### Fitting Your Mask

#### Fitting Your Mask

1. **Refer to the mask assembly diagram:**
   - Adjust Headgear by connecting one of the clips (A).
   - Pull the SnapFlap Cover (B) back to the retracted position.
   - Insert the Silicone Seal (C) into the mouth, one side at a time, if you should sit in the upper region between the cheeks and the teeth. Move your lips around so they fit comfortably in the way over the Silicone Seal.
   - Return the SnapFlap Cover (B) to its normal position, and adjust the mask tightness by rotating the Clip (D) as shown.
   - With Headgear (E) sitting loosely around base of neck, reconnect clip.
   - Adjust Headgear with Velcro™ tab (F) to remove slack.

2. **Use Nasal Plugs (G):**
   - At least the first three weeks of use. Refer to Nasal Plug Instructions.
   - Connect to CPAP/Bi-Level machine set at prescribed pressure.

#### Fitting Tips

- **If the mask leaks around the teeth:** Tighten the SnapFlap Cover (B) or rotating the Clip (D).
- **If problems persist:** Try using the larger Silicone Seal, which is included in your Oracle™ Oral Mask box.
- **It is recommended to use the Headgear with your Oracle™ Oral Mask, for optimum comfort and performance. However, if preferred, it is optional to use a descriptive set of Headgear.
- **Do not overtighten Headgear.
- **To release clip:** Simply pull on the Easy-Release Cord (H).
- **If discontinuing use of Headgear:** Carefully remove by unhooking both clips from SnapFlap™ Cover.

### Using Your Mask

#### Oracle CPAP/Bi-Level bypasses the nasal airway and requires optimum humidity. For best results, use with Fisher & Paykel Healthcare SleepStyle™ 600 Series CPAP system with Theramask™ Technology at the following settings:

- Comfort Setting (I)
- Create Setting (J)

**Heated Humidification MUST be used in conjunction with the Oracle™ Oral Mask.**

- Ensure water chamber is filled.
- Breathe through your mouth only.

#### Oracle

- If you are using the SleepStyle™ 600 Series CPAP system and experiencing a dry mouth, try the following:
  - Turn the comfort up one setting per night until a slight misting occurs in the Flexitube (K).
  - If you are still experiencing dryness, it could be due to a small air leak out of the nose. Nasal Plugs (L) could be used.

- If you are still experiencing dryness, it could be due to a small air leak out of the nose. Nasal Plugs (L) could be used. (This is especially true if you are experiencing dryness when you use your Oracle™ Oral Mask weakens or cracks, discontinue use immediately.

### Oxygen/Pressure Port Connector

If pressure readings and/or additional oxygen are required, use an Oxygen/Pressure Port Connector is available. (Product #60064)

1. **ASSEMBLING YOUR MASK: (Product #60064):**
   - Connect the large end of the Connector (A) to the Non-Rebreathing Valve (B) and the small end of the connector to the main-breathing tube (C).
   - Open the Port Cuffs (D) and place the Pressure and/or Oxygen Tube (E) firmly on the Port.
   - The two ports are identical, either Port may be used for oxygen or pressure measurement.

2. **Connecting the Non-Rebreathing Valve (F):**
   - Connect Elbow (G) and place the Pressure and/or Oxygen Tube (H) firmly on the Port.
   - The two ports are identical, either Port may be used for oxygen or pressure measurement.

### Technical Specifications

**Expiration Flow Information:**

- All masks for CPAP and Bilevel have internal flow limiters to regulate the airflow that you exhale from the mask. The Oracle™ Oral Mask incorporates the unique Fisher & Paykel Healthcare SleepStyle™ Exsufflation system that is designed to adjust the airflow that is expirated from the mask. This naturally reduces draft and noise.

- The Exsufflator does not significantly change the amount of air flowing from the mask. Therefore, the masks can be used with or without the Exsufflator. It is important that these vents are not blocked by any object.

### Cleaning Your Mask At Home

To ensure continuing safety and comfort, your Oracle™ Oral Mask should be cleaned and sanitized at least once per week. To clean your mask follow these instructions for reassembly.

- Inspect the Non-Rebreathing Valve. Ensure the silicone flaps are present and undamaged.
- Wash all parts except the Headgear (I) and Exsufflator (J) in warm soapy water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to air dry out of direct sunlight.
- Alternatively, the Silicone Seal (C) may be soaked for 10 minutes in a clean solution of approximately 0.5% of (3% of) water and 2.5% (4% of) antiseptic. Rinse in fresh water and allow to air dry out of direct sunlight.

**DO NOT remove Elbow (K) unless Diffuser (E) has been removed. The Diffuser (E) should not be washed or cleaned. Simply replace it with a new Diffuser if it becomes sticky or deteriorates. It should last two to three months. Small dots may appear on the Diffuser (E) – this is not affecting its performance. The Oracle™ Oral Mask may be used with or without the Diffuser (E) and Diffuser Cap (F).

**Every 7 Days:**

- Rinse the Headgear in warm soapy water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to air dry out of direct sunlight. It is not necessary to remove the Clip (D) from the headgear when washing.

