

SomnoGuard® SP Soft

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

Content: 2 oral trays, 4 sets of connecting straps (23 mm – 34 mm), storage case, user instructions

To achieve an optimal therapeutic result, it is recommended that SomnoGuard® SP Soft 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® SP Soft is a prefabricated, two-piece mandibular advancement device that allows limited mouth opening. The hard outer tray shells are filled with 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 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 incrementally adjusted by two connecting straps of equal length that connect the upper and the lower tray. The opening of the respiratory tract depends on the extent of the adjusted lower jaw advancement. SomnoGuard® SP Soft is also suitable for patients with a receding lower jaw (retrognathia).



Fig. 1

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:

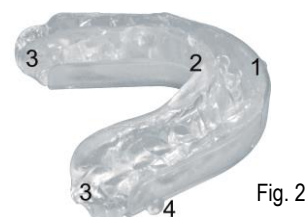
- During the first nights the appliance might not be kept in the mouth for the whole night. This is normal. The adaptation process may take 1 – 2 weeks.
- The average durability of SomnoGuard® SP Soft is about 1 ½ years. Bruxism and strong jaw movements might decrease the average durability of your oral 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 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:

1. Heat one of the trays in a boiling water bath for about 3 ½ minutes with the 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:** We recommend to use a mirror if you fit the appliance yourself.
2. Use a spoon or a small pliers to take the tray out of the water. Carefully shake off any excess water by only holding the fixation knobs of the rigid tray shell. Allow it to cool for 15 seconds. Make sure that the thermoplastic material does not cause burns whilst still being mouldable. **Note:** Nitrile gloves are most suitable for the fitting.
3. Place the tray **centrally** over the upper teeth with the marker on the front edge between the front teeth and the front teeth 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. Then close the mouth and bite down until the upper teeth touch the bottom around the whole tray to create deep teeth impressions. **Note:** Drink some warm water in advance so that your teeth get used to the warmth.
4. Keep the upper and lower jaw closed and use the fingers to firmly press excessive thermoplastic material at the outer sides of the tray against the teeth and gums. Slightly open the mouth and use the fingers to press excessive thermoplastic material at the inner sides of the tray against the teeth, gums and the palate. Keep the tray in place for another 30 seconds before carefully removing it from the mouth by touching the fixation knobs of the rigid tray shell.
5. In a still warm and mouldable condition, cut off excessive thermoplastic material beyond the edge of the rigid shell, preferably with a pair of curved scissors (Fig. 2 [1]). Leave some excess material up about 2 – 4 mm beyond the edge at the inner sides of the tray (Fig. 2 [2]). Beyond the last back tooth (molar) excess lining should be flat along the bottom surface of the rigid tray shell (Fig. 2 [3]).
6. Let the tray cool down for a few seconds in a cold water bath to harden the lining.
7. Heat the second tray in a boiling water bath for about 3 ½ minutes and allow it to cool for 15 seconds (steps 1 – 2).
8. Place the moulded upper tray on the upper teeth first. Then place the heated lower tray **centrally** over the lower teeth with the front marker of the lower tray in a 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 around the whole tray to create deep teeth impressions.
9. Keep the upper and lower jaw closed and use the fingers to firmly press excessive thermoplastic material at the outer sides of the tray against the teeth and gums. Remove the upper tray from the mouth. Keep the lower tray stable and stick out the tongue so that the frenulum of tongue leaves its impression in the material. Then slightly open the mouth and use the fingers to press excessive thermoplastic material at the inner sides of the tray against the teeth and gums. Keep the tray in place for another 30 seconds before carefully removing it from the mouth by touching the fixation knobs of the rigid tray shell. The following procedure corresponds to step 5 – 6.
10. For those with a normal bite attach a pair of the 29 mm long connecting straps at the front fixation knobs of the upper tray and the rear fixation knobs of the lower tray. The embossed strap length should face inwards and should not be visible on the reverse side. Use shorter or longer straps for those with an abnormal bite or to set the required advancement of the lower jaw. **Note:** There should be no lining residues around the fixation knobs (Fig. 2 [4]). If you see any residue, heat only the exterior rigid wall around the knob and remove it carefully.
11. If one of the trays does not fit perfectly, heat it in the boiling water bath for about 10 – 15 seconds and let it cool for a few seconds. Place the oral 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 30 seconds from the mouth and let it cool down in a cold water bath.
12. **Setting 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. If necessary, the advancement can slowly be increased as you adapt to wearing the device. For this purpose use the next shorter connecting straps.



Note:

- 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.
- Those fixation knobs not needed for fastening the straps can be removed with nipper pliers. Rough edges should be smoothed with a file.

MD Medical device

REF Art. No.: 03070000

 Follow instructions for use

 Warnings

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

 **Manufacturer:**

Tomed GmbH • Medical Products
Im Rapsfeld 57 • 50933 Köln (Cologne) • Germany
Tel.: +49 221 17067206 • Fax: +49 221 17067207
Email: info@tomed.com • www.tomed.com

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