

## Basics

Snoring is normally not dangerous and simply a social problem. But when recurrent breathing arrests occur during sleep, it can be an indication of the dangerous obstructive sleep apnoea syndrome. Obstructive sleep apnoea results from the temporary blockage by anatomical abnormalities of the upper airway during inspiration, whereby breathing stops and causes an increase in the carbon dioxide level in the blood (Fig. 1).



Fig. 1: Blockage of the upper airway



Fig. 2: Open airway with oral device

As the airway narrows the velocity and pressure of the inspired air increases which in turn cause the soft tissue of the throat to vibrate producing snoring sounds.

Millions of people in Germany snore every night – men and women in equal measure. Over the age of 35 years, obstructive sleep apnoea occurs in about 2% of all women and 4% of all men. In Germany, 2 to 3 million people suffer from obstructive sleep apnoea, but about 95% of snorers aren't aware of their disease and the risks that occur with the obstructive sleep apnoea syndrome.

Mandibular advancement appliances are becoming increasingly important as treatment alternatives to nCPAP in the treatment of primary snoring and mild to moderate obstructive sleep apnoea in adults. These appliances advance your lower jaw, thereby extending the airway at the base of the tongue and reducing the speed of the inspired air. This leads to a reduction or removal of annoying snoring sounds (Fig. 2).

It is important that prior to treatment a proper diagnosis is made by your physician differentiating habitual snoring from obstructive sleep apnoea. Before your appointment you should fill out the questionnaire in this brochure, preferably with your partner, and take it with you when you see your doctor. The treatment your doctor recommends will depend on your test results.

For the treatment of snoring and obstructive sleep apnoea Tormed currently offers, amongst others, the following one-part "boil & bite" mandibular advancement appliances:

## SomnoGuard®

SomnoGuard® consists of a hypoallergenic thermoplastic body. After heating the appliance in boiled water the thermoplastic copolymer becomes soft and mouldable. While soft, the appliance is fitted to your upper and lower jaws and when cooled it is ready to be worn at night. Fitting the appliance can be carried out without special equipment. Photographs of the appliance before and after the fitting can be seen at the front page.



Fig. 3: SomnoGuard®



Fig. 4: SomnoGuard® 2.0

SomnoGuard® 2.0 is a modified appliance made in accordance with the recommendations of Dr. Abrams, an ENT specialist and dentist from Hamm (Westfalia, Germany). It differs from the SomnoGuard® by a 3.0 mm thicker molar biting zone. This thicker molar area means that fitting is faster and easier for those patients with a "deep bite".

### SomnoGuard® has the following features and advantages

- Easy fitting within minutes, preferably by medical professionals
- Easy handling and care
- Clinical efficacy well proven by several clinical trials performed with the SomnoGuard® with success rates between 50% to 80% in reducing snoring and the RDI. The efficacy seems to be comparable to that of custom made appliances (6). Literature references are listed at the end of this brochure
- Average lifetime of about one year (lifetime in case of bruxism may be shortened considerably)
- The most cost-effective option to treat snoring and sleep apnoea

### In brief a good choice for mobile and active people.

### Clinical experience

During a clinical trial with 44 sleep apnoea patients using SomnoGuard® for 122 days on average (max. 543 days), Maurer, Hormann et al. demonstrated that this mandibular advancement appliance is highly effective in the reduction of snoring and the respiratory parameters RDI, AI and HI (6). This leads to an improvement of sleep quality. The symptoms of obstructive sleep apnoea, consistent with the

<sup>1</sup>Respiratory Disturbance Index (RDI): number of apnoeas (Apnoea Index = AI) plus hypopnoeas (Hypopnoea Index = HI) per hour of sleep each lasting longer than 10 seconds.

success criteria of the trial, were classified as "improved" or "cured" in 68% of cases (cf. to Fig. 5 and Fig. 6).

