

FLEXIFIT™ 406 NASAL MASK

PATIENT INSTRUCTIONS FOR USE

THE FLEXIFIT™ 406 NASAL MASK IS INTENDED FOR MULTIPLE PATIENT OR SINGLE PATIENT ADULT USE BY INDIVIDUALS WHO HAVE BEEN DIAGNOSED BY A PHYSICIAN AS REQUIRING CPAP OR BI-LEVEL VENTILATOR TREATMENT.

FITTING YOUR MASK

1. Remove plastic cover from Silicone Seal.
 2. Holding your mask in one hand, spread the Stretchgear™ Headgear (H) with your free hand just enough to fit comfortably over your head.
 3. Lightly hold the mask against your face, covering the nose, then slowly pull the headgear over your head.
 4. Attach the Headgear to the Glider™ Strap (E).
 5. Pull the lower straps as low as possible down back of neck. Gently tighten straps to remove slack. Connect to CPAP machine set at prescribed pressure.
- If necessary, tighten the lower straps to eliminate any leaks (avoid over-tightening the straps).
 - When you need to remove your mask, unhook the Stretchgear™ Headgear from the Glider™ Strap.

FITTING TIPS

- Forehead pads should rest gently on the forehead without top straps being pulled too tight.
- If there are any leaks after gently tightening the top and lower straps, pull the mask slightly out from the face while straps are still attached. This will allow silicone seal to inflate with air. Put the mask back onto the face.

CLEANING YOUR MASK

To ensure continuing safety and comfort for your FlexiFit™ 406 Nasal Mask:

BEFORE FIRST USE:

- Hand-wash the Stretchgear™ Headgear (H) in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to dry out of direct sunlight.

BEFORE EACH USE:

- Inspect the mask for deterioration. Do not use if damaged.

AFTER EACH USE:

1. Disassemble the Silicone Seal (C), Foam Cushion (D) and the Headgear (H) from the Mask Base (A).
2. Wash the Silicone Seal and Mask Base in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water.
3. Wipe the Foam cushion with a damp cloth. (Do not immerse the Foam Cushion in water.)
4. Leave all parts to dry out of direct sunlight before reassembling.

EVERY 7 DAYS:

1. Hand-wash the Stretchgear™ Headgear (H) in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to dry out of direct sunlight.

CAUTION

- Do not soak the mask for longer than 10 minutes.
- Do not wash the mask in the dishwasher.
- Do not clean the mask with products containing alcohol, anti-bacterial agents, antiseptic, bleach, chlorine or moisturizer.
- Do not store the mask in direct sunlight.

The above actions may deteriorate or damage the mask and shorten its life.

If your FlexiFit™ 406 Nasal Mask weakens or cracks, discontinue use and seek replacement immediately.

ASSEMBLING YOUR MASK

Your FlexiFit™ 406 Nasal Mask is fully assembled and ready to use. However, when you need to clean your mask follow these instructions for reassembly.

1. Place Silicone Seal (C) face down onto flat surface. With thick side of Foam Cushion (D) facing down, place into Silicone Seal.
2. Starting with the slot at the apex of the Silicone Seal, assemble onto Mask Base (A). Push firmly together.
3. Lay the Stretchgear™ Headgear (H) flat, with the loop side down. Position the assembled mask over the Headgear and attach the four straps into the corresponding slots in the Forehead Rest (F) and the Glider™ Strap (E). This can be done without undoing the Velcro™ tabs, by sliding the headgear into the slots.

The FlexiFit™ 406 NASAL MASK and accessories are Latex free.

Many people find CPAP therapy causes dryness of the nose and throat. Heated humidification can substantially reduce these symptoms.

WARNINGS

- This mask should be used only with CPAP or Bi-Level equipment recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP or Bi-Level machine is turned on and operating properly.

Explanation of Warning: CPAP and Bi-Level machines are intended to be used with special masks which have exhaust flow holes to allow continuous flow of air out of the mask. When the CPAP/Bi-Level machine is turned on and functioning properly, new air from the CPAP/Bi-Level machine flushes the exhaled air out through the mask exhaust flow holes. However, when the CPAP/Bi-Level machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be re-breathed. Re-breathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation.

- At low CPAP pressures the flow through the exhaust flow holes may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.
- Do not block the gas exhaust ports. Before use, always ensure that gas is flowing out the exhaust ports.
- Do not use the mask if vomiting or feeling nauseous.
- Discontinue using the mask if there is an allergic reaction to any part of the mask. Consult your physician if this occurs.
- If reusing the FlexiFit™ 406 Nasal Mask between different patients, refer to the Multi-Patient Cleaning Instructions for the FlexiFit™ 406 Nasal Mask.

