

# SomnoGuard<sup>®</sup>, SomnoGuard<sup>®</sup> 2.0 and SomnoGuard<sup>®</sup> AP

## Medical oral appliances to treat snoring and sleep apnoea in adults

### Content:

- SomnoGuard<sup>®</sup> and SomnoGuard<sup>®</sup> 2.0: monobloc mouthpiece, filler material, wooden spatula, storage case and user instructions
- SomnoGuard<sup>®</sup> AP: 2-part mouthpiece, storage case, user instructions, 3 adjustment screws (12, 16 and 20mm) made from stainless steel, 1 screw driver, 1 spanner, 1 stainless steel locknut

Read instructions carefully before use.

## Instructions

Date of information: 10 July 2007

### Who should use the SomnoGuard<sup>®</sup> oral appliances?

SomnoGuard<sup>®</sup> mandibular advancement devices are designed for adult patients who snore and suffer from mild to moderate obstructive sleep apnoea. Patients with proven obstructive sleep apnoea should only use the SomnoGuard<sup>®</sup> appliances under the guidance of their physician and after having assessed both the benefits and risks to their health, as well as having considered the other therapies available (e.g. nCPAP). Patients with sleep apnoea should be able to extend their lower jaw forward at least 7mm.

*It is recommended that the SomnoGuard<sup>®</sup> mandibular advancement devices are fitted by physicians (e.g., ENT doctors, sleep lab doctors or dentists) or their trained medical staff. A video CD-ROM entitled "SomnoGuard<sup>®</sup> - Fitted by an Expert" is available from Tomed or your local supplier showing the major steps in fitting the SomnoGuard<sup>®</sup> and SomnoGuard<sup>®</sup> 2.0. The CD runs on all PCs using Windows.*

### Warning:

Snoring can be a symptom of breathing arrests that may contribute to serious health problems such as cardiovascular diseases. Ask for your doctor's help to find out why you snore.

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## 1. The fitting process for SomnoGuard<sup>®</sup> and SomnoGuard<sup>®</sup> 2.0

### Mode of action

SomnoGuard<sup>®</sup> mandibular advancement devices aim to reduce snoring and the nocturnal breathing arrests that characterise obstructive sleep apnoea. The SomnoGuard<sup>®</sup> oral appliances have been developed to reposition the lower jaw by moving it slightly forward. When the lower jaw is in such a position the upper airway is widened and you can breathe more easily without snoring. To use these appliances you must be able to breathe normally through the nose and have all your own teeth. An opening in the front part of the mouthpiece allows you to breathe through the mouth (if necessary) in an emergency situation. However using the 2-part appliance "SomnoGuard<sup>®</sup> AP" enables you to breathe through your mouth whenever you need to do so.

SomnoGuard<sup>®</sup> 2.0 differs from SomnoGuard<sup>®</sup> because of a 1.5 mm thickened molar biting zone on each side and an increase in the height of the molar side wall by 1 mm. As opposed to the classic "SomnoGuard<sup>®</sup>" time consuming use of the filling strip can thus be avoided when SomnoGuard<sup>®</sup> 2.0 is used by patients with a "deep bite".

### Fitting preparation:

1. The pack includes a wooden spatula. Push the spatula through the hole in the mouthpiece so that its tip protrudes out of the back by a few millimetres. This spatula helps you to hold the mouthpiece with your fingers while fitting.
2. First put the unfitted mouthpiece into your mouth with the spatula pointing away from your face. The upper part of the mouthpiece has a notch in it. The upper part of the mouthpiece forms the biting channel for the upper jaw, the lower part the biting channel for the lower jaw.
3. Before doing the real fitting, practise the process with cold water. Put the mouthpiece in the unheated water, as you will have to do later with hot water for the actual fitting. If you fit the device yourself practise in front of a mirror. The timing is critical. Make sure you use a watch with a second hand that you can read easily.

### Custom-Fitting

1. Boil about 1 litre of water in a saucepan. The water must be deep enough to completely cover the mouthpiece.
2. Take the pan off the hob and immerse the appliance with the wooden spatula in a sloping but not vertical position. Whilst immersed in the hot water, move and turn the appliance with the spatula. Differentiate between fitting SomnoGuard<sup>®</sup> or SomnoGuard<sup>®</sup> 2.0 as follows:

#### SomnoGuard<sup>®</sup>

People with considerable fitting experience should immerse the oral appliance for 25 to 35 seconds to achieve an optimal teeth and jaw impression into the plastic. However, those who have limited or no fitting experience should immerse the SomnoGuard<sup>®</sup> in the hot water for no longer than 20 to 25 seconds as this reduces the risk of the inner and outer walls of the appliance sticking together. After heating, the mouthpiece will appear transparent. Gently feel the biting channel to check that the plastic is mouldable. In the heating process be careful that the inner and outer sides of the appliance do not stick together. If necessary take the appliance briefly out of the hot water (using the spatula) and push the sides back to their original position with your fingers.

