

INSTRUCTIONS FOR USE

SomnoDent AVANT[®]

RxOnly



English



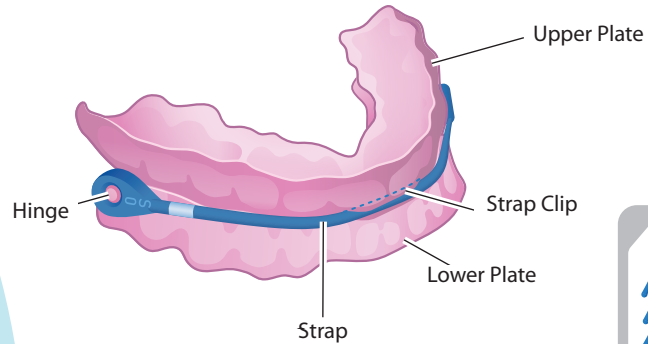


Thank you for selecting SomnoDent Avant

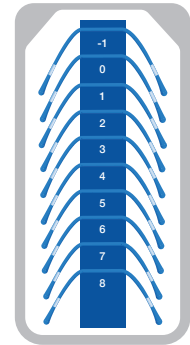
These instructions provide you with important information on the correct use and care of your SomnoDent Avant (hereafter referred to as “device”).



Important: Please read this entire guide carefully before using your device. Contact your dental sleep professional should you have any questions.



Storage Container



Strap Kit

*Kit size may vary

Indications for use

SomnoDent Avant is a patient-matched mandibular advancement device (MAD), available under medical prescription and intended for the treatment of patients 18 years of age or older with:

- » Mild to moderate obstructive sleep apnea (OSA)
- » Severe obstructive sleep apnea in the case of continuous positive airway pressure (CPAP) failure, non-compliance or refusal
- » Snoring

Contraindications

These devices are contraindicated for patients who:

- » Have central sleep apnea
- » Have severe respiratory disorders
- » Have temporomandibular joint dysfunction (TMJ)
- » 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 and changes in occlusion
- » TMJ pain or tenderness
- » Obstruction of oral breathing
- » Excessive salivation
- » Gingival or dental soreness

Before first use

Before first use, thoroughly clean your device by following the cleaning instructions in this manual.

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 your device. If any of these side effects continue, contact your dental sleep professional and maintain regular sleep dental check-ups.

Changes in bite or jaw stiffness and pain upon removal of your device may be alleviated with clenching exercises. To assist with these exercises, use a SomnoMed Morning Repositioner or chew gum upon removal of your device. The Morning Repositioner is supplied separately. Please contact your dental sleep professional for more information.

Using your device

Important

- » Keep your device away from pets and small children
- » Always follow maintenance instructions for cleaning and care of your device
- » You may initially experience a mild plastic smell or taste. This will disappear with use
- » If any device components are damaged or broken, halt use to avoid injuries such as choking or laceration
- » If the strap is creased or deformed, it should be discarded and replaced before further use of the device

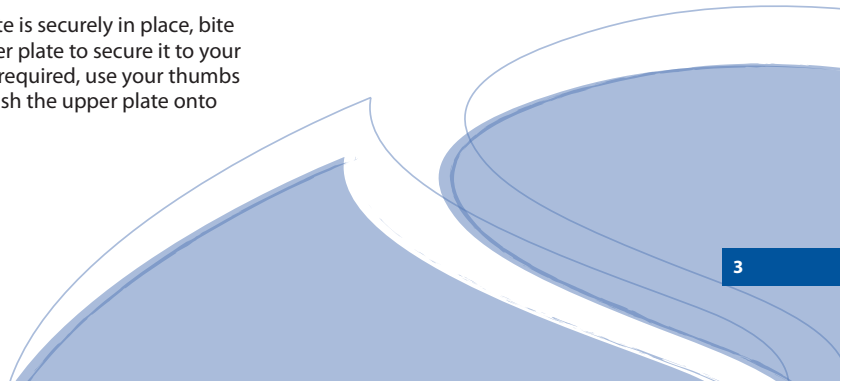
Fitting your device

Check the strap is properly attached to the upper and lower plates before fitting your device. Please refer to the section “Fitting the strap to your device” to learn how to correctly attach the strap.

1. Hold the upper and lower plates together and gently mount the lower plate to your bottom row of teeth.
2. Press down on the plate with your index fingers on both sides to ensure the fit is secure and comfortable.
3. Once the lower plate is securely in place, bite down into the upper plate to secure it to your top row of teeth. If required, use your thumbs on both sides to push the upper plate onto your teeth.

