

SomnoGuard® 3

Medical oral appliance to treat snoring and mild or moderate obstructive sleep apnoea in adults

Content: monobloc mouthpiece, wooden spatula, storage case, user instructions

To achieve an optimal therapeutic result, it is recommended that SomnoGuard® 3 is fitted by a physician (e.g. dentist, ENT physician, physician in the sleep laboratory, general practitioner) or his / her trained medical staff.

Instructions (Read carefully before use)

Date of information: 12.07.2024

Description: SomnoGuard® 3 is a prefabricated, one-piece mandibular advancement device made of thermoplastic material. The upper part of the oral appliance is characterised by a notch. After heating the appliance in a hot water bath, the thermoplastic material becomes easily mouldable. Teeth impressions are formed when biting into the soft material. After the appliance cools down in a cold water bath, the material hardens and maintains its new shape. The opening of the respiratory tract depends on the extent of the lower jaw advancement.

Indications:

After consultation with a physician:

- Treatment of primary snoring and mild or moderate obstructive sleep apnoea in adults
- In case of CPAP intolerance and in order to reduce CPAP pressure
- Sporadic use by patients with obstructive sleep apnoea instead of CPAP when travelling

Contraindications:

- Age under 18 years
- Central sleep apnoea
- Severe respiratory disorders
- Epilepsy
- Temporomandibular joint disorder
- Insufficient number of teeth, large tooth gaps or teeth that are too short to hold the appliance in place
- Periodontitis, loose teeth, unstable dental crowns or prostheses, tooth decay
- (Strong) gag reflex
- Limited protrusion capacity of the lower jaw
- Obstructed nasal breathing

Attention: A dentist should be consulted before starting treatment, especially if the condition of the teeth is uncertain or if there are (pronounced) tooth or bite misalignments. In the case of (suspected) respiratory diseases, the medical history must be checked for respiratory disorders, asthma and breathing problems prior to therapy.

Possible side effects:

- Dry mouth or increased salivation
- Pain or feeling of pressure on the teeth or gums, painful tension in the jaw and chewing muscles
- Transitory bite changes, which should disappear within 30 – 60 minutes after removing the appliance from the mouth
- In case of a long-term treatment, changes of tooth position and bite are possible.
- Isolated allergic or inflammatory reactions or irritation in the mouth

If the above-mentioned or other side effects persist, the appliance should not be used (temporarily) and the physician and / or dentist should be consulted.

Warnings:

- Snoring can be a symptom of breathing arrests that may contribute to serious health problems such as cardiovascular diseases. Ask for your medical professional's help to find out why you snore before starting treatment.
- The effectiveness and safety of the therapy should be checked regularly by a sleep physician and a dentist experienced in sleep medicine. The therapeutic effect of the oral appliance therapy should be controlled by adequate diagnostic measures quite soon after the beginning of treatment, especially with those patients having breathing arrests at night due to obstructive sleep apnoea.
- You should visit your dentist at regular intervals. Take your appliance with you.
- If breathing discomfort occurs with the appliance, immediately stop using it. Consult your doctor.
- In case of severe pain from TMJ or other persistent discomfort, stop using the appliance and consult your physician or dentist. He or she will then find out whether this condition has been caused by the oral appliance and can modify the appliance if necessary.
- Thoroughly check the appliance for any uncommon changes (such as cracks or debonding) before and after every use. Do not use the appliance if it is damaged in any way.

Special notes:

- During the first nights the appliance might not be kept in the mouth for the whole night. This is normal. The adaptation process may take 1 – 2 weeks.
- The average durability of SomnoGuard® 3 is about 6 – 12 months. Bruxism and strong jaw movements might decrease the average durability of your oral appliance. Consult your dentist for therapeutic alternatives especially designed for bruxists. The cleaning routine of the appliance and acid in the saliva also have an effect on durability.
- The appliance may become discolored over time. This discoloration may be caused by the acid in the saliva and / or the cleaning routine.
- **Please also refer to the illustrations for fitting our SomnoGuard® oral appliances on the internet at www.somnora.de**

Care: Clean your oral appliance every morning with a soft toothbrush and a special cleaning product (e.g. Curaprox "daily" gel for daily cleaning, Curaprox "weekly" concentrate for weekly cleaning; available from TOMED) or 1 – 2 drops of a colourless washing-up liquid. Always rinse the appliance with cold water, let it dry in the open air and keep it in the storage case provided.

