

SomnoGuard® AP 2

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

Date of information: 13.11.2024

Content: 2 oral trays (upper and lower jaw tray), 2 stainless steel adjusting screws (12 and 16 mm), locknut, spanner, adjusting tool, storage case, user instructions

To achieve an optimal therapeutic result, it is recommended that SomnoGuard® AP 2 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)

Description: SomnoGuard® AP 2 is a two-piece, thermoplastic mandibular advancement device that is laterally movable. The two oral trays consist of a hard outer tray shell and a thermoplastic material. After heating the trays in a boiling water bath, the thermoplastic material becomes easily mouldable. Deep teeth impressions are formed when biting into the soft thermoplastic material. After the appliance cools down in a cold water bath, the material hardens and maintains its new shape. The part with the guide bar ("C-bar") characterises the upper tray designed for the upper jaw. The C-bar is the track for the screw head of the lower tray. The lower jaw advancement can be infinitely adjusted by turning the screw. The opening of the respiratory tract depends on the extent of the adjusted 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

Attention: A dentist should be consulted before starting treatment, especially if the dental condition 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.

As the patient must achieve at least the head bite position as protrusion with SomnoGuard® AP 2, the device is only suitable to a limited extent for patients with a retrognathic bite. A dentist should be consulted in case of uncertainty.

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

Attention: Discuss with your doctor or dentist whether the oral appliance should not be used (temporarily), depending on the side effects.

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 for checkups and review of the device and its use. Take your appliance with you.
- If breathing discomfort occurs with the appliance, immediately stop using it. Consult your medical professional.
- 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 had 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.
- To avoid breakage and bending, the locknut must first be loosened before turning the adjusting screw with the adjusting tool.
- If the screw is bent, it must be replaced. Do not bend the screw straight, as this could weaken the screw and cause it to break.
- Make sure that the locknut is fixed against the screw housing and that the adjusting screw in the front part of the tray does not protrude from the screw housing. Use the longer screw if necessary.

Special notes:

- To connect both jaw trays, the screw head of the lower tray is inserted laterally into the guide bar ("C-bar") of the upper tray. Then place the device into the mouth, first over the upper and then the lower teeth.
- Use both hands to remove the device from the mouth. Carefully pull the upper and lower jaw tray vertically from the teeth one after the other by simultaneously applying gentle pressure on the right and left side edges of the tray with both index fingers / thumbs. Never pull the tray off only at one side edge, as this could damage it.
- 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® AP 2 is about 1 ½ years. 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 **visual material** for fitting our SomnoGuard® oral appliances on the internet at www.somnora.de

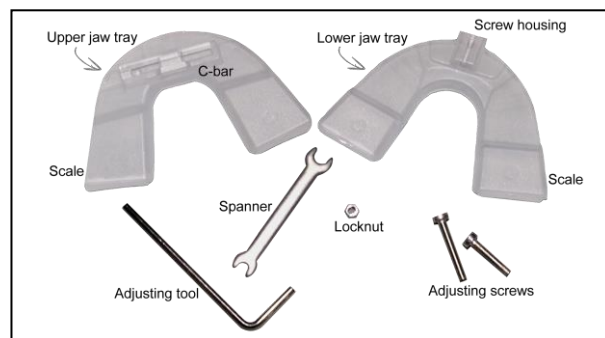


Fig. 1: SomnoGuard® AP 2 components

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:

1. First, thoroughly clean the teeth and interdental spaces. Check the maximum possible mandibular advancement and make a note for later.
2. Heat the upper tray (i.e. the part with the guide bar/ C-bar) in a boiling water bath for about **3 ½ minutes** with the hard outer tray shell facing the bottom. As the tray heats up, the thermoplastic filling will become clear and the tray will rise to the surface. **Note:** *Nitrile gloves are most suitable for the fitting.*
3. Use a spoon or small pliers to take the tray out of the water. Carefully shake off any excess water by only touching the outer tray shell. Allow it to cool down in the air for about **15 seconds**. **Attention:** *Make sure that the material does not cause burns when inserted into the mouth.*
4. Place the tray **centrally** under the upper teeth so that the marker on the front edge is between the front teeth and the front teeth are as close to the front of the tray as possible. Press the bottom of the tray from the front to the rear firmly against the teeth using your thumbs and forefingers. Keep the tray in place for about **30 seconds** before carefully removing it from the mouth by only touching the outer tray shell.
5. Let the tray cool down for a few seconds in a cold water bath to harden the lining.