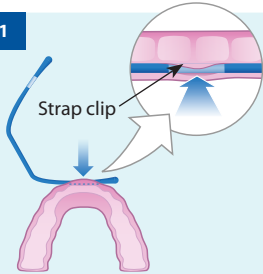
Removing your device

1. Disengage the lower plate from the teeth first. Use your thumbs on both sides to push the plate upwards.
2. Gently pull the upper plate down using both index fingers and thumbs. Remove the entire device from your mouth in one motion.



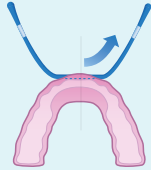
Fitting the strap to your device

STEP 1



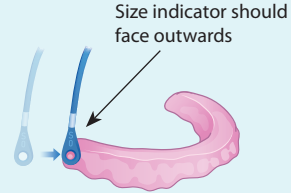
- (a) Locate the white section at the end of the strap. This section is slightly thinner to enable it to fit into the strap clip.
- (b) Press this white section into the strap clip located on the upper plate as shown above.

STEP 2



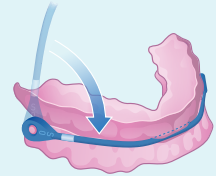
- Slide the strap through the strap clip until its centre is inside the clip.
- TIP!** Use a soft toothbrush to clear any obstruction on the strap, strap clip, or hinge prior to fitting.

STEP 3



- (a) Connect the strap by holding it in an upright position with the size indicator facing outwards.
- (b) Hold the lower plate horizontal. Use your thumb to press the right strap hole onto the right hinge on the lower plate.
- (c) Keep the strap vertical and lower plate horizontal. Repeat this process to connect the left strap hole to the left hinge.

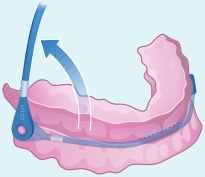
STEP 4



- Close the upper and lower plates together to lock the strap onto the hinges.

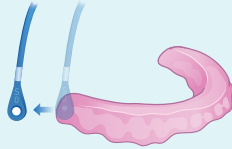
Removing the strap from your device

STEP 1



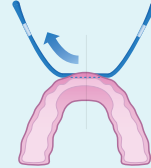
- (a) Remove the device from your mouth.
- (b) To remove the strap, lift the upper plate away from the lower plate until the strap is in an upright position.

STEP 2



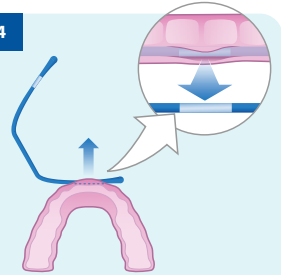
- (a) Keep the strap upright and the lower plate horizontal. Pull the right strap hole off the right hinge.
- (b) Repeat for the left hinge.

STEP 3



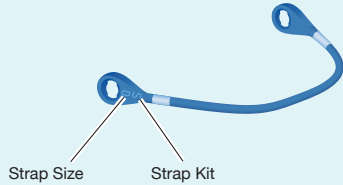
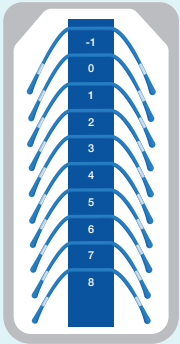
Slide the strap through the strap clip until the end of the strap is reached.

STEP 4



Pull the strap out of the strap clip.

Strap Kits



Available Strap Kits

Strap Kits [#]	S, M, L
Strap Sizes	-1, 0*, 1, 2, 3, 4, 5, 6, 7, 8

([#]) – Each device includes one strap kit

(*) – Default starting strap

The strap kit issued with your device is the one determined to best suit your jaw size. The above table displays the various strap kits available and the strap sizes included in each kit. The * symbol indicates the default strap size that is initially attached to your device. The default strap size sets the starting position that has been determined by your dental sleep professional.

Adjusting your device



Decreasing Strap Size



Increasing Strap Size

Your device is supplied with a strap kit that contains 10 different strap sizes. Each increase in strap size extends the device's mandibular advancement by 1 mm. Each decrease in strap size reduces the device's mandibular advancement by 1 mm.

