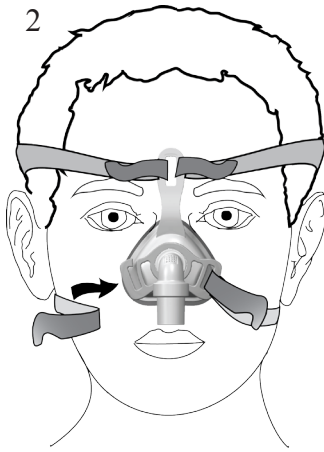


Innova™ Nasal Vented Mask

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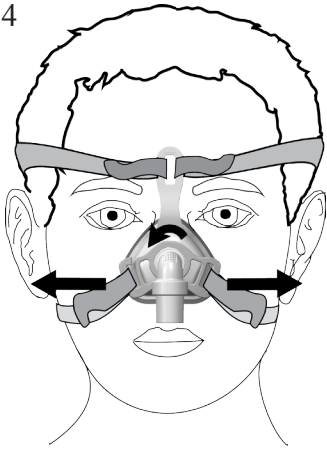
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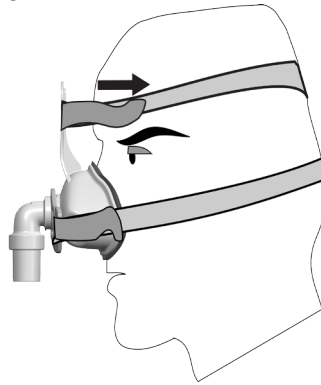
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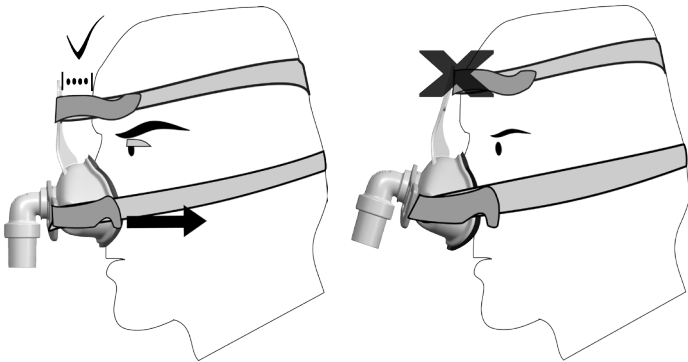
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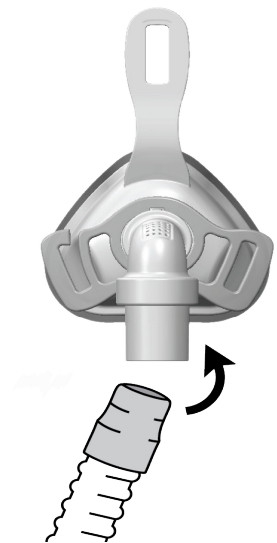
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6