**Caution:**

- Do not soak the mask for longer than 10 minutes.
- Do not wash the mask in the dishwasher.
- Do not place the mask with products containing alcohol, chlorine, antiseptics or bleach.
- Do not store the mask in direct sunlight.

**The Oracle™ Oral Mask and accessories are Latex Free.**

### Oracle™ 452 Oral Mask Exhust Flow

**Details:**

- **Exhust Flow Rate:** All masks for CPAP and Bilevel have internal flow limiters to regulate the airflow that you exhale from the mask. The Oracle™ Oral Mask incorporates the unique Fisher & Paykel Healthcare SleepStyle™ Exsufflation system that is designed to adjust the airflow that is expirated from the mask. This naturally reduces draft and noise.

- The Exsufflator does not significantly change the amount of air flowing from the mask. Therefore, the masks can be used with or without the Exsufflator. It is important that these vents are not blocked by any object. This controlled leak ensures an adequate CO2 is expired from the mask.

<table>
<thead>
<tr>
<th><strong>Exhust Flow Rate</strong></th>
<th><strong>Flow (l/min)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>0.22</td>
</tr>
<tr>
<td>Medium</td>
<td>0.34</td>
</tr>
<tr>
<td>High</td>
<td>0.50</td>
</tr>
<tr>
<td>Exsufflator</td>
<td>0.60</td>
</tr>
</tbody>
</table>

**Resistance to Flow:**

- **Oxygen/Pressure Port Connector:** Pressure drops through mask at 2 psi (0.14 kPa) 0.34 l/min.

**Mask Dead Space:**

- **Conducting Channels:**
  - Operating pressure range is 1.5–2.5 cmH2O
  - Operating temperature range is 30–45°F (0–7°C)
  - Valve activation/deactivation pressure is 0.2 cmH2O.
FAILURE TO PROPERLY CLEAN THIS DEVICE MAY RESULT IN INADEQUATE DISINFECTION

**High Level Disinfection Parameters**

- **Thermal Disinfection**: Soak parts in hot water bath for 10 minutes at 70°C (158°F).
- **Cidex® OPA**: Immerse for 20 minutes at 80°C (176°F)
- **OR**: 30 minutes at 70°C (158°F).
- **OR**: 30 minutes at 80°C (176°F).
- **OR**: 20 minutes at 176°F.

**Contraindications**

- This mask should not be used by anyone incapable of removing the mask unaided, in the case of vomiting and aspiration, without continuous supervision.
- This CPAP mask should be used only with CPAP/Bi-Level systems recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP/Bi-Level system is turned on and operating properly. The vent slots associated with the mask should never be blocked.

**Warnings**

- If a patient using this device develops these symptoms, a dentist should be consulted before continuing use.
- If symptoms occur, a physician or dentist should be consulted before continuing use.
- Do not use if patient suffers from bruxism.
- This valve ensures CO₂ exhaled gas from the tubing. Some rebreathing may occur.
- Use of this device may cause tooth soreness, gingival soreness, and/or tooth movement. If symptoms occur, a physician or dentist should be consulted before continuing use.
- This mask should also not be used by anyone incapable of removing the mask unaided.

**Cautions**

- Use the mask for its intended use only as directed in this booklet.
- **Use** the Oracle™ Oral Mask only with the headgear provided.
- The prescribing physician should consider the dental history and oral health status of the patient prior to prescribing the device.
- If a patient has loose teeth or periodontal disease, a dentist should be consulted prior to use.
- If symptoms occur, a physician or dentist should be consulted before continuing use.

**Cleaning/Desoiling**

- Before cleaning, remove visible soil by disassembling and thoroughly cleaning the mask with a small brush under running potable tap water.
- Follow manufacturer instructions for high level disinfection.

**Multi-Patient Cleaning Instructions**

- The Oracle™ Oral Mask has been validated to withstand 30 cycles of the above parameters. DO NOT USE IF DAMAGED.

- The Oracle™ Oral Mask is provided patient ready. To re-use between patients please follow the guidelines below.

- Multi-Patient Cleaning Instructions

  - Follow manufacturer instructions for high level disinfection.
  - Soak parts in hot water bath for 10 minutes at 70°C (158°F).
  - Immerse for 20 minutes at 80°C (176°F).
  - Rinse thoroughly in potable water.

  - Thermal Disinfection
    - Soak parts in hot water bath for 10 minutes at 70°C (158°F).
    - Immerse for 20 minutes at 80°C (176°F).
    - Rinse thoroughly in potable water.

  - Cidex® OPA
    - Immerse for 20 minutes at 80°C (176°F).
    - Rinse thoroughly in potable water.

  - Thermal Disinfection
    - Soak parts in hot water bath for 10 minutes at 70°C (158°F).
    - Immerse for 20 minutes at 80°C (176°F).
    - Rinse thoroughly in potable water.

  - Cidex® OPA
    - Immerse for 20 minutes at 80°C (176°F).
    - Rinse thoroughly in potable water.

- OR

  - Replace with new part.

- Replace with new part.

- OR

  - Replace with new part.