

MASCHERA IN SILICONE BESMED

BESMED SILICONE MASK

Manuale d'uso - User manual

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.



SM-86503 (GIMA 34220)
SM-86513 (GIMA 34221)
SM-86523 (GIMA 34222)

SM-86131 (GIMA 34223)
SM-86141 (GIMA 34224)
SM-86151 (GIMA 34225)



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Made in Taiwan



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INSTRUCTION FOR USE

Besmed Silicone Mask

Model:

- SM-86503 - Transparent Silicone Mask, Size 0, Infant
- SM-86513 - Transparent Silicone Mask, Size 1, Infant Large
- SM-86523 - Transparent Silicone Mask, Size 2, Child
- SM-86131 - Silicone Mask, Size 3, Child Large
- SM-86141 - Silicone Mask, Size 4, Adult
- SM-86151 - Silicone Mask, Size 5, Adult Large


Product Description

Besmed Silicone mask is designed for connection to manual resuscitators for use as an adjunct to artificial respiration and cardiopulmonary resuscitation, automatic resuscitators, and ventilators. Six different sizes are available, from infant to large adult. Anti-slip design for easy holding and an adjustable soft-cuff for promoting better seal and patient comfort.

Intended Use

Besmed Silicone mask is intended to be used with manual resuscitators, automatic resuscitators, and ventilators. It provides a seal such that positive pressure from the positive pressure source is directed into the patient's nose and mouth.

Besmed Silicone mask Technical Specifications

Product Name	Silicone Mask	
Manufacturer	Besmed Health Business Corp.	
Reference No.	SM-86503, SM-86513, SM-86523	SM-86131, SM-86141, SM-86151
Representative Photo		
Patient category	Adult/Child/Infant	

Material		Silicone	
Color		Transparent	
Component type		Accessory	
Device type		Reusable	
Patient Usage type		Single patient reuse	
Patient Weight		Size 0	<2 kg
		Size 1	2 ~10 kg
		Size 2	10 ~25 kg
		Size 3	25 ~60 kg
		Size 4	60 ~100 kg
		Size 5	>100 kg
Specifications	Engagement of 22 mm latching sockets to cones	Did not disconnected at (50 ± 5) N for 10 s	
	Leakage from 22 mm latching sockets	No signs of leakage at (8 ± 0.5) kPa	
	Drop procedure for 22 mm latching sockets	No signs of damage	
Package		Non-sterile packages	
Connection diameter		22 mm	
Operation temperature		25±5 °C, Room Temperature	
Storage temperature		-20°C ~ 60 °C	
Relative humidity		30 - 70% RH	
Shelf life		5 years	
Attestation	Test Item	Guideline	Result
	Conical connectors	ISO 5356-1	PASS
	Cytotoxicity	EN ISO 10993-5:2009	PASS
	Sensitization	EN ISO 10993-10:2023	PASS
	Skin Irritation	EN ISO 10993-23:2021	PASS
	Usability	IEC 62366-1	PASS

Intended users

Medical personnel received the training of respiratory care.

Indication

Besmed Silicone mask is used with manual resuscitators ventilators, with an appropriate perimeter of Besmed Silicone mask reduces the pressure sensitivity and enhances facial contour with comfort.

Instruction for use

1. Check for clean airflow passage prior to use.
2. Connect to breathing circuit or resuscitation with appropriate fitting.
3. Set the gas to the proper flow and check for gas flow through the device.
4. Position the elastic strap behind the neck.
5. Make sure all connections are compatible and fit firmly
6. Gently pull the ends of the strap until the mask is secure.

Contraindications

Besmed Silicone mask is possibly not suitable for the use to the patients with recent facial, oral, skull surgery, or trauma, and patients who have claustrophobia, vomiting, or active GI bleeding. Inability to maintain an adequate seal between the mask and the patient's face, which may result in inadequate oxygenation.

Risks/Side Effects

1. Inappropriate size of mask and strap tension may cause discomfort.
2. Mask related complication includes claustrophobia, ulceration, facial rash, or itching.
3. Cramped hands and tired muscles and limits the user's ability to perform other tasks especially in obese and patients with a larger head

Cleaning and Sterilization**1. Cleaning**

1.1 Hand wash the mask thoroughly to remove adhering substances from each component while soaking in a commercially available, anionic detergent such as ANIOSYME DD1 for 10 mins. Use 1:200 ratio of dilution in tepid water for each mask keeping the temperature 35 °C.

1.2 Rinse the mask with 5 liters of water and proceed to the sterilization step.

2. Sterilization

2.1 Sterilize the mask, SM-86503, SM-86513, and SM-86523 with (Autoclave max. 134°C), for 20 mins.

2.2 Sterilize the mask, SM-86131, SM-86141, and SM-86151 with (Autoclave max. 121°C), for 20 mins.

2.3 Reprocess limit is 40 cycles max.

2.4 Air dry out of direct sunlight for 25 min. Make sure the masks are dry before use. If not air-dried, please extend the air-drying time.

2.5 Inspect all components; if any tears or any damage, please replace them.















Warning



- Read this instruction before use.
- Do not use if the package is open or damage or contaminated.
- Any skin redness, itching or any abnormal situation happens, stop using this mask.
- Do not use any alcohol, bleaching chemical or cleaning solution that contains conditioners or lubricant.
- 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.

Disposal

Dispose of in accordance with local regulations

LEGEND OF SYMBOLS

	Medical Device compliant with Directive 93/42/EEC		Product code
	Importated 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		Ftalati free

 A symbol representing a temperature limit, showing a thermometer with a vertical line extending above the top of the scale.	Temperature limit	 A triangular warning symbol with the words "NON STERILE" written inside.	Non-sterile
 The letters "MD" in a bold, black font inside a square border.	Medical Device		

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.