Similar outcome results have been reported in two clinical trials performed in Belgium by Vanderverken, Braem, van de Heyning et al.: (4,5). The authors reported an RDI reduction of 65% in the SomnoGuard® pilot study of 20 patients (4). In both clinical trials (20 and 36 patients respectively) a major outcome was a significant reduction of daytime sleepiness and snoring.

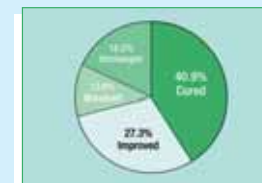


Fig. 5: Clinical trial outcome

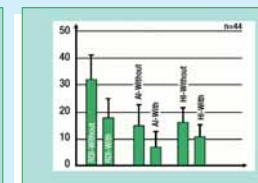


Fig. 6: Influence on respiratory parameters

In a clinical trial of the predecessor of SomnoGuard® with 39 patients, Maurer et al. demonstrated that the mean RDI improved significantly from 16.6/h to 8.2/h in the whole group. Time with snoring dropped from 16.3% to 6.6%. 59.1% of the sleep apnoea patients were successfully treated as their RDI dropped below 10/h (1). Comparable results have also been published in a study by Schoenhofer, Hochban et al. (2).

### Tolerability

When wearing SomnoGuard® for the first time side-effects like short-term toothaches in the morning, temporary jaw joint pains or hypersalivation in the morning were reported sporadically. In individual cases patients reported also a gag reflex. In the trial with the predecessor familiarisation time was between 0 and 21 days, the average was 4 days and the compliance rate 74.4% (1).

Side Effects (N=20)	1-Month	6-Month
Hypersalivation	11	2
Morning discomfort	9	3
Loss of device	8	1
Pain from TMJ or teeth	6	2
Breathing problems	4	2
Device too big	4	0
Nausea	1	1
Suffocation	1	0
Altered bite	0	0

Fig. 7: Side-effects of the SomnoGuard® observed in the pilot study

SomnoGuard® is commonly very well tolerated as the table on the left demonstrates. Side-effects reported were minor, temporary and resolved within three to four weeks (3, 4). A similar incidence of side-effects had been reported for all clinical trials performed to date (1–6).

From the extensive clinical investigations with SomnoGuard® and the predecessor model we conclude that SomnoGuard® is a very inexpensive, safe and effective mandibular advancement device at least for the temporally limited treatment of snoring and also, under strict medical guidance, for obstructive sleep apnoea.

Four to eight weeks after starting the therapy with SomnoGuard® your prescribing physician should monitor the success of the therapy, because to date there are no reliable predictors for a success with mandibular appliances in general.

References

1) Maurer JT, Hormann K et al.: Einsatz eines intraoralen Schnarchtherapiegerätes aus thermolabilem Kunststoff, HNO 2000, 48: 302 – 308, 2) Schoenhofer B, Hochbahn W, Köhler D et al.: Immediate Intraoral Adaptation of Mandibular Advancing Appliances of Thermoplastic Material for the Treatment of Obstructive Sleep Apnea, Respiration 2000, 67: 83 – 88, 3) Maurer JT, Hörmann K et al.: Kombinierte operative und prothetische Therapie bei schwerer Schlafapnoe – Ein Fallbericht, Laryngo-Rhino-Otol 2001, 80: 278 – 281, 4) Vanderveken, OM, Braem, MJ, van de Heyning, PH et al.: A pilot study of a novel mandibular advancement device for the control of snoring, Acta Otolaryngol 2004, 124:628-633, 5) Vanderveken, OM, Braem, MJ, Willemen, M, van de Heyning, PH et al.: Subjective Assessment of a one-piece mandibular advancement device out of thermoplastic material on snoring and daytime sleepiness; Lectured on the occasion of the "7th World Congress on Sleep Apnea" in Helsinki on 2 July 2003, partly published in "Das Schlafmagazin" 2003, 3: 9-10, 6) Maurer, JT, Hormann K, Huber, K et al.: A mandibular device for the ENT office to treat obstructive sleep apnea, Otolaryngol Head Neck Surg. 2007, 136: 231 – 235.

