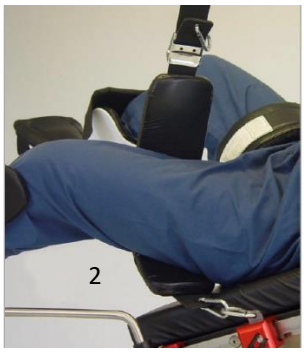
Instructions for Use

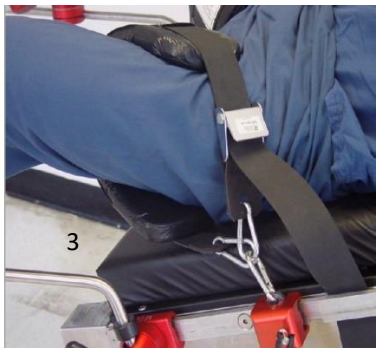
REF **Nissen Straps 800-0055**

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)

- *Length: 48" +/- 0.5" (122 cm +/- 1 cm)*

- *Width: 6” +/- 0.5” (15 cm +/- 1 cm)*
- *Depth: 2” +/- 0.5” (5 cm +/- 1 cm)*
- *Device Weight: 3.5 +/- 0.5 lbs. (1.5 +/- .22 kg)*

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*
- *Device supports 600 lbs. (272 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)*
- *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! *Maximum load should not exceed appropriate proportion of a patient weighing 600 lbs. (272 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 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.

UDI Basic UDI-DI: 081001460F0062E6

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.
	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)
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 **Authorized Representative**

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