

INSTRUCTIONS FOR USE – USA



O₂VENT™ W
REMOVABLE
MEDICAL
DEVICE



Name of User

Name of Sleep Physician

Name of Dentist

Serial No. of Device

Date of first fitting/purchase

Date of follow up with Physician/Dentist

INTRODUCTION

Obstructive Sleep Apnea (OSA) occurs when patients experience repetitive episodes of partial or complete blockage of the upper-airway during sleep. This is caused by obstructions of the nose, soft palate, tongue and/or pharyngeal walls (abnormal relaxation of the pharyngeal muscles during sleep). OSA sufferers usually snore, and may wake up gasping or choking. However, many people with OSA are unaware of any sleep disturbance. OSA is a common cause of excessive daytime tiredness, fatigue and poor concentration.

INDICATIONS FOR USE

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

This product is customized. Please contact your Prescribing Professional for fittings and consultations.

WHAT ARE THE RISKS OF OSA?

- Detrimental effects on sleep-quality and health
- Increases the risk of obesity
- High blood pressure
- Stroke
- Heart attack
- Type-2 diabetes
- Depression, impotence, mood disorders and increased risk of motor vehicle and workplace accidents

CONTRA- INDICATIONS

The **O₂Vent W** device is contraindicated for patients who:

- Have central sleep apnea
- Have severe respiratory disorders
- Have loose teeth or advanced periodontal disease or restorative needs
- Are under 18 years of age
- Patients with TMJ (Temporomandibular Joint) pain

THE BASICS OF YOUR **O₂Vent™ W** DEVICE



O₂Vent W device with titanium airway and polymer inserts



O₂Vent W Adjustment Key

O₂Vent W device kit contents:

- **O₂Vent W** device
- Adjustment Key
- Oventus tub
- Effervescent antibacterial cleaning tablets
- Instructions for Use booklet
- Warranty

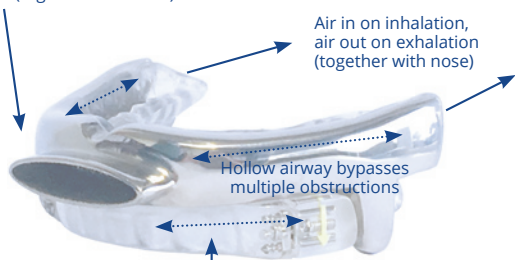
The **O₂Vent W** device may be used in conjunction with other accessories in the **O₂Vent** product line. For the full range of **O₂Vent** products, please visit www.oventusmedical.com or contact your Prescribing Professional.

HOW YOUR **O₂VENT™ W** DEVICE WORKS

Like all oral appliances that bring the jaw forward, the **O₂Vent W** device stabilizes jaw position and brings the tongue forward to reduce airway collapse. In addition, the unique airway design allows for breathing through the device to bypass obstruction in the nose which can contribute to snoring and sleep apnea.

The Adjustment Key allows for forward or backward adjustment of the lower jaw to optimize treatment.

Air in on inhalation, air out on exhalation (together with nose)



Air in on inhalation, air out on exhalation (together with nose)

Hollow airway bypasses multiple obstructions

Lower jaw adjustment helps clear tongue obstruction

Adjustment screw to optimize treatment

USING YOUR O₂VENT™ W DEVICE

Your Prescribing Professional and hygienist team will ensure that your device is appropriately customized for you. Your therapy will include initial scans or impressions which allow the device to be manufactured so that it is fully customized and fits comfortably in your mouth.

After your Prescribing Professional fits the device, it may take some time to get used to wearing it. The final fitting may include one or more titration adjustments to advance your jaw forward, to attain optimal positioning for your treatment.

You or your Prescribing Professional can further adjust the lower jaw position forward or backward to optimize treatment and minimize side effects. Device adjustments should only be done under the direction of your Prescribing Professional.

DIRECTIONS FOR DAILY USE

1. Inspect the device prior to each use. If you observe any material separation, material degradation or cracks, or any debris in the airway, please stop using the device and call your Prescribing Professional to discuss.
2. If the device is damaged or broken, the device must NOT be used any longer. Immediately take it to your Prescribing Professional who will arrange for it to be repaired.
3. Use your thumbs to push the upper tray from the bottom to snap it over your teeth. Repeat the same process for the lower tray.
4. Gently relax your jaw once the **O₂Vent W** device is in your mouth.
5. Check the device for any changes in adjustment during overnight use. If there is movement or change in adjustment, please call your Prescribing Professional.
6. To remove the **O₂Vent W** device, open your mouth, gently loosen the lower tray and remove. Do the same for upper tray. NOTE: the upper and lower trays are not locked together.



The O₂Vent W trays should never be worn separately. Always wear both trays when using the device.

TITRATING YOUR *O₂VENT™ W* DEVICE USING THE ADJUSTMENT KEY

FORWARD ADJUSTMENT:

To pull your lower jaw forward (increase titration), insert the Adjustment Key into the keyhole of the adjustment screw and turn in the direction of the arrow.



- Adjustments should be made with the device removed from the mouth. The lower tray can be adjusted without the upper tray attached.
- Take a few nights (up to one week) to get used to having the device in your mouth.
- If snoring persists then position lower jaw forward using the Adjustment Key as advised by your Prescribing Professional until symptoms resolve.
- If pain or discomfort arises then reverse the last turn and continue to position the lower jaw back until resolved. If the pain does not resolve, remove the device and seek advice from your Prescribing Professional.
- Ensure that the same number of turns are performed on each side of your device.

TITRATING YOUR O₂VENT™ W DEVICE USING THE ADJUSTMENT KEY

BACKWARD ADJUSTMENT:

To return your lower jaw (reduce titration), insert the Adjustment Key into the keyhole of the adjustment screw and turn in the opposite direction to the arrow.



