Instructions for use

CE 2862

[Product Name]

Guedel Airway

[Intended Use]

It is mainly used to establish oropharyngeal airway and preventing airway obstruction caused by tongue falling back.

[Type and Size]

Type	Size	Designated Size	REF
Transparent	000#	4	OAN000
	00#	5	OAN00
	0#	6	OAN0
	1#	7	OAN1
	2#	8	OAN2
	3#	9	OAN3
	4#	10	OAN4
	5#	11	OAN5
	6#	12	OAN6

[Contents]

This product is composed of bite pad and airway.

[Indication]

Guedel Airway is mainly indicated in the following situations where urgent maintenance of airway patency is necessary due to upper airway obstruction:

1) Airway obstruction caused by disturbance of consciousness: patients lose consciousness due to coma, anesthesia, poisoning and other reasons, and the tongue falls back to block the airway.

2) Airway management in short-term emergency or operation: such as cardiopulmonary resuscitation (CPR), emergency transport, oral and throat simple operations (such as sputum suction).

3) Obstruction caused by eliminating pharyngeal muscle relaxation: some patients have upper respiratory tract stenosis due to muscle relaxation (such as drunkness and overdose of sedative drugs), and the product can stretch the pharyngeal soft tissue and improve ventilation.

[Contraindications]

Includes diseases or conditions such as:

1) Patients awake or with light anesthesia (except for short periods)
2) Patients with acute inflammation of the airway
3) Patients whose front four teeth are at high risk of being broken or lost
4) Patients with throat trauma, hemorrhage, inflammation, tumor, or anatomical deformity

[Patient target group]

Infant to Adult.

[Intended users]

Professional medical staff

[Use Method]

1. A satisfactory depth of anesthesia should be achieved before the guedel airway is inserted to suppress the laryngopharyngeal reflex.

2. Selet the appropriate guedel airway.

3. Open the patient's mouth, and lay tongue retractor or tongue plate on tongue base, and then lift it upward to move the tongue away from the posterior pharyngeal wall, after that, put guedel airway in mouth until its end protrates 1-2cm from the incisor, and at that time, the front end of guedel airway is about to reach posterior wall of the oropharynx.

4. Lift the lower jaw with both hands so that the tongue is away from the posterior pharyngeal wall, and then place the thumbs of both hands on the flange of each side of the guedel airway and push it down at least 2cm until the flange of the guedel airway reaches the top of the lip.

5. Relax mandibular condyle to make it fall back to temporomandibular joint. Check oral cavity to avoid the condition that tongue or lip is clipped at the position between tooth and guedel airway.

[Warnings and Precautions]

1. Please read the instructions for use in detail before use.
2. The product is mainly used to establish oropharyngeal airway and preventing airway obstruction caused by tongue falling back.
3. Appropriate sizes should be selected according to the patient's situation. The guedel airway should not be too short. If it is too short, the tongue may still block the upper airway at the oropharyngeal level. The guedel airway should not be too long; if it is too long, it may reach the throat and touch the epiglottis, or even push the epiglottis toward the glottis or into the upper part of the esophagus.
4. For patients awake or under light anesthesia, the stimulation of the product to the epiglotis and glottis can cause coughing and laryngeal spasm. The best treatment method is to push the product out by 1-2cm or replace it with an product of appropriate length. Although spraying local anesthetics in the pharynx and/or applying ointment containing water-soluble

local anesthetics on the outside of the guedel airway can reduce the laryngeal reflex, it should be contraindicated in patients with a full stomach.

5. When the product is correctly positioned and of proper size, the pharyngeal curvature is located just behind the base of the tongue, and the front of the airway lumen is located near the epiglottis.
6. After the guedel airway is placed in the patient's mouth, the clinician should regularly check whether the product is out of place. If it is out of place, the product should be replaced in place in time.
7. After the product is inserted, clinicians should regularly check whether the product is blocked by the patient's secretions. If it is blocked, sputum suction should be taken in time. The appropriate suction tube should be selected according to the size of the product airway lumen.
8. The product has been sterilized by Ethylene oxide with validity for 5 years, if it has expired, it is prohibited to use.
9. Please check the package before use. Do not use the product if the package is damaged.
10. Once the sterile package is opened, it must be destroyed even if the product has not been used.
11. This product is for single use. Please destroy it after use, the destruction procedures shall be handled harmlessly by qualified or authorized institutions according to the local relevant regulations.
12. Please strictly abide by the corresponding surgical procedures, prohibited illegal operations. This device should be used by trained professional medical staff only within professional medical institutions under fully disinfected environment.
13. Please inform the manufacturer in case of any incidents related to the device occur and report to the competent authority of the Member State in which the incidents occurred, if applicable.

[Shelf-life]

5 years

[Sterilization Method]

Ethylene oxide

[Storage and Transport Conditions]

1. No heavy pressure, direct sunlight, rain or snow dipping, so as not to damage the device.
2. Handle with care when transporting to avoid violent collision.
3. Keep away from fire and heat sources in case that the device might be out of shape.
4. This product should be stored in a non-corrosive gas, well-ventilated and clean environment.

[Production Date]

See on the package.

[Symbol Explanation]

	Manufacturer	CN	Date of manufacture, Country of manufacture
EC REP	Authorized representative	LOT	Batch code
	Use-by date		Do not use if package is damaged and consult instructions for use
	Consult instructions for use or consult electronic instructions for use		Caution
	Do not resterilize, Indicates a medical device that is not to be resterilized		Do not re-use
	Single sterile barrier system	STERILE EO	Sterilized using ethylene oxide
MD	Medical device	UDI	Unique device identifier
CE 2862	CE Marking	REF	Catalogue number
	Keep away from sunlight		Keep dry
	Fragile, handle with care		Stacking layer limit

[Manufacturer]
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