

INSTRUCTIONS FOR USE

OXY-MAIS™ Oxygen Face Mask

Device Description:

The Oxygen Mask is a medical device designed to cover the patient's nose and mouth and is used to deliver supplemental oxygen from an oxygen source to the patient. The mask is made of medical-grade materials and is intended for single use.

The Oxygen Mask is consisting of:

- A Moulded face mask manufactured from non-toxic and non-irritant medical grade PVC material.
- Provided with adjustable elastic strap for proper positioning of mask on the nasal area.
- 2 mtr. long multichannel, kink-resistant tube is provided to ensure continuous flow of oxygen.
- Swivel connector for easy attachment to oxygen tube.

Intended Use:

The Oxygen Mask is intended to deliver oxygen to patients requiring supplemental oxygen therapy in clinical or homecare settings, as prescribed by a healthcare professional.

Intended Users:

- Healthcare professionals
- Trained caregivers (as applicable)

Patient Population:

Adult / Pediatric / Neonatal (as applicable – specify on label).

Sterility Status:

- Sterile (Sterilized by EO)

Contraindications:

- Do not use in patients who cannot tolerate a face mask.
- Do not use if the patient has known hypersensitivity to any material used in the mask.

Warnings:

- For single use only. Do not re-use or re-sterilize.
- Do not use if the package is damaged or opened prior to use.
- Use only as prescribed by a healthcare professional.
- Ensure correct oxygen flow rate as per clinical requirement.
- Incorrect use may result in inadequate oxygen delivery.

Precautions:

- Do not overtighten the elastic strap to avoid patient discomfort or skin injury.
- Monitor the patient during oxygen administration.
- Do not modify the device in any way.

Instructions for Use:

1. Check the package integrity before opening.
2. Remove the Oxygen Mask from the packaging.
3. Connect the oxygen supply tubing securely to the mask connector.
4. Place the mask over the patient's nose and mouth.
5. Adjust the elastic strap to ensure a comfortable and secure fit.
6. Set the oxygen flow rate as prescribed by the healthcare professional.
7. Monitor the patient during use.
8. After use, remove the mask and dispose of it appropriately.

Adverse Events:

Any serious incident related to the use of this device should be reported to the manufacturer and to the competent authority in accordance with applicable regulations.

Storage Conditions:

- Store in a clean, dry place.
- Protect from direct sunlight and excessive heat.
- Store at temperature and humidity conditions as stated on the label.

Shelf Life: 5 Years.

Disposal:

Dispose of the used Oxygen Mask in accordance with Bio-Medical Waste Management Rules and local regulations.

Symbols Used on Label:



Consult Instruction For Use



Do Not Reuse



Unique Device Identifier



Catalogue Number



Do Not Resterilize



Sterilised By Ethylene Oxide



Lot No./Batch No.



Caution



Single Sterile Barrier System



Manufacturer



Do Not Use If Package Is Damaged



Medical Device



Date Of Manufacturing



Keep Dry



Non-Pyrogenic



Use By / Expiry Date



Keep Away from Sunlight

 **Manufactured by:**

Mais India Medical Devices Pvt. Ltd.

525-P, Sector-37, Pace City-II,

Gurgaon, Haryana-122001 (INDIA)

Mfg. Lic. No.: MFG/MD/2019/000037

ISO & CE Certified Company

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