

Instructions for Use



**O2Vent
Optima[®]**
Oral Appliances
for Sleep Apnea
Therapy



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®

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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).
- 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

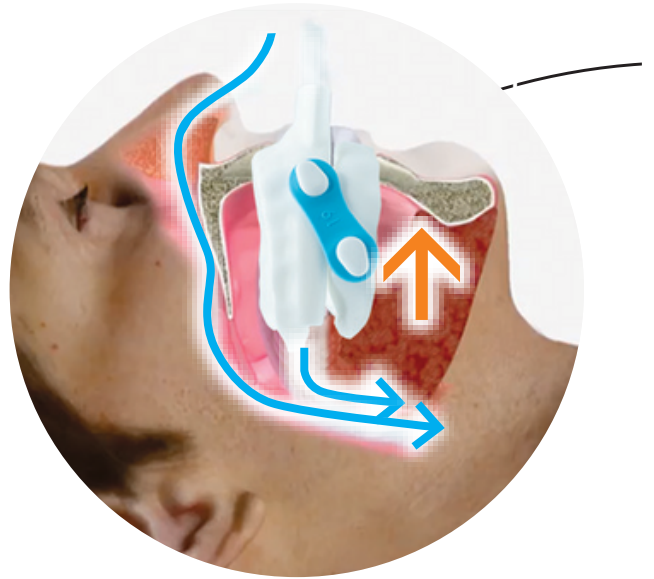
The O2Vent Optima process:

1. Your Dental Healthcare Professional will provide us with an image or impression of your teeth.

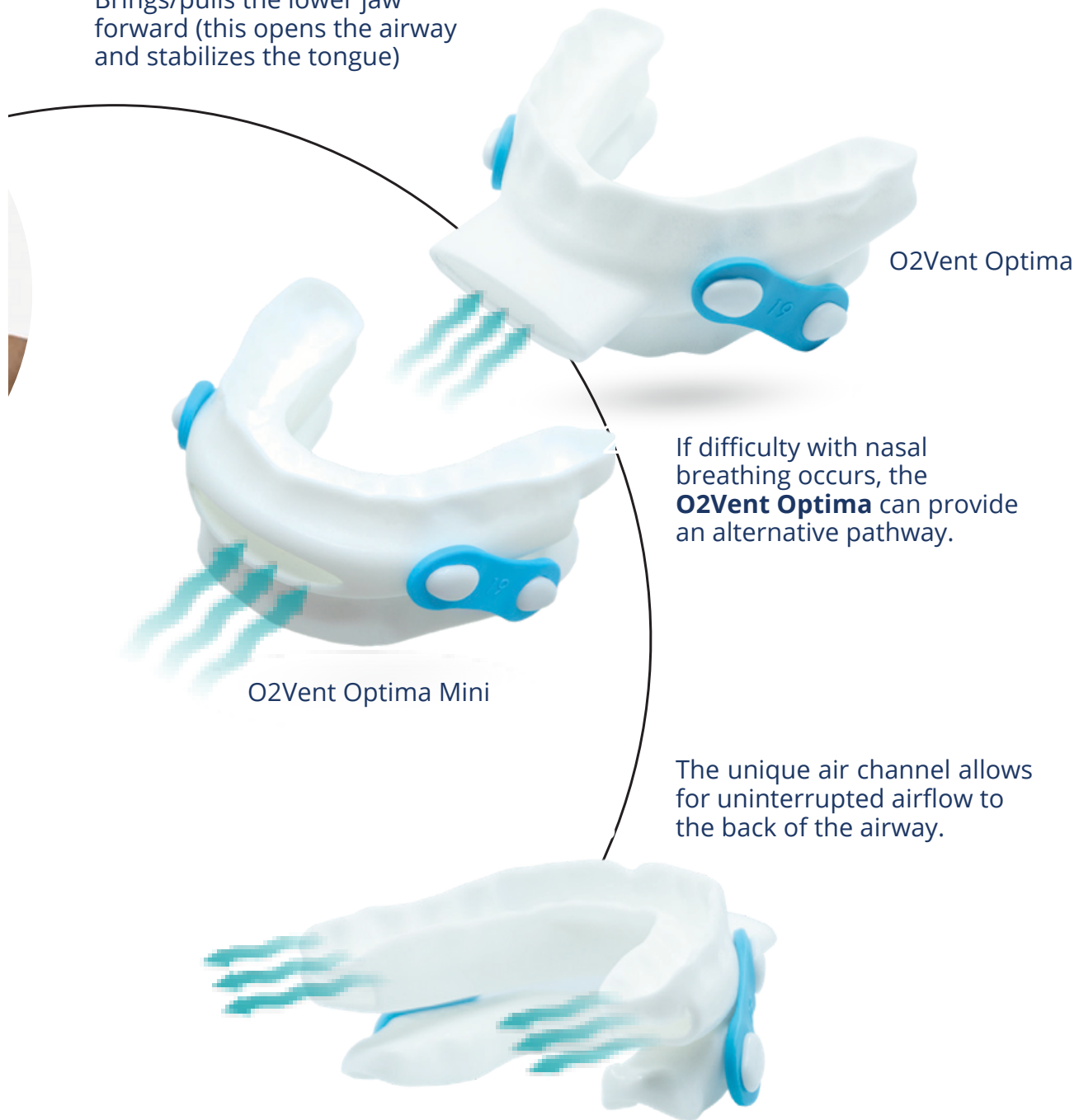
2. Your **O2Vent Optima** will be designed specifically to fit your teeth.

