

Non-Rebreathing Masks

Products covered;

- Hi-concentration non-rebreathing mask



Medical device class; 2A

Intended use

Device is intended to be used to deliver medical oxygen for administration to a patient.

Intended user

The device must only be used by clinical staff or healthcare professionals who have received training in emergency oxygen delivery procedures.

Intended use environment

The devices are intended for use healthcare facilities and first response environments.

The devices are single-use non-sterile

Material

PVC (DHEP FREE), PP, Neoprene (strap), Aluminium (nose clip)

Where phthalates are in the materials the "phthalates" symbol is on the product label.

Materials do not contain latex or substances derived from animals

Instructions for use

NOTE. These directions are general guidelines intended for use by qualified medical personnel.

1. Attach the oxygen tube to the 7 mm connection on the mask. If the mask is for aerosol connect the aerosol tubing to the 22mm connection on the mask.
2. Attach oxygen supply tubing /aerosol tubing to gas source and set prescribed flow.
3. Check for gas flow through the device. Always verify proper function of the valves: The valve between the mask and the reservoir should open on inspiration and close on exhalation.
4. The valve located on external mask surface should open during exhalation. 2 valves are on outside of mask to allow delivery of highest possible oxygen percentage. However sufficient oxygen flow must be delivered into the mask for patient inhalation requirement. Remove one flap if this is not the case to allow air entrainment at one side if oxygen flow below patient need. This will allow full inhalation at a lower oxygen percentage.
5. Place the mask on the patient's face with the elastic strap below the ears and around the neck. Gently pull the ends of the strap until the mask is secure. Mould the metal strip on the mask to fit across the bridge of the nose.
6. For ear Loops style; Place mask on patient's face with one elastic loop around each ear. Gently pull the end of each elastic loop until the mask is secure. Do not over tighten.

7. Mould the metal strip on the mask over the patient's nose.

Storage

- ⇒ Do not store at extreme temperature or humidity.
- ⇒ Store in clean and dry place.
- ⇒ Do not use if the package open or damaged
- ⇒ Do not store in direct sunlight

Cleaning

DISPOSABLE FOR SINGLE PATIENT USE NOT INTENDED FOR CLEANING OR REPROCESSING

There is a risk of cross contamination if these devices are reused. They have not been validated for reprocessing or reuse.

Sterilization

Supplied non sterile

Disposal

The devices may be disposed of using local procedures for contaminated medical waste.

The materials are capable of being recycled if a safe process for recycling medical waste is available.

Warnings and cautions

Be sure all connections are secure

Non Re-breathing Masks – make sure bag is inflated before attaching to patient

Contraindications when using air entrainment (venturi) jets

1. The assessment of the correct % O² must be monitored by checking the patient's blood oxygen levels using equipment such as pulse oximeters or other accurate monitoring devices.
2. Product may contain phthalates and could pose a risk for vulnerable patients including pregnant women or infants. Check the device label for the indication of the presence of phthalates.
3. Be sure all connections are secure.
4. Cleaning or reprocessing for reuse will raise the risk of cross contamination.
5. Meditech Systems Ltd will not take responsibility for use outside of the intended use or by other than the intended users.
6. FIRE RISK IF OXYGEN IS USED IN THE PRESENCE OF NAKED FLAME OR HEAT SOURCE LIKELY TO CAUSE IGNITION.

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Explanation of symbols:

 = Single Use. The definition of single use is for use on a single patient for a single procedure.


 = Do not reprocess / re-sterilise


 = Use by date


 = Lot or batch number.

 = Manufacturer

 = Temperature range

 = Consult instructions for use

 = Keep away from sunlight

 = Keep dry



= Date of manufacture.
= Device catalogue number / product code / stock



= Caution



= Device catalogue number / product code / stock



= Contains latex



= Do not use if packaging is wet or damaged.



= Contains or Presence of Phthalates.



1639

=CE mark and notified body number

This is an explanation of the symbols that may be found on Meditech Systems Ltd's products.

ADVERSE INCIDENT REPORTING

Adverse incidents may be reported to the Competent Authority in the country / region where the incident occurred.