

INSTRUCTIONS FOR USE



SomnoDent[®] AVANT[™] SLEEP APNEA APPLIANCE

RxOnly Medical Device



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Name

Physician

Dentist

Model

Serial No.

Date of Purchase

Dear SomnoDent User,

Thank you for selecting SomnoDent therapy.

Your SomnoDent Avant is manufactured to the highest medical device standards. SomnoMed is recognized as the leading manufacturer of medical oral appliances for the treatment of sleep disordered breathing.

These instructions will provide you with useful information on the correct use and care of your SomnoDent device.

Please read this information carefully and contact your dental sleep professional should you have any questions.

Thank you,

SomnoMed®

Restful Nights, Refreshing Days!

INTRODUCTION

Worn during sleep, SomnoDent devices fit over the upper and lower teeth. The device slightly moves the lower jaw forward, helping to keep the airway open and allowing the patient to breathe normally.

The SomnoDent line of devices are customized to each patient and offer superior comfort and quality. They are uniquely compliant and highly effective.



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WHAT IS OBSTRUCTIVE SLEEP APNEA (OSA)?



NORMAL

During normal sleep the airway remains open and breathing is not disrupted.



SNORING

When tongue & soft palate relax the tissue can vibrate as air passes over them causing snoring.



SLEEP APNEA

The airway can close over periodically and prevent air from getting to the lungs. These cessations of breathing are called apneas.

INDICATIONS FOR USE

The SomnoDent intraoral devices are intended for the treatment of night time snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.

CONTRAINDICATIONS

These devices are contraindicated for patients who:

- have central sleep apnea
- have severe respiratory disorders
- have temporomandibular joint dysfunction
- have loose teeth
- have advanced periodontal disease
- are under 18 years of age

PRECAUTIONS

Dentists 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 device.

WARNINGS

Use of these devices may cause:

- tooth movement & changes in occlusion
- TMJ pain or tenderness
- obstruction of mouth breathing
- excessive salivation
- gingival or dental soreness

POSSIBLE SIDE EFFECTS

You may experience some temporary side effects such as sore jaw joints, increased salivation, dry mouth, sore teeth, irritation of the soft tissue in the mouth and/or a slight change in bite.

These possible side effects should diminish within an hour of removing the device. If any of these side effects continue, contact your sleep dentist and maintain regular sleep dental check-ups.

Changes in bite or jaw stiffness and pain upon removal of your SomnoDent may be alleviated with clenching exercises. Use a SomnoMed Morning Repositioner to assist with these exercises or you may find it useful to chew gum upon removal of your device. The Morning Repositioner is supplied separately, please contact your sleep dentist for more information.

WEARING YOUR SOMNODENT

TIP! Use lip balm during the first few nights of wearing your SomnoDent to help keep your lips moist.

Fit Your Avant Strap to Upper Plate

Press a white end of the blue strap into the strap clip on the upper plate. Slide strap around until center is inside the strap clip.

Fit Your Avant Strap to Lower Plate

Hold strap upright and press strap hole over the hinge. Repeat on the opposite side. Twist strap down upon completion.

Inserting Your Device

Hold the upper and lower plates together and gently mount the lower plate to your teeth. Press down on the plate with your index fingers on both sides to ensure that it fits securely and comfortably.

Once the lower plate is securely in place, bite down into the upper plate to secure it onto your teeth. Use your thumbs on both sides if required to push the upper plate onto your teeth.

Removal of SomnoDent Avant

Disengage the lower plate from the teeth first by using your thumbs on both sides to push the plate upwards. Then using both your index fingers and thumbs, gently pull the upper plate down and remove the whole device from your mouth at once. Disassemble parts outside of the mouth when cleaning (see cleaning instructions.)

IMPORTANT TO NOTE

- Keep your device away from sunlight!
- Keep your device away from pets & small children!
- Always follow maintenance instructions for cleaning and care of your device
- You may initially experience a mild plastic taste & smell. This will disappear with storage and use.

CLEANING

Always clean your device in the morning immediately after having removed it from your mouth.

After each use, rinse in cold or lukewarm, water and clean with a soft toothbrush and liquid soap. Then rinse well. Avoid hot or boiling water as it will damage the device. Water temperature for cleaning should be no more than 45°C to avoid damage.

TIP! For easier access to all surfaces while cleaning, you may need to remove your SomnoDent Avant strap.

Never use hot or boiling water!
Hot or boiling water will damage your device.

NOTE!

- Do not use toothpaste, as it contains abrasives, and may damage the device.
- Do not use mouthwash to clean the device, as doing so will cause the material in the SomnoDent to deteriorate.