#### SomnoGuard<sup>®</sup> 2.0

At first only the molar area with the thickened biting level should be heated in hot water for around 40 seconds. Thereafter the whole appliance should be heated for another 20 to 35 seconds according to the individual fitting experience as described before.

3. Then take the mouthpiece out of the hot water with the spatula. Gently shake it to get rid of the last water drops. Wait until the temperature has cooled down for about 12 to 15 seconds, and test whether the plastic's temperature is acceptable for fitting on the back of your hand, making sure that you can still mould the mouthpiece. If you fit the device yourself use a mirror. Open your mouth wide and insert the device into your mouth using the spatula. The notch must be at the top. First position the lower jaw in the lower channel of the mouthpiece, then the upper jaw in the upper channel. The thermoflexible mouthpiece is automatically adjusted to any dental arch width if the fitting is performed correctly.

4. Check that the spatula is secure in the opening of the mouthpiece and protrudes a few millimetres through it, otherwise the opening may close permanently during the fitting process. Move the lower jaw forward to approximately half the maximum extension possible (see figure 3 which shows the desired position). Bite the plastic hard. Be careful not to bite the borders of the mouthpiece otherwise you might ruin it. Suck in while closing your mouth and press your tongue against the lower inner surface of the front teeth under the spatula. While doing this, press on the outer walls of the mouthpiece with your fingers to make sure that it is moulded properly.



Figure 1: Normal jaw position

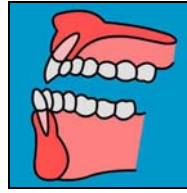


Figure 2: Maximum jaw extension



Figure 3: The desired position is about half maximum extension.

5. Once the mouthpiece has cooled (approx. 30 seconds), take it out of your mouth (still using the spatula) and insert it into cold water for approximately 10 seconds to fix your individual fit. If you have followed all the steps carefully and correctly the appliance will show a distinct impression of your teeth over the whole of the mouthpiece, and the border walls of the mouthpiece will not be damaged (see figure 2 on the box). Only then can you be certain that the mouthpiece will lightly grip your teeth and stay in the required position during sleep.

6. Take the spatula out of the opening. Put the mouthpiece back into your mouth to check that it fits properly. Having the lower jaw extended forward should still be comfortable. If it is not, repeat steps 1 to 5. Most users get a more comfortable fit by moulding a second time. Repeating this process more than once can damage the material and thus the appliance. Note that if you refit the mouthpiece you cannot leave it in boiling water for more than 25 seconds. If refitting is required, heat the upper and lower parts of the mouthpiece separately.

7. If you do not stop snoring completely, re-mould with your lower jaw extended a little farther forward but not at maximum extension.

### Application of the filler material

If you have a "deep bite" your dentist can raise the molar area, i.e. the position of the molar teeth, with the filler material provided in the pack which is made out of the same copolymer as the oral appliance itself. For modifications such as these the mouthpiece should always be fitted by your dentist.

A "deep bite" is apparent when no distinct impression of the teeth can be seen in either channels of the appliance after the first fitting. When raising the molar area it is necessary for both the part of the appliance that needs correction, and the filler material to be immersed separately in hot water for approximately 15 seconds. The soft and warm filler material can then be pressed into the biting channel at the appropriate place. Only use as much of the filler material as is necessary. The remaining material can be used to raise other biting zones of your mouthpiece if necessary. Usually it is only necessary to remodel one biting channel to achieve a good and equal jaw impression in both channels. After fixing the filler material into the biting channel immerse the corrected part of the mouthpiece in hot water for approximately 20 seconds. Bite into the appliance carefully without moving your lower jaw forward, and then insert it into cold water to harden it. The oral device is now ready to use.

Malformations and damages, for example bitten side walls, can often be corrected and remodelled as described previously. The mouthpiece can be refitted, however repeating this process more than once can damage the material and thus the appliance. You may have to refit the mouthpiece to reduce the advancement of the lower jaw (for example if muscular pain occurs in the joint) or to increase the extension if you still snore. The opening on the front part of the mouthpiece can be closed with the filler material if necessary.

