

STEALTH

NASAL PILLOW MASK



NASAL PILLOW MASK

4 Sizes of pillows available:

Super Small, Small, Med & Lg

REF NO.: 7901

Intended Use

The nasal pillow mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bilevel system.

The mask to be used by adult patients for whom positive airway pressure has been prescribed. The mask is for single-patient re-use in the home environment and multi-patient re-use in the hospital/ institutional environment.

Features

- *Easy to fit, assemble, and maintain.
- *4 Pillow Cradles with 4 different pillow sizes. (Super Smail. Small, Medium & Large)
- *Pillows can be independently changed on a cradle to accommodate nostril asymmetry.
- *Quick release floating elbow with 360 degree rotation and extended silicone tube.
- *Quiet vent design.

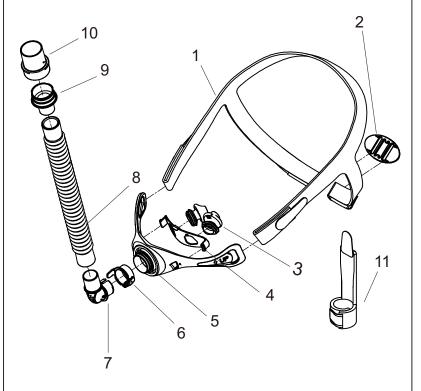




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- 1 -

Parts of the Nasal Pillow

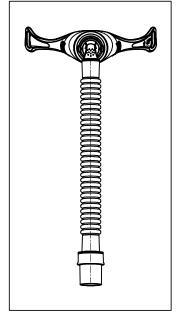


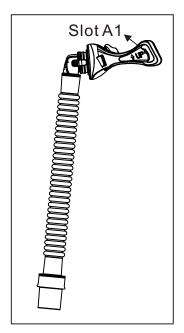
Description No.

- Top headgear 1.
- Rear headgear 2.
- Pillows (Super Smail, Small, Med & Lg) 3.
- Pillow Cradle 4.
- Slicone Base 5.
- 6. 7. Quick Release Connector Ring
- Elbow connector
- Silicone tube 8.
- 9. Swivel connector
- 10.
- Tubing connector Optional over-the-head tube strap 11.

- 2 -

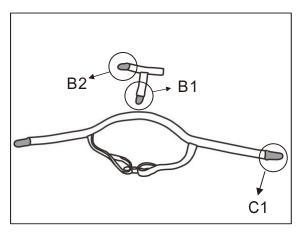
Outline of assembled Nasal Pillow Mask





Front View

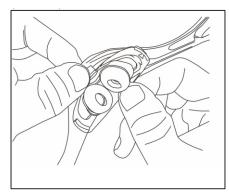
Lateral View



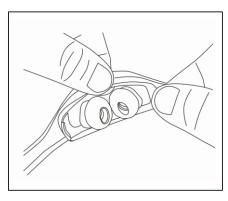
Headgear

- 3 -

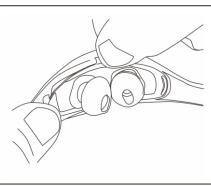
Assembling your Nasal Pillow Mask



First - insert the small upper Tab on the Pillow Cradle into the slot on the Silicone Base



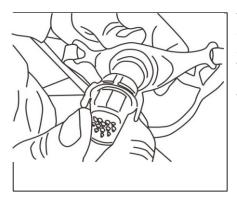
Next - while holding the small upper tab in place, Insert the large tab on the right side of the Pillow Cradle into the side slot on the Silicone Base



Last - while continuing to hold the small upper tab in place, insert the other large tab on the left side of the Pillow Cradle into the left side slot on the Silicone Base.

Note: It is important that the small upper tab on the Pillow Cradle remains properly inserted into its slot in the Silicone Base to ensure a proper seal with no leaks.

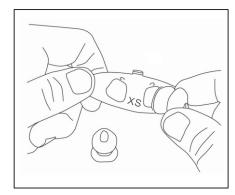
Connecting & Disconnecting the Quick Release Elbow.



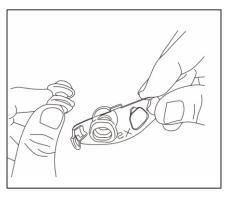
To disconnect the Quick Release Elbow, squeeze the small tabs on the connector ring and pull it from the Silicone Base.

To connect the Quick Release Elbow, push it into the Silicone Base until it snaps into place.

