

SomnoGuard® AP

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

Content: 2-part mouthpiece, storage case, user instructions, 2 stainless steel adjustment screws (12 and 16 mm – 12 mm screw fitted in appliance), 1 stainless steel locknut, 1 stainless steel spanner, 1 adjusting tool

Read instructions carefully before use.

Instructions

Date of information: 10 August 2011

Description:

SomnoGuard AP is a laterally movable and infinitely adjustable two-part mandibular advancement device. The adjustable appliance consists of an upper and a lower tray. The upper and the lower trays are each made of two components: A clear transparent polycarbonate outer tray shell filled with a thermoplastic copolymer. After heating the trays in boiling water, the thermoplastic material becomes mouldable. Deep teeth and jaw impression are easily formed when firmly biting into the soft thermoplastic material. The part with the guide bar ("C-bar") and the engraved line in the thermoplastic material characterises the upper tray designed for the upper jaw ("upper tray"). The C-bar is the track for the screw head of the lower tray and allows advancement of the lower jaw from 0 to approx. 10 millimetres depending upon the length of the adjusting screw used.

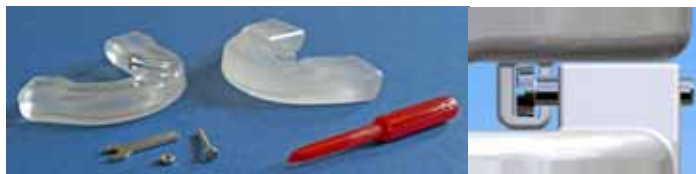


Fig. 1: SomnoGuard® AP

Indications:

- Primary snoring and mild to moderate obstructive sleep apnea 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 any of the following conditions exist, seek advice from a medical professional before using this appliance:

- Central sleep apnoea
- Mandibular joint disorder
- (Strong) gag reflex, larger gaps between the teeth, unstable dental crowns, decay, parodontosis
- Limited mandibular advancement. Patients with sleep apnoea should be able to extend their lower jaw forward at least 7mm.

If the patient's dental condition appears uncertain and in case of occlusal abnormalities (e.g. crossbite, overbite, underbite) a check up visit with a dentist is necessary and strongly recommended prior to the start of treatment. In case of long term use regular dental check-ups are required.

Possible side effects:

- Initial hypersalivation which normalises with adaptation to the appliance.
- Morning discomfort by temporary pain from TMJ or teeth, reducing commonly with adaptation
- Mouth dryness
- During the first days it may happen that the device cannot be kept in the mouth for the whole night. This is normal. The adaptation may take 1 to 2 weeks.

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

Mode of action

SomnoGuard® AP has been developed to reposition the lower jaw forward by any degree up to 10 millimetres. At the same time a limited sideward movement is possible. Due to the advanced lower jaw position the upper airway is wider and you can breathe more easily without snoring. In addition nocturnal breathing arrests are reduced. SomnoGuard® AP allows you to breathe through your mouth when you have difficulties breathing through your nose (e.g. when you have a cold).

Fitting the appliance

1. Fill a medium sized saucepan with about 1 litre of water to a depth of about 7 cm and boil vigorously. Immerse the upper part of the appliance (i.e. the part with the guide bar or C-bar) for 3½ minutes in the boiling water. As the device heats up the thermoplastic filling will become clear and the device will rise to the surface.
2. Take the upper part out with a spoon and allow it to cool for 15 seconds. Make sure that the temperature of the device is acceptable for fitting whilst being hot enough to allow the mouthpiece to be moulded.
3. If you fit the appliance yourself practise especially steps 4 and 8 in front of a mirror.
4. Place the upper tray on the upper jaw teeth with the incisors as near to the front wall as possible. Press the bottom of the tray beginning from the front to the rear with your thumbs and forefingers firmly against the teeth. Press the excessive still mouldable thermoplastic behind the teeth firmly against the teeth and gums at the interior side of the mouth with a finger to achieve a good grip. Keep the oral appliance for another 30 seconds in place before removing the upper jaw tray carefully by the rigid shell out of the mouth.

5. In a still warm and mouldable condition, cut off (preferably with a pair of curved scissors) any excess soft mouldable thermoplastic material beyond the edge of the rigid tray (refer to #1 and #3 in figure 2). Leave some excess material up about 2 to 4 mm beyond the edge. 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 #2 in figure 2).

6. Cool down the upper tray in a cold water bath for approx. 0.5 to 1 minute to harden the lining.

7. Heat the lower part with the smallest screw (12mm) fully engaged in the housing in the same manner as the upper part. In this position the device roughly adopts the normal jaw position. .

8. When the lower part has cooled down for 15 seconds connect both parts by engaging laterally the head of the adjusting screw in the guide bar of the upper tray (refer to the right part of figure 1). Put the upper tray that has been already fitted to the upper teeth and bite the plastic of the lower part firmly as deep as you can and as near to the front as possible. After a few seconds

take the whole appliance out of your mouth. Based on regular bite conditions lower jaw advancement is thereby set at about 30% of the maximum extension. The follow-up maneuvers are then the same as described above for steps 5 to 6.

9. To improve the fit place the moulded top and bottom trays separately into hot water for 10 to 15 seconds. Put the trays together. Position the device in your mouth using the impressions created by the former fitting. Then suck in any saliva and bring your cheeks against the device. Massage your cheeks so that the device moulds to the shape of your gums and arches. After about 60 seconds remove the appliance. You can repeat this procedure at any time to increase the retention of the device. Make sure that the appliance allows for side to side movement of the jaw and it feels comfortable. If it does not feel comfortable start the fitting again.

10. By turning the screw you can now adjust the protrusion. The notches on each side of the screw are at 4 mm intervals and staggered so that the distance between a notch on one side and the next notch on the other side is 2mm.

11. The adjusting screws are 12 and 16 mm long. **For safety reasons** the screws should be engaged always a minimum of 6 to 7 mm into the 9 mm long housing, but never extending out of the front. Do always loosen the locknut with the spanner before making use of the adjusting tool which might break or bend otherwise.

Note:

- Do not discard lining material trimmed away 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 locked by the lining of the tray, complete refit.

When necessary, heat lining material that was previously trimmed away in a hot water bath. Fill in mouldable, warm material into the tray locally where needed. Heat tray locally again, then press teeth firmly into the tray and follow the directions above.

- 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.

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 lower 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 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.

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 bending of the adjusting screw. 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.

- With the locknut included in the pack a specific protrusion can be fixed. The locknut should then be put on the adjustment screw and fixed lightly against the housing using the spanner.

- Please note the additional fitting instructions such as videos and slide shows on the internet at www.tomedcare.com.

Care

Brush your oral appliance every morning with a soft toothbrush and 2 to 3 drops of a washing-up liquid or a liquid denture cleaner (e.g. Curadent® BDC daily, reduces plaques without damaging the plastic. Curadent BDC daily can be ordered from Tomed or your supplier). Rinse, let it dry in the open air and keep it in the storage case provided.



Fig. 2: Upper jaw tray



Fig. 3: Lower jaw tray



Fig. 4: Adjustment screw



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

Manufacture:

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