Attention: Do not clean the appliance with products that contain bleach as it could damage the appliance. Before using a care product, make sure that you are not allergic to the ingredients.

Fitting the appliance:

Preparation:

1. The pack includes a wooden spatula. Push the spatula through the hole in the mouthpiece so that its tip protrudes out of the back by 1 cm (Fig. 1). This spatula helps you to hold the mouthpiece with your fingers while fitting.
2. To try it out, first put the unfitted mouthpiece into your mouth with the spatula pointing away from your face. The upper part of the mouthpiece has a notch in it. The upper part of the mouthpiece forms the biting channel for the upper jaw, the lower part the biting channel for the lower jaw.
3. Before doing the real fitting, practise the process with cold water. If you fit the device yourself – contrary to our recommendation – practise in front of a mirror.



Fig. 1: Appliance with spatula

Custom-Fitting:

4. Boil about 1 litre of water in a saucepan (*Do not use plastic bowls*). The water must be deep enough to completely cover the mouthpiece.
5. Take the pan off the hob. Immerse the appliance with the wooden spatula in a sloping but not vertical position. Whilst immersed in the hot water, move and turn the appliance with the spatula. We recommend to immerse the oral appliance for about 20 seconds to achieve optimal teeth and jaw impression into the plastic. **Attention:** *The thermoplastic material must not touch the walls of the saucepan since it would stick to it and deform.* After heating, the mouthpiece will appear transparent. Gently feel the biting channel to check that the plastic is mouldable. In the heating process be careful that the inner and outer sides of the appliance do not stick together. If necessary, take the appliance briefly out of the hot water (using the spatula) and push the sides back to their original position with your fingers.
6. Then take the mouthpiece out of the hot water with the spatula. Gently shake it to get rid of the last water drops. Wait until the temperature has cooled down for about 15 seconds, and test whether the plastic's temperature is acceptable for fitting on the back of your hand, making sure that you can still mould the mouthpiece. Open your mouth wide and insert the device into your mouth using the spatula. The notch must be at the top. First position the lower jaw in the lower channel of the mouthpiece, then the upper jaw in the upper channel. The thermoplastic mouthpiece is automatically adjusted to any dental arch width if the fitting is performed correctly.
7. Check that the spatula is secure in the opening of the mouthpiece and protrudes through it, otherwise the opening may close permanently during the fitting process. Move the lower jaw forward to approximately half the maximum extension possible (Fig. 4 shows the desired position with normal bite conditions). Bite the plastic hard. Be careful not to bite the borders of the mouthpiece otherwise you might ruin it. Suck in while closing your mouth and press your tongue against the lower inner surface of the front teeth under the spatula. While doing this, press on the outer walls of the mouthpiece with your fingers to make sure that it is moulded properly.



Fig. 2: Normal jaw position



Fig. 3: Maximum jaw extension



Fig. 4: In normal jaw conditions, the desired position corresponds to the head bite position

8. Once the mouthpiece has cooled (approx. 30 seconds), take it out of your mouth (still using the spatula) and insert it into cold water for approximately 10 seconds to fix your individual fit. If you have followed all the steps carefully and correctly the appliance will show distinct impressions of your teeth over the whole of the mouthpiece, and the border walls of the mouthpiece will not be damaged (Fig. 5). Only then you can be certain that the mouthpiece will lightly grip your teeth and stay in the required position during sleep.
9. Take the spatula out of the opening. Put the mouthpiece back into your mouth to check that it fits properly. Having the lower jaw extended forward should still be comfortable. If it is not, repeat the fitting process. Most users get a more comfortable fit by moulding a second time. Note that if you refit the mouthpiece you must not leave it in the hot water for more than 15 seconds. If refitting is required, heat the upper and lower parts of the mouthpiece separately.
10. If the reduction of snoring is not satisfactory, remould with your lower jaw extended a little farther forward but not at maximum extension. You may have to refit the mouthpiece to reduce the advancement of the lower jaw (for example if muscular pain occurs in the joint) or to increase the extension if you still snore. Malformations and damages, for example bitten side walls, can often also be corrected and remodelled by just locally heating the device (approx. 10 seconds).



Fig. 5: Appliance after fitting



Medical device



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Follow instructions for use



Warnings



The product meets all the provisions of the
Medical Device Regulation 2017/745 which apply to it.



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