Important:

- » Your dental sleep professional will prescribe the strap size that is correct for your therapy.
- » The strap will contour to the unique shape of your device during the first week or two of wear. During this time there may be slight changes in the device's mandibular advancement. This is normal for a new strap and does not continue after the strap has contoured to your device.

Cleaning

Clean your device immediately after each use.

1. Rinse in cold or lukewarm water with a temperature no greater than 45°C/113°F.
2. Clean with a soft toothbrush and mild liquid soap.
3. Rinse well in cold or lukewarm water.

SomnoMed recommends using SomTabs, cleaning tablets specially formulated to clean oral devices. SomTabs clean hard to reach areas to effectively eliminate odours.

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

Caution

- » Never use hot or boiling water on your device
- » Do not use toothpaste as it contains abrasives that may damage your device
- » Do not use mouthwash to clean your device
- » Do not use ultrasonic cleaning
- » Do not use organic solvents like ethanol, acetone, etc
- » Do not expose your strap to denture cleansers for more than 30 minutes each week

Storage

Use the storage container supplied with the lid off to store your device. Ensure the storage container is clean and dry. Store your device out of direct sunlight.

Important: Do not store your strap in water or other liquid.

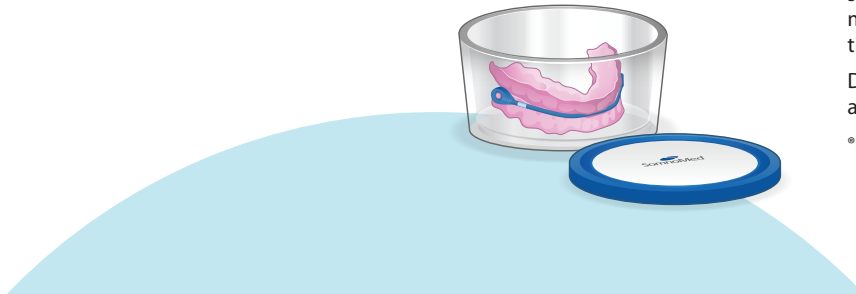
Maintaining the appearance of your device

To reduce the possibility of discolouration, always brush your teeth thoroughly before use. Do not smoke or drink coffee, tea, colas or wine with your device in place.

Amalgam fillings or the use of Pyralvex® (a solution for mouth ulcers and denture irritation) may cause discolouration of your device over time.

Discolouration of the material will not adversely affect the performance or life of your device.

®Pyralvex is a trademark and brand of Meda AB, Sweden.



Travelling

Protect your device when travelling by using the supplied storage container. Ensure your device is thoroughly clean and dry before storing.

Important: Do not travel with your device stored in water or any other liquid.

Regular Inspection

Regularly inspect your device for signs of damage, including cracking. If your device is damaged or broken, it must no longer be used. This will avoid injuries, such as choking or laceration.

If your device is damaged, immediately contact your dental sleep professional. They will arrange for your device to be repaired by an authorised SomnoMed facility.

Warranty

During the warranty period for material defects applicable in the end consumer's country, SomnoMed shall assume responsibility for the warranty for material defects (but not for damage to the contractual merchandise by the end consumer).

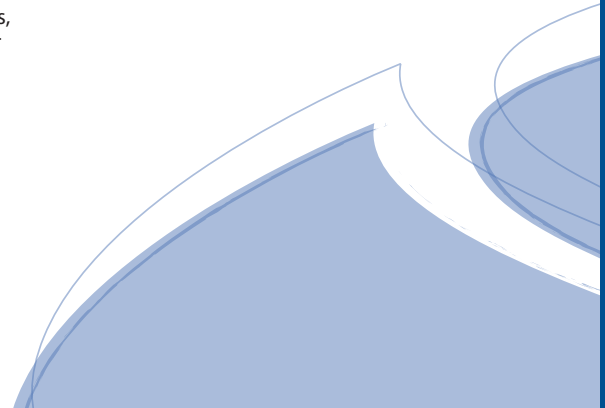
Refer to www.somnomed.com for the latest information on SomnoMed's warranty policy.

The warranty does not cover damage from improper use, abuse, pet chewing, exposure to excessive heat, exposure to caustic cleaners, or where dental work is completed post order placement.

Returning your device

Warranty repair work can only be completed by an authorised SomnoMed facility. You must return your device through your dental sleep professional. Do not return your device directly to SomnoMed.

Do not include any accessories with your return. New accessories will not be issued with device repairs.





somnomed.com

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