

**KNGMED**

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**Reusable Silicone Breathing Masks**

7600217-S

7600217-M

7600217-L

**Nasal Mask**

## General Description

Reusable Silicone Breathing Masks are noninvasive accessories used to deliver airflow from positive airway pressure (PAP), anesthesia and ventilation devices to the patient. Masks are for single-patient use at home or for multi-patient use in a hospital/healthcare setting. In order to ensure the correct use of masks at home, in the hospital/health institution environment, cooperation should be made with the doctor and healthcare personnel.

## Intended Use



















The Nasal Mask is intended to be used for patients who have been prescribed CPAP or VPAP therapy and to provide a patient interface for application of noninvasive ventilation are under the specific direction of a physician. It is used in conjunction with CPAP, Bi-PAP, Auto-PAP therapy devices in home, or multi-patient in hospital and medical centers.

## Notes:

Exhalation is built into this mask. A separate exhalation device is not required.

This mask is not made with natural rubber latex or DEHP.

## SYMBOLS OF THE COMPONENTS

Image of Symbol	Meaning of Symbol	Image of Symbol	Meaning of Symbol
	Manufacturer		Non-sterile
	Read instructions for use		European Conformity Mark
	Protect from sunlight		Batch Code
	Keep dry and cool area		Catalog Number
	Store between 0 °C (± 5) and +50 (± 5).		Expiration Date
	Latex Free		Unique Device Identifier
	It is a medical device		Anti-Aspyxia Valve
	Don't use the product with damaged packaging		Made in Türkiye
	Does not contain DEHP.		Humidity Limitation between 40% and 70%

## Indications

It is indicated to be used for the conditions which required CPAP, Bi PAP and Auto PAP therapy like obstructive sleep apnea syndrome, chronic obstructive pulmonary disease with exacerbation, acute congestive heart failure with pulmonary edema, acute lung injury, neuromuscular disorders, pneumonia, ventilator weaning.

## Contraindications

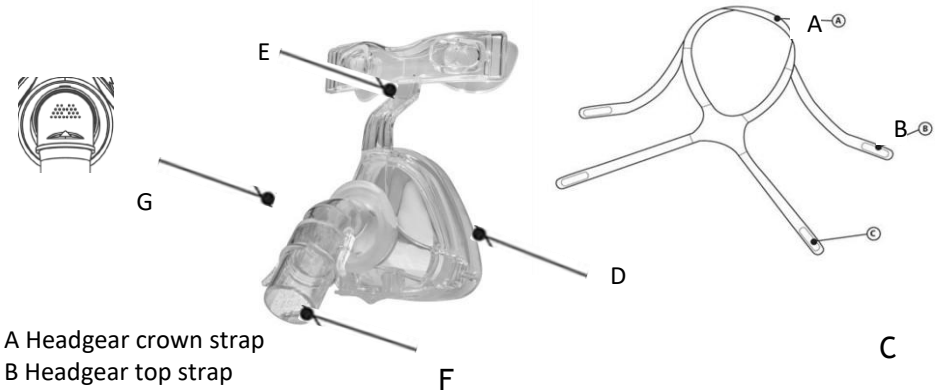
There are no contraindications.

## **⚠ Warnings and precautions**

- This mask is not suitable for providing life support ventilation.
- Inspect all parts of your Nasal Masks for damage; replace that are visibly deteriorated due to cracking, crazing, tears, etc.
- Discontinue use and contact your healthcare professional, if skin redness, irritation or discomfort occurs while using mask.
- Consult a physician or dentist if you encounter tooth, gum, or jaw soreness after using the masks.
- Consult a physician if you experience the following symptoms while using the mask or after removing it: Drying of the eyes, eye pain, eye infections, or blurred vision.
- Do not block or seal off the exhalation ports.
- Do not overtighten the headgear straps. Watch for signs of overtightening, such as excessive redness, sores, or bulging skin around the edges of the mask. Loosen the headgear straps to alleviate problems.
- This mask is designed for use with CPAP or bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or bi-level system is turned on and operating properly.
- Do not block or try to seal the exhalation port. Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. This warning applies to most models of CPAP systems.
- If oxygen is used with device, the oxygen flow must be turned off when the device is not operating. Otherwise, Oxygen accumulated in the device enclosure will create a risk of fire.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and bi-level machines.