- Do not use ultrasonic cleaning.
- Avoid organic solvents like ethanol, acetone etc. for cleaning.
- Do not expose your strap to denture cleansers for more than 30 minutes each week. SomnoMed recommends using SomTabs for 15 minutes twice a week.

STORAGE INSTRUCTIONS

Always store your SomnoDent in a dry container with the lid off when not in use. A storage container is included for your convenience.

NOTE! Do not store your strap in water or any other liquid. To retain optimal properties, your strap must be regularly cleaned and stored dry.

MAINTAINING APPEARANCE OF YOUR SOMNODENT

To reduce the possibility of discoloration do not smoke or drink coffee, tea, colas or wine with the device in place. Always brush teeth thoroughly before use.

Patients with amalgam fillings or users of Pyralvex (a solution for mouth ulcers and denture irritation) may over time notice discoloration in the Flex lining of their SomnoDent.

Discoloration of the material will not adversely affect the performance or longevity of the device.

TRAVELING WITH YOUR SOMNODENT

Before traveling, thoroughly clean and dry your device then protect your SomnoDent Avant by placing it inside the supplied storage container without water.

Please note the SomnoDent storage container is not air or water tight.

REGULAR INSPECTION

Regularly inspect your SomnoDent Avant for signs of damage and cracks. If the device is damaged or broken it must NOT be used any longer in order to avoid injuries, such as choking or laceration.

REPAIRS

Damaged or broken devices must not be used any longer in order to avoid injury.

Immediately contact your sleep dentist, who will arrange for the device to be repaired by an authorized SomnoMed facility.

All repairs, including those under warranty, must be taken to your sleep dentist and not sent directly to SomnoMed!

WARRANTY

SomnoDent Avant has an expected life of 3 years from the date of shipment from SomnoMed to the providing dentist.

For information on the SomnoMed warranty policy please reference the information on our website, www.somnomed.com.

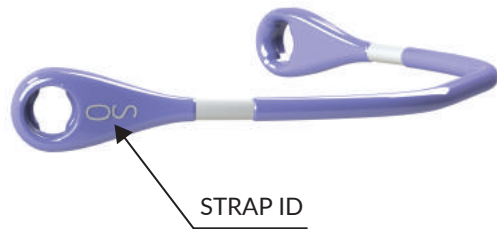
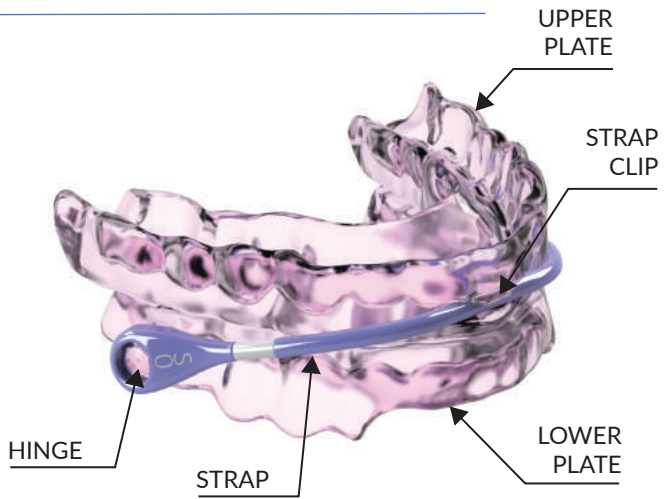
Examples of non-covered warranty returns

Device breakage not during normal use, pet chewing, exposure to excessive heat, exposure to caustic cleaners, and patient having dental work post order placement.

Returning your SomnoDent case

Warranty repair work may only be completed by an authorized SomnoMed facility. The device must come from the sleep dentist, not the patient. Dentists should send the device, original models & bite for repairs along with the repair form. Do not include any accessories. We will not issue new accessories with device repairs. Warranty will be voided if any structural changes are made to the device.

GET TO KNOW YOUR AVANT DEVICE



ADJUSTING YOUR AVANT DEVICE



- Your SomnoDent Avant is shipped to your dentist with the "0" strap attached to the device.
- Your SomnoDent Avant is adjusted by changing the Avant Strap.
- Each increase in Strap Number provides +1mm of advancement from the previous strap.

TO MOVE FORWARD: Use a strap with a higher number than the current strap.

TO MOVE BACKWARD: Use a strap with a lower number than the current strap.

