



## **ULTRA FOR MEDICAL PRODUCTS CO.**

+ **Product Name: Ultramed Guedel airway**

+ **Classification: product is classified Class IIa , Rule 5**

- **Reference:** MDD 93/42/EEC, Annex IX amended by Directive 2007/47/EC, September 2007.

+ **Product history:**

- ✓ The Guedel Airway is a short-term use device and is being used as medical device for many years under different brands. Guedel Airway is made from PP, LDPE materials which are widely used in hospitals and clinics.
- ✓ Fresh clinical trials & evaluation is not necessary since it is not a new product & we take literature route to demonstrate that our product & the materials are similar to the already established products & meet various requirements.
- ✓ Product on Market from 1992 with no adverse events of Recalls.
- ✓ Product is conventional Product and fully equivalence with many products in market.
- ✓ The product is approved by the Ministry of Health.
- ✓ This product is CE marked

+ **Product is available as variants to fit intended patient population whether adult or paediatric.**

+ **Intended User: Charge doctor.**

+ **Intended Patient Population:**

-The device is used for patient of different ages with obstructed oropharyngeal airway which can lead to bit of tongue and airway occlusion.

+ **Final product release criteria (Features):**

- Bite block to prevent biting of tongue and airway occlusion.
  - Rounded traumatic edges.
  - The rigid construction is kink-resistant.
  - Smooth airway path for easy cleaning.
  - flange to prevent over insertion
  - curved body to conform over tongue/palate
  - Color coded for easy identification of sizes.
  - Sizes: 00, 0, 1, 2, 3, 4, 5.
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- Sterile by ETO

#### **✚ Medical condition to be treated (indication of using Ultramed Guedel airway):**

- When a patient becomes unconscious, regardless of the cause, maintaining a patent airway is critical. One of the most common causes of airway obstruction in an unconscious patient is the tongue. Once a person loses consciousness, the tongue may fall to the back of the throat and block the patient's airway. Using an oropharyngeal airway is an effective way to maintain an open airway, which allows you to ventilate the patient effectively if needed.
- The main indication for use of an oropharyngeal airway is if the patient is at risk for airway obstruction due to relaxed upper airway muscles or blockage of the airway by the tongue.
- Using an oropharyngeal airway can prevent airway occlusion.

#### **✚ Principle of operation (mode of action):**

- Guedel airway is suitable for maintaining an unobstructed oropharyngeal airway during general anesthesia and in unconscious patients.
- Keep the patient in laying position and place the Guedel Airway into the mouth between upper and lower jaws.
- Start by using the head-tilt/chin-lift technique to open the airway.
- Use thumb and for finger to open the mouth.

#### **✚ Key performance claim:**

- 1- The airways are Colour coded to help recognize the sizes; the length of the tube is marked on the flange with a number.
- 2- The flange limits the depth of insertion - so doctor can't accidentally lose the tube in somebody's airway.
- 3- The reinforced bite block prevents occlusion of the airway by clenching of the teeth.
- 4- The rigid construction is kink-resistant.

#### **✚ Contraindications:**

##### **Using Ultramed Guedel airway is contraindicated in the following cases:**

- Long term use; can lead to puncture of the mucus membrane which can damage the soft tissue of mouth.
- The device cannot be retained in human body for over 29 days, and 14 days is strongly recommended.
- A wake patient: A wake patient will not tolerate this airway, as it will stimulate their gag reflex.
- Severe coagulopathy: this device, although possessing rounded edges, is still made of very hard plastic and it can still cause lacerations to the oral mucosa. If you have no platelets, you may end up with a lung full of blood from some sort of little posterior pharyngeal bleeder before anybody notices.
- Patient with a known hypersensitivity of one of materials used.

✚ How the device is used:

	<b>Ultramed Guedel airway Action</b>	<b>Rational</b>
<b>Insertion of Guedel airway</b>		
1.	Establish need for guedel airway.	Guedel Airway is used to maintain an unobstructed oropharyngeal airway and it prevents biting of tongue and airway occlusion.
2.	Perform hand hygiene.	This prevents the transmission of microorganisms.
3.	Wash hands with warm soapy water. Dry thoroughly. Put on gloves and aprons.	To reduce risk of infection.
4.	Apply clean gloves.	Using gloves decreases the transfer of microorganisms. 
5.	victim should be assisted to a position that is comfortable – this is normally sitting or supported at an angle of 45°	To ensure the victim is comfortable, reduce distress in the victim and gain greatest benefit of using guedel airway.
6.	Raise bed to a comfortable working height.	This helps prevent biomechanical injury to the health care provider.
7.	Select the proper size of the Guedel airway	Measure the OPA from the victim's earlobe to the corner of the mouth and select the suitable size to it to avoid over insertion. 

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8.

Open the victim mouth

Use the cross-finger technique to open the victim's mouth.