- As with all masks at low CPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- Attaching an exhalation device requires therapy pressure level adjustment to compensate for increased leak.
- Longtime use of masks can cause pressure ulcers

## Parts



- A Headgear crown strap
- B Headgear top strap
- C Headgear bottom strap
- D Mask cushion
- E Frame
- F Tubing quick release
- G Elbow with built-in exhalation ports (Do not block)

## Before Use

- Read and understand the instructions.
- Remove all packaging before using the Nasal Masks. Hand wash mask.
- Inspect all parts of your Nasal Masks for damage; replace that are visibly deteriorated due to cracking, crazing, tears, etc.
- Clean patient's face.
- Always keep the vent holes clear and open.

## Disinfection

**⚠ This process should be used for multiple uses in the hospital.**

This Mask can be Autoclave vapor at 121 °C 15 Minutes for 10 times.

1. Enclose those components of the mask that can be disinfected sterilization peel pouch as described in the instructions for the autoclave.
2. Place in the autoclave for the required time. See overleaf for appropriate mask validated times.
3. Remove the mask from the autoclave.
4. Store in clean conditions.

5. After autoclaving and using the product 10 times, dispose of all parts according to your institution's protocol. Follow all local, state, and federal regulations with respect to environmental protection.

### **Cleaning your mask in the home**

#### **⚠ This process should be used for a single patient at home.**

Your mask and headgear should only be gently handwashed. Daily/After each use:

- Disassemble the mask components according to the disassembly instructions.
- Thoroughly clean the separated mask components (excluding headgear), by gently rubbing in warm (approximately 86°F/30°C) water using mild soap.
- To optimise the mask seal, facial oils should be removed from the cushion after use.
- Use a soft bristle brush to clean the vent.
- Inspect each component and if required, repeat washing until visually clean.
- Rinse all components well with drinking quality water and allow to air dry out of direct sunlight.
- When all components are dry, reassemble according to the reassembly instructions. Weekly:
  - Handwash the headgear.

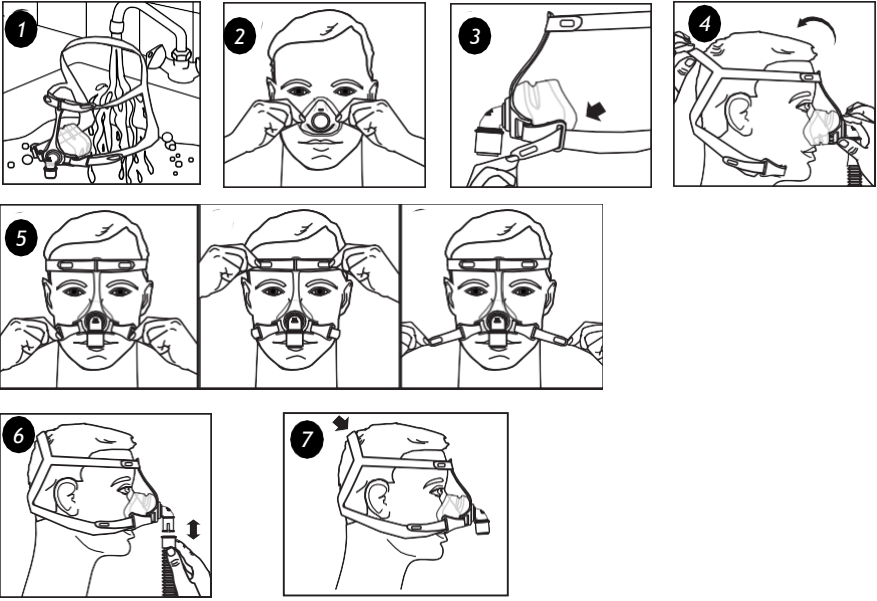
#### **⚠ Cautions:**

- Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
- Do not place the fabric parts into the dryer.
- Any deviation from these instructions may impact the performance of the product.
- Inspect the entire mask for damage or wear (cracking, crazing, tears, damage, etc). Discard and replace any parts as necessary.

### **Dishwashing Instructions**

- In addition to hand washing, the mask may be cleaned in the dishwasher once a week. ⚠ Caution: Use a liquid dish washing detergent only to wash the mask.
- Remove the headgear. Do not wash the headgear in the dishwasher.
- Separate the cushion and the frame and wash in the top shelf of the dishwasher.
- Air dry. Make sure the mask is dry before use.
- ⚠ Warning: Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any parts as necessary.

## Achieving the Right Fit



### Before Putting on the Mask:

Hand wash mask.(1)

Sizing: The cushion should fit the width of your nose without blocking the nostrils.

The top of the cushion may sit between the bridge and tip of your nose. (2)

### Putting on the Mask

Prior to fitting your mask, remove the quick release connection (F) . Connect to your device air tubing.