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 the following way.



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



O2Vent Optima device features*

Airway channel allows the air to flow from the front to the back of the device, bypassing multiple obstructions

Airway channel allows the air to flow from the front to the back of the device, bypassing multiple obstructions



Air in on inhalation,
air out on
exhalation

Airflow is directed
towards the back
of the throat

Notches to allow (optional)
attachment of dental
elastic bands

Connector band
enables adjustment to
optimize treatment

* 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.

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

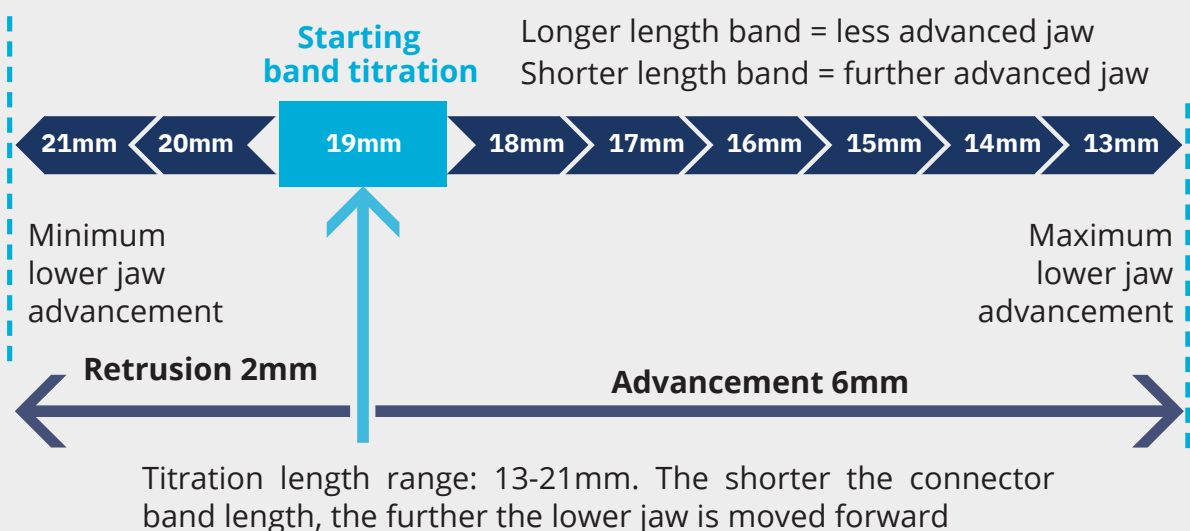
- **Adjustments to the titration setting using connector bands are to be made under the direction of your treating Dental Healthcare Professional.**
- Your **O2Vent Optima** will be delivered ready to use, fitted with the 19mm connector bands as the recommended starting titration for all new users (unless a different band length is ordered).
- 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 **O2Vent 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 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 a suitable container and an antibacterial denture 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 tub provided about $\frac{3}{4}$ full (about $\frac{1}{2}$ " below the top) with warm water.
- Place the antibacterial denture 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 provided tablets, or follow the recommended time according to other antibacterial denture cleanser packet instructions.



