

Oxygen Masks and Tubing & Aerosol Masks

Products covered;

- Simple oxygen mask non-rebreathing
- Simple aerosol mask non-rebreathing
- Focus Flow Open oxygen mask

Medical device class; 2A

Intended use

For delivery of medical oxygen or humidified oxygen for administration to a patient.



Oxygen Mask



Aerosol Mask



Focus Flow Open Oxygen Mask

GMDN;

35173 Oxygen mask non-rebreathing

35172 Aerosol mask non-rebreathing

Intended user

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

Intended use environment

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

If the devices are to be used in homecare environments, they must be used under the supervision of a suitably trained healthcare professional.

The devices are single-use non-sterile

Material

PVC, PP, Neoprene (strap), Aluminium (nose clip), Opti-flex TPOD2620

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
4. 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.
5. **When administering Nebulised aerosol (water/saline) to a patient on humidification treatment it is important to observe for any build-up of moisture in the tubing. This is caused by "rainout" of humidified gas on route to the patient from the nebuliser or heated humidifier. This moisture build up can cause resistance to flow and alter oxygen levels delivered if allowed to build up**

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

1. Be sure all connections are secure
2. Non Re-breathing Masks – make sure bag is inflated before attaching to patient
3. 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.
4. FIRE RISK IF OXYGEN IS USED IN THE PRESENCE OF NAKED FLAME OR HEAT SOURCE LIKELY TO CAUSE IGNITION.

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. Cleaning or reprocessing for reuse will raise the risk of cross contamination.
3. Meditech Systems Ltd will not take responsibility for use outside of the intended use or by other than the intended users.

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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.



= Manufacturer

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|---|---|---|--|
|  | = Do not reprocess / re-sterilise |  | = Temperature range |
|  | = Use by date |  | = Consult instructions for use |
|  | = Lot or batch number. |  | = Keep away from sunlight |
|  | = Date of manufacture. |  | = Keep dry |
| | = Device catalogue number / product code / stock |  | = Contains latex |
|  | = Caution |  | = Do not use of packaging is wet or damaged. |
|  | = Device catalogue number / product code / stock |  | = Contains or Presence of Phthalates. |
|  | ¹⁶³⁹ = CE mark with 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.