

Instructions for Use



O2Vent
Optima[®]

Oral Appliances
for Sleep Apnea
Therapy



OVENTUS[®]

Name of User

Name of Sleep Physician

Name of Dentist

Device name and Serial No.

Date of first fitting/purchase

Connector band starting titration length and strength

Date of follow up with Physician/Dentist

Instructions for use for **O2vent Optima**[®]

Contents

Introduction	2
Indications for use	3
Product designs and description	4
Your O2Vent Optima kit	5
How your O2Vent Optima device works	6
O2Vent Optima device features*	8
- Optional use of elastic bands	10
Using your O2Vent Optima	12
- Inserting your O2Vent Optima	12
- Removing your O2Vent Optima	12
- Finding the right titration setting	13
Tips for wearing your O2Vent Optima	15
Risks and Contraindications	16
O2Vent Optima cleaning instructions	17
General warnings and precautions	20
Maintenance	22
Replacing Connector Bands	23
Keep a log of your O2Vent Optima titration	25

Introduction

Congratulations, you have taken the first steps to improve your sleep and well-being!

Your Dental Healthcare Professional has chosen the **O2Vent Optima® (O2Vent Optima)** for your snoring and/or obstructive sleep apnea (OSA) therapy. OSA is a condition where a sufferer experiences repetitive episodes of partial or complete blockage of the upper-airway during sleep. This is caused by obstructions of the nose, soft palate and tongue.



Ensure that you read these Instructions for Use **BEFORE** inserting and using your **O2Vent Optima**.

Indications for use

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.



O2Vent Optima Mini

Product designs and description

O2Vent Optima is available in two design options to help your Dental Healthcare Professional provide the most suitable treatment for you.

- The **O2Vent Optima** features an extended airway at the mouth opening.
- The **O2Vent Optima Mini** comes without the extended airway.

The **O2Vent Optima** designs feature the following components:

**O2Vent Optima* parts
(before assembly)**

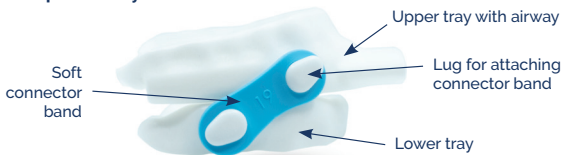


**O2Vent Optima Mini* parts
(before assembly)**



Each device features a lower tray, upper tray and connector bands

O2Vent Optima* (fully assembled)



* Assembly is the same for both **O2Vent Optima** designs.

Your **O2Vent Optima** kit

Your **O2Vent Optima** is created specifically to fit your teeth. Your device comes fully assembled with 19mm length connector bands*. All **O2Vent Optima** kits contain:

- One set of either 'soft' (light blue) or 'firm' (dark blue) connector bands, as selected by your Dental Healthcare Professional, to adjust titration. Each set of bands has 9 length size options ranging from 13-21mm. The size is marked on the band. The strength is marked on the opposite side with an 'S' for 'soft' (light blue bands) or an 'F' for 'firm' (dark blue bands).
- Oventus tub
- Instructions for use
- Warranty
- Antibacterial cleanser tablets

It is important that you check the contents of your **O2Vent Optima** kit and make sure that you find everything listed above. Please contact your Dental Healthcare Professional if anything is missing.

* In some instances, your Dental Healthcare Professional may recommend a different starting length for your connector bands based on your jaw anatomy. 'Soft' strength bands are the default strength and are light blue, 'firm' strength bands are dark blue.



