Instructions for Use

REF Premium Head & Chin Straps 800-0369

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 features of patient positioning device before use with 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. *Once patient is intubated, hold patient's head/neck and raise shoulder chair up so patient is in Fowler (sitting) position*
3. *Loosen ball joint - adjust head positioner around patient's head making sure patient's ears are uncovered - tighten ball joint*
4. *Hold head positioner flaps alongside of patient's head, placing Forehead Strap across forehead as shown. Attach securely and avoid covering patient's eyebrows.*
5. *Center Chin Strap over chin, secure strap to one side of head positioner. 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
Premium Head and Chin Straps holds a patient's head securely during operative procedure.

GENERAL SPECIFICATIONS
Device Dimensions (maximum)
- *Length: 21"+/- 0.5" (53 cm +/- 1 cm) (Head)*
- *Length: 22"+/- 0.5" (56 cm +/- 1 cm) (Chin)*
- *Width: 2"+/- 0.5 (5 cm +/- 1 cm) (Both Head and Chin)*
- *Device Weight: .066 lbs. +/- .02 lbs. (.03 kg +/- .009 kg)*
- *Attaches to head section of SchureMed Shoulder Chairs*
- *Single-person installation*

GENERAL INFORMATION

- *Product not made with Natural Rubber Latex*
- *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*
- *Store device between –4°F to +86°F (-20°C to 30°C)*

SINGLE PATIENT USE—Please dispose after each use

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: 081001460F0012DP

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.
EC REP	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.
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalogue or Item Number	Indicates the manufacturer's catalogue or item number so that the medical device can be identified.
SN	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.
MD	Medical Device	Indicates the item is a medical device.
UDI	Unique Device Identifier	Indicates a barcode as containing unique device identifier information.
CE	CE Marking	European Conformity.
	Single Patient Use	Indicates the item is a single patient use medical device.

Manufacturer

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CE MD

EC REP **Authorized Representative**

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