Detailed and continuously updated clinical trial data is published on [www.tomedcare.com](http://www.tomedcare.com)

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Self-check Questionnaire for Snorers

The Ruhrland-Hospital in Essen-Heidhausen (Germany), Department of Sleep Medicine, compiled the following questionnaire for the diagnosis of sleep apnoea. Complete all sections fully. By adding up your score, you can determine whether it is likely that you suffer from sleep apnoea and whether therefore you should consult your doctor who may refer you to a sleep laboratory for sleep study.

Score your answer to each question as follows:

0 = never, 1 = rarely, 2 = often, 3 = very often

Questions	0 never	1 rarely	2 often	3 v. often
1. Are you sleepy during the day?				
2. Do you doze off during the day spontaneously?				
3. Do you find it difficult to concentrate for long periods?				
4. Do you feel less efficient than you used to?				
5. Do you snore loudly or do others say you do?				
6. Has your partner witnessed you stopping breathing during your sleep?				
7. Do you wake up in the morning with headache?				
8. Do you feel tired and dizzy in the morning?				
9. Do you fall asleep when watching TV, reading, working at the office, driving car or talking to others?				
10. Do you have difficulties getting off to sleep at night?				
11. Do you wake up during the night?				
12. Do you wake up earlier than you used to, or is it taking you longer to get back to sleep than used to be the case?				
13. Do you fidget in your sleep and/or is your bed rumpled in the morning?				

The publication of this questionnaire was generously authorised by the Federal Sleep Apnoea Association of Germany e.V., Deipenbecktal 171, 45289 Essen; Phone: +49 (0) 20157 0657, Fax: +49 (0) 20157 2798; Internet: [www.bsd-web.de](http://www.bsd-web.de).

The likelihood with which sleep apnoea may be present, depends upon the total score as follows:

- 0 bis 14 Unlikely, everything appears to be ok
- 15 bis 25 Rather probable
- > 25 Very probable

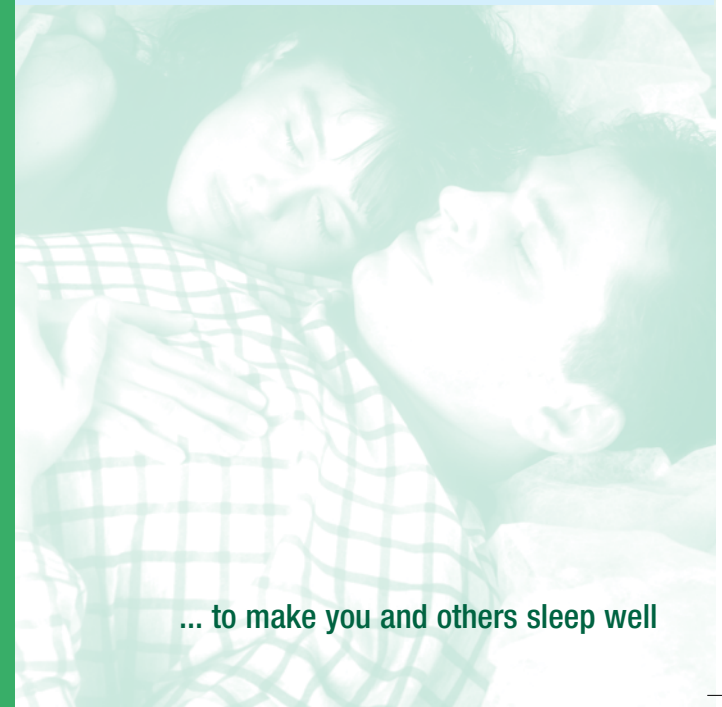
**TOMED**

Dr. Toussaint GmbH

*Dedicated to  
Customer Value*

**SomnoGuard®**

Intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnoea in adults



... to make you and others sleep well