SomnoDent® sleep apnea appliance

Instructions for use and care





Sleep, breathe – live better!



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Dear SomnoDent® user

As you may already know and as has been demonstrated by many scientific studies, you may expect your new oral sleep appliance to offer healthy, restful sleep.

Please read the instructions on the correct use and care of your SomnoDent® oral sleep appliance carefully.

The instructions for care and storage of your Somno-Dent® oral sleep appliance are applicable for the following types:

- SomnoDent® Flex
- SomnoDent® Classic
- SomnoDent® Edent

Do not hesitate to contact your dentist if you have any further questions.

Your SomnoMed® Team

Treatment with SomnoDent®



Normal

During normal sleep the muscles that control the tongue and soft palate hold the airway open.



Snoring

These muscles relax during sleep. The tissues of the upper airway vibrate as air passes over them, creating a snoring noise.



Sleep apnea

If the muscles are too weak to hold the tongue and pharyngeal muscle in position, the airway may become obstructed and dangerous respiratory arrests may occur.

For further information visit www.somnomed.eu

How the SomnoDent® oral sleep appliance works

The SomnoDent® oral sleep appliance treats obstructive sleep apnea and snoring by advancing the lower jaw, which keeps the airways open.



The appliance is made to measure for you and consists of a upper and lower splint with a patented "fin quide".

Note:

As with many new products you may experience sensitivity to taste and odor when you use the appliance for the first time. This will disappear quickly if you store your appliance in lukewarm water during the day for no more than three days. Clean the appliance thoroughly after removing it from the water bath.

After that, the SomnoDent® oral sleep appliance must be stored dry in the storage container during the day (see also page 5).

Instructions for daily use

1. Inserting the upper splintPlace the upper splint in your

mouth. Press upwards on the splint with both thumbs to ensure that it fits securely and comfortably.



2. Inserting the lower splint

Place the lower splint in your mouth. Press down on both sides of the splint using your index fingers to ensure that it fits securely.



3. Push the fins gently into the guide

Once the upper and lower splint are securely in position, bring your lower jaw slightly forwards to allow the 'fins' to engage the guide in the upper jaw. Slowly close your mouth until your lips lightly touch each other.

Tip: Use lip balm for the first few nights.

Removal

Always remove the lower splint first. Using your thumbs on both sides under the edge of the splint, gently push the lower splint up and remove it.



To remove the upper splint, gently push it down with both your index fingers and thumbs and remove it.

Using the bite tab

When you remove the splint in the morning your bite may temporarily feel slightly different. The bite tab will help you relax your muscles. Place it between your upper and lower front



teeth and move your lower jaw back until the feeling of tension dissipates.

Important:

Always clean your appliance after each use!

Cleaning the appliance

We recommend the following procedure for cleaning your Somno-Dent® oral sleep applicance:

- In the morning after removing the appliance rinse it under running water and clean it thoroughly with a toothbrush every day.
- Clean the titration screws on the left and right carefully with the included cleaning brush.
- After cleaning the SomnoDent® oral sleep appliance dry it and store in the container.
- Keep the appliance and container away from direct sunlight.
- Use the cleaning agent recommended by SomnoMed®.

Cleaning the titration screw

Clean the spaces inside the titration screw carefully and thoroughly with the cleaning brush.



Recommendations and instructions for cleaning

The soft SMH B-Flex inside of the SomnoDent® oral sleep appliance may become discoloured by contact with amalgam fillings, mouthwash solutions, medications (coagulation agents) and hemoglobin. Coffee, tea, red wine, cola beverages and nicotine may also cause discoloration. This will not affect the function and longevity of the appliance.

Important:

Always clean your teeth thoroughly before inserting the appliance.

Warnings for cleaning

Cleaning tablets containing active oxygen for dentures may **permanently damage** the plastic of your SomnoDent® oral sleep appliance. This will invalidate the warranty. Toothpaste may also damage your oral sleep appliance.

Never use hot or boiling water!

Hot or boiling water damages your SomnoDent® oral sleep appliance and this will invalidate the warranty.

Repair of damaged devices

Damaged or broken devices must not be used. Continuing use may cause injury. Contact your dentist immediately. The dentist will arrange for your oral sleep appliance to be repaired by an expert.

For **repairs** and **warranty claims** always contact your dentist immediately.

Warranty

Your SomnoDent® oral sleep appliance is custom made from premium grade, biocompatible materials. This will ensure accuracy of fit, comfort and durability.

It is warranted against manufacturing defects and material faults for two years in EU countries. It is warranted for one year in Norway. Iceland and Switzerland.

