INSTRUCTIONS FOR USE

NASOPHARYNGEAL AIRWAYS

***Please Read All Instructions Carefully Before Use (Sterile, for single use only)**

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PRODUCT DESCRIPTION:

It is a soft curved PVC tube bevelled, smooth and polished patient end for easy intubation and distal end is flared. It is inserted into the nasal passageway to secure an open airway. When a patient becomes unconscious, the muscles in the jaw commonly relax and can allow the tongue to slide back and obstruct the airway. The purpose of the flared end is to prevent the device from becoming lost inside the patient's nose.

INTENDED PURPOSE:

A catheter passed through the nares and advanced to the depth of the nasopharynx to remove air choke or obstruction and intended for short term use.

INDICATIONS:

Patients who are difficult to oxygenate or ventilate via bag mask ventilation for the following condition:

- Maxillofacial injuries
- Semi-conscious patient
- Respiratory distress
- Airway obstruction

CONTRAINDICATIONS:

- Bleeding disorders
- Nasal or cranial trauma (ie. recent palatal surgery – risk of damage to surgical site(s)
- Newborn septal deviation
- Nasal polyps
- Craniofacial abnormality
- Hemorrhage
- Large nasal polyps
- Recent nasal surgery

LIMITATION:

NA

INTENDED USER

Doctor or Qualified Healthcare Professional

INTENDED PATIENT POPULATIONS

All Age Group

DIRECTIONS FOR USE:

- Check product is within its specified sterile shelf life.
- Visually check whole device for completeness, discolouration, damage and flaws.
- Check that there is no blockage or occlusion in the airway
- Any Instructions and contraindications given are not exhaustive and it is the clinician's responsibility to ensure the safe, correct use of this product.
- Select correct size of airway.
- Lubricate outer airway tube with a suitable water based lubricant, ensuring that the distal tip remains patent.
- Insert airway into patient's nasal cavity and ensure that the airway is operating correctly.
- If oxygen is required, connect the oxygen tube onto the oxygen elbow before connecting the elbow into the airway.
- To ensure a secure connection, use a push & twist action on all fittings.
- If the respiratory indicator is required, connect the hydrophobic filter to a suitable male sampling line before connecting to an appropriate monitor.
- When observing the respiratory rate, oxygen should only be administered at a flow rate of less than 8 LPM.
- Any blocked or occluded devices should be removed immediately.

WARNING:

- The use of this product is restricted to a qualified Doc tor or Healthcare professional only.

PRECAUTIONS AND CAUTIONS:

- Single Use Only.
- The product should remain unopened until the point of use.
- Sterile if package is unopened, undamaged and within shelf life date.
- Do not re-sterilise.
- Do not expose to temperatures above 49°C
- This product must be in a pre-use condition and checked prior to use
- Do not use if the patient is suffering from a blocked nose, nasal congestion or nasal polyps.
- Do not use if the patient has a history of epistaxis or fractured nasal bone.

ADVERSE EFFECTS:

- If the Nasopharyngeal Airway is too long it can create a direct route of ventilation of the stomach causing,
  - Gastric distention
  - Increasing vomiting risk
  - Decreasing oxygenation and ventilation of the lungs
- Epistaxis
- Turbinate fracture
- Intracranial placement through a basilar skull fracture
- Retropharyngeal dissection or laceration
- Sinusitis

CLINICAL BENEFITS:

- Reduce risk of intracranial penetration
- NPA was successful in 80%
- Prevent speech disorders
- Reduced velopharyngeal function
- Improves nasal breathing
- Decrease in nasal resistance

RESIDUAL RISKS:

- Turbinate fracture
- Epistaxis due to mucosal tears, Infection

SUPPLY:

12,14,16,18,20,22,24,26,28,30,32,34,36 FG/FR

Nasopharyngeal Airway – SMD 720

METERIAL USED:

Name of Component	Material Used
Catheter	PVC
Flange	PVC

STERILITY`:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused devices.

STORAGE:

The Device should be stored in their original box in a cool and dry place between 5 to 45° C, preferably away from direct and indirect sources of light and heat. Do not use after expiry.

Store product inside containers or outer boxes in a clean, dry area. Do not expose to direct sunlight or UV light.

DEVICE DISPOSAL:

Used Devices may be contaminated with infectious and/or other hazardous materials. Discard used devices in the container meant for infectious waste. Unused expired devices should be disposed of as per local regulations.

NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

SYMBOLS:

REF	**Catalogue No.**		**See instructions for Use**
	Cautions		**Keep Dry**
	Do not use it if the packaging is damaged.	SBS	**Sterile Barrier System**
	Single-Use		**Do not Re-sterilize**
LOT	**Batch / Lot No.**	STERILE EO	**Ethylene Oxide Sterilized**
	Date of Mfg.	UDI	**Unique Device Identifier**
	Date of Exp.	MD	**Medical Device**
	Avoid Direct Sunlight	45°C 5°C	**Keep in a dry place between 5°C to 45°C**
PHT DEHP	**Phthalate Free**		

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