'Soft'
strength
connector
bands

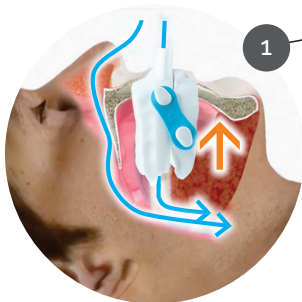


'Firm'
strength
connector
bands

How your **O2Vent Optima** device works

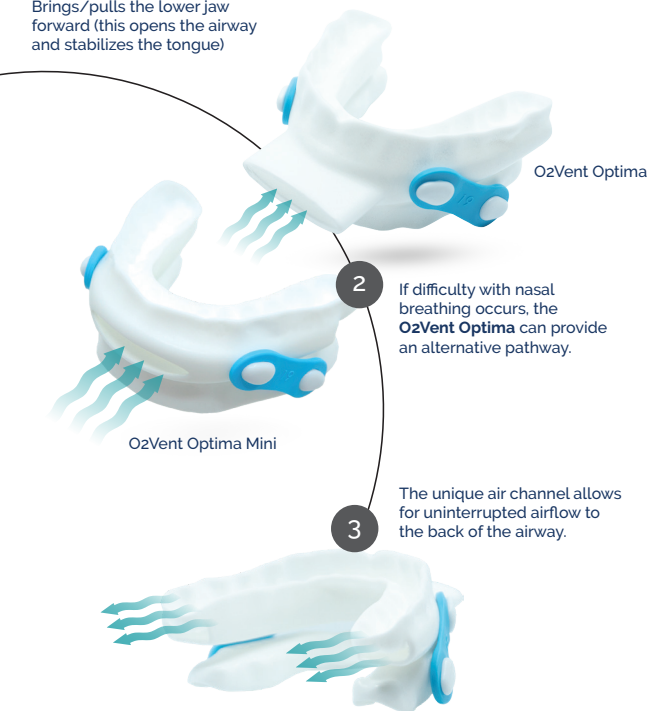
The **O2Vent Optima** process:

1. Your Dental Healthcare Professional will provide Oventus an image or impression of your teeth.
2. Your **O2Vent Optima** will be designed specifically to fit your teeth.
3. Your Dental Healthcare Professional will fit and assess your device to ensure it is working to treat your snoring and/or sleep apnea.

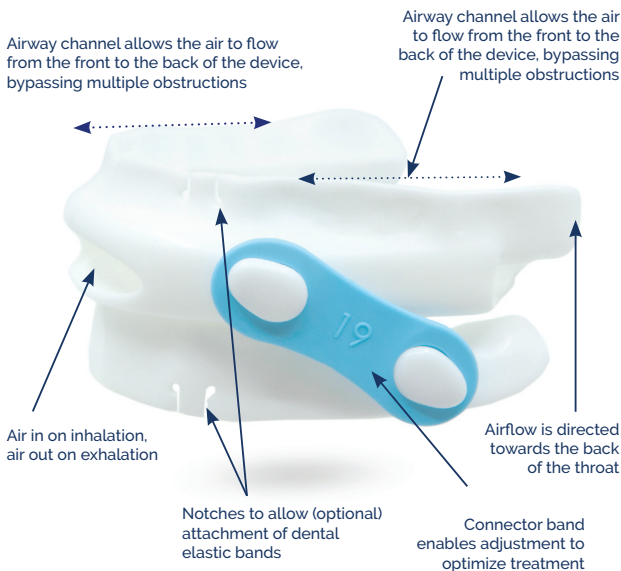


Regardless of the design (with or without the extended airway) the **O2Vent Optima** works in the following way.

Brings/pulls the lower jaw forward (this opens the airway and stabilizes the tongue)



O2Vent Optima device features*



* Elastic bands not included. If you have problems with mouth opening during sleep, your Dental Healthcare Professional can provide the recommended length and strength elastic bands, to keep your device in a closed position.

The **O2Vent Optima** consists of the following parts (refer to image on page 4):

- Upper tray (upper teeth)
- Lower tray (lower teeth)
- Connector bands

The upper and lower trays are connected to each other by the connector bands and will be delivered assembled:

- The bands are used to move the lower jaw (i.e. adjust the trays) forward or backward.
- In order to adjust the trays to your specific needs, the bands come in different lengths to enable titration adjustment. There are 9 length size options ranging from 13-21mm.
- Your new **O2Vent Optima** is delivered fully assembled with the 19mm connector band as the recommended starting titration length for all new users*.
- The shorter the connector band, the further the lower jaw is moved forward.
- After the initial use, your Dental Healthcare Professional will help you to find the right length of connector bands to receive the best therapy.

* In some instances, your Dental Healthcare Professional may recommend a different starting length for your connector bands based on your jaw anatomy.

