

Instructions for Use

REF Disposable Face Masks 800-0164

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 patient positioning device's features before use with patient. Always practice 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, hold patient's head/neck and 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 patient's ears are uncovered. Then tighten ball joint.
4. Holding head positioner flaps alongside patient's head, place face mask over face as shown - making sure eyes, nose and mouth are uncovered
5. Affix top and bottom VELCRO® straps of mask on one side to head positioner. Then affix other side as shown - making sure facemask is centered over face.

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

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

- Length: **Strap:** 29" +/- 0.5" (74 cm +/- 1 cm), **Face Mask:** 9" +/- 0.5" (23 cm +/- 1 cm)
- Width: 13.5" +/- 0.5" (34 cm +/- 1 cm)
- Depth: 1" +/- 0.5" (2.5 cm +/- 1 cm)
- Device Weight: 0.25 +/- 0.5 lbs. (.11 +/- .22 kg)
- Attaches to head section of SchureMed Shoulder Chairs
- Single-person installation

COMPONENT OVERVIEW

Disposable Face Mask securely holds a patient's head during operative procedure. Straps are soft and pliable to attach to head frame.

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: 081001460F0011DM

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.