NOTE: Your device can be adjusted within a 6.0 mm range. One turn (top to bottom) using the Adjustment Key is 90°. This will adjust the pitch of the screw by 0.1 mm resulting in a 0.1mm titration.

The screws will only allow a 90° turn in one full adjustment. Adjustments should be made with the Adjustment Key pointed towards you with the view of the key hole of the adjustment screw. **Note to count your turns.**

Both sides should always be adjusted equally. Once the screw is at the end of the titration, do not use the Adjustment Key further to tighten the screw. This may lock or snap the screw in the device.

KEEP A LOG OF YOUR TITRATION SETTINGS

The table below is an **example** of how you may keep a log of your titration setting and should be completed for the first month. The table is provided on the back page.

Date	Comment	How many turns	Titration
1st May 2018		None	
2nd May 2018	Snoring, made adjustment	One turn both sides	+0.1mm
3rd May 2018	Still snoring, adjusted further	Three turns both sides	+0.3mm
4th May 2018	Less snoring, adjusted further	One turn both sides	+0.1mm
5th May 2018	No snoring	None	
6th May 2018	Some jaw discomfort, adjusted back	One turn both sides	-0.1mm
7th May 2018	Improved	None	

CARING FOR YOUR **O₂Vent™ W** DEVICE

Your **O₂Vent W** device is made of quality biocompatible materials to provide comfortable and effective treatment. To maintain the lifetime of your device, we recommend you follow the cleaning regime.



DAILY CLEANING

After each use of your **O₂Vent W** device, it is recommended that you follow these cleaning instructions:

1. Remove the device from your mouth and rinse in lukewarm water.
2. Clean the device with a soft clean toothbrush (not the same toothbrush you use to brush your teeth as toothpaste can damage the device).
3. Thoroughly rinse the device with lukewarm water, including the airway entry and exit points.
4. Shake as much of the water as possible from the device, especially from the airways.
5. Dry your device after each cleaning with a clean tissue or towel and store it in the Oventus tub provided, with the lid open to allow the internal airway to dry.
6. Ensure you clean your teeth before you insert your device.

TWICE A WEEK – CLEANING YOUR O₂VENT™ W DEVICE

Clean your device more thoroughly twice a week, or more frequently as required, using the provided Oventus tub and an effervescent antibacterial cleaning tablet, designed for oral appliances. To clean your device twice weekly:

- Clean your device as you would for Daily Cleaning (refer to Page 12).
- Fill the Oventus tub to $\frac{3}{4}$ full with warm water.
- Separate the two parts of the device.
- Place the cleaning tablet and the two parts of the device in the water so that they are completely submerged.
- Leave to soak for 15 minutes.
- Remove and rinse both the device parts and Oventus tub thoroughly with lukewarm water, including the airway entry and exit points, to remove the cleaning solution.
- Dry your device parts with a clean tissue or towel and place back in the Oventus tub, with the lid open, to allow the internal airway to dry.
- Before using your device, assemble the two parts of the device together again.



OTHER CLEANING HINTS FOR YOUR **O₂VENT™ W** DEVICE

- Over time, the polymer might change color depending on several parameters including how well you take care of your device. It will not affect the effectiveness of your device. Certain foods and liquids can stain your device. Be sure to brush your teeth before inserting your device at each use.
- Never use chlorine based products, bleach or acetic acid.
- Never put the device in water warmer than 45°C / 113 °F. Cleaning with hot or boiling water can damage your device and will void the warranty.
- Never use toothpaste or mouthwash to clean your device, as they may be too abrasive and cause discoloration.

Your **O₂Vent W** device should be cleaned and stored in the Oventus tub provided as shown, during transport or when not in use. Keep your device away from sunlight and out of reach of pets and children.



Store your **O₂Vent W** device in the Oventus tub

DEVICE PRECAUTIONS



- If dental work such as fillings, crowns and extractions are carried out, it may affect the fit of the inserts, which may need replacing. Please seek advice from your Prescribing Professional.
- Never attempt to remove or dislodge the polymer inserts. If the polymer is damaged significantly or separates from the titanium, it must be replaced by the manufacturer. To replace the polymer insert material, contact your Prescribing Professional. **Once the screw is at the end of the titration, do not use the Adjustment Key further to tighten the screw. This may lock or snap the screw in the device and it must be replaced by the manufacturer. Do not disassemble any of the *O₂Vent W* device elements as it is a medical device that must not be tampered with.**
- The *O₂Vent W* device should not be worn by the user during any radiology procedures such as X-rays, Computer Tomography (CT) scanning or Magnetic Resonance Imaging (MRI).

POTENTIAL SIDE EFFECTS

During the adjustment time and while you are getting used to your **O₂Vent W** device, it is normal to experience some side effects which may include:

- Excessive salivation
- Temporary bite change. This will subside approximately 30 minutes after the **O₂Vent W** device is taken out of the mouth in the morning.
- Permanent bite change
- Gingival or dental soreness
- Dry mouth
- Gum irritation
- Cheek or tongue pain
- Jaw discomfort/pain
- Jaw set (lock)
- Temporomandibular Joint pain (TMJ)
- Tooth movement or loosening
- Tooth discomfort/pain

If any side effects persist following adjustment, please seek advice from your Prescribing Professional.

WARRANTY:

Please see the Oventus Warranty Policy Card included with your device.

CAUTION:

Federal (US) law restricts this device to sale by or on the order of a dentist.



Oventus Manufacturing Pty Ltd
1 Swann Road, Indooroopilly,
QLD, 4068, Australia
www.ventusmedical.com

