

Snoring and Obstructive Sleep Apnoea

If you suffer from annoying snoring possibly resulting in the need for separate bedrooms, your problem may be reduced or even eliminated using modern appliance therapy. Between 10 and 30% of all adults snore, and in the age group 40 to 60, 60% of men and 40% of women snore, so you are not alone

During sleep throat muscles are relaxed. Thus, the rear throat range narrows itself. With the increasing pressure and the changed flow rate of the breathing air the soft parts begin to vibrate and the typical snoring sounds develop. Snoring in most cases does not require special treatment,

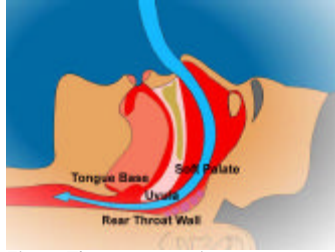


Fig. 1: The upper respiratory system

since, apart from the irritating noise which puts a great strain on relationships, it does not otherwise represent a serious health risk. This form of snoring (without breathing arrests and without any reduction in the blood oxygen levels, "Hypoxaemia") is often called primary or habitual snoring. Heavy snoring can on the other hand be a good indication of obstructive sleep apnoea syndrome (OSAS), which is a more serious breathing disorder. Patients with obstructive sleep apnoea have repeated breathing arrests ("Apnoeas"), sometimes lasting up to one minute - or longer, and this occurs several hundred times each night. The apnoeas result from the temporary blockage of the airway during inspiration. (See fig. 1 "A"). Sometimes the cause is a collapse of the bronchial tube. In the age group > 35, obstructive sleep apnoea occurs in approx. 2% of all women and 4% of all men. There are 2 to 3 million people alone in Germany suffering from this disease, which therefore has all the character of a public disease. Risk factor No.1 is obesity. Further predisposing factors include among other things: anatomical abnormalities in the jaw area, e.g., a receding chin, enlarged palate and throat tonsils, long and pendulous uvula, an enlarged tongue (fig. 1 "A"), blocked nose, alcohol consumption and sleeping pills.

Symptoms of the illness are: regular heavy snoring; excessive daytime sleepiness; reduced physical and mental agility; restlessness during sleep;; sleeping partner worried when breathing stops; disturbed sleep by micro-arousals; reduced libido; impotence and depression. If the respiratory system is not working properly, the organs are not properly oxygenated. Additionally, sleep apnoea can cause high blood pressure, heart failure and stroke. It is important for your health and well-being that a proper diagnosis differentiating primary snoring from obstructive sleep apnoea is made by your physician. 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. After taking a history your physician will examine the upper respiratory

system and if necessary perform further investigations to determine the type and cause of your sleep disturbances, such as:

- Measurement of your breathing patterns, oxygen saturation, heart rate, body position and body movement as well as snoring sounds with an ambulatory screening device that can be used at home during sleep
- Test sleep in the sleep laboratory ("polysomnography") to determine the following parameters: sleep stages (EEG, EMG and EOG), breathing flow, chest and abdominal movements, leg movements, cardioactivity (ECG), muscle tone (EMG), body position, oxygen saturation and snoring sounds.

Depending on the result of the tests the following therapy options may be proposed. There may be others not listed.

- Conversion of life style, e.g. weight reduction, improvement of the sleep hygiene, reduced alcohol consumption
- Drug treatment, e.g. with Theophyllin
- Use of mandibular advancement appliances such as SomnoGuard which advance your lower jaw and improve the airway at the base of the tongue. This option is most effective with obstructions at the tongue base.
- Machine based artificial pressure respiration, e.g. with nCPAP devices, for maintaining an open airway during sleep.
- Surgical intervention, e.g. removal or reduction of the soft palate and/or tonsils, uvula, and/or tongue base, lower jaw advancement.

SomnoGuard[®] – Mandibular Advancement Device for the Treatment of Snoring and Nocturnal Breathing Arrests

Worn in the mouth like a sports mouthguard, SomnoGuard reduces nocturnal snoring and apnoea occurring with obstructive sleep apnoea.