O2Vent Optima device features CONTINUED

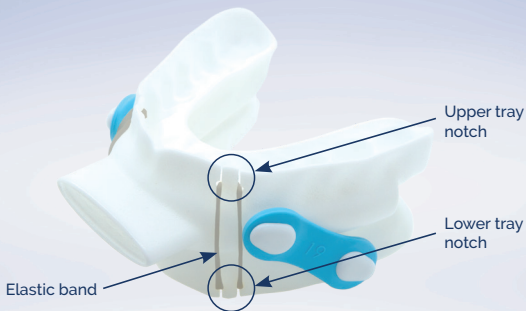
Optional use of elastic bands

Your Dental Healthcare Professional may determine that your **O2Vent Optima** device requires intra oral elastic bands (elastic bands) .

All **O2Vent Optima** devices allow for the addition of elastic bands to secure the upper and lower trays of your device while in use.

If instructed to attach elastic bands, your Dental Healthcare Professional may supply you with the elastic bands or advise where to purchase them.

An example of an **O2Vent Optima** device with elastic bands added is shown below.



To attach elastic bands (to both **O2Vent Optima** and **O2Vent Optima Mini**):

Hook each elastic band around the notch in the upper and lower trays (on each side) as shown on page 10, and insert your **O2Vent Optima** device into your mouth according to the instructions on page 12.

Elastic band precautions

- Ensure the elastic bands are replaced **daily** as they will lose their strength and elasticity which could result in breakage.
- Should your **O2Vent Optima** device dislodge from your teeth as a result of the elastic bands, a different size and/or strength elastic band may be required. In this case, please seek advice from your prescribing Dental Healthcare Professional.
- Should you experience any pain or discomfort when using your **O2Vent Optima** device with elastic bands attached, please seek advice from your Dental Healthcare Professional.



WARNING: Choking hazard – small parts
Keep away from children under 3 years.

Using your O2Vent Optima

Inserting your O2Vent Optima

Before your sleep period

1. Inspect your **O2Vent Optima**; make sure the air channel is clear.
2. Make sure your **O2Vent Optima** is connected with the bands and they are the same length on each side.
3. Make sure your **O2Vent Optima** is clean.
4. Rinse the **O2Vent Optima** and brush your teeth before inserting.
5. Using your thumbs, insert the upper tray and gently "push" onto the upper teeth; the tray should fit snugly.
6. Insert the lower tray, "push" onto the lower teeth; the tray should fit snugly.

Removing your O2Vent Optima

After your sleep period

7. Remove your **O2Vent Optima** by gently opening your mouth, lift up the lower tray and then pull down on the upper tray. You might feel a little "resistance" initially.
8. Make sure **BOTH** trays are loosened before removing.



The **O2Vent Optima** trays should never be worn separately. Always wear both trays (assembled with the connector bands) when using the device.

Please check to ensure your connector bands are securely fastened on your **O2Vent Optima** before using. Loose bands may pose a choking risk.

Finding the right titration setting

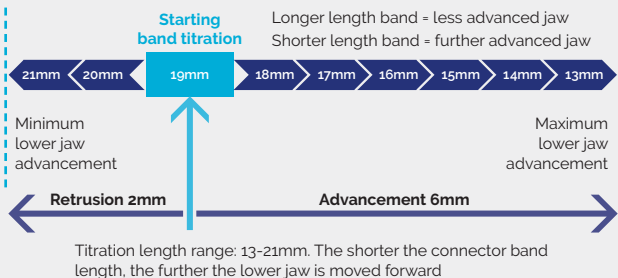
- **Adjustments to the titration setting using connector bands are to be made under the direction of your treating Dental Healthcare Professional.**
- Your **O2Vent Optima** will be delivered ready to use, fitted with the 19mm connector bands as the recommended starting titration for all new users.
- During the **initial** phase of using your **O2Vent Optima**, you will work closely with your Dental Healthcare Professional to find the correct position. **It is important that you wear your O2Vent Optima each sleep period according to your Dental Healthcare Professional recommendations.**
- Ensure the connector band lengths are the same on each side.
- The titration may take several weeks or longer to achieve the best therapy.
- If your Dental Healthcare Professional suggests a shorter or longer length band, refer to the diagram on page 14 for length and titration information.
- After your settings have been established, you should wear your **O2Vent Optima** each sleep period.

Using your O2Vent Optima CONTINUED

The diagram below shows the lower jaw positioning range that can be set by the connector band lengths. This is a guide only.

Note: The shorter the connector band, the further the lower jaw is advanced. The longer the connector band, the less the lower jaw is advanced.

