

INSTRUCTIONS FOR USE – USA



O₂VENT[®]
OPTIMA

ORAL APPLIANCE
FOR SLEEP APNEA
THERAPY



Name of User

Name of Sleep Physician

Name of Dentist

Serial No. of Device

Date of first fitting/purchase

Connector band starting titration length

Date of follow up with Physician/Dentist

INSTRUCTIONS FOR USE FOR O₂VENT® OPTIMA

CONTENTS

Introduction	2
Indications for use	3
Optima description	4
Your Optima kit	5
How your Optima device works	6
Using your Optima	9
Inserting your Optima	9
Removing your Optima	9
Finding the right titration setting	10
Tips for wearing your Optima	12
What are the risks of OSA	13
Contraindications	13
Cleaning instructions	14
General warnings and precautions	17
Maintenance	19
Replacing connector bands	20
Keep a log of your titration	21

INTRODUCTION

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

Your Dental Healthcare Professional has chosen the O₂Vent® Optima (***Optima***) specifically 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.

INDICATIONS FOR USE

The ***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.

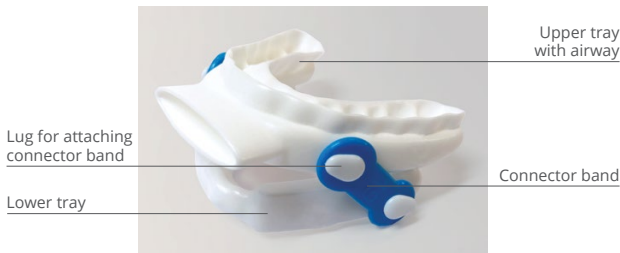


OPTIMA DESCRIPTION

Your **Optima** features the following components:



Optima parts (before assembly):
lower tray, upper tray and connector bands



Optima (fully assembled)

YOUR *OPTIMA* KIT

Your customized *Optima* comes fully assembled with 19mm length connector bands*. The *Optima* kit contains:

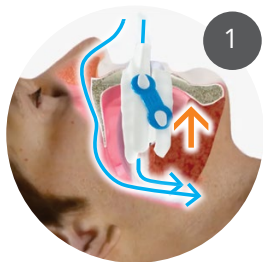
- Two sets of connector bands to adjust titration. Each set of bands has 9 length size options ranging from 13-21mm. The size is marked on the band.
- Oventus tub
- Instructions for use
- Warranty
- Antibacterial cleanser tablets

It is important that you check the contents of your personalized *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.

HOW YOUR *OPTIMA* DEVICE WORKS

In general, the *Optima* works in the following way.

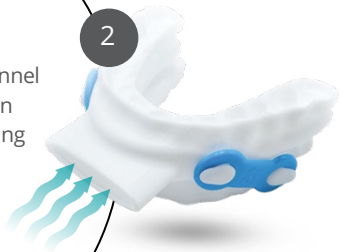


1

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

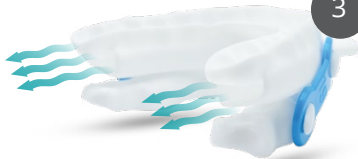
Provides a unique air channel in case of nasal congestion or difficulties with breathing through the nose.

2

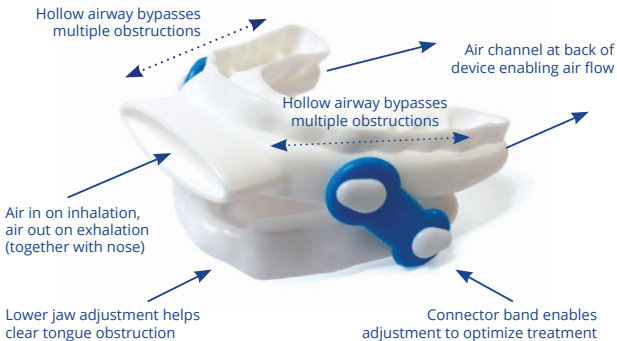


3

The air channel allows the air to flow smoothly to the back of the airway.



THE **OPTIMA** DEVICE



In order to make the **Optima**, an image of your teeth is taken by the dentist. This image is sent to Oventus where your customized **Optima** will be made. When the **Optima** is ready, your Dental Healthcare Professional will fit and assess how well the **Optima** works to treat your snoring and/or OSA.

HOW YOUR *OPTIMA* DEVICE WORKS CONTINUED

The ***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 ***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 *OPTIMA*

INSERTING YOUR *OPTIMA*

BEFORE YOUR SLEEP PERIOD

1. Inspect your *Optima*; make sure the air channel is clear.
2. Make sure your *Optima* is connected with the bands and they are the same length on each side.
3. Make sure your *Optima* is clean.
4. Rinse the *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 *OPTIMA*

AFTER YOUR SLEEP PERIOD

7. Remove your *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 *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 *Optima* before using. Loose bands may pose a choking risk.

