

CANNULA DI GUEDEL BESMED BESMED GUEDEL AIRWAY CANULE OROPHARYNGÉE BESMED VÍA AÉREA BESMED GUEDEL

**Manuale d'uso - User manual - Manuel de l'utilisateur - Guía de uso
Guia para utilização**

ATTENZIONE: Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.

ATENÇÃO: Os operadores devem ler e entender completamente este manual antes de usar o produto.



**AW-61440 (GIMA 57751)
AW-61450 (GIMA 57752)
AW-61460 (GIMA 57753)
AW-61470 (GIMA 57754)**

**AW-61480 (GIMA 57755)
AW-61490 (GIMA 57756)
AW-61410 (GIMA 57757)
AW-61411 (GIMA 57758)**



Besmed Health Business Corp.
No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District,
New Taipei City 24888, Taiwan
Made in Taiwan



Mdi Europa GmbH
Langenhagener Str. 71, 30855
Hannover Langenhagen, Germany



Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com



INSTRUCTION FOR USE OF BESMED GUEDEL AIRWAY

1. INTENDED USE

Besmed Guedel airway intended to provide a clear airway through the oral cavity and the pharynx by preventing blockage by the tongue. It is used to maintain the patency of the respiratory passages through the oral cavity and pharynx while patient remain in unconscious condition.

2. PRODUCT DESCRIPTION

Besmed Guedel airway is an oropharyngeal airway to maintain or open a patient's airway. It preventing the tongue from covering the epiglottis, which could prevent the person from breathing. Flexible and anatomical shape to minimize airway trauma. In endotracheal intubation, guedel airway is inserted orally into the trachea to allow gas exchange, often via mechanical ventilation. The tube can be placed under direct visualization.

2.1 Indications

Besmed Guedel airway is intended to provide a clear airway through the oral cavity and the pharynx by preventing blockage by the tongue. It is used to maintain the patency of the respiratory passages through the oral cavity and pharynx while patient remain in unconscious condition.

2.2 Contraindications

- Avoid inserting a guedel airway in conscious or semiconscious patients because it may stimulate gagging and vomiting.
- Improper sizing airway, it can cause bleeding or close the glottis and airway.

2.3 Intended User


Medical personnel received the training of respiratory care.

2.4 Risks/ Side Effects


A potential risk associated with using guedel airways is the possibility of vomiting, which will lead to aspiration. It may also worsen airway obstruction if the airway is too small or inadequately sized (i.e., too small). Inappropriately sized airways may also cause laryngospasm (e.g., too large). The insertion of a guedel airway can also cause damage to the oral structure or dentition.

3. SPECIFICATION/MATERIAL/APPLICATION

3.1 Device Family and technical specification

| Representative Photo | Ref. No. | Product Description |
|----------------------------------------------------------------------------------|----------|------------------------------------|
|  | AW-61440 | Guedel Airway, Size 40mm (Pink) |
| | AW-61450 | Guedel Airway, Size 50mm (Blue) |
| | AW-61460 | Guedel Airway, Size 60mm (Black) |
| | AW-61470 | Guedel Airway, Size 70mm (White) |
| | AW-61480 | Guedel Airway, Size 80mm (Green) |
| | AW-61490 | Guedel Airway, Size 90mm (Yellow) |
| | AW-61410 | Guedel Airway, Size 100mm (Red) |
| | AW-61411 | Guedel Airway, Size 110mm (Orange) |

3.2 BESMED GUEDEL AIRWAY TECHNICAL SPECIFICATIONS

| | |
|----------------------|-----------------------------------------------------------------------------------|
| Product Name | Guedel Airway |
| Manufacturer | Besmed Health Business Corp. |
| Reference No. | AW-61440, AW-61450, AW-61460, AW-61470, AW-61480, AW-61490, AW-61410, AW-61411 |
| Representative Photo |  |
| Material | Airway body: LDPE |
| | Bite block: PE |

| Identification | Color coded | | | |
|------------------|-----------------|-------|----------|--------|
| Color | AW-61440 | Pink | AW-61180 | Green |
| | AW-61150 | Blue | AW-61190 | Yellow |
| | AW-61160 | Black | AW-61110 | Red |
| | AW-61470 | White | AW-61111 | Orange |
| Size | 40 mm – 120 mm | | | |
| Usage type | Single use | | | |
| Patient category | Infant to Adult | | | |

| | | | |
|------------------------|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| Patient population | | Non Sterile package | |
| Duration of contact | | Limited (≤ 24 h) | |
| Specifications | Resistance to collapse of the buccal portion | 83,46% | 84,44% |
| | Patency of lumen | The steel ball (ϕ 3.6 mm and ϕ 4.3 mm), diameter greater than 75% of minimum inside dimension of guedel airway, was able to pass through the guedel airways. | |
| Operataion temperature | | 25 ± 5 °C, Room Temperature | |
| Storage temperature | | -20°C to 60°C | |
| Relative humidity | | 30 - 80 % RH | |
| Shelf life | | 5 anni | |
| | | Test Item | Guideline |
| Attestation | | Functional test | ISO 5364:2016 |
| | | Cytotoxicity | ISO 10993-5 |
| | | Skin Irritation | ISO 10993-10 |
| | | Sensitization | ISO 10993-10 |
| | | Usability | IEC 62366-1 |
| | | | Result |
| | | | PASS |
| | | | PASS |
| | | | PASS |
| | | | PASS |
| | | | PASS |

3.3 Application

Choosing the right size of the guedel airway by measuring against the side of the patient's face.



4. DIRECTION OF USE

4.1 Read this instruction manual carefully before use.

4.2 Wash hands with warm soapy water. Dry thoroughly. Put on gloves and aprons.

4.3 Patient should be assisted to a comfortable position, which is normally sitting or supported at an angle of 45° .

4.4 Adjust the height of the bed so you can work comfortably.

4.5 Select the proper size of the guedel airway by measuring from the first incisors to the angle of the jaw and select the suitable size to it to avoid over insertion.

4.6 Remove the package and insert into the patient's mouth upside down.

4.7 Once contact is made with the back of the throat, the airway is rotated 180 degrees, allowing for easy insertion.

4.8 Assure the tongue is secured.











5. WARNING/ CAUTION










- Read this instruction before use.
- Replace a new one when the package is open or component damaged prior to use.
- Failure to do so may result in serious injury to the patient and/or the user.
- Never use the product outside the recommended technical specifications (intended use).
- The guedel airway is a single use device. Please discard it after use.
- It is used only on unconscious patients. Patients who are conscious or semiconscious are not allowed to use it.
- Any serious incident that has occurred in relation to the device should be reported to Besmed or its Authorized Representative/competent authorities and the Regulatory Authorities of the country.

6. DISPOSAL

Dispose of in accordance with local regulations.

7. LEGEND OF SYMBOLS

| | | | |
|-------------------------------------------------------------------------------------|--------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------|
|  | Medical Device compliant with Regulation (EU) 2017/745 |  | Product code |
|  | Imported by |  | Manufacturer |
|  | Please read instructions carefully |  | Date of manufacture |
|  | Lot number |  | Disposable device, do not re-use |
|  | Expiration date (see box / package) |  | Keep in a cool, dry place |

| | | | |
|-----------------------------------------------------------------------------------|------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------|
|  | Keep away from sunlight |  | Authorized representative in the European community |
|  | Not made with natural rubber latex |  | No-DEHP formulation |
|  | Temperature limit |  | Non-sterile |
|  | Medical Device |  | Disposable device, do not re-use |
|  | Unique device identifier | | |

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.