O2Vent Optima lower jaw positioning range



Tips for wearing your **O2Vent Optima**

It is important to use your **O2Vent Optima** during each sleep period to receive the best possible outcome.

Tips

- If you are having problems adapting, try wearing your **O2Vent Optima** while watching TV or reading. It will help you to get used to using it.
- It might be helpful for you to track how much you use your **O2Vent Optima**, this will help you to get into the habit of applying your **O2Vent Optima** before your sleep period. Refer to page 25 for a usage log.

Morning Jaw Exercises

As recommended by the American Academy of Dental Sleep Medicine (AADSM), morning jaw exercises are often indicated to improve jaw discomfort. To help with jaw discomfort, some suggested activities include:

- Moving the chin backwards and close your back teeth together while biting down. Repeat 5 to 10 times.
- Eat breakfast or chew sugar-free gum; it will help to return to a normal bite.

Should you experience morning discomfort, seek the advice of your Dental Healthcare Professional.

Risks and Contraindications

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 **OzVent Optima** 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

O2Vent Optima cleaning instructions



Recommended after each use

- Rinse the **O2Vent Optima** with lukewarm water and clean with a soft clean toothbrush (not the same toothbrush you use to brush your teeth, as toothpaste can damage the device).
- Thoroughly rinse the device with lukewarm water, including through the airway entry and exit points.
- Ensure the airway entry and exit are free from any debris.
- Dry your device after each cleaning with a cloth and shake to clear water from the airway.
- Return to the Oventus tub to store, with the lid open to allow the internal airway to dry.

O2Vent Optima cleaning instructions

CONTINUED

Recommended cleaning twice a week

Clean your **O2Vent Optima** device more thoroughly twice a week, or more frequently as required, using the provided Oventus tub and an antibacterial cleanser (free from chlorine, bleach, acetic acid or alcohol-based products).

Step 1

- Conduct the daily cleaning (refer to page 17).

Step 2

- Fill the Oventus tub provided about $\frac{3}{4}$ full (about $\frac{1}{2}$ " below the top) with warm water.
- Place the antibacterial cleanser and the **O2Vent Optima** device in the water so that they are completely submerged and leave them to soak for 15 minutes if using the Oventus provided tablets, or follow the recommended time according to other antibacterial cleanser packet instructions.



Soaking **O2Vent Optima** twice a week

- Remove and rinse both the **O2Vent Optima** device and Oventus tub thoroughly with lukewarm water, including through the airway entry and exit points, to remove the cleaning agent.
- Dry your device after each cleaning with a clean cloth.
- Return to the Oventus tub to store, with the lid open to allow the internal airway to dry.



After soaking the **O2Vent Optima** device with an antibacterial cleanser, remove device and rinse thoroughly with lukewarm water. Wash hands thoroughly before and after handling cleanser tablets. Do not mix with other cleansers.

Many antibacterial cleansers contain persulfates which are a known allergen. Keep out of reach of children. Use only as directed. If product comes into contact with eyes, wash eyes thoroughly with water for several minutes. Do not put antibacterial cleanser tablets or cleaning solution in mouth. If ingested, seek medical assistance immediately.

USA – call the Poison Control Center on 1-800-222-1222.

Canada – call your provincial or territorial Poison Centre. In an emergency call 911.

Australia – call the Poison Information Centre on 131 126.



General warnings and precautions

Use of the O2Vent Optima may cause the following side effects:

- Tooth movement, discomfort, pain or changes in dental occlusion
- Dental soreness
- Pain or soreness to the temporomandibular joint (TMJ)
- Excessive salivation
- Cheek or tongue pain
- Jaw discomfort, pain or jaw set (clenched jaw)
- Temporary bite change. This may subside approximately 30 minutes after the **O2Vent Optima** is taken out of the mouth after each sleep period
- Permanent bite change may occur as a result of long term use
- Gingivitis. This is a common and mild form of gum disease (periodontal disease) that causes irritation, redness and swelling (inflammation) of your gingiva, the part of your gum around the base of your teeth. Untreated gingivitis can progress to gum disease that spreads to underlying tissue and bone. This is known as Periodontitis, a much more serious condition that can lead to tooth loss. Should you experience any of these symptoms, seek the advice of your Dental Healthcare Professional.
- Dry mouth. This is a common side effect of using the **O2Vent Optima** device. Dry mouth can lead to gum disease such as gingivitis. Should you experience this symptom, seek the advice of your Dental Healthcare Professional.