CAUTION

- Use the mask for its intended use only as directed in this booklet.
- US Federal Law restricts this device to sale by, or on order of, a physician.

US PATENT NUMBER 6 615 834

Other Patents Pending

FOR ADDITIONAL INFORMATION CONTACT YOUR LOCAL HOMECARE PROVIDER

OXYGEN/PRESSURE PORT CONNECTOR

If pressure readings and/or additional oxygen are required, an Oxygen/Pressure Port Connector is available (Code 900HC452).

1. Connect the large end of the Connector (T) to the swivel (G) on the mask and the small end of the Connector to the main breathing tube (R).
2. Open the Port Cap(s) (P) and place the Pressure and/or Oxygen Tube (S) firmly over the Port(s) (Q).

(The two ports are identical; either port may be used for oxygen or pressure measurement. Only remove the Port Cap from ports that are being used.)

- **Note:** At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient's breathing pattern, mask selection, and the leak rate.
- **Warning:** If oxygen is used with CPAP/Bi-Level machine, the oxygen flow must be turned off when the CPAP/Bi-Level machine is not operating.

Explanation of Warning: When the CPAP/Bi-Level device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the CPAP/Bi-Level machine enclosure. Oxygen accumulated in the CPAP/Bi-Level machine enclosure will create a risk of fire.

- **Warning:** Do not smoke while using or in the vicinity of someone using oxygen with this mask.
- **Warning:** Do not use Polyvinyl Chloride (PVC) Pressure and/or Oxygen tubing. Use silicone tubing instead.

Explanation of Warning: Contact with PVC can cause premature cracking of ports.

TECHNICAL SPECIFICATIONS

EXHAUST FLOW

Nasal masks for CPAP and Bi-Level have exhaust flow holes to expel the air that you exhale from the mask.

PRESSURE (CMH ₂ O)	3	5	7	9	11	13	15	17	19	21	23	25
FLOW (L/MIN)	18	24	28	32	36	39	42	45	48	50	53	55

RESISTANCE TO FLOW

Pressure drop through mask @ 50 l/min 0.1 cmH₂O

Pressure drop through mask @ 100 l/min 0.4 cmH₂O

MASK DEAD SPACE

44cc

OPERATING CONDITIONS

- Operating pressure is 3-25 cm H₂O
- Operating temperature range is 40-120°F (5-50°C)

MULTI-PATIENT CLEANING INSTRUCTIONS

Your FlexiFit™ 406 Nasal Mask is provided patient-ready. To reuse between patients please follow the guidelines below.

CLEANING/DESOLING

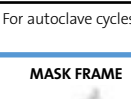
- Before cleaning, remove visible soil by disassembling and thoroughly cleaning the mask with a small brush under running potable tap water.

FAILURE TO PROPERLY CLEAN THIS DEVICE MAY RESULT IN INADEQUATE DISINFECTION

HIGH-LEVEL DISINFECTION PARAMETERS

- NB: For autoclave cycles, components should be enclosed in a sterilization peel pouch.

MASK FRAME



SILICONE SEAL



ELBOW



SWIVEL



AUTOCCLAVING

Autoclave, 15 minutes' exposure at 121°C (250°F).

OR

THERMAL DISINFECTION

Soak parts in hot water bath for 30 minutes at 70°C (158°F).

OR

STERRAD® 100S

Follow manufacturer's instructions for Sterrad® 100S Sterilization system.

OR

CIDEX® OPA

Follow manufacturer's instructions for high-level disinfection. Immerse for 12 minutes at 20°C (68°F).

Rinse thoroughly in potable water.

OR

SPOROX 11®

Follow manufacturer's instructions for high-level disinfection. Immerse for 6 hours at 20°C (68°F).

Rinse thoroughly in potable water.

HEADGEAR



Hand-wash the Headgear in pure soap dissolved in lukewarm water. Air-dry out of direct sunlight.

FOAM CUSHION



Replace with new part.

THE FLEXIFIT™ 406 NASAL MASK HAS BEEN VALIDATED TO WITHSTAND 20 CYCLES OF THE ABOVE PARAMETERS. DO NOT USE IF DAMAGED.

Disclaimer: It is the user's responsibility to qualify any deviations from the recommended methods of reprocessing.

CONTACT YOUR LOCAL HOMECARE PROVIDER FOR ADDITIONAL INFORMATION.