

Instructions for Use

ExVent[®]
Optional
accessory for use
with **O2Vent[®]**
Optima[®]



Introduction

The **ExVent[®]** is an optional accessory that can only be used with the **O2Vent Optima[®]**. Your Healthcare Professional will determine if using the ExVent is right for you.



Why might ExVent be needed?

The **ExVent** provides the airway with extra, mild "end of breath" support, also known as Expiratory Positive Airway Pressure (EPAP).

How does it work?

The **ExVent** is inserted into the extended airway of the O2Vent Optima (not compatible with the O2Vent Optima **Mini**, as it does not have an extended airway). The **ExVent** includes a valve with air holes. This valve opens and closes as you breathe.

Figure 1: ExVent – breathing in

Upon breathing in, the **ExVent's** valve fully opens which allows for the free flow of air into the airway.



Figure 2: ExVent – breathing out

When breathing out, the valve closes, directing your breath through the air holes in the valve. This creates EPAP.

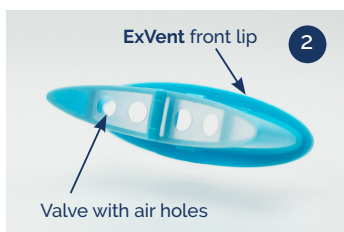


The **ExVent** offers three different levels of airway support: low, medium and high. This refers to the amount of airway pressure the **ExVent** generates. Talk to your Healthcare Professional about which strength to use when starting treatment with **ExVent**.

Indications for use

The **ExVent** is an optional accessory to be used with the O2Vent Optima device in adult patients with mild to moderate obstructive sleep apnea.

The O2Vent Optima is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild or moderate obstructive sleep apnea (OSA). The device is indicated for use during sleep to aid in the treatment of these conditions.



Contraindications

The **ExVent** is an accessory for the O2Vent Optima device. Both are contraindicated for patients who:

- have central sleep apnea
- have a severe respiratory disorder
- have loose teeth or advanced periodontal disease or restorative needs
- are under 18 years of age.

About ExVent

The ExVent valves are available in three pressure strengths to deliver airway support. These are labeled and colored:

- **Low** airway support (Light Blue)
- **Medium** airway support (Yellow)
- **High** airway support (Dark Blue)

The higher the pressure strength, the more resistance you will experience when breathing out. If you find breathing out through a particular strength difficult, speak to your Healthcare Professional.



LOW



MEDIUM

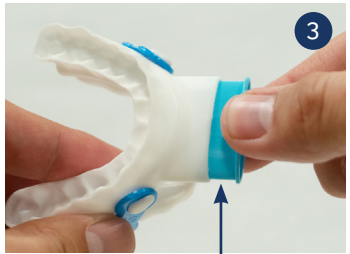


HIGH

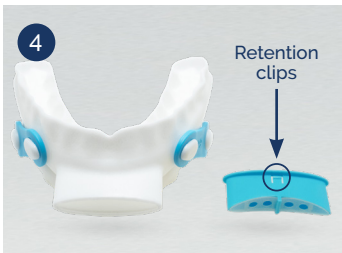
Instructions to insert ExVent into your O2Vent Optima device

The **ExVent** must be inserted into your O2Vent Optima device before inserting into your mouth (to be worn during sleep periods).

1. Hold the **ExVent** between your fingers in the middle as shown.
2. Ensure that the **ExVent** valve (that opens and closes) is lying flat against the back of the **ExVent** when you insert it. Refer to image bottom left of page.
3. Insert the **ExVent** into the extended airway of your O2Vent Optima.
4. When correctly inserted, the retention clips will "click" into place.
5. Once the **ExVent** is inserted, follow the Instructions for Use for your O2Vent Optima.



Insert the **ExVent** into the extended airway of your O2Vent Optima.