If any side effects or ongoing band breakages or dental issues persist while using the **O2Vent Optima**, please seek advice from your Dental Healthcare Professional.

Precautions:

- Dental 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 prescribing the **O2Vent Optima** device
- Never use chlorine, bleach, acetic acid or alcohol-based products (including mouthwash) to clean your **O2Vent Optima**
- Only use warm water, not to exceed 45°C or 113°F (boiling water may cause damage)
- Do not use toothpaste or mouthwash to clean your **O2Vent Optima**
- If you require dental work such as fillings, crowns, extractions etc., these may change the fit of your **O2Vent Optima**. You should always discuss this with your Dental Healthcare Professional
- The **O2Vent Optima** may change color over time, **which could** be due to certain foods/liquids. This will not change the effectiveness of the device. If you use colored mouthwash after cleaning your teeth, wait 15 minutes before inserting your **O2Vent Optima**, to avoid discoloration. For best results, follow the recommended cleaning instructions.
- The **O2Vent Optima** trays should never be worn separately. Always wear both trays (assembled with the connector bands) when using the device.
- Please check to ensure your dental elastic bands (if using) and connector bands are securely fastened on your **O2Vent Optima** before using. Loose bands may pose a choking risk.

Maintenance

Your **OzVent Optima** should be 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.

Connector bands

Once you have determined the band length that optimizes your therapy, you can re-order them in packs of 25.

To re-order the connector bands, ask your Dental Health Professional.

The **OzVent Optima** connector bands have a recommended usage time frame of one month, as usage can affect the band length and the titration of your device. The connector bands should be replaced every month or more frequently if required.

Replacing Connector Bands

The connector bands (bands) are essential for keeping your **O2Vent Optima** device assembled and to maintain the lower jaw position.

Routine band replacement

- It is recommended to change both bands monthly as they may lose elasticity.

How to identify that the bands need changing

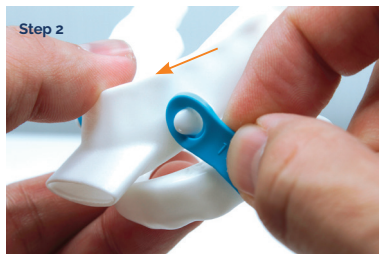
- If the length of the current band is longer than a new band
- If the band's holes have stretched from circular to oval shape
- If your Dental Healthcare Professional recommends changing the band strength (soft v/s firm), you may need to trial a different length band to achieve treatment success.

Replacing connector bands on your O2Vent Optima

Step 1 – Separate the upper and lower device trays, as shown.



Replacing Connector Bands CONTINUED



Step 2 – To remove, peel the band away from the wide end of the lug. Repeat on the second side.



Step 3 – Add the new band with the size/number facing out, by hooking the band opening over the narrow end of the lug and pulling it over the wide end. Repeat this action with the other end of the band to connect the upper and lower trays.

Step 4 – Repeat step 3 with the second band.

Keep a log of your **O2Vent Optima** titration

It may be helpful to keep a usage log of your **O2Vent Optima** for the first month of wear. It may take several weeks or longer to achieve the best therapy. Refer to page 14 for the lower jaw positioning range as a guide.

Date	Connector band length	Comment
EXAMPLE: 1 Jan 2021	19mm	After 1 week wearing, still snoring, some dribble. Changed to shorter band
EXAMPLE: 8 Jan 2021	18mm	Still snoring, less dribble. Changed to shorter band
EXAMPLE: 22 Jan 2021	17mm	Worn for 2 weeks. No snoring. Dribble stopped



MANUFACTURER AND AUSTRALIAN SPONSOR:

Oventus Manufacturing Pty Ltd
1 Swann Road, Indooroopilly
QLD 4068, Australia

MANUFACTURED FOR:

Australia: Oventus Medical Limited

USA: Oventus Medical USA, Inc.

Canada: Oventus Medical Canada, Inc.

Australia:

1300 533 159 (Toll Free)

customercare@oventusmedical.com

USA and Canada:

1-866-835-0116 (Toll Free)

support@oventusmedical.com

O2Vent.com

R_x Only



PRODUCT CODE:
Ozvent Optima: O2VB
O2Vent Optima Mini: O2VBM
R134_2021-02