

MASCHERA CON CUSCINO MONOUSO BESMED

BESMED DISPOSABLE CUSHION 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.



CM-65304 (GIMA 57700)
CM-65314 (GIMA 57701)
CM-65324 (GIMA 57702)
CM-65334 (GIMA 57703)
CM-65344 (GIMA 57704)
CM-65354 (GIMA 57705)
CM-65464 (GIMA 57706)



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

CM-65810 (GIMA 57711)
CM-65820 (GIMA 57712)
CM-65830 (GIMA 57713)
CM-65840 (GIMA 57714)
CM-65850 (GIMA 57715)



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INSTRUCTION FOR USE

Group Name: Besmed Disposable Cushion Mask

Models:

- CM-65810 - ULTRA-SMT Anesthesia Mask, w/o hook, Size: 1, Infant
- CM-65820 - ULTRA-SMT Anesthesia Mask, w/o hook, Size: 2, Pediatric
- CM-65830 - ULTRA-SMT Anesthesia Mask, w/o hook, Size: 3, Small, Adult
- CM-65840 - ULTRA-SMT Anesthesia Mask, w/o hook, Size: 4, Medium, Adult
- CM-65850 - ULTRA-SMT Anesthesia Mask, w/o hook, Size: 5, Large, Adult
- CM-65304 - Disposable Air Cushion Mask, w/ hook, Size: 0, Infant
- CM-65314 - Disposable Air Cushion Mask, w/ hook, Size: 1, Large, Infant
- CM-65324 - Disposable Air Cushion Mask, w/ hook, Size: 2, Child
- CM-65334 - Disposable Air Cushion Mask, w/ hook, Size: 3, Large, Child
- CM-65344 - Disposable Air Cushion Mask, w/ hook, Size: 4, Adult
- CM-65354 - Disposable Air Cushion Mask, w/ hook, Size: 5, Large, Adult
- CM-65364 - Disposable Air Cushion Mask, w/ hook, Size: 4, Extra Large, Adult

Intended Use

Besmed Disposable Cushion mask is intended to channel anesthesia gases or mixture of oxygen to the patients for inhalation via patient's mouth and nose. Anesthesia masks are to be used in conjunction with anesthesia and ventilator breathing systems. It provides a seal such that positive pressure from the positive pressure source is directed into the patient's nose and mouth.

Product Description

Besmed Disposable Cushion mask is designed for connection to breathing circuit for use as an adjunct to artificial respiration and cardiopulmonary resuscitation, automatic resuscitators, ventilators. Its a non-invasive method to either induce or maintain general anesthesia. It also used in resuscitation procedures as an effective mode of ventilation for unconscious patients. According to patient category, there are six different sizes are available from neonates to adult. Anti-slip design for easy holding. Transparent dome provides clear observation of patient's condition and anatomical shape with soft touch provides better seal and patient comfort.

Technical Specifications of Besmed Disposable Cushion mask

Group Name	Disposable Cushion Mask
Manufacturer	Besmed Health Business Corp.

Patient category		Neonate/Infant/Pediatric / Child/Adult	
Material		TPR, PP, PVC	
Color and specifications		Mask dome: Transparent	
Component type		Accessory	
Device type		Disposable	
Patient Usage type		Single patient use	
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	
Latex/DEHP content		None	
Package		Non-sterile package	
Connection diameter		Diameter	Patient group (size)
		15 mm	Size 0, Size 1
		22 mm	Size 2, Size 3, Size 4, Size 5
Operation temperature		25 ± 5 °C, Room Temperature	
Storage temperature		-20°C ~ 60°C	
Relative humidity		30 - 60% RH	
Shelf life		5 years	

	Test Item	Guideline	Result
Attestation	Conical connectors	EN ISO 5356-1:2015	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 Disposable Cushion mask is designed to ensure a tight seal around the patient nose and mouth to deliver oxygen gases to the patient. Besmed Disposable Cushion masks are transparent to facilitate visual inspection of breathing condition of the patient. Signs of inadequate ventilation can be identified early such as reduced chest movement, absent or quiet breathing sounds, patient cyanosis, audible gas leaks. Also, late signs of inadequate ventilation include haemodynamic consequences of hypoxaemia or hypercarbia.

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 Disposable Cushion 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.

















Warning/ Caution

1. Read this instruction before use.
2. Do not use if the package is open or damage or contaminated.
3. Any skin redness, itching or any abnormal situation happens, stop using this mask.
4. Single use devise only. Do not re-use.
5. Do not soak, wash, rinse or sterilize the product.
6. 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		No-DEHP formulation
	Temperature limit		Non-sterile

 The MD icon consists of the letters "MD" in a bold, black, sans-serif font, enclosed within a black square border.	Medical Device	 The no re-use icon is a circle with a diagonal slash through it, indicating that the device is not to be reused.	Disposable device, do not re-use
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GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.