GIMA
PROFESSIONAL MEDICAL PRODUCTS

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

Manuale d'uso - User manual - Manuel de l'utilisateur - Guía de uso

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.*

REF

AW-61140 (GIMA 34431)
AW-61150 (GIMA 34432)
AW-61160 (GIMA 34433)
AW-61170 (GIMA 34434)
AW-61180 (GIMA 34435)
AW-61190 (GIMA 34436)
AW-61110 (GIMA 34437)
AW-61111 (GIMA 34438)
AW-61112 (GIMA 34383)
AW-61700 (GIMA 34439)

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

EC REP

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CE 0344

STERILE EO

MD

LATEX

DEHP

+60°C
-20°C

2 STERILIZE

M34431-M-Rev.7-03.25

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-61700	Guedel Airway, 40-110mm
	AW-61140	Guedel Airway, 40mm, Pink
	AW-61150	Guedel Airway, 50mm, Blue
	AW-61160	Guedel Airway, 60mm, Black
	AW-61170	Guedel Airway, 70mm, White
	AW-61180	Guedel Airway, 80mm, Green
	AW-61190	Guedel Airway, 90mm, Yellow
	AW-61110	Guedel Airway, 100mm, Red
	AW-61111	Guedel Airway, 110mm, Orange
	AW-61112	Guedel Airway, 120mm, Purple

3.2 BESMED GUEDEL AIRWAY TECHNICAL SPECIFICATIONS

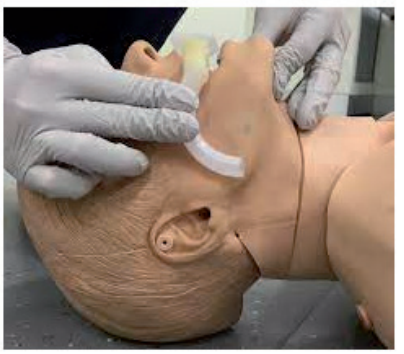
Product Name	Guedel Airway
Manufacturer	Besmed Health Business Corp.
Reference No.	AW-61700, AW-61140, AW-61150, AW-61160 ,AW-61170, AW-61180, AW-61190, AW-61110, AW-61111, AW-61112
Representative Photo	
Material	Airway body: LDPE
	Bite block: PP

Identification	Color coded			
Color	AW-61150	Blue	AW-61180	Green
	AW-61160	Black	AW-61190	Yellow
	AW-61170	White	AW-61110	Red
	AW-61112	Purple	AW-61111	Orange

Size		40 mm – 120 mm		
Usage type		Single use		
Patient population		Infant to Adult		
Package		Sterile package		
Sterilization method		Ethylene oxide		
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 years		
		Test Item	Guideline	Result
Attestation		Functional test	ISO 5364:2016	PASS
		Cytotoxicity	ISO 10993-5	PASS
		Skin Irritation	ISO 10993-10	PASS
		Sensitization	ISO 10993-10	PASS
		Usability	IEC 62366-1	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

CE	Medical Device compliant with Regulation (EU) 2017/745	REF	Product code
	Importated by		Manufacturer
	Please read instructions carefully		Date of manufacture

LOT	Lot number		Disposable device, do not re-use
	Expiration date (see box / package)		Keep in a cool, dry place
	Keep away from sunlight	EC REP	Authorized representative in the European community
	Temperature limit	STERILE EO	Sterile
MD	Medical Device		Disposable device, do not re-use
	Do not resterilize		Single sterile barrier system
	Not made with natural rubber latex		No-DEHP formulation
UDI	Unique device identifier		

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.