7

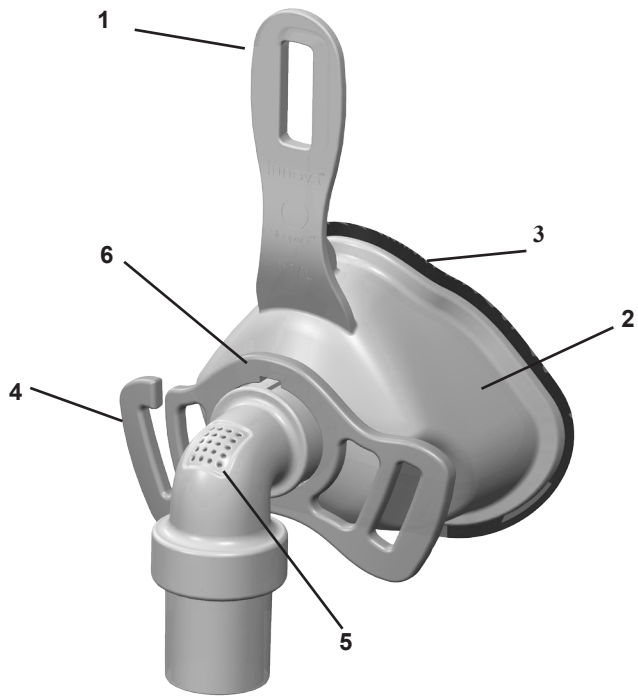


 Sleepnet®

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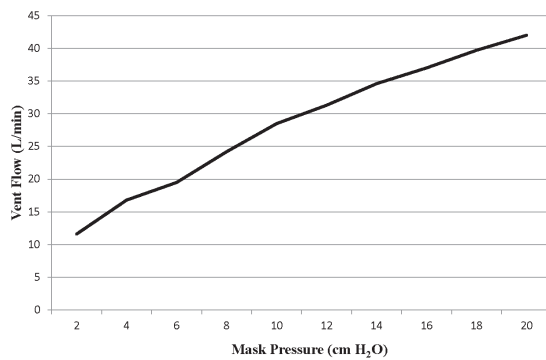
EU Rep: Medical Product Services GmbH
Borngasse 20, 35619 Braunfels Germany
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CE₀₁₂₃
90118-W Rev. A



- Innova™ Mask**
1. Touchless Spacebar™
 2. Mask Shell
 3. Airgel™ Cushion
 4. Quick Release Headgear Connector
 5. Vented Elbow Assembly
 6. Active Headgear Connector™

VENT HOLE PRESSURE/FLOW CHARACTERISTICS (Approx.)



Innova™ Nasal Vented Mask

CONTENTS: Innova™ Nasal Vented Mask with headgear
THIS PRODUCT IS NOT MANUFACTURED WITH NATURAL RUBBER LATEX
Rx ONLY MADE IN U.S.A.



The Innova™ Vented Nasal Mask is intended to provide an interface for application of positive airway pressure therapy, such as CPAP or bi-level. The mask is intended for single patient use in the home or multi-patient use in the hospital or institutional environment on adult patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

GENERAL INFORMATION - WARNINGS AND CAUTIONS

CAUTION: U.S. Federal Law restricts this device for sale by or on the order of a physician.

CAUTION: Do not expose the mask to temperatures above 140°F (60°C).

CAUTION: This mask may be cleaned and used repeatedly on the same person. Do not sterilize. **USA ONLY:** For multiple patients use, high level disinfection protocol must be followed

WARNING: At low baseline pressure, the flow through the vent holes may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.

WARNING: This mask should be used with the positive airway pressure device recommended by the manufacturer, your physician, or a respiratory therapist. The mask should not be used unless the positive airway pressure device is turned on and operating properly. The mask's vent holes should never be blocked. The vent holes allow a continuous flow of air out of the mask. When the positive airway pressure device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask's vent holes. When the positive airway pressure device is not operating, exhaled air may be re-breathed. Re-breathing of exhaled air can, in some circumstances, lead to suffocation. This warning applies to most models of nasal positive airway pressure devices and masks.

WARNING: If oxygen is used with this CPAP mask, the oxygen flow must be turned off when the CPAP machine is not operating. Explanation of the warning: When the CPAP device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the CPAP machine enclosure. Oxygen accumulated in the CPAP machine enclosure will create a risk of fire.

WARNING: No smoking or open flames such as candles may be used when oxygen is in use.

WARNING: Do not use the mask with baseline pressure less than 4 cm H₂O or greater than 20 cm H₂O.

WARNING: Consult manufacturer for proper O₂ enrichment tubing.

WARNING: If skin irritation or any other adverse reaction develops, discontinue use and contact your health care professional.

WARNING: Using a mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.

WARNING: Significant unintentional leak may occur without properly fitting the mask. Follow the USER INSTRUCTIONS FOR THE INNOVA™ NASAL MASK provided.