In spite of comprehensive studies and reports confirming the success of SomnoDent® oral sleep appliances, SomnoMed® cannot guarantee that using a SomnoDent® oral sleep appliance stops snoring and/or alleviates obstructive sleep apnea because the conditions of each individual differ

The warranty does not include:

- Adjustment of appliances after treatment that changes the shape of the teeth (new crowns, bridges).
- Corrections required as a result if incorrect bite impressions, e.g. protrusion too short or too long, incorrect occlusal plane.
- Repairs required because of incorrect titration and use.

Warnings / Contraindications

Do not wear the appliance if any of the following are present:

- initial and advanced periodontitis
- loose teeth
- if you are under the age of 18

If you wear dentures, please follow the instructions of your dentist regarding the use of SomnoDent® oral sleep appliances.

Possible side effects

Increased salivation when you start using the appliance is possible. Wearing the appliance may cause temporary muscle tension (muscle ache). This should slowly diminish after removing the appliance. If these side effects persist even after using the bite tab, contact your dentist.

Long-term use may cause slight changes in your bite. Therefore, we recommend routine inspections by your dentist.

Storage and transportation of your appliance

Always store your SomnoDent® oral sleep appliance in the storage container after cleaning it thoroughly. The container is also suitable for use during travel and when visiting the dentist.

Regular inspection of your SomnoDent® sleep appliance

Regularly inspect your oral sleep appliance for signs of damage, cracks or flaws. If the appliance is damaged, immediately take it to your dentist, who will arrange for it to be repaired by a SomnoDent® laboratory.

Take the appliance to your regular dental checkups.

Re-adjustment of the appliance after dental restoration

After a new dental restoration, i.e. crowns, bridges or fillings, the appliance has to be checked and adjusted by your dentist.

Titration instructions

The SomnoDent® sleep apnea appliance has been adjusted by your dentist to meet.

However, occasional feelings of tension may occur at the beginning of the treatment. These can usually be alleviated by slight titration (fine adjustment) of the advancing mechanism

Key housing for fine adjustment

The key housings to the left and right of the maxillary splint can be fine-adjusted if required.

The quarter turn

Each turn – from stop to stop – corresponds to a quarter turn (90°).

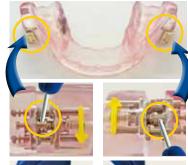
This means that the supplied titration key is inserted once and turned in the direction of the arrow until the stop. Then the titration key needs to be inserted again for the next quarter turn.

A guarter turn of the key housing – in direction of the arrow - equals an advance of 0.1 mm.

A titration key is included in the delivery range.



The titration key is inserted into the **upper** opening of the screw thread and turned downwards (in direction of the arrow) until it reaches the stop.



Right:

The titration key is inserted into the **lower** opening of the screw thread and turned upwards (in direction of the arrow) until it reaches the stop.



Left:





10 quarter turns

= 1 mm advance

How far can the screws be titrated (fine-adjusted)?

When delivered from the laboratory (corresponds to bite registration), the SomnoDent® sleep apnea device can be titrated backwards by 1 mm (10 quarter turns) and forwards by 5 mm (50 quarter turns).

SomnoMed® recommends that the screws are only turned to a maximum of 5 mm (50 quarter turns) forward advance (from ex-factory condition).



In **ex-factory position A**a forward advance of

a forward advance of 5 mm (50 quarter turns) and 1 mm backwards (10 quarter turns) are possible. If, by accident, the screws are turned by more than 50 quarter turns, the key will continue to turn but without any advance movement.

This is a safety feature to prevent small components from entering the oral cavity.

What happens if you cannot remember how far you have turned?

If you are unsure as to how many turns you have performed, carefully turn both screws back (against the direction of the arrow) until the gap on the housing is closed and you can feel slight resistance. Please **do not continue turning** as this may damage the screw and/ or the housing.

You can return to the original position (ex-factory setting) with 10 quarter turns in the direction of the arrow on both sides of the sleep apnea device.

Important:

Make a note of the number of turns for each side.

Titration protocol

Dentist / Practice stamp:

Serial number of the sleep apnea device:			
Initial setting _	_ % of maximum		
possible protru	sion of	mm	
Date	Number of turns to the left	Number of turns to the right	

SomnoDent® sleep apnea appliance

SomnoDent® storage, cleaning and travel container and SomnoDent® accessories

The SomnoDent® oral sleep appliance is delivered safely and protected in the SomnoDent® container. Always keep your oral sleep appliance in this practical container after cleaning it thoroughly.

The SomnoDent® accessory set with cleaning brush, bite tab and titration key is secured in the bottom of the container.

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and travel container

SomnoDent® accessories
(fastened in the bottom of the container)





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