

# RESPIRONICS

## Instructions for Use

### Whisper Swivel II

The Whisper Swivel II is a multi-patient use exhalation port that provides a continuous leak path in the patient circuit when used with CPAP and bi-level systems. It is functionally and clinically equivalent to the original Whisper Swivel.

**⚠ Caution:** U.S. federal law restricts this device to sale by or on the order of a physician.

**ℹ Note:** This product does not contain natural rubber latex and DEHP.

#### Symbols



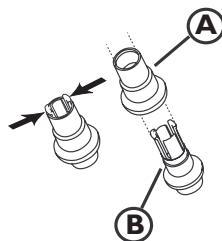
Warning or  
Caution



Note

#### ⚠ Warnings:

- The body of the Whisper Swivel II must be inserted into the sleeve until they snap together to ensure a proper fit (Figure 1). Otherwise, in some circumstances, suffocation can occur.
- As with most CPAP devices, at low CPAP pressures, the air flow through the exhalation port may not be enough to clear all the exhaled gas (CO<sub>2</sub>) from the mask. You may rebreathe in some of the air that you have exhaled.
- Hand wash prior to first use. Inspect for damage or wear. Discard and replace any components as necessary.
- This warning applies to almost all CPAP devices. The Whisper Swivel II should be used with the CPAP system recommended by your healthcare professional or respiratory therapist. As with any exhalation device, do not apply the mask to your face unless the CPAP device is turned on and operating properly. To allow a continuous flow of air out to the mask, the vent holes in the exhalation port must never be blocked. When the CPAP device is turned on and functioning properly, new air from the CPAP device flushes exhaled air out through the exhalation port's vent holes. However, when the CPAP device is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.



**Figure 1**

A = Sleeve  
B = Body

#### Cleaning Instructions for Home Use

1. Disconnect the Whisper Swivel II from the mask and tubing. (Note: To disconnect the tubing, bend at the tubing connection.) Disassemble the Whisper Swivel II by pressing together the two tabs at the top of the swivel separating the two parts.
2. Gently hand wash the Whisper Swivel II parts in a solution of warm water and a mild shampoo or dish detergent.

**⚠ Caution:** Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

3. Rinse thoroughly. Allow to air dry.
4. Reassemble the parts by sliding the body into the sleeve until they snap together.

5. Inspect the Whisper Swivel II for any remaining debris or damage. Repeat the cleaning instructions if necessary. Replace if damaged.

## Cleaning, Disinfecting, and Sterilizing Instructions for Institutional Use

ⓘ **Note:** For Institutional Use, the Whisper Swivel II must be disinfected or sterilized prior to each patient's use. Adequate disinfection or sterilization can only be performed after the device has been thoroughly cleaned following the pre-processing instructions below.

### Pre-Processing Instructions

1. Disassemble the Whisper Swivel II by pressing the two tabs at the top of the swivel and separating the two parts. Soak the swivel parts in a commercially available enzymatic cleaner (e.g., Klenzyme™) following the manufacturer's instructions.
2. Manually clean the Whisper Swivel II with a soft bristle brush in a solution of cool tap water and a commercially available anionic detergent (e.g., Manu Klenz™).

⚠ **Caution:** Do not use cleaning solutions containing conditioners or moisturizers.

3. Rinse thoroughly following the manufacturer's instructions. If no rinsing instructions are provided, rinse the swivel thoroughly under cool running tap water. Air dry.

ⓘ **Note:** If this procedure does not adequately remove adhering substances, replace the Whisper Swivel II.

4. Reassemble the parts by sliding the body into the sleeve until they snap together.

### Disinfecting the Whisper Swivel II

1. Disassemble the Whisper Swivel II by pressing the two tabs at the top of the swivel and separating the two parts.
2. Soak the swivel parts in a commercially available 2.4% or 2.5% glutaraldehyde solution (e.g., Cidex™ or Cidex™ Formula 7) following the manufacturer's instructions.
3. Rinse the swivel parts thoroughly following the manufacturer's instructions. If no instructions are provided, rinse the swivel thoroughly under cool running tap water. Air dry.
4. Inspect the swivel parts for signs of wear or deterioration. Replace if damaged.
5. Reassemble the parts by sliding the body into the sleeve until they snap together.

ⓘ **Note:** Testing has shown that the Whisper Swivel II can withstand up to 15 disinfection cycles using a 2.5% glutaraldehyde solution (e.g., Cidex™ Formula 7) following the manufacturer's instructions.

### Sterilizing the Whisper Swivel II

1. Disassemble the Whisper Swivel II by pressing the two tabs at the top of the swivel.
2. Sterilize the swivel parts using ethylene oxide per standard protocols for plastic components. Aerate per standard protocol requirements.
3. Inspect the swivel parts for signs of wear or deterioration. Replace if damaged.
4. Reassemble the parts by sliding the body into the sleeve until they snap together.

ⓘ **Note:** Testing has shown that the Whisper Swivel II can withstand up to 15 sterilization cycles following the above instructions.

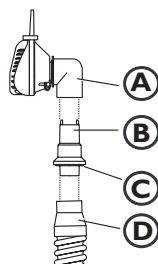
⚠ **Warning:** A minimum of eight hours of post-aeration is required after EtO exposure.

### Connecting the Whisper Swivel II

1. Firmly insert the top end of the Whisper Swivel II into the end of the mask's rotating connector (Figure 2). Slightly twist the Whisper Swivel II to ensure a tight seal. To reduce the amount of air flow blowing onto the user, position the swivel so that the name *Respironics Inc.* is facing the user.
2. Connect the flexible tubing to the rotating end of the Whisper Swivel II.

▶ **Figure 2**

A = Rotating Connector  
B = Whisper Swivel II  
C = Vent Holes (Exhaled Air)  
D = Flexible Tubing



**Sterilization Validation Specifications**

EtO sterilization validation for this product was performed at the parameters listed below. Use these or equivalent parameters in your EtO sterilization process.

**Preconditioning**

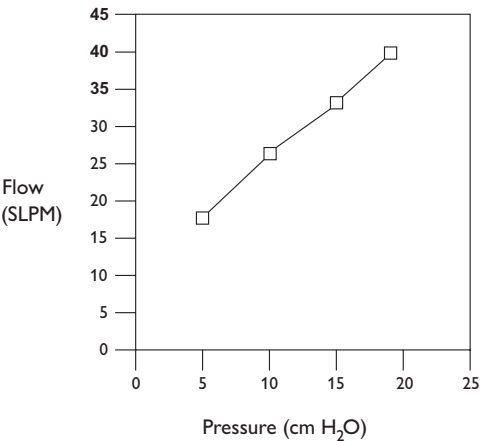
Vacuum:	21" Hg (± 1 Hg)
Humidity:	70% (± 10%)
Temperature:	54° C (± 2°)
Time:	60 minutes

**Exposure Cycle**

EtO Concentration:	12% (± 1%)
Humidity:	70% (± 10%)
Temperature:	54° C (± 2°); 129.2° F(±3.6°)
Concentration:	600 mg/L (± 50 mg/L)
Exposure Time:	120 minutes

**Intentional Leak**

Typical Exhaust Flow / Pressure Performance of the Whisper Swivel II



**Disposal**

Dispose of in accordance with local regulations.