Thread the top straps (B) through the top slot in the mask frame (E).(3)

With both lower headgear straps (C) released, hold the mask against your face and pull the headgear over your head. Bringing the lower straps below your ears, attach the headgear clips into the lower hooks on the mask frame.(4)

Unfasten the Velcro, pull the upper headgear straps evenly until they are comfortable and reattach the Velcro.(5) Do not overtighten.

Repeat step 5 with the all headgear straps.

Attach the quick release connection to the elbow. (6)

Your mask and headgear should be positioned as shown. (7)

**Note:**

Do not overtighten the headgear.

The location of the headgear crown strap(A) may vary depending on head size.

Position the strap so the mask sits comfortably.

**Using the mask**

Connect the flexible tubing (included with CPAP or bi-level device) to the quick release swivel. Turn the therapy device on. Lie down. Breathe normally.

Assume different sleeping positions. Move around until comfortable. If there are any excessive air leaks, make final adjustments. Some air leaking is normal.

**Tubing Quick Release**

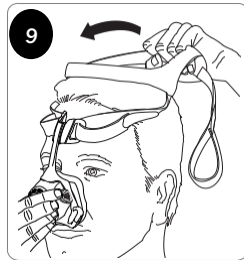
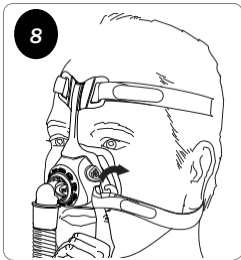
The elbow is equipped with a tubing quick release for the CPAP tubing. Pull on the tubing quick release and it will disengage from the elbow and come loose with the tubing

**Comfort Tips**

The most common mistake is overtightening the headgear. The headgear should fit loose and comfortable. If your skin bulges around the mask or if red marks appear on your face, loosen the headgear.

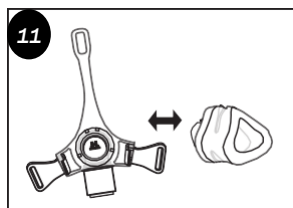
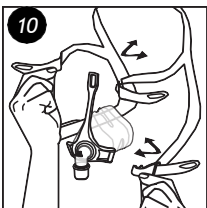
Re-seat the mask by pulling it directly away from your face and gently setting it back into place.

**Removing the mask**



To remove your mask, Disconnect a bottom clip (8) and pull the mask and headgear up over your head.(9)

**Disassembly / Assembly**



**Removing the Headgear**

Peel away the tabs and pull through the slots in the mask frame or clip. (10)

## **Removing the Cushion**

Pull cushion away from the frame.(11)

## **Intended Patient Population**

The mask is to be used by adult patients (> 30 kg) requiring non-life-support ventilator assistance.

## **Intended User**

The device is to be used by healthcare professionals (doctors, nurses, technicians) or by laypersons who have been prescribed non-invasive ventilation therapy and who are capable of understanding and following the instructions for use.

## **Expected Clinical Benefits**

The expected clinical benefits and claims of KNGMED REUSABLE SILICONE BREATHING MASKS are as follows:

Reusable Silicone Breathing Masks deliver airflow from positive airway pressure (PAP) and ventilation devices to the patient in an effective and safe way.

## **Possible Side Effects and Adverse Events**

There are no known complications or side effects.

## **Device Limitations or Incompatibility Risks**

- The mask shall only be used with compatible CPAP, BiPAP, or Auto-PAP devices as specified
- by the manufacturer.
- It must not be used with life-support ventilators.
- Do not use non-original or modified accessories.
- Reuse and reprocessing must follow validated cleaning and disinfection procedures.

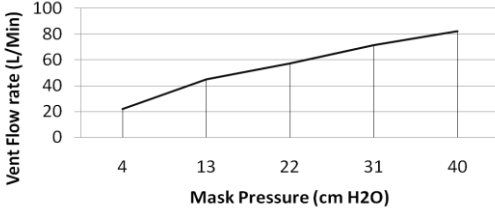
## **Application Site In The Body**

The device is applied externally to the patient's face to deliver positive airway pressure through the nasal and/or oral region.

## **ADVERSE CASE**

Serious adverse events related to the reusable silicone breathing mask device must be reported to the competent authority of the Member State in which the user and/or patient is resident and to the manufacturer.

## Technical Specifications: Pressure Flow Curve



Therapy pressure range:	4 hPa - 20 hPa	
Drop in Pressure at	50 l/min	100 l/min
	0.2 hPa	0.4 hPa
Deadspace	S 90 mL	
	M 93 mL	
	L 95 mL	
Sound Levels	27 dBA	

## Disposal

The device must be treated as a medical waste and disposed of in accordance with local regulations.



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