

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.

eIFU Language Versions

To download and print the Instructions for Use, please go to www.schuremed.com

Symbol Glossary

Symbol	Title
4	Manufacturer
w	Date of manufacture
EC REP	Authorized Representative in the European Community
CH REP	Authorized Representative in the Swiss
	Importer
REF	Catalogue Number
SN	Serial Number
<u>^</u>	Warning
MD	Medical Device
UDI	Unique Device Identifier
C€	CE Marking
2	Single Patient Use



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