



THE O₂VENT™ MONO – INSTRUCTIONS FOR USE

INTENDED USE

The Oventus **O₂Vent Mono** is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and obstructive sleep apnoea, OSA. The device is indicated for use during sleep to aid in the treatment of these conditions, including patients with nasal obstructions or who cannot tolerate CPAP (Continuous Positive Airway Pressure). The **O₂Vent Mono** is not indicated for the treatment of central sleep apnoea. The Oventus **O₂Vent Mono** is for prescription use only.



THE BASICS OF YOUR DEVICE

Your **O₂Vent Mono** is made up of two parts:

- 1** The main mouthguard which forms the breathing port at the front leading to the airways on each side to the rear of the device is made from medical grade titanium and is polished in the region in contact with your lips and inner cheeks. The titanium part is designed to last for greater than 5 years of normal use.
- 2** The “landing” area for the top and bottom teeth is customised to your teeth and is made from medical grade polymers which are comfortable, and with normal use, should not damage your teeth. Please note that the polymer may change appearance through normal use. Although this is normal, regular care will prolong its colour. The polymer is replaceable using strict manufacturing processes at Oventus. To replace the polymer insert material, contact your Oventus Clinician.

A temporary material may be used on the upper insert of your device in the beginning to ensure your jaw is retained in the correct position. This is then changed over by Oventus manufacturing to the polymer material when the clinician and patient are both happy with the jaw position for treatment.

HOW YOUR DEVICE WORKS

Like all oral devices that bring the jaw forward, the **O₂Vent Mono** stabilises jaw position and brings the tongue forward to reduce airway collapse. However, in addition to this, the unique airway allows for breathing through the device to bypass obstruction in the nose which can contribute to snoring and sleep apnoea.

Three dimensional printing allows the device to be customised to your mouth for comfort, reduces the size of the device and allows optimised airway shape and pathway.



KIT CONTENTS

The **O₂Vent Mono** is delivered in a labelled dental case which is placed in a suitable toiletry bag together with the Instructions for Use brochure, a sonic cleaner with two (2) AA batteries and one (1) strip of Retainer Brite® cleaning tablets.

USING YOUR DEVICE

Knowing what to do (and what not to do) when using your device can make all the difference to your treatment. Your Oventus Clinician and hygienist team will ensure that your device is appropriately designed from the start. Your therapy will include initial scans or impressions which allow the device to be manufactured so that it is fully customised and fits comfortably in your mouth.

After your Oventus Clinician 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. During this adjustment time it is normal to experience some hyper salivation or dry mouth as well as minor tooth pain upon awakening. If any side effects persist, seek advice from your Oventus Clinician.

INSERTION AND REMOVAL OF THE OVENTUS O₂VENT™ MONO

To insert your **O₂Vent Mono**, place the upper part of the device on the teeth and seat it completely by pressing firmly on the right and left back portions of the device. Place the lower part of the device on the teeth and seat it in the same manner as the upper.

To remove your Oventus **O₂Vent Mono**, place your fingers on the upper borders of the upper device and press firmly downward, "rocking" the device from side to side until it releases from the teeth. Then, remove the lower device by placing your thumbs on both sides of the device at the lower borders. Firmly push upwards on one side then the other to "rock" the lower device off the teeth. If the device is too rigid or retentive, we will need to adjust your device at your next office visit to achieve easier removal.

DAILY CLEANING

After each time you use your device, it is recommended that you follow these cleaning instructions:

- Remove the device from your mouth and rinse in lukewarm water.
- Clean the device with a soft clean toothbrush (not the same toothbrush you use to brush your teeth as toothpaste can damage the device).
- Rinse well with lukewarm water.
- Shake as much of the water as possible from the device, especially from the airways.
- Dry your device after each cleaning with a clean tissue or towel and place it back in the storage box.
- Ensure you clean your teeth before you insert your device.

TWICE A WEEK

Clean your device more thoroughly using the sonic cleaner and an effervescent antibacterial tablet designed for oral devices. To clean using your sonic cleaner:

- Fill the tub halfway with warm water.
- Place the tablet and the device in the water ensuring that it is completely submerged.
- Switch the cleaner to the on-position and leave for 15 minutes.
- Turn off the sonic cleaner and remove device from the solution.
- Rinse both the device and the tub thoroughly with warm water to remove the cleaning solution.
- Dry your device with a clean tissue or towel and place it back in the storage box.

NOTE

Over time, the polymer might change colour depending on several parameters such as how well you take care of your device; it will not affect the efficacy of your device. Take care to avoid drinking coloured liquids while wearing your device. Be sure to brush your teeth before inserting your device at each use.

CARING FOR YOUR O₂VENT™ MONO

Your device is made of biocompatible materials to ensure your comfort and effective treatment. To maintain the lifetime of your device, we recommend you follow the cleaning regime.

CAUTION

- Never try and pick at or remove the polymer. If the polymer is damaged significantly or separates from the titanium it may need to be replaced by the manufacturer. To replace the polymer insert material, contact your Oventus Clinician.
- The polymer is designed to last at least 12 months with normal use. It can be returned for a new polymer insert when required. Contact your Oventus Clinician for information on the additional cost.
- Never use chlorine based products, bleach or acetic acid.
- Never put the device in water warmer than 45°C / 113 °F.
- Never use toothpaste or mouthwash to clean your device especially the polymer areas, as they may be too abrasive.
- Do not leave your device outside of the box within reach of pets or children.

CONTRAINDICATIONS

The **O₂Vent Mono** is contraindicated for patients who:

- have central sleep apnoea
- 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.

WARNINGS

The use of the **O₂Vent Mono** may cause:

- tooth movement or changes in dental occlusion
- gingival or dental soreness
- pain or soreness to the Temporomandibular Joint
- excessive salivation.

The **O₂Vent Mono** should not be worn by the user during any radiology procedures such as X-rays, Computer Tomography (CT) scanning or Magnetic Resonance Imaging (MRI).

PRECAUTIONS

Dentists should consider the medical history of the patients, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the **O₂Vent Mono**.

This is a prescription device only – it must be prescribed by a qualified Oventus Clinician.

**For more information or assistance,
please contact Oventus at 1300 533 159
or by email at reception@oventus.com.au**

www.oventus.com.au



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AND A BETTER LIFE**