GENERAL INFORMATION

The mask has a non-transferable three month limited warranty for manufacturer's defects from the date of purchase by the initial consumer. If a mask used under normal conditions should fail, Sleepnet will replace the mask or its components. For additional information about the Sleepnet Warranty, please visit <http://www.sleepnetmasks.com/products/our-promise.cfm>.

NOTE: The mask has a service life of 6 months.

NOTE: Please dispose of the mask and accessories in accordance with local and regional guidelines.

NOTE: THIS PRODUCT IS NOT MANUFACTURED WITH NATURAL RUBBER LATEX

CLEANING AND MAINTENANCE - SINGLE PATIENT USE

Cleaning is recommended on a daily basis. Hand wash the mask and components in warm water using a mild detergent. Rinse the mask thoroughly after washing. Visually verify that the vent holes are clear and allow the mask to air dry. Washing your face prior to fitting the mask will remove excess facial oils and help extend the life of the mask.

NOTE: Inspect mask prior to each use. Replace the mask if parts are damaged or gel is exposed due to tear or punctures.

NOTE: The gel cushion, although silky to touch, will not tear, leak or detach from the mask under normal use and following recommended cleaning and maintenance protocols. However, the gel cushion is not indestructible. It will tear, cut and rip if subjected to mishandling or abuse. Do not clean in a dishwashing machine. The warranty does not cover these types of product failures. Therefore, please handle your new mask with care.

INSTITUTIONAL USE

Contact the manufacturer for the recommended method of disinfection. When using CIDEX OPA® solution, use at full strength.

TECHNICAL INFORMATION

Resistance to air flow at 50 L/min: 0.25 cmH₂O

Resistance to air flow at 100 L/min: 0.95 cmH₂O

Dead space (approx): S/M size - 76 ml M/L size - 102 ml

Operating Temperature: Do not expose the mask to temperatures above 140°F (60°C)

USER INSTRUCTIONS FOR THE INNOVA™NASAL MASK

1. Remove the mask and the headgear from the package.
2. Place the headgear on a table, label side down with the narrowest part close to you.
3. Set the mask with the gel side down onto the center of the headgear.
4. Take each headgear strap and connect it to its respective location on the mask by looping the Velcro strap through the headgear slots and attaching it back to itself (Figure 1).
5. Once the headgear has been properly attached to the mask, follow the fitting tips below to fit the mask:
6. Detach one Velcro strap by sliding the Velcro® loop off the quick release hook, slip the headgear over the head and center the mask on the face.
7. Find the detached Velcro® strap and slide the Velcro loop back on the quick release hook (Figure 2).
8. Be sure the headgear straps are parallel and the headgear is fully extended and flat across the back of the head (Figure 3).
9. Adjust the bottom headgear straps by using the Velcro® tabs. Make sure the Active Headgear Connector™ is parallel to the face and that there is equal tension from the headgear on both sides. After tightening, make sure the Active Headgear Connector™ can move freely (Figure 4).
NOTE: Do NOT over tighten the headgear.
NOTE: The Touchless Spacebar™ will be tilted away from the face after tightening the bottom straps.
10. Adjust the upper headgear straps by using the tabs. Be sure they are tightened evenly and that the Touchless Spacebar™ is parallel to the forehead (Figure 5).
NOTE: The Touchless Spacebar™ should NOT touch the forehead. It should be parallel to the forehead (Figure 6).
11. Adjust the bottom headgear straps to make sure the bottom of the mask is sealed comfortably on the face.
12. For optimal seal and comfort, mask should be snug, but not tight. Adjust the tension by detaching the Velcro® straps, tightening or loosening the straps, and reattaching the Velcro®.
13. Connect the mask tubing assembly to the positive airway pressure device tubing and turn the device on to the prescribed pressure (Figure 7).
14. Turn head from side to side while lying on the bed and identify areas of leak that may prevent sleep.
15. In the event of leaks, tighten the Velcro® tabs closest to the area of leak. Do NOT over tighten the headgear.