Soaking **O2Vent Optima** twice a week

- Remove and rinse both the **O2Vent Optima** device and 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 tub to store, with the lid open to allow the internal airway to dry.



After soaking the O2Vent Optima device with an antibacterial denture 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 denture 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 denture 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 **O2Vent Optima** should be stored in a denture case or suitable container during transport.

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 **O2Vent 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

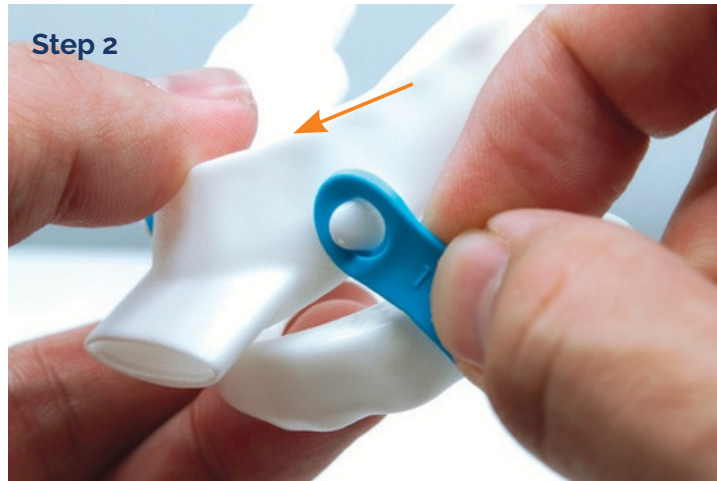
- If the length of the current band is longer than a new band
- If the band's holes have stretched from circular to oval shape
- If your Dental Healthcare Professional recommends changing the band strength (soft v/s firm), you may need to trial a different length band to achieve treatment success.

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.

MANUFACTURER AND AUSTRALIAN SPONSOR

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5 Moorak Street, Taringa QLD 4068 Australia
www.openairway.au
info@openairway.com
Ph: [+61-1300-533-159](tel:+61-1300-533-159)

MANUFACTURED FOR

Open Airway Dental Solutions Ltd, Canada
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info@openairway.ca
Ph: [+1-866-835-977-8267](tel:+1-866-835-977-8267)



PRODUCT CODE:
O2vent Optima: O2VB
O2Vent Optima Mini:
O2VBM R134.02

O2Vent Optima[®]

Limited Warranty



This Limited Warranty is provided by Open Airway Dental Solution Pty Ltd and its Affiliates ("Open Airway"), and warrants that all O2Vent Optima[®] Devices ("Device") supplied shall be free from Defects in materials and workmanship and will perform in accordance with product specifications during the Warranty Period (specified in Section B below). All capitalised terms not defined in-text are defined in Section A.

This Limited Warranty gives you specific legal rights, and you may also have other rights and remedies available under applicable laws in the Area where your Device was supplied.

Open Airway's obligations under this Limited Warranty are expressly limited to repairing or replacing any Device found, in the sole discretion of Open Airway, to have a Defect during the Warranty Period.

R131.01

The Open Airway logo, Open Airway[®] and O2Vent Optima[®] are trade marks of Open Airway Dental Solutions Pty Ltd.

Questions (all countries)

For the questions related to this Limited Warranty, contact your Dental Healthcare Professional, or you may contact Open Airway as follows:

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

MANUFACTURED FOR:
Open Airway Dental Solutions Ltd, Canada
www.openairway.ca
info@openairway.ca
Ph: +1-866-835-977-8267

Australian consumers

This section and the following applies only to our goods and a Device supplied within Australia.

