

SomnoGuard® SPX

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

Content: 2 identical oral trays, 2 screw connectors, set of connecting straps (connectors without screws in lengths 23 – 32 mm), fitting aid, spanner, storage case, user instructions

To achieve an optimal therapeutic result, it is recommended that SomnoGuard® SPX 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: 01.01.2024

Description: SomnoGuard® SPX is a two-piece mandibular advancement device that allows limited mouth opening. The two oral trays consist of a hard outer tray shell and a prefabricated thermoplastic material with memory effect. After heating the trays 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 lower jaw advancement can be adjusted by two connectors between the upper and the lower tray. The opening of the upper airway depends on the extent of the adjusted lower jaw advancement. SomnoGuard® SPX is also suitable for patients with a receding lower jaw (retrognathia).

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 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:

- Use both hands to remove the tray 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® SPX is about 1 – 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.

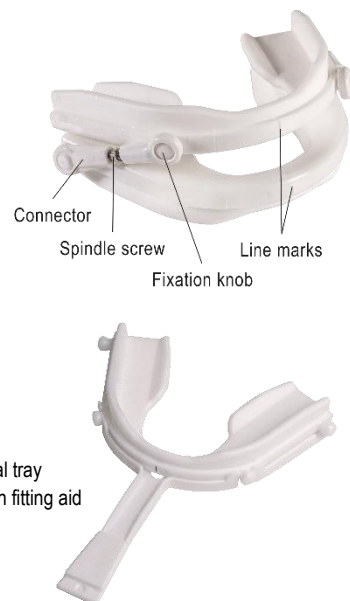
Care: Clean your oral appliance every morning with a soft toothbrush and a special cleaning product (e.g. Curaprox "daily" gel for daily cleaning, Curaprox "weekly" concentrate for weekly cleaning; available from TOMED) or 1 – 2 drops of a colourless washing-up liquid. Always rinse the appliance with 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:

Please also note the **fitting video** on the internet at [somnora.de/en/products/somnoguard-spx-schnarchschiene](https://www.somnora.de/en/products/somnoguard-spx-schnarchschiene)

Required tools: disposable gloves (*nitrile gloves are particularly suitable*), 2 sufficiently high bowls with approx. 10 cm base diameter (*Do not use plastic bowls*), kettle or saucepan, pointed tweezers, side cutter



Preparation:

1. First, thoroughly clean the teeth and interdental spaces. Check the maximum possible mandibular advancement and make a note for later.
2. Check whether the oral trays in their original form match the dental arches of the upper and lower jaw.
If not, the width of the trays can be altered after heating them in hot water (see step 6).
3. Fill one bowl with very cold water. In addition, boil some water in a kettle or saucepan and pour it into the second bowl.
Note: Fill sufficient water into the bowls, so that the oral tray will be completely covered with water when immersed with the help of the fitting aid.

Fitting the upper tray:

4. Click one of the oral trays with the front fixation knobs on the fitting aid.
Note: The tray is not removed from the fitting aid before step 11, after it has completely hardened in the cold water bath.
5. Hold the fitting aid with the tray in the hot water bowl for about **60 seconds**.
Attention: The heated thermoplastic material must not touch the walls of the bowl since it would stick to it and deform.
6. Take the fitting aid with the tray out of the water and allow it to cool down in the air for about **60 seconds**. If the tray does not match the dental arch (see step 2), its width can be altered during cooling by carefully and lightly pulling the rear fixation knobs apart or pressing them together with the fingers or pointed tweezers. **Avoid pressing or pulling apart too much, as this could damage the tray.** **Attention:** Make sure that the material does not cause burns when inserted into the mouth.
7. Moisten the disposable gloves with some water. Moisten lips, open mouth wide and relax cheeks.
8. Place the fitting aid with the tray centrally under the upper teeth with the line mark on the front edge between the front teeth.
Attention: The outer wall of the tray must not be folded inwards.
9. Press the bottom of the tray (on both sides) from the front to the rear firmly against the upper teeth using your thumbs and forefingers.
Attention: Outer and inner walls of the tray must not be bitten down.
10. Keep the mouth closed with slightly advanced lower jaw for about **1 ½ minutes** – meanwhile swallow several times, press the thermoplastic material with the tongue against the inner walls and massage the cheeks from the outside. In between, open the mouth and gently press the thermoplastic material with your fingers at the outer and inner walls of the tray against the teeth.
11. The thermoplastic material is now hardened. Remove the fitting aid with the tray vertically and carefully from the mouth. Hold the fitting aid with the tray in the bowl filled with cold water for about **20 seconds**. Now remove the completely hardened tray from the fitting aid.
12. Place the tray on the teeth and check its fit. If it does not fit perfectly, the fitting process can be repeated. After reheating, the thermoplastic material reverts almost to its original form (memory effect). For a complete refit, put the whole tray in the hot water for about **60 seconds**. For a partial correction, put the single spot of the tray in the hot water for about **10 – 15 seconds**. **Attention:** There should be no thermoplastic material on the hard outer tray shell and around the fixation knobs. If necessary, carefully remove it by heating the spots locally in the hot water bath.

Fitting the lower tray:

13. Leave the upper tray on the teeth while fitting the lower tray (important).
14. Empty both bowls and fill them with fresh boiled / cold water (as in step 3 above).
15. Repeat steps 4 – 7 with the second oral tray.
16. Slightly move the lower jaw forward. Place the heated lower tray with the fitting aid on the lower teeth so that the line marks on the upper and lower tray form a vertical line (with advanced lower jaw).
17. Gently press the thermoplastic material at the outer and inner walls of the lower tray against the teeth using your fingers. With a forward lower jaw (the upper and lower tray should lie symmetrically on top of each other) firmly clench the teeth and keep them closed for about **1 ½ minutes** – meanwhile, massage the cheeks from the outside. **Attention:** In between, open the mouth and check whether the outer and inner walls are close to the teeth – correct if necessary. Make sure that the tongue stays at the base of the mouth and does not press the inner walls of the tray upwards.
18. Repeat steps 11 and 12.

Connecting the trays and setting the lower jaw advancement:

19. The package includes two screw connectors as well as a set of connecting straps (connectors without screws). The extent of the lower jaw advancement depends upon the length of the connectors. The shorter the connectors, the larger the lower jaw advancement. At the beginning of the treatment, the lower jaw advancement should only correspond to approximately 50 % of the maximum possible advancement (see step 1). If necessary, the advancement can slowly be increased as you adapt to wearing the device.

It is recommended to start the therapy with the screw connectors and – once the optimal protrusion has been determined – to use the connectors from the set (connectors without screws) for long-term use. However, the therapy can also be started directly with the connectors without screws. One end of each connector is bent, the other end is straight. The holes in the ends are tapered so the diameter is narrower on one side than the other. Attach the bent end with the narrow opening to the front fixation knobs of the upper tray. The bent side should now be facing the tray. Then attach the straight end with the narrow opening to the rear fixation knobs of the lower tray. The four unused fixation knobs are then removed with a side cutter or similar.

Attention: The length of the two connectors must be identical. An asymmetrical adjustment can lead to mandibular joint disorders and damage to the appliance.

1. Screw connectors:

Each screw connector has a spindle screw in the centre. After attaching the screw connectors to the fixing knobs of the trays (see above), the length of the connectors can be altered by turning the spindle screws with the spanner. The lower jaw advancement is the largest when the screws are screwed in completely.

Attention: Always turn the two spindle screws evenly to ensure that the connectors are of equal length. With the help of the small marking on the spindle screw, the rotation of the screw can be traced.

2. Set of connecting straps (connectors without screws):

The screw connectors can be replaced in the long term with the connectors from the set (connectors without screws). Measure the length of the screw connectors and select the appropriate connector lengths from the set.



Medical device



Art. No.: 03090000



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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Doc. No.: UI.SPX.0124.GE.01