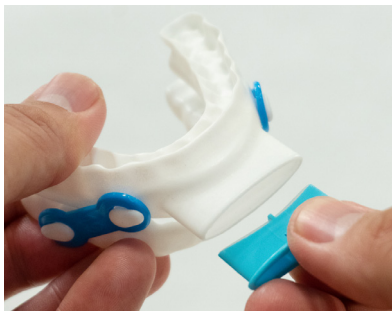
Correctly inserted ExVent

On rare occasions, the part of the **ExVent valve that opens and closes might stick, fold over or twist. Should this happen, remove the **ExVent**, check that it is dry and realign so the valve sits flat against the body of the **ExVent**. Use a new **ExVent** if necessary.

Daily cleaning of your ExVent

After each use of your O2Vent Optima oral device, it is recommended that you:

- Remove the device from your mouth and rinse in lukewarm water
- Remove the **ExVent** from the front inlet of the O2Vent Optima device by gently squeezing the middle to disengage the retention clips before pulling it out, taking care not to damage the **ExVent**
- Thoroughly rinse the **ExVent** with lukewarm water
- Pat dry the **ExVent** with a clean tissue or towel (do not rub/wipe) and store in the case that is provided with the O2Vent Optima device
- Leave the **ExVent** to dry in a well-ventilated area. Do not place the **ExVent** into the O2Vent Optima device to dry.



For cleaning of your O2Vent Optima device, please refer to the Instructions for Use provided with your device.

Tips for use:

1. If you are finding it uncomfortable or difficult to breathe out of your **ExVent**, you can insert your O2Vent Optima device and **ExVent** into your mouth prior to your sleep period, to practice getting used to it while awake.
2. One exercise to help you adapt to your **ExVent** is to breathe in (WITHOUT your O2Vent Optima device in your mouth) and then slowly breathe out with your lips tightly pressed together, as if blowing a kiss.

Additional cleaning

Separate, clean and thoroughly rinse both your O2Vent Optima device and **ExVent** twice a week, or more frequently as required, using an antibacterial cleanser (free from chlorine, bleach, acetic acid or alcohol-based products)



- Single patient multiple use.



- Caution: Federal law restricts this device to sale by or on the order of a healthcare practitioner.
- Healthcare Professionals should consider the medical history of the patient, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before recommending the **ExVent**.
- When cleaning, do not use bleach-based products or acetic acid.
- Do not put your **ExVent** in water warmer than 45°C or 113°F.
- Before insertion, check that your O2Vent Optima device and **ExVent** are not damaged and are completely dry before use. Do not use if damaged. Replace.
- **Choking hazard – small parts.** Keep away from children under 3 years.

ExVent potential side effects

The most commonly experienced side effects may include:

- Dry mouth/throat/lips
- Nasal congestion/runny nose
- Throat or ear discomfort
- Breathing discomfort
- Headache
- Difficulty falling asleep and staying asleep

Warning:

- If you experience difficulties with your **ExVent** and/or O2Vent Optima, contact your prescribing Healthcare Professional.
- Follow-up testing and evaluation should be conducted to ensure treatment effectiveness.

Replacement of ExVents

Your **ExVent** should be replaced every three months, or more frequently if your Healthcare Professional recommends it.

Your Healthcare or Dental Healthcare Professional can order Annual Resupply Packs (4 x **ExVents**) for you.

ExVent Product Codes:

Low Airway Support – Annual Resupply Pack:	EXVL-AR
Medium Airway Support – Annual Resupply Pack:	EXVM-AR
High Airway Support – Annual Resupply Pack:	EXVH-AR
Multipack (one of each, Low, Medium and High Airway Support):	EXVMP



MANUFACTURER AND AUSTRALIAN SPONSOR:

Open Airway Dental Solutions Australia Pty Ltd
5 Moorak Street, Taringa QLD 4068 Australia
Ph: +61-1300-533-159
info@openairway.com | www.openairway.au

MANUFACTURED FOR:

AUS
Open Airway
Dental Solutions
Australia Pty Ltd

USA/CA
Open Airway
Dental Solutions Ltd.
Canada/USA

UK/EU
Open Airway
Dental Solutions
UK Ltd



Compliance Management Solutions Europe Ltd
2 Bulgaria Street 2850 Petrich, Bulgaria