Fig. 2: Upper jaw tray



Fig. 3: Lower jaw tray



Fig. 4: Adjusting screw & locknut




Fig. 5: Fitted SomnoGuard® AP 2

6. Heat the lower tray (i.e. the part with the adjusting screw) in a boiling water bath for about **3 ½ minutes** and allow it to cool down for about **15 seconds** (see steps 2 – 3).
7. Couple the lower tray with the upper tray by inserting the head of the adjusting screw of the lower tray with gentle pressure from the side into the insertion groove at the bottom of the upper tray. Check the temperature of the material with your fingers. Place the upper tray on the upper teeth. Then place the lower tray **centrally** over the lower teeth with the front marker of the lower tray in vertical alignment with the marker of the upper tray and the lower front teeth as close to the front of the tray as possible. Bite down until the teeth touch the bottom of the whole tray to create deep teeth impressions. Keep the upper and lower jaw closed for about **10 seconds** whilst using your fingers to firmly press excessive thermoplastic material at the outer sides of the tray against the teeth and gums. **Caution:** *Hold the tray steady.*
8. Remove the appliance from the mouth and decouple the trays carefully. Place the lower tray on the lower teeth again. Keep the tray stable and stick out the tongue so that the tongue frenulum leaves its impression in the material. Then slightly open the mouth and use your fingers to firmly press excessive thermoplastic material at the inner sides of the tray against the teeth and gums. Keep the tray in place for about **30 seconds** before carefully removing it from the mouth.
9. In a still warm and mouldable condition, you can slightly cut off excessive thermoplastic material beyond the edge of the outer tray shell, preferably with a pair of curved scissors (Fig. 2 [1]). Leave some excess material of about 2 – 4 mm beyond the edge at the inner sides of the tray (Fig. 2 [3]). Beyond the last back tooth (molar) excess lining should be flat and smooth along the bottom surface of the outer tray shell (Fig. 2 [2]).
10. Let the tray cool down for a few seconds in a cold water bath to harden the lining.
11. Again, heat the upper tray in a boiling water bath for about **30 seconds** and allow it to cool down for a few seconds.
12. Couple the upper tray with the lower tray and check the temperature of the material with your fingers. Place the upper tray carefully on the upper teeth without changing the teeth impressions of the first fitting. Place the lower tray on the lower teeth. Bite down until the upper teeth touch the bottom of the whole tray to create final, deep teeth impressions. Keep the upper and lower jaw closed for about **10 seconds** whilst using your fingers to firmly press excessive thermoplastic material at the outer sides of the tray against the teeth and gums.
13. Remove the appliance from the mouth and decouple the trays carefully. Place the upper tray on the upper teeth again. Slightly open the mouth and use your fingers to firmly press excessive thermoplastic material at the inner sides of the tray against the teeth, gums and palate. Keep the tray in place for about **30 seconds** before carefully removing it from the mouth. The following procedure corresponds to steps 9 – 10.
14. **If one of the trays does not fit perfectly**, heat it in a boiling water bath for about 10 – 15 seconds, let it cool down for a few seconds and couple it with the second tray. Place the appliance carefully in the mouth without changing the teeth impressions of the first fitting. Suck in and swallow the saliva. Massage the cheeks from the outside to achieve an optimal fit. Remove the appliance after about 30 seconds from the mouth and let it cool down in a cold water bath. Rough edges can easily be removed by dipping the appliance briefly into a hot water bath and then smoothing the edges with a wet finger.
15. By loosening the locknut and turning the adjusting screw with the adjusting tool, you can now adjust the protrusion. Thereafter the locknut must be fixed against the housing (Fig. 4). The tick marks on both trays allow the reading of the mandibular protrusion symmetrically in 1 mm increments. The adjusting screws are 12 and 16 mm long. **Important:** *For safety reasons, the screws should be always engaged a minimum of 7 mm into the 9 mm long housing, but never extend out of the front (Fig. 4).* Use the longer screw if necessary.
16. **Setting the lower jaw advancement:** At the onset of treatment, lower jaw advancement should not exceed about 50% of the maximum lower jaw protrusion. If necessary, the advancement can slowly be increased as you adapt to wearing the device.

MD Medical device

REF Art. No.: 03050200

 Follow instructions for use

 Warnings

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

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Doc. No.: UI.AP2.1124.GE.01