



## Instructions for Use

**REF** Reusable Head & Chin Straps 508-1345

### INTENDED USE

Intended use is to hold patient's head during operative procedure. The intended users of this device are medical professionals within hospitals and surgery centers.

### INSTRUCTIONS

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



1. Place patient on surgical table/shoulder chair in supine position
2. After intubating patient, while holding patient's head and neck – raise shoulder chair up, so patient is in Fowler (sitting) position
3. Loosen ball joint and adjust head positioner around patient's head. Make sure the patient's ears are uncovered. Then tighten ball joint.
4. While holding head positioner flaps alongside patient's head, place Forehead Strap across forehead as shown. Securely attach and avoid going over patient's eyebrows
5. Take Chin Strap (cup for chin) and place patient's chin in strap's cup. Hold cup to chin and secure one side of strap to head positioner as shown. Making sure head is properly positioned, secure strap's other end to opposite side of head positioner.

**NOTE:** Head should be securely positioned. If not, make straps a little tighter.

### COMPONENT OVERVIEW

Reusable Head and Chin Straps is used to securely hold a patient's head during operative procedure.

### GENERAL SPECIFICATIONS

*Device Dimensions (maximum)*

- Length: 21" +/- 0.5" (53 cm +/- 1 cm) (Head), 25" +/-0.5" (64 cm +/- 1 cm) (Chin)
- Width: 2" +/- 0.5" (5 cm +/- 1 cm) (Both Head and Chin)
- Device Weight: 0.25 +/- 0.5 lbs. (.11 +/- .22 kg)
- Attaches to head section of SchureMed Shoulder Chairs
- Single-person installation

### 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*
- *Store device between  $-4^{\circ}\text{F}$  to  $+86^{\circ}\text{F}$  ( $-20^{\circ}\text{C}$  to  $30^{\circ}\text{C}$ )*

## **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*

## **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.*



**WARNING!** *Do not reuse device if there are obvious signs of damage or functional issues. Consult manufacturer before reusing.*

## **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: 081005737F0005KP

## **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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