

INSTRUCTIONS FOR USE – USA



O₂VENT™ T
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

INTENDED USE

The *O₂Vent T* 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.

Patients with OSA 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.

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 T** 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™ T* DEVICE



O₂Vent T device with titanium airway and polymer inserts



O₂Vent T Adjustment Key

O₂Vent T device kit contents:

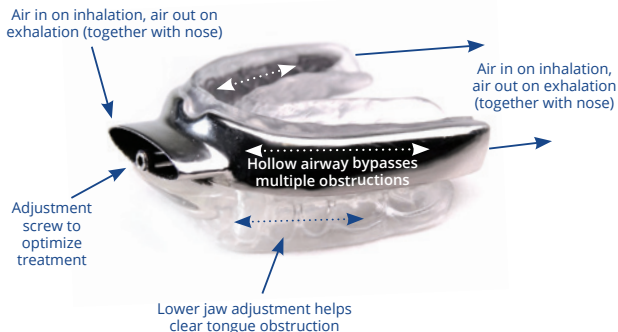
- *O₂Vent T* device
- Adjustment Key
- Oventus tub
- Effervescent antibacterial cleaning tablets
- Instructions for Use booklet
- Warranty

The *O₂Vent T* 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™ T** DEVICE WORKS

Like all oral appliances that bring the jaw forward, the **O₂Vent T** 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.



USING YOUR O₂VENT™ T 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. Before using your device, the upper and lower trays must be assembled (as shown in the steps below):

DEVICE ASSEMBLY

STEP 1:

Hold the upper and lower tray components as shown



STEP 2:

Insert the hook into the slot on the lower tray



STEP 3:

Rotate the upper tray 90° so it aligns with the lower tray



The assembled device is now ready for use



Caution: Do not force the upper tray past 90° rotation, otherwise the device may be damaged. Do not force the device vertically apart when it is assembled as this may also damage the device.

4. Once assembled, to insert into your mouth, use your thumbs to push the upper tray from the bottom to snap it over your teeth. Repeat the process for the lower tray.
5. Gently relax your jaw once the **O₂Vent T** device is in your mouth.
6. To remove the **O₂Vent T** device, gently open your mouth while the hook is still engaged. Lift up on the lower tray and then pull down on the upper tray to loosen both trays. Ensure both trays are loosened before removing both trays from the mouth together.
7. The upper and lower trays must be disengaged for cleaning (as shown in the steps below):

DEVICE DISENGAGEMENT

STEP 1:

Rotate the device upper 90° (either clockwise or anticlockwise)



STEP 2:

Lift the device upper from the lower to disengage the hook

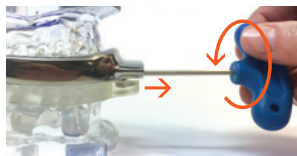


The **O₂Vent T** trays should never be worn separately. Always wear both trays when using the device.

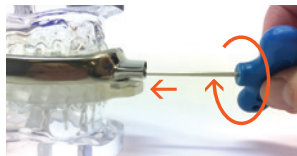
TITRATING YOUR O₂VENT™ T DEVICE USING THE ADJUSTMENT KEY

Adjustments should always be made with both upper and lower trays engaged, whilst in the mouth.

- To pull your lower jaw forward (increase titration) with the appliance **in the mouth**, turn the Adjustment Key counter clockwise towards your left ear (see image below).



- To return your jaw (reduce titration) with the appliance **in the mouth**, turn the Adjustment Key clockwise towards your right ear (see image below).



- 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 with a maximum of two full turns per night 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.



Note: Adjustments (Key Turns) should always be made with both upper and lower trays engaged, **whilst in the mouth**.

ADJUSTMENTS MEASURE

ONE full Key Turn of Adjustment Key	Counter clockwise	Advances lower jaw forward	Increases titration by +0.5mm
TWO full Key Turns of the Adjustment Key	Counter clockwise	Advances lower jaw forward	Increases titration by +1.0mm
ONE full Key Turn of the Adjustment Key	Clockwise	Reduces the advancement of lower jaw	Reduces titration by -0.5mm
TWO full Key Turns of the Adjustment Key	Clockwise	Reduces the advancement of lower jaw	Reduces titration by -1.0mm

The adjustment screw should be adjusted a **maximum of 1mm per night** (ie 2 full Key Turns of the Adjustment Key). Once the screw is at the end of the titration, do not use the Adjustment Key further to tighten the screw. This may 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	Adjustment (to be made with device in the mouth) <i>(specify ONE whole Key Turn or TWO whole Key Turns)</i>	Direction of Key Turn <i>[Forward = counter clockwise (+)]</i> <i>[Backward = clockwise (-)]</i>	Titration
1st May 2018		No adjustment		
2nd May 2018	Snoring. Made adjustment	1 whole turn	Counter clockwise	+0.5mm
3rd May 2018	Still snoring. Adjusted further	2 whole turns	Counter clockwise	+1.0mm
4th May 2018	No snoring	No adjustment		
5th May 2018	Jaw discomfort. Adjusted back	1 whole turn	Clockwise	-0.5mm
6th May 2018	Less jaw discomfort. Will adjust more	1 whole turn	Clockwise	-0.5mm
7th May 2018	Improved	No adjustment		

CARING FOR YOUR **O₂Vent™ T** DEVICE

Your **O₂Vent T** 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 T** 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™ T 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 13).
- Fill the Oventus tub to $\frac{3}{4}$ full with warm water.
- Separate the two parts of the device (must be disengaged as shown on Page 9).
- 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 (refer Page 8).



OTHER CLEANING HINTS FOR YOUR **O₂Vent™ T** 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 T** 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 T** 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 snap the screw in the device and it must be replaced by the manufacturer. Do not disassemble any of the *O₂Vent T* device elements as it is a medical device that must not be tampered with.
- The *O₂Vent T* 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 T** 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 T** 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.

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



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