9.

Insert the oropharyngeal airway

**For an adult:**

- 1- Grasp the victim's lower jaw and tongue and lift upward.
- 2- Insert the OPA with the curved end along the roof of the mouth.
- 3- As the tip approaches the back of the mouth, rotate it one-half turn (180 degrees).
- 4- Slide the OPA 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 OPA sideways and then rotate it 90 degrees.



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10	Ensure the correct placement	<p>-The flange should rest on the victim's lips. - Flange to prevent over insertion.</p> 
11	<b>Removal of Guedel airway</b>	
12	Perform hand hygiene	<p>This reduces the transmission of microorganisms.</p> 
13	Remove the device from the mouth.	Perform hand hygiene Because it short term use (not used for more than 30 days)

**✚ Intended purpose(use):**

- Guedel Airway -ULTRAMED invasive device but not surgically.
- Used to provide access to maintain an unobstructed oropharyngeal airway and it prevents biting of tongue

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and airway occlusion.

- For single use.
- Supplied sterile using Ethylene Oxide sterilization
- Designed to have a validity of sterilization for 5 years.

**✚ Material Used:**

- P.P. (Polypropylene).
- L.D.P.E. (Low Density Polyethylene).

**✚ Instruction for Use:**

**General Steps of inserting the Guedel airway:**

- 1- Explain to patient you are going to using Guedel airway for him.
- 2- Perform hand hygiene.
- 3- Wash hands with warm soapy water. Dry thoroughly. Put on gloves and aprons.
- 4- victim should be assisted to a position that is comfortable – this is normally sitting or supported at an angle of 45°
- 5- Raise bed to a comfortable working height.
- 6- Select the proper size of the Guedel airway by Measure the OPA from the victim's earlobe to the corner of the mouth and select the suitable size to it to avoid over insertion.
- 7- If possible, lubricate the airway before insertion (practically, in the emergency situation, this is rarely done).
- 8- Open the victim mouth by using the cross-finger technique to open the victim's mouth.
- 9- Insert the oro-pharyngeal airway

**For an adult:**

- Grasp the victim's lower jaw and tongue and lift upward.
  - Insert the OPA 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).
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- Slide the OPA 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 OPA sideways and then rotate it 90 degrees.

10- Ensure the correct placement; the flange should rest on the victim's lips.

**+ Cautions:**

- Do not use if package is open or damaged.
- Discard after single use.

**+ Precautions While Using Nasogastric tube**

**+ Precautions before use:**

- Before inserting an OPA, be sure the victim is unresponsive; has no oral trauma, such as broken teeth; and has not had recent oral surgery.
- Use an appropriately sized OPA for the victim.

**+ Precautions when inserting Guedel airway:**

- Ensure the correct placement: The flange should rest on the victim's lips, Flange to prevent over insertion.
- If the victim gags, remove the OPA immediately.
- Discard after single use.

If the victim gags, remove the OPA immediately.

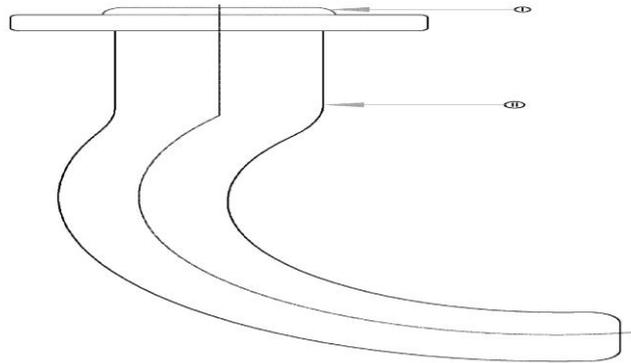
Conditions of Handling, Preservation and Storage:

- Not more than 5 cartoons on each other.
- Nice Ventilated place.
- Out of direct Sun light.
- Room temperature.

**+ Warning:**

- The device is for single use only; Reusing can be associated with Cross infection, Device Malfunction and Reactions to endotoxins as sterilization will not inactivate toxins produced by the breakdown of Gram-negative bacteria even if the bacteria themselves are killed.

✚ Configuration:  
Product design



- ❖ there are neither medicinal substances nor animal tissue used in the manufacturing of **Ultramed Sterile Guedel airway**.
- ❖ The product doesn't contain human blood derivatives.
- ❖ The product is free from Phthalates or other products that could leak from the device that maybe carcinogenic, mutagenic or toxic.
- ❖ The product is free from TSE species derived materials.

✚ **Packaging & sterilization:**

- ✓ The product is sterilized as individual unit using **EO** (Ethylene Oxide).
  - ✓ **The finished product conforms to the specifications and functional requirements for 5 years from the date of sterilization**
  - ✓ **Device life in use:** The device is single use device which must be discarded after use.
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