

Nebuliser mask kit



Mask



Nebuliser chamber

GMDN; Mask = 35172

Nebuliser chamber = 35457

Medical device class; 2A

Intended use

Face mask and nebuliser chamber / jar for administration of nebulised substances to patients. The nebulisation can be driven by a medical oxygen supply or low pressure compressed 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.

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

Mask; PVC , PP, Neoprene (strap), Aluminium (nose clip)

Nebuliser chamber; PP and Styrene homopolymer

Materials do not contain latex or substances derived from animals

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

Instructions for use

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

1. Fill the nebuliser jar with the liquid to be nebulised. This will be dictated by the healthcare professional.
2. Connect the oxygen tubing to the 7 mm connection on the base of the nebuliser jar making sure the connection is secure.
3. Connect the 17mm male connector of the nebuliser jar into the 17mm socket on the oxygen mask making sure the connection is secure.
4. Connect the free end of the oxygen tubing to the air/gas source making sure the connection is secure.
5. Set air/gas flow to the required rate and check that the air/gas is flowing through the nebuliser jar.

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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. 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.
2. Be sure all connections are secure.
3. Cleaning or reprocessing for reuse will raise the risk of cross contamination.
4. Meditech Systems Ltd will not take responsibility for use outside of the intended use or by other than the intended users.
5. It is the responsibility of the end user to determine what substances are to be put in the nebulizer jar and ensure they are compatible for use with the materials listed above.
6. FIRE RISK IF OXYGEN IS USED IN THE PRESENCE OF NAKED FLAME OR HEAT SOURCE LIKELY TO CAUSE IGNITION.

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.		= Manufacturer
	= 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 if packaging is wet or damaged.
	= Device catalogue number / product code / stock		= Contains or Presence of Phthalates.
	= 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.

MIFU-007N (GGV1)

Issued; 07/2023