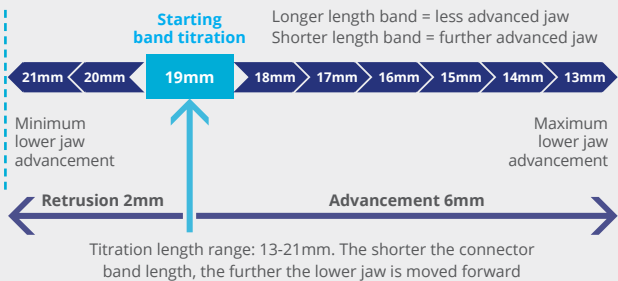
FINDING THE RIGHT TITRATION SETTING

- **Adjustments to the titration setting using connector bands are to be made under the direction of your treating Dental Healthcare Professional.**
- Your *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 *Optima*, you will work closely with your Dental Healthcare Professional to find the correct position. ** It is important that you wear your *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 10 for length and titration information.
- After your settings have been established, you should wear your *Optima* each sleep period.

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.

OPTIMA LOWER JAW POSITIONING RANGE



TIPS FOR WEARING YOUR *OPTIMA*

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

TIPS


- If you are having problems adapting, try wearing your *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 *Optima*, this will help you to get into the habit of applying your *Optima* before your sleep period. Refer to page 21 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.



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 ***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

OPTIMA CLEANING INSTRUCTIONS



RECOMMENDED AFTER EACH USE

- Rinse the **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.

RECOMMENDED CLEANING TWICE A WEEK

Clean your **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 14).

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 **Optima** device in the water so that they are completely submerged and leave them to soak, following the recommended time according to the cleanser packet instructions.



Soaking **Optima** twice a week

OPTIMA CLEANING INSTRUCTIONS CONTINUED

- Remove and rinse both the **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 Optima device with an antibacterial cleanser, remove device promptly and rinse thoroughly with lukewarm water. Wash hands thoroughly before and after handling cleanser tablets. Do not mix with other cleansers.

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. In the USA, please call Poison Control Center at 1-800-222-1222.



GENERAL WARNINGS AND PRECAUTIONS

Use of the **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 will subside approximately 30 minutes after the **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 **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 dental issues persist while using the **Optima**, please seek advice from your Dental Healthcare Professional.



GENERAL WARNINGS AND PRECAUTIONS

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 **Optima** device
- Never use chlorine, bleach, acetic acid or alcohol-based products (including mouthwash) to clean your **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 **Optima**
- If you require dental work such as fillings, crowns, extractions etc., these may change the fit of your **Optima**. You should always discuss this with your Dental Healthcare Professional
- The **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 **Optima**, to avoid discoloration. For best results, follow the recommended cleaning instructions.
- The **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 **Optima** before using. Loose bands may pose a choking risk.

MAINTENANCE

Your **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.

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.

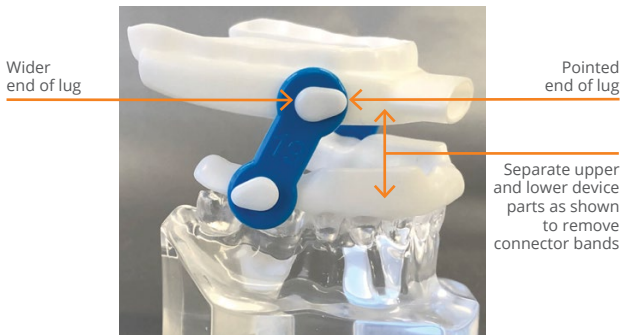
The **Optima** connector bands have a recommended usage time frame of one month, as usage can affect the band length and the titration of your device. The connector bands should be replaced every month or more frequently if required.

REPLACING CONNECTOR BANDS

The connector bands are essential for keeping your **Optima** device assembled, with the lower jaw set at the chosen position eg. with 19mm bands. **The connector bands should be replaced on each side every month** as they may lose elasticity. To identify when the bands need changing, compare their length against a new band. If the bands are longer or the holes stretch from circular to oval, it is time to change both bands.

To remove a connector band from your **Optima** device, pull the upper and lower device pieces apart (as shown in diagram). Peel the band away from the wider end of the “lug” and off the “lug” point.

To apply a connector band, hook the band over the pointed end of the “lug” and pull gently to hook over the wider “lug” end.



KEEP A LOG OF YOUR **OPTIMA** TITRATION

It is recommended that you keep a usage log of your **Optima** titration setting for the first month of wear (recording which length connector bands you try, to advance your lower jaw). Your entry may be weekly or daily. It may take several weeks or longer to achieve the best therapy. Refer to page 10 for the lower jaw positioning range as a guide.

Date	Connector band length	Comment
EXAMPLE: 1 Sep 2018	19mm	<i>After 1 week wearing, still snoring, some dribble. Changed to shorter band</i>
EXAMPLE: 8 Sep 2018	18mm	<i>Still snoring, less dribble. Changed to shorter band</i>
EXAMPLE: 22 Sep 2018	17mm	<i>Worn for 2 weeks. No snoring. Dribble stopped</i>

WARRANTY:

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

CAUTION:

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



MANUFACTURER AND AUSTRALIAN SPONSOR:

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

Manufactured for:
Oventus Medical USA, Inc
Toll Free in USA:
[1-866-835-0116](tel:1-866-835-0116)
support@oventusmedical.com
www.o2vent.com



OVENTUS

RX ONLY

PRODUCT CODE: O2VB

R61US_ Sep 2019