

SomnoGuard® SP Soft

Medical oral appliance to treat snoring and sleep apnoea in adults

Content: 2 oral trays, 4 sets of interchangeable flexible connecting straps, storage case and user instructions.

It is recommended that the SomnoGuard SP Soft mandibular advancement device is fitted by physicians (e.g., ENT doctors, sleep lab doctors or dentists) or their trained medical staff.

Instructions (Read carefully before use)

Date of information: 12.10.2009

Description:

The mandibular advancement device SomnoGuard SP Soft consists of two identical trays that fit over the teeth of the upper and lower jaws. Interchangeable plastic straps of equal length connect each of the two forward knobs of the upper jaw tray with each of the two rearward knobs of the lower jaw tray. They enable various degrees of incremental lower jaw advancement. Lower jaw advancement prevents the soft tissue of the throat from collapsing and obstructing the upper airway. Up to 10 mm of lower jaw advancement can be achieved. The SomnoGuard SP Soft is suitable for patients with a receding lower jaw (retrognathia).



Indications:

- Primary snoring and mild to moderate obstructive sleep apnoea in adults
- CPAP-intolerance
- Sporadic use by patients with obstructive sleep apnoea instead of CPAP when travelling according to the advice of their medical professional

Contraindications:

If you have any of the following conditions, see advice from a medical professional before using this appliance:

- Temporomandibular joint dysfunction (TMJ)
- Larger tooth gaps, unstable dental crowns, decay, parodontosis
- (Strong) gag reflex
- Central sleep apnoea- Limited mandibular advancement. Patients with obstructive sleep apnoea should be able to extend their lower jaw forward at least 7 mm.

If the patient's dental condition appears uncertain and in case of occlusional abnormalities (e.g., crossbite, overbite, under-bite) a dental check up is necessary and strongly recommended before starting treatment. If the appliance is used long term, regular dental checks are required.

Possible side effects:

- During the first few nights the patient may not be able to keep the appliance in the mouth for the whole night. This is normal. The adaptation period may take 1 to 2 weeks.
- Initial hypersalivation, which normalises with adaptation to the appliance.
- Morning discomfort by temporary pain from TMJ or teeth, reducing commonly with adaptation
- Mouth dryness
- Transitory bite changes which will normally disappear within 30 minutes after removal of the appliance from the patient's mouth.

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

Fitting:

1) Place one of the two identical trays in a bowl of boiling water. Heat the tray in the water bath for about 3½ minutes until the lining material turns completely clear and transparent and has become mouldable. Take the tray out of the water and shake off any excess water. Wet your hands or gloves with water before starting the fitting process. **Note:** To prevent damage to the softened lining material, handle the warm device by the rigid walled tray only. To prevent burning the mouth, test the temperature of the device on the back of the hand before placing it in the mouth.

2) Place the first of the two trays on the upper teeth with the incisors as near to the front wall as possible and the vertical mark located at the centre between the front incisors. Press the bottom of the tray with your thumbs firmly against the teeth, until the teeth touch the bottom around the whole tray. Some lining material is likely to be displaced on the palate side. It should be pressed firmly against the teeth with a wet finger, to achieve a good grip. Keep the device in place for 30 seconds. Remove the upper jaw tray carefully by the rigid part. There should not be any lining residues around the fixation knobs (refer to 4 in the photograph on the right).

3) While the lining is still warm and mouldable, trim off any excess lining material beyond the front edge of the tray (refer to 1 in the photograph) using a pair of scissors. At the interior back side of the tray you can leave some excess material up to about 3 mm beyond the edge (refer to 2 in the photograph). Do not trim off excess lining beyond the last back tooth (molar). There, the excess lining should be flat along the bottom surface of the rigid tray (refer to 3 in the photograph).

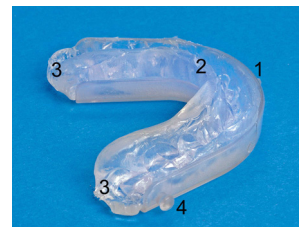
4) Reheat the upper tray again for 20 to 30 seconds, and then put it back in the mouth. To increase retention you should push the material behind the front teeth slightly into a forward position with the fingers (refer to 2 in the photograph).