Inserting Nasal Pillows into the Cradle



Insert the pillows into the Cradle. The pillows and cradle are shaped to only fit one way.

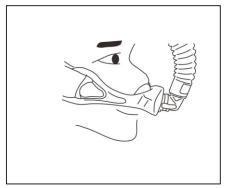


Line the pillows up accordingly and be sure that the pillow's first groove is properly seated into the cradle

FITTING YOUR STEALTH NASAL PILLOWS MASK



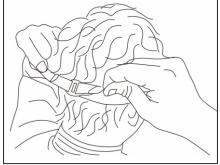
hold the pillows at your nose, and pull the headgear over your head.



Adjust the Nasal pillows to the most comfortable position



Adjust the side straps of the headgear upward to the most optimal

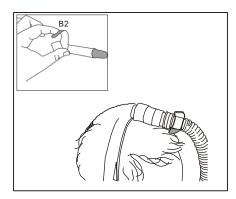


Adjust the rear straps to the best fit.

Notes:

- 1) Over tightening of your headgear straps may cause excess pressure on your nose and can actually cause leaking.
- 2) Further adjustment of the side and back headgear straps after connected to the CPAP or BiLevel may be necessary to ensure an optimal fit.

USING THE OPTIONAL OVER-THE-HEAD STRAP



Fasten the air tubing through tube holder strap B2, the tubing can be positioned in the center of head.



Complete.

⚠ Caution

US federal law restricts this device to sale by or on the order of a physician.

Marnings

This mask is designed for use with CPAP or bilevel systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or bilevel 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 device is turned on and functioning properly, new air from the device flushes the exhaled air out through the attached mask exhalation port. However, when the device is not operating, enough fresh air will not be provided through the mask, and exhaled air may be re-breathed. At low pressures, the airflow through the exhalation port may not be enough to clear all of the exhaled gas (CO2) from the mask. You may breathe in some of the air that you have exhaled.

*If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating.

Explanation of the Warning:

When the device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.

- *Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- *At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, nasal interface selection, and the leak rate.
- *Some users may experience skin redness. If this happens, contact your health care professional.

Cleaning the Interface:

The pillows, cradle, silicone base and tubing should be cleaned daily or as needed.

*Hand wash in warm water with a mild liquid dishwashing detergent.

Do not use bleach, alcohol, or cleaning solutions containing alcohol.

Do not use cleaners containing conditioners or moisturizers.

*Rinse thoroughly. Pat with a towel and air dry completely before use.

*Inspect all parts for damage or wear; replace if necessary.

Cleaning the Headgear:

Hand wash the headgear weekly or as needed. Lay the headgear flat or line dry.

Disposal:

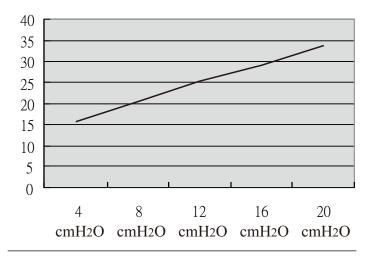
The nasal pillow mask does not contain any hazardous substances and may be disposed of with your normal household refuse.

Technical specifications

Pressure-Flow Curve

Note: The mask contains passive venting that meets the requirements for protection against rebreathing as specified in ISO 17510-2. As a result of manufacturing variations, the vent flow rate may vary.

Pressure	4 cmH2O	8 cmH2O	12 cmH2O	16 cmH2O	20 cmH2O
Flow	15.7 LPM	20.4LPM	25.1 LPM	29.0 LPM	33.7 LPM



Standards

CE designation in accordance with EC directive 93/42/EEC, class lia. ISO 14971, ISO13485,

ISO 10993-1 and ISO 17510-2.

Therapy Pressure

4 to 20cmH₂O.

Resistance

Drop in pressure measured

at 50L/min: $2.1cmH_2O$ & 100L/min: $8.0cmH_2O$

Sound

 $27.2 \; dBA \; @ \; 10cmH_2O; \; 34.6 \; dBA \; @ \; 20cmH_2O$

Environmental Conditions

Operation temperature: -18°C~50°C Storage temperature: -40°C~60°C Storage relative humidity: <85%

PART NUMBERS

Part No. Description

7901 STEALTH Nasal Pillow Interface

7905 Replacement Headgear

7906 Replacement Nasal Pillows & Cradle - Super Small

7907 Replacement Nasal Pillows & Cradle - Small
 7908 Replacement Nasal Pillows & Cradle - Medium
 7909 Replacement Nasal Pillows & Cradle - Large



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