INSTRUCTIONS FOR USE
GUEDEL AIRWAYS /OROPHARYNGEAL AIRWAYS
***Please Read All Instructions Carefully before Use (Sterile, for single use only)**

SMDPL/IFU/GA/01 Rev. No.:00, Dt. 12.08.2023

PRODUCT DESCRIPTION:

An oropharyngeal airway (also known as an oral airway, OPA or Guedel pattern airway) is a medical device called an airway adjunct used in airway management to maintain or open a patient's airway. It does this by preventing the tongue from covering the epiglottis, which could prevent the person from breathing.

Oropharyngeal airways come in a variety of sizes, from infant to adult, and are used commonly in pre-hospital emergency care and for short term airway management post anaesthetic or when manual methods are inadequate to maintain an open airway. This piece of equipment is utilized by certified first responders, emergency medical technicians, paramedics and other health professionals when tracheal intubation is either not available, not advisable or the problem is of short-term duration.

Oropharyngeal airways are indicated only in unconscious people, because of the likelihood that the device would stimulate a gag reflex in conscious or semi-conscious persons. This could result in vomit and potentially lead to an obstructed airway. Nasopharyngeal airways are mostly used instead as they do not stimulate a gag reflex.

In general, oropharyngeal airways need to be sized and inserted correctly to maximize effectiveness and minimize possible complications, such as oral trauma.

Guedel Airways / Oropharyngeal Airways (SMD 705):

A white Color curved shape PVC hollow pipe with a colored block fixed with it

INTENDED PURPOSE:

A curved PVC tube inserted through the mouth to facilitate airway patency for gas exchange and provide passage for insertion of suction catheter through its lumen for suctioning purpose. The device works by preventing the tongue from obstructing airflow. It is intended for short term use.

INDICATIONS:

Patient is at risk of airway obstruction due to relaxed upper airway muscles or blockage of the airway by the tongue

CONTRAINDICATIONS:

Guedel airway is contraindicated in the following cases:

Avoid using an oropharyngeal airway on a conscious patient with an intact gag reflex. If the patient can cough, they still have a gag reflex, and an oral airway is contraindicated. If the patient has a foreign body obstructing the airway, an oropharyngeal airway should not be used. An oropharyngeal airway should not be used on patients who have nasal fractures or an actively bleeding nose.

INTENDED USER

Doctors or Trained health care professional only.

INTENDED PATIENT POPULATIONS

Infants, Paediatrics and Adults

DIRECTIONS FOR USE:

- Choose the appropriate size of Device.
- Open the package from the peel-open area and remove the device.
- Perform hand hygiene.
- Wash hands with warm soapy water. Dry thoroughly. Put on gloves and aprons.
- Patient should be assisted to a position that is comfortable this is normally sitting or supported at an angle of 45°
- If possible, lubricate the airway before insertion (practically, in the emergency situation, this is rarely done).
- Open the Patient mouth by using the cross-finger technique and Insert the Guedel airway.
- Ensure the correct placement; the flange should rest on the victim's lips.

For an adult:

- Grasp the victim's lower jaw and tongue and lift upward.
- Insert the Guedel Airway with the curved end along the roof of the mouth.
- As the tip approaches the back of the mouth, rotate it one-half turn (180 degrees).
- Slide the Guedel Airway into the back of the throat.

For a child or an infant:

- Use a tongue blade or a tongue depressor and insert with the tip of the device pointing toward the back of the tongue and throat in the position it will rest in after insertion. Or Insert the Guedel Airway sideways and then rotate it 90 degrees.

WARNING:

 # The use of this product is restricted to a qualified Doctor or Healthcare professional only. No need for specific hazard alert information before using the device.

PRECAUTIONS AND CAUTIONS:

- Prior to using read entire instructions for use. Failure to do so may result in severe patient injury.
- Before inserting an Oropharyngeal/Guedel Airways, be sure the Patient is unresponsive; has no oral trauma, such as broken teeth; and has not had recent oral surgery.
- If the Patient gags, remove the Oropharyngeal/Guedel Airway immediately.
- ***STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES FROM IMPROPER USE.***
- Do not clean or Re-use the device, for single use only.
- Discard after use.
- Store in a Cool and dry place.
- Do not expose to heat or direct sunlight.
- The product should be used immediately after opening the packing.
- Do not use if the package is opened and damaged.
- Do not Re-sterile the Device.
- Do not use the device after expiry Date mentioned on the Label.
- If the patient is sensitive or allergic to PVC, do not use the device.

ADVERSE EFFECTS:

- Aspiration
- Laryngospasm
- Damage to the Dentition

CLINICAL BENEFITS:

- No difficult or discomfort to the patients
- Low frequency of complications
- Reduce adverse respiratory event
- Overcome soft tissue obstruction
- No apparent cause of partial obstruction
- No increase morbidity
- Ease of insertion
- Better outcome

RESIDUAL RISKS:

- Type I allergy, Anaphylaxis
- Hypoxia, Low Saturation
- Infection, Injury and bleeding

SUPPLY:

SMD 705

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MATERIAL USED:

Component	Material	Specification/Grade
Guedel Curved Pipe	LDPE (Low Density Poly Ethylene)	Medical Grade
Bite Block	HDPE (High Density Poly Ethylene) & Poly Propylene	Medical Grade

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 Device.

STORAGE:

These products 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.

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.		**Sterile Barrier System**
	Single-Use	STERILIZE	**Do not Re-sterilize**
LOT	**Batch / Lot No.**	STERILE EO	**Ethylene Oxide Sterilized**
	Date of Mfg.	LATEX	**Latex Free**
	Date of Exp.	MD	**Medical Device**
	Avoid Direct Sunlight	45°C 5°C	**Keep in a dry place between 5°C to 45°C**
PVC DEHP	**Phthalate Free**		**Pyrogen Free**

UDI **Unique Device Identifier**

EC REP CE 0123
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