### **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.

## eIFU Language Versions

To download and print the Instructions for Use, please go to [www.schuremed.com](http://www.schuremed.com)

## Symbol Glossary

Symbol	Title
	Manufacturer
	Date of manufacture
	Authorized Representative in the European Community
	Authorized Representative in the Swiss
	Importer
	Serial Number
	Warning
	Medical Device
	Unique Device Identifier
	CE Marking



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