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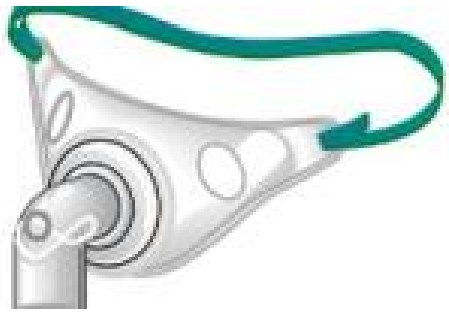
CE 1639

Tracheostomy Mask



GMDN; 35179

Medical device class; 2A

Intended use

For supplying medical oxygen or oxygen/air mix to a patient with a tracheostomy. Can be connected to 22mm aerosol tubing or used with a venturi jet connected directly to the mask.
May be used with humidified oxygen/air.

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.

The devices are single-use non-sterile

Material

PVC, PP (connector), Neoprene (strap)
Where phthalates are in the materials the “phthalates” symbol is on the product label.
Materials do not contain substances derived from animals.
Latex free

Instructions for use

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

1. Connect aerosol tubing (not supplied) between the mask and the gas source.
2. If using with a venturi jet to deliver percentage O2 connect the venturi jet (not supplied with the mask) to the 22mm connection on the mask and connect an oxygen supply to the venturi jet.
3. The mask inlet swivels 360° to position the tubing for supine or upright patients.
4. Set the gas to the flow prescribed by the physician and check for gas flow through device.
5. Position the elastic strap behind the neck.
6. Gently pull the end of the strap until the mask is secure.
7. When using suction, loosen the mask and drop the mask out of the work area.
8. 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

Warnings and cautions

1. Be sure all connections are secure
2. FIRE RISK IF OXYGEN IS USED IN THE PRESCENCE OF NAKED FLAME OR HEAT SOURCE LIKELY TO CAUSE IGNITION.

Contraindications when using air entrainment (venturi) jets

1. Be sure all connections are secure.
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.

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.

Ordering information:

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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

= Manufacturer

= Temperature range

= Consult instructions for use

= Keep away from sunlight

= Lot or batch number.


= Date of manufacture.

= Device catalogue number / product code / stock


= Caution

= Device catalogue number / product code / stock

=CE mark and notified body number


= Keep dry

= Contains latex


= Do not use of packaging is wet or damaged.

= Contains or Presence of Phthalates.

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.