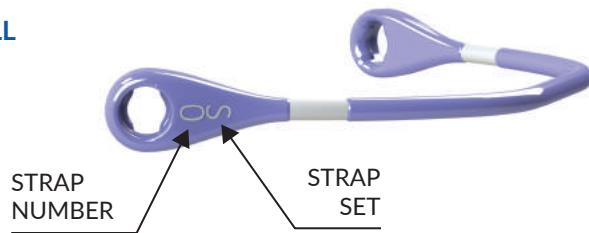
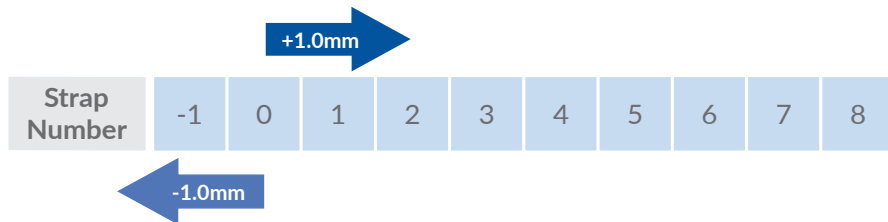
IMPORTANT TO NOTE!

- When wearing your device for the first time it is recommended you start with the "0" strap unless otherwise prescribed by your sleep dentist.
- The SomnoDent Avant strap may contour to the patient's unique appliance with wearing. This change may occur during the first week or two of wear and does not continue to occur while wearing the device.

MY AVANT STRAPS

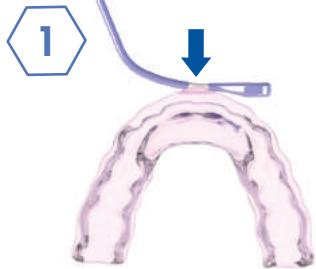
- There are 10 different sizes of Avant Straps supplied with your SomnoDent Avant, providing up to +8mm forward protrusion and -1mm reverse protrusion.
- Each increase in strap provides +1mm of advancement and each decrease -1mm backwards.
- A Strap Set has been issued with your device to best suit the size of your jaw. Make a note of the Strap Set supplied by circling the set below.

MY AVANT STRAP SET IS: **L**ARGE **M**EDIUM **S**mall

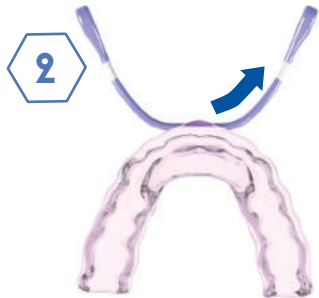


FITTING THE AVANT STRAP

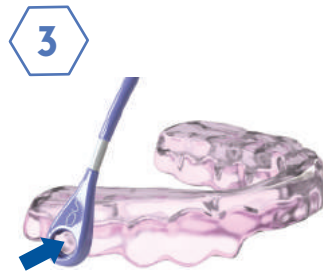
TIP! Use a soft toothbrush to clear away any obstructions on the Strap, Strap Clip or Hinge prior to fitting.



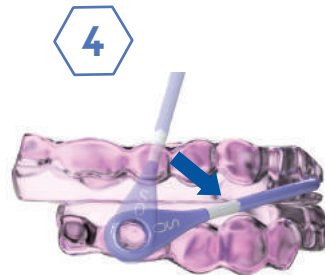
STEP 1: Hold Upper Plate and press a white end of the Strap into the Strap Clip.



STEP 2: Slide Strap around until the center is inside the Strap Clip.



STEP 3: Hold Strap so it is upright. Press the right Strap Hole over the right Hinge on the Lower Plate. Keep Strap upright and repeat for left Hinge.



STEP 4: Twist Strap down so the Upper and Lower Plates meet.

REMOVING THE AVANT STRAP

1



STEP 1: Twist Strap up until it is upright.

2



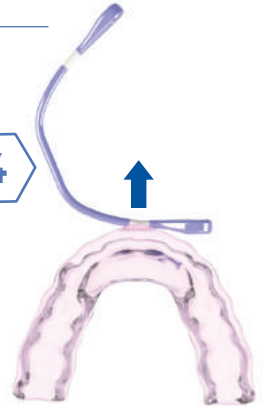
STEP 2: With the Strap upright, pull the right Strap Hole off the right Hinge. Repeat for the left Hinge.

3



STEP 3: Slide Strap around until the Strap Clip is at a white end of the Strap.

