

SomnoGuard® SPX

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

Content: 2 identical oral trays, 2 adjustable connectors, spanner, storage case, user instructions

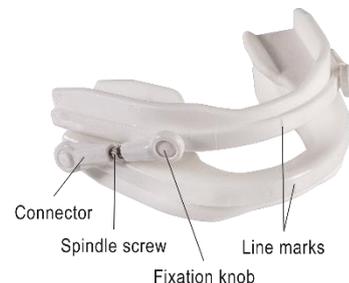
To achieve an optimal therapeutic result it is recommended that SomnoGuard® SPX is fitted by a physician (e.g., dentist, ENT physician, physician in the sleep laboratory, general practitioner) or their trained medical staff.

Instructions (Read instructions carefully before use)

Date of information: 01.05.2019

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 infinitely 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:

- 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, according to the advice of a medical professional

Contraindications:

- Central sleep apnoea
- Epilepsy
- Temporomandibular joint disorder
- Insufficient number of teeth, large gaps between the teeth
- Periodontitis, loose teeth, unstable dental crowns or prostheses, tooth decay
- (Strong) gag reflex
- Limited mandibular advancement

Attention: If the patient's dental condition appears uncertain and in case of occlusal abnormalities a dental check-up is strongly recommended before starting the treatment.

Possible side effects:

- Mouth dryness or initial hypersalivation, which normalises with adaptation to the appliance
- Morning discomfort by temporary pain from TMJ or teeth, which normally reduces with adaptation
- Transitory bite changes, which will normally disappear within 30 minutes after removing the appliance from the mouth
- In case of a long-term treatment, changes of tooth position are possible.
- During the first few 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.

In case of any persisting or severe side effects stop using the appliance and consult your medical professional.

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.
- 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. Consult your medical professional.
- In case of severe pain from TMJ or other persistent discomfort, stop using the appliance and consult your medical professional. He or she will then find out whether this condition has been caused by the oral appliance and can modify the appliance if necessary.
- You should visit your dentist at regular intervals, especially if you are wearing the appliance every night. Take your appliance with you.

Special notes:

- 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.
- The average durability of SomnoGuard® SPX is about 1 ½ years. Bruxism and strong jaw movements might decrease the average durability of your oral appliance. Consult your medical professional for therapeutic alternatives especially designed for bruxists.
- **Please also refer to the visual material for fitting our SomnoGuard® oral appliances on the internet at www.tomed.com**

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 their distributors) or 1 – 2 drops of a colourless washing-up liquid. **Do not clean it with products that contain bleach as it could damage the appliance.** Always rinse the appliance with cold water, let it dry in the open air and keep it in the storage case provided.

Fitting the appliance:

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

Preparation:

1. First, thoroughly clean your teeth and interdental spaces.
2. Check whether the oral trays in their original form match the dental arches. If not, the width of the trays can be altered after heating them in hot water (see steps 6 and 13).
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 in the bowls, so that the trays will be fully covered with water (about 4 cm).

Fitting the upper tray:

4. With the hard outer tray shell facing downwards, put one of the trays in the hot water bowl for about **60 seconds**.
Attention: The thermoplastic material should not touch the walls of the bowl since it would stick to it and deform.
5. Use the tweezers to grab one of the fixation knobs and take the tray out of the water. Allow it to cool down in the air for about **60 seconds** while carefully shaking off excess water. **Attention:** Make sure that the material does not cause burns when inserted into the mouth.
6. Moisten the disposable gloves with water. Keep your mouth wide open and relax the cheeks. Holding the fixation knobs, place the tray centrally under the upper teeth with the line mark on the front edge between the front teeth. **Note:** If the tray does not match the dental arch (see step 2), the width can now be altered by gently pulling the fixation knobs apart or pressing them together.
7. Press the bottom of the tray from the front to the rear against the upper teeth using your thumbs and forefingers. Keep the tray in place and gently press the thermoplastic material with your fingers at the outer and inner wall of the tray against the teeth. With a slightly forward lower jaw, keep the mouth closed for about **1 ½ minutes** – meanwhile swallow and gently press the thermoplastic material with your tongue against the inner wall.
Attention: In between, open the mouth and check whether the outer and inner wall are close to the teeth – correct if necessary.
8. The thermoplastic material is now hardened. Grab the fixation knobs to vertically and carefully remove the tray from the mouth. Let the tray cool down in the bowl filled with cold water for about **20 seconds** to harden the material.
9. 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 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:

10. Leave the upper tray on the teeth while fitting the lower tray.
11. Replace the water in the hot water bowl with freshly boiled water (as in step 3 above). Reuse the water in the cold water bath.
12. Put the second tray in the hot water bath for about **60 seconds** and – once removed – allow it to cool down for about **60 seconds** as described in steps 4 – 5 above.
13. Keep your mouth wide open and relax the cheeks. Slightly move the lower jaw forward. Place the heated lower tray on the lower teeth – make sure that the line marks on the upper and lower tray form a vertical line. **Note:** If necessary, alter the width of the tray as instructed in step 6.
14. Keep the tray in place and gently press the thermoplastic material at the outer and inner wall 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**. **Attention:** In between, open the mouth and check whether the outer and inner wall 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 wall of the tray upwards.
15. Repeat steps 8 and 9.

Connecting the upper with the lower tray:

16. The package includes two connectors. 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 can be removed with a side cutter.

Setting the lower jaw advancement:

17. The extent of the lower jaw advancement depends upon the length of the connectors. The shorter the connectors, the larger the lower jaw advancement. Each connector has a spindle screw in the centre. 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. At the beginning of the treatment the lower jaw advancement should correspond to approximately one third of the maximum possible advancement. If necessary, the advancement can slowly be increased as you adapt to wearing the device. **Attention:** Always turn the two screws evenly to ensure that the connectors are of equal length. Mandibular joint disorders might occur with an asymmetric adjustment.



Visit our website (e.g. for the fitting video)



The product meets all the provisions of the directive 93/42/EEC which apply to it.

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