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## 2. The fitting process for SomnoGuard® AP

### Mode of action

SomnoGuard® AP has been developed to reposition the lower jaw forward by any degree up to 12mm. At the same time a limited sideways 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. The part with the guide bar ("C-bar") for the bolt head is the part for the upper jaw ("upper part"). The part with the screw thread is the part for the lower jaw ("lower part").
2. Fill a medium sized saucepan with about 1 litre of water to a depth of about 7cm and boil the water vigorously. Remove the pan from the heat and immerse the upper part for 3½ minutes in the boiled water. As the device heats up the thermoplastic filling will become clear and the device will rise to the surface.
3. 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.
4. If you fit the appliance yourself practise in front of a mirror.
5. Fit the upper part to the upper jaw and make sure that the front teeth are pushed firmly to the front of the device. Bite the plastic through to the base of the device within the 15 seconds of removing the device from the water bath and maintain this position for about 10 seconds. Remove from the mouth and insert into cold water.
6. 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.
7. When the lower part has cooled down for 15 seconds connect both parts. 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 and insert it into cold water. Put the device into your mouth again to check the fitting.
8. By turning the screw you can 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.
9. The stainless steel adjusting screws are 12, 16 and 20 mm long. **For safety reasons** the screws should be engaged always a minimum of 7 mm into the 9 mm long housing, but never extending out of the front.
10. If necessary you can repeat the fitting. Heat the parts again so that the mouthpiece becomes soft. Push the material into the channels with your fingers and repeat the fitting.
11. 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 45 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.

12. While fitting the bottom tray the trays may stick together limiting side-to-side movement. To prevent this you may need to trim off excess material on either part of the appliance with a pair of sharp scissors. To make trimming easier soften the material in hot water for 10 seconds. Any rough edges may be smoothed with a wet finger while the material is still warm. It is recommended that you keep the off-cuts of any excess thermoplastic material: you may need them to fill up the trays of the appliance if a future refitting is necessary.

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### The first weeks with your mandibular advancement device

Maximum comfort may not be immediate. Allow a two to three week adaptation period. During the first few days you may not be able to keep SomnoGuard® in your mouth the whole night, or the mouthpiece may fall out during the night. This is normal so don't give up straight away! It is important to suck on the mouthpiece while putting it on to get rid of the accumulated saliva in the channels of the appliance. This way the retention on the teeth is improved. With time you'll get used to SomnoGuard®, it will become more comfortable every night. However you should normally expect initial discomfort from the mouthpiece around the teeth and the joint areas. The uncomfortable feeling disappears within the first few minutes of taking SomnoGuard® out of your mouth. If you use SomnoGuard® regularly, the feeling of a foreign body in your mouth will completely disappear within a few weeks.

In most patients there are no significant side-effects during the adaptation period, so do not give up! In a few weeks you and your partner will be very satisfied with the result.

### Specific Notes:

Chin supporting devices available from Tomed or your local supplier will prevent the problem of waking with a dry mouth for those nCPAP or oral appliance users who sleep with their mouth open.

If you have a receding chin (retrognathia), full dentures or have missing teeth, consult your dentist before using SomnoGuard®. In the minority of patients use of the mouthpiece can cause joint pain. This is, however, temporary. If you feel acute pain in the joint area with a SomnoGuard® appliance or if the pain persists, stop using the oral appliance immediately and consult your dentist or doctor. Do not use your SomnoGuard® device if you already have jaw joint problems. If you have difficulties breathing through the nose (e.g. when you have a cold) make sure that you can get enough air through the opening in the front part of the mouthpiece. If you feel that you won't get enough air, you should not use your SomnoGuard® or SomnoGuard® 2.0 until you have fully recovered and can breathe normally again. If you have a blocked nose do not use these appliances before consulting your doctor. Unlike the SomnoGuard® and SomnoGuard 2.0 breathing through your mouth is always possible when using the 2-part SomnoGuard® AP.

You should consult your dentist if you have existing dental disease (e.g., periodontitis), large gaps between the teeth or malocclusion (e.g., crossbite, overbite, underbite) to find out whether use of a mandibular advancement device is an appropriate therapeutic option for you. It is strongly recommended that you visit your dentist at regular intervals if you are wearing your appliance every night.

If you grind your teeth during sleep (bruxism) the life span of all SomnoGuard® appliances may be reduced considerably. Users of the two-part SomnoGuard® AP are advised for safety reasons to check thoroughly the appliance every morning for any uncommon changes (e.g. cracks, bending of the adjusting screw etc.). You must not use the appliance if it is damaged in any way but should consult your dentist about therapeutic alternatives especially designed for bruxists.

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, as shown in figure 4.

Users of medical gases (e.g., oxygen) should consult their doctor before using the SomnoGuard® oral appliances. Remove the SomnoGuard® appliance from your mouth before eating or taking medicines. On special request screws and locknut made from biocompatible titanium are available for those who suffer from allergic reactions to stainless steel.



Figure 4: Adjusting screw with locknut

### Care

Brush SomnoGuard® 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 is available from Tomed or your local supplier.) Rinse, let it dry in the open air and keep it in the storage case provided.

### Manufacture:

Tomed Dr. Toussaint GmbH - Medical Products  
Lindberghstr. 3a, D-64625 Bensheim (Germany)  
Tel.: +49-6251-983344, Fax: +49-6251-983345

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