

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

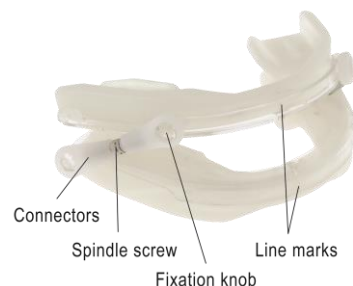
To achieve an optimal therapeutic result it is recommended that SomnoGuard® SPX is fitted by a physician (e.g., dentist, ENT physician, physician in the sleep laboratory) or their trained medical staff.

Instructions (Read instructions carefully before use)

Date of information: 01.04.2017

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 respiratory tract 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 had 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 your 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 illustrations 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 authorised distributors) or 1 – 2 drops of a colourless washing-up liquid. **Do not use conventional denture cleaner or cleaning tabs. The bleach 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 (**Note:** Do not use plastic bowls), kettle or saucepan, pointed pliers, side cutter, file

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. Have two small bowls ready. Fill one bowl with very cold water. In addition, bring water to a boil in a kettle or saucepan. Fill the second bowl with the boiled water and allow it to cool down for about **1 ½ minutes**. **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. Put one of the trays for about **40 seconds** – the hard outer tray shell facing the bottom – in the bowl with hot water. **Attention:** The thermoplastic material should not touch the walls of the bowl since it would stick to it and deform.
5. Use pointed pliers to grab one of the fixation knobs and take the tray out of the water. Allow it to cool down for about **15 seconds** – meanwhile carefully shake off excess water. **Attention:** Make sure that the material does not cause burns when inserted in the mouth.
6. Moisten the disposable gloves with some water. Hold the fixation knobs and 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 at the outer and inner wall of the tray against the teeth using your forefingers. Clench your teeth and keep the upper and lower jaw closed for about **1 minute** – meanwhile swallow and gently press the thermoplastic material with your tongue against the inner wall.
8. Slightly open your mouth and once again gently press the thermoplastic material at the outer and inner wall of the tray against the teeth using your forefingers. Keep the upper and lower jaw closed for about **2 more minutes**.
9. 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.
10. Place the tray on the teeth to check its fit. If the tray does not fit perfectly, the fitting process can be repeated (see step 16).

Fitting the lower tray:

11. Empty the hot water bowl. Bring fresh water to a boil, pour it in the bowl and allow it to cool down for about **1 ½ minutes** (as in step 3 above). The cold water bath can still be used.
12. Put the second tray for about **40 seconds** in the hot water bath and allow it to cool down for about **15 seconds** as described in steps 4 – 5 above.
13. Place the moulded upper tray on the upper teeth. Position your tongue back-/ downwards and do not move it. Slightly move your lower jaw forward. Place the heated lower tray on the lower teeth – make sure that the line marks of the upper and lower tray form a vertical line. **Note:** If necessary, alter the width of the tray by gently pulling the fixation knobs apart or pressing them together as instructed in step 6.
14. Gently press the thermoplastic material at the outer and inner wall of the lower tray against the teeth using your forefingers. With a slightly forward lower jaw firmly clench your teeth. Keep your tongue back-/ downwards and close the upper and lower jaw for about **1 minute** without swallowing.
15. Repeat steps 8 – 9.
16. Place the lower tray on the teeth to check its fit. If the trays do not fit perfectly, the fitting process can be repeated. It is also possible to partially heat a single spot in the hot water bath to remodel it. After reheating, the thermoplastic material approximates to its original form (memory effect). **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.

Connecting the upper with the lower tray:

17. 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 fixation knobs that are not needed for attaching the connectors can be removed with a side cutter. Rough edges can be smoothed with a file.

Setting the lower jaw advancement:

18. The extent of the lower jaw advancement depends on the length of the connectors. The shorter the connectors, the larger the lower jaw advancement. Both connectors have a spindle screw in the centre. The length of the connectors can be altered by turning the screws with the spanner. The lower jaw advancement is the largest when the screws are screwed in completely. At the beginning of 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/ symmetrically to ensure that the connectors are of equal length. Mandibular joint disorders might occur with an asymmetrical adjustment.

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

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