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

E. How do I make a claim under this Limited Warranty?

To make a claim for your Device under the Limited Warranty, you must return the Device to the Dental Healthcare Professional who supplied it to you within 30 days of becoming aware of the claimed Defect.

Your claim must be received within the Warranty Period (i.e. within 36 months from the Delivery Date).

The Dental Healthcare Professional and Open Airway will assess the Device for required repairs or Defects and will determine whether to send your Device to an authorised Open Airway for servicing.

You may need to attend your Dental Health Professional's office in person for such assessment.

Warranty claims for a Device must be accompanied by dated proof of when supplied by the Dental Healthcare Professional.

Return postage fees will be assessed on a case by case basis when making a claim under this Limited Warranty. You are otherwise responsible for any costs and expenses, including for example transport costs, in making a claim under this limited Warranty.

A. Definitions

"Affiliates" means Open Airway Dental Solutions Pty Ltd.

"Area" or "Areas" means a State, Province, Territory, or other governmental region.

"Defect" means faulty componentry or Device functionality resulting from product design or manufacturing.

B. What does the Limited Warranty cover?

During the Warranty Period, as set out below, Open Airway will repair or replace (at the discretion of Open Airway) any Device with a Defect, subject to the terms of this Limited Warranty.

The Warranty Period for a Device begins on the date you receive your prescribed Device from your Dental Healthcare Professional ("Delivery Date") and ends when the Warranty Period below has elapsed:

DEVICE	WARRANTY PERIOD
O2Vent Optima ® nylon device-upper and lower tray	36 months from the Delivery Date*

* The Warranty Period is not extended if the Device is adjusted or Open Airway repairs or replaces the Device, except as provided in Section C3.

C. What conditions apply to this Limited Warranty?

This Limited Warranty is subject to the following conditions:

1. The Device must have been used, maintained and cleaned only in accordance with the Instructions for Use included with the Device and must only have been used by the individual for whom it was supplied.

2. Minor adjustments to the Device may be performed from time to time by a licensed Dental Healthcare Professional qualified through appropriate education and training in your Area. The Dental Healthcare Professional must perform such adjustments according to any directions and requirements provided by Open Airway, as updated from time to time. Open Airway shall not be responsible for the failure of any adjustment or fitting made by unqualified or unlicensed persons or for any act, omission, or negligence of a Dental Healthcare Professional.

3. **This Limited Warranty is void if, following a proper fitting, the patient receives any dental work, or suffers injury, damage, or changes to the mouth or teeth, unrelated to the Device, that changes the Device fit, requiring a new Device and warranty.**

D. Limitations

The following limitations apply to this Limited Warranty:

1. This Limited Warranty is not transferrable or exchangeable and it extends only to the person for whom it was supplied by a licensed Dental Healthcare Professional.

2. This Limited Warranty only applies in the Area where the Device was supplied.

3. This Limited Warranty does not cover damage caused by (a) improper or unreasonable use, (b) unauthorized modifications or repair, or (c) wear and tear due to normal use, including any change of colour that may occur over time.

This Limited Warranty excludes coverage of, and does not provide relief for, incidental, consequential, special or punitive damages or losses of any kind or nature, including but not limited to loss of use or inconvenience. Some Areas may not allow the exclusion of incidental or consequential damages, so the above exclusion may not apply to you.

4. Open Airway may request or require proof of purchase, photographs, invoice copies or other information from the customer relevant to the Device to assess any claim under this Limited Warranty.

5. Open Airway explicitly excludes any liability for any personal injury, unforeseeable risks, or events beyond its reasonable control, including but not limited to labour shortages, government action, natural disasters, pandemics and epidemics.

6. This Limited Warranty supersedes any and all other warranties or representations made by Open Airway, whether written or oral.

7. To the extent permissible by applicable law, this Limited Warranty replaces all other expressed or implied warranties, including warranties of merchantability and fitness for a particular purpose. If applicable law prohibits this disclaimer of an implied warranty then, the Open Airway limits the duration of all implied warranties to the duration of this express Limited Warranty. Some Areas may not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.