

## SomnoGuard SP®

Medical oral appliance to treat snoring and sleep apnea in adults



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

### Fitting Instructions (Read carefully before use)

#### Description:

The mandibular advancement device SomnoGuard SP® consists of two identical trays that fit over the teeth of the upper and lower jaws. Interchangeable plastic elastic straps of equal length connecting each the two forward knobs of the upper jaw tray with each the two rearward knobs of the lower jaw tray. They enable varying degrees of incremental lower jaw advancement. Lower jaw advancement prevents the soft tissue of the throat from collapsing and obstructing the upper airway. The oral appliance provides varying incremental lower jaw advancement settings from approx. -3 mm up to +10 mm. Thus, it is also suitable for patients with a recessive lower jaw (retrognathia).



#### Indications:

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

#### Contraindications:

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

- Mandibular joint disorder or TMJ
- Larger tooth gaps, unstable dental crowns, decay, parodontosis
- Disorders like epilepsy and debility
- (Strong) gulping/gag reflex
- Central sleep apnea
- Limited mandibular advancement. Patients with obstructive sleep apnea should be able to extend their lower jaw at least 7mm.

If the patient's dental condition appears uncertain and in case of occlusional abnormalities (e.g. crossbite, overbite, underbite), a check up visit with a dentist is necessary and strongly recommended prior to the start of treatment. If the device is used in the long-run regular periodic control visits with a dentist are required.

#### Possible side effects:

- Initial hypersalivation which normalizes with adaptation to the appliance.
- Morning discomfort by temporary pain from TMJ or teeth, reducing commonly with adaptation
- Mouth dryness
- Short-time bite changes which will disappear normally within 30 minutes after removal of the device from the patient's mouth.
- During the first few days it may happen that the appliance cannot be kept in the mouth for the whole night. This is normal. The adaptation period may take from one to two weeks.

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 becomes moldable. Take the tray out of the water and shake off any excess water from it. 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 outer wall of the 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 jaw 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 moldable, trim off any excess lining material beyond the front edge of the tray (refer to #1 in the photo) 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 photo). 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 down 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 in step #1, 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 not be any lining residues around the fixation knobs (refer to #4 in figure). If you see such residue, heat only the exterior rigid wall side locally 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 elastic straps correctly. Any minor sharp or intruding edges can be modified with gentle use of the strap, fine nail file, emery board, etc.
- 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 moldable, 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 clear thermoplastic lining material of the SomnoGuard SP 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 standard SP 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. If this is the case, have your professional contact NoSnoreZone.com (Therapy Control Products Inc.) for availability and details.

**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 apnea. 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, such as ChinUpStrip (available at NoSnoreZone.com) will prevent the problem of waking with a dry mouth for those CPAP 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. In case of evidence that the damage is due to a fabrication failure, the manufacturer will replace the appliance within a period of one year after the date of purchase.
- You should visit your dentist at regular intervals if you are wearing your appliance every night.

**Care**

- Soak your oral appliance every morning in DentureBrite. It reduces plaque without damaging the plastic. (DentureBrite can be ordered from NoSnoreZone.com)
- Rinse and let the appliance dry in the open air and keep it in the storage case provided.