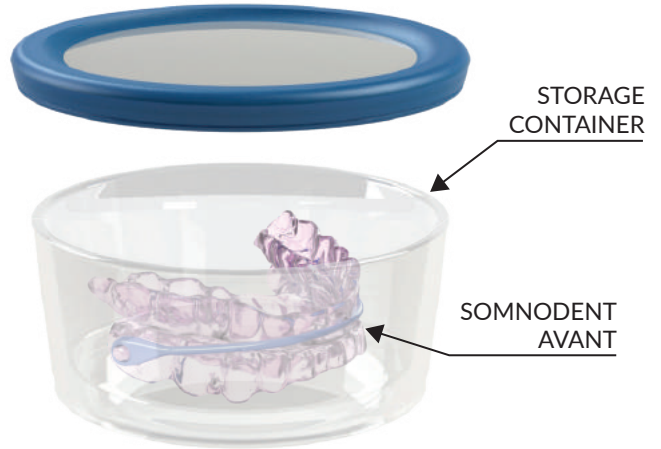
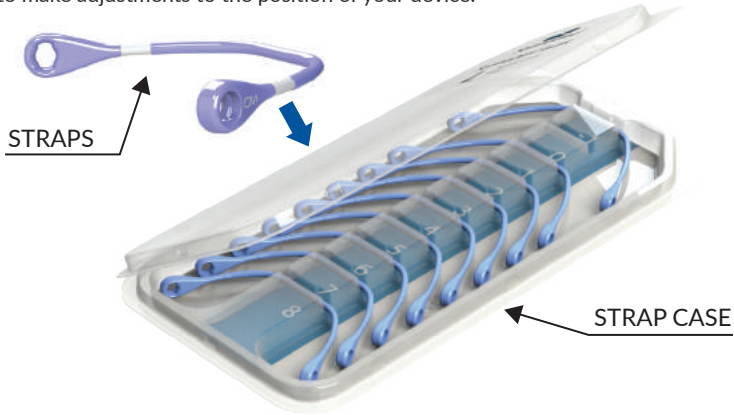
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STEP 4: Pull Strap out of the Strap Clip.

ACCESSORIES

Place your SomnoDent Avant into the storage container for storage during the day or when not in use.
The Strap Case will hold the 9 remaining strap sizes for you to make adjustments to the position of your device.



SOMNODENT AVANT ADJUSTMENT LOG

Date	Strap Number Used

Date	Strap Number Used

*Make sure you keep a Sleep Diary for the first 30 nights (located at the back of this User Guide).



Sleep and Comfort Diary

Log your Sleep and SomnoDent Comfort Rating in the diary provided on the following pages for the first 6 weeks and discuss any issues with your sleep dentist.

SomnoDent works best when fitted correctly and should be snug yet relatively comfortable in your mouth.

SomnoDent Therapy is clinically validated as an effective treatment for obstructive sleep apnea, so make sure you start your treatment tonight, so you can experience Restful Nights and Refreshing Days!

Comfort Ratings

- 5 **Excellent Comfort:** Able to sleep entire night without a problem
- 4 **Good Comfort:** Able to sleep most of the night without discomfort
- 3 **Fair Comfort:** Able to wear it and sleep a little, but I take my device out at some stage during the night
- 2 **Poor Comfort:** Wore my device but was unable to sleep with it
- 1 **Need Assistance:** Unable to wear my device, even while awake.

NIGHT	DATE	SLEEP & WEARING NOTES	HOURS WORN	COMFORT LEVEL	STRAP NUMBER WORN
1				5 4 3 2 1	
2				5 4 3 2 1	
3				5 4 3 2 1	
4				5 4 3 2 1	
5				5 4 3 2 1	
6				5 4 3 2 1	
7				5 4 3 2 1	
8				5 4 3 2 1	
9				5 4 3 2 1	
10				5 4 3 2 1	
11				5 4 3 2 1	
12				5 4 3 2 1	
13				5 4 3 2 1	
14				5 4 3 2 1	
15				5 4 3 2 1	

NIGHT	DATE	SLEEP & WEARING NOTES	HOURS WORN	COMFORT LEVEL	STRAP NUMBER WORN
16				5 4 3 2 1	
17				5 4 3 2 1	
18				5 4 3 2 1	
19				5 4 3 2 1	
20				5 4 3 2 1	
21				5 4 3 2 1	
22				5 4 3 2 1	
23				5 4 3 2 1	
24				5 4 3 2 1	
25				5 4 3 2 1	
26				5 4 3 2 1	
27				5 4 3 2 1	
28				5 4 3 2 1	
29				5 4 3 2 1	
30				5 4 3 2 1	

NIGHT	DATE	SLEEP & WEARING NOTES	HOURS WORN	COMFORT LEVEL	STRAP NUMBER WORN
31				5 4 3 2 1	
32				5 4 3 2 1	
33				5 4 3 2 1	
34				5 4 3 2 1	
35				5 4 3 2 1	
36				5 4 3 2 1	
37				5 4 3 2 1	
38				5 4 3 2 1	
39				5 4 3 2 1	
40				5 4 3 2 1	
41				5 4 3 2 1	
42				5 4 3 2 1	
43				5 4 3 2 1	
44				5 4 3 2 1	
45				5 4 3 2 1	

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