5) Cool the upper tray in a cold-water bath for 1 to 2 minutes to harden the lining.

6) Place the moulded upper tray on the upper teeth.

7) Heat the second tray in boiling water as described above, and place it carefully onto the lower teeth with the front marker on the front wall in a vertical alignment with the marker of the upper tray. Then bite the trays firmly together for 45 to 60 seconds. Then continue with the fitting as described above. Important: The lower front teeth should also be positioned as near to the front tray wall as possible.

8) Test the fit by inserting both the upper and lower trays — still without connecting straps — on the teeth of the upper and lower jaws with the front marks of both trays lining up. This procedure should be repeated several times by the patient. The process ensures that the appliance will not grip the teeth too tightly. Both trays should be in a comfortable position and exert



an equal, but not too strong, pressure on the teeth. If necessary, fitting can be repeated as described above until a comfortable fit is achieved.

9) Finally, before using the appliance, attach to each side a pair of the 27 mm long flexible connecting straps at the front fixation knobs of the upper tray and the rear fixation knobs of the lower tray. This strap length is ideal for those with a normal bite. The embossed strap length should not be visible on the reverse side. Use shorter or longer straps to set the required advancement. **Note:** There should be no lining residues around the fixation knobs (refer to 4 in the photograph above). If you see any residue, heat only the exterior rigid wall around the knob for a few seconds in a warm water bath, then put a strap on the knob and move it around. Fixation knobs must be free to fasten the flexible straps correctly.

Note:

- Do not discard lining material trimmed off during fitting. You may need it for a later refit or corrections, e.g., support of the molars, local lining repair, local fitting changes if teeth are insufficiently gripped by the lining of the tray, complete refit. If necessary, heat the lining material that was previously trimmed away in a hot water bath. Fill in mouldable, warm material into the tray locally where needed. Reheat the whole tray again and repeat fitting as described above.
- Rough edges can be trimmed and polished if necessary. Normally, dipping the appliance briefly into a hot water bath and then smoothing the edges with a wet finger will be sufficient.
- Those fixation knobs not needed for fastening the straps can be removed with nipper pliers. Rough edges should be finished with a file.
- The soft lining material of the SomnoGuard SP Soft provides a high degree of comfort when used on the upper teeth, but sometimes less than ideal grip on the lower teeth. It may therefore be helpful to use one tray of the "Soft" version worn at the upper teeth with the "Hard" lining alternative of the SomnoGuard SP Hard version providing great retention when fitted to the lower teeth.

Setting the lower jaw advancement:

At the onset of treatment lower jaw advancement should not exceed about 30% of the maximum lower jaw protrusion. With adaptation and if necessary, e.g. if snoring does not stop completely, lower jaw advancement can slowly be increased in intervals up to finally about 60 % of the maximum low jaw protrusion.

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 for therapy control.
- If breathing discomfort occurs with the device stop immediately using it. Consult your medical professional.
- In case of severe pain from TMJ or long lasting other 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.

Special notes:

- Chin supporting devices available from Tomed or your supplier will prevent the problem of waking with a dry mouth for those nCPAP or oral appliance users who sleep with their mouth open.
- Check the appliance thoroughly every morning for any uncommon changes, such as cracks or debonding. You must not use the appliance if it is damaged in any way, but should consult your medical professional.
- You should visit your dentist at regular intervals if you are wearing your appliance every night.

Care

Brush your oral appliance every morning with a soft toothbrush and 2 to 3 drops of a wash-up liquid or a liquid (not an abrasive) denture cleaner (e.g. Curadent BDC daily, available from your supplier or Tomed). Clean your device weekly with a denture cleanser to maintain a hygienic device condition (e.g. Curadent BDC weekly, available from your supplier or Tomed). Do not use any bleaching solutions containing hydrogen peroxide. Your appliance would be damaged. Finally, always rinse with cold water, let it dry in the open air and keep it in the storage case provided.



The product meets the requirements of Council Directives
MDD 93/42/EC and 2007/47/EC for medical products

Manufacturer:

Tomed Dr. Toussaint GmbH – Medical Products
Wiesenstr. 4, D-64625 Bensheim
Tel. +49 6251-983344, Fax: +49 6251-983345

SGSPS.UI.1009.GE. 01