Description

SomnoGuard consists of a hypoallergenic thermoplastic body. It was developed in conjunction with the sleep laboratory of a German ENT university clinic and is based on clinical experiences over several years with the predecessor model SnorBan.

Fitting the appliance can be carried out without special equipment. After heating the mouthpiece in boiling water the appliance is carefully fitted with the lower jaw advanced by approx. 50 to 75 % of the maximum lower jaw extension. If necessary the appliance can be fitted for a second time in order to improve the fit. In the front of the appliance there is a small rectangular hole for situations which require emergency breathing, (e.g., blocked nose).



Fig. 2: Mouthpiece before fitting



Fig. 3: Mouthpiece after fitting

Clinical experience

Since the development of SomnoGuard is based on the clinical experiences made with its predecessor, its equivalence of efficacy was confirmed at 26 patients before market launch in comparison with the predecessor model SnorBan since middle of 1997. Regarding the reduction of snoring and the Respiratory Disturbance Index (RDI, being a measure for the number of breathing arrests and phases with decreased respiration per sleep hour) SomnoGuard proved thereby just as effective as the predecessor model. However, regarding tolerability and the mouthpiece's duration of life, clear improvements could be obtained with SomnoGuard. The clinical studies accomplished before with SnorBan are already published and furnished essentially the following results: In a clinical study enrolling 39 patients with sleep apnea performed at the sleep lab of the ENT university clinic of Mannheim (Germany) the authors J.T. Maurer, K. Hoermann et al. demonstrated that under SnorBan both the sleep architecture and the breathing disturbances as well as the snoring significantly improved. The period of snoring was lowered likewise highly significantly from 16,3% to 6,6%. A subjective improvement of snoring indicated 76.9% of the patients on asking. Likewise the RDI value was high-significantly lowered by SnorBan.

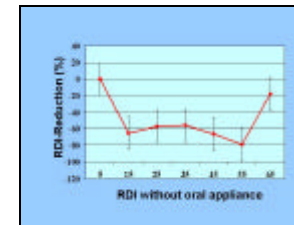


Fig. 4: Influence on RDI value

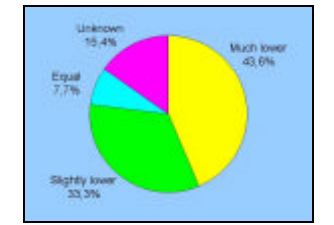


Fig. 5: Subjective influence on the sounds of snoring

The success rate, defined as a reduction in the RDI to <10 as success, amounted to 59.1% under polysomnographic control. Isolated observed side effects were brief morning toothache, temporary jaw pain as well as increased salivation during the first few nights of use. A few patients also reported nausea. The acclimatizing time was between 0 and 21 days but only 4 days on average. In a second study of patients suffering predominantly from obstructive sleep apnoea, which was performed at a respiratory hospital at Schmalleberg, in cooperation with the dental medicine university hospital of Marburg (both sites located in Germany), the authors B. Schoenhofer, D. Koehler et al. reported

a clinically significant improvement of 50% in 22 patients using SnorBan. Side effects observed in this study were comparable to those of the first study noted above.

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 control, for obstructive sleep apnoea.

Hints for doctors' prescriptions

SomnoGuard is listed under item number 14.24.07.3001 in the medical aid directory of the Central Association of the German Health Insurances. Therefore, all German health insurance companies are now responsible for the costs of buying SomnoGuard if the patient suffers from obstructive sleep apnoea. On the prescription the medical diagnosis must be noted by the physician. SomnoGuard (PZN 1423323) is available in pharmacies or direct from Tomed. If Tomed receives patients' prescriptions they will deliver SomnoGuard without freight charges and invoice the relevant health insurance companies.

Distributor:

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Self-check questionnaire for snorers

The Ruhrland-Hospital in Essen – Heidhausen (Germany), Dep. 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. Enter the figures into the boxes below.

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 in the following situations, when:				
<input type="radio"/> watching TV? <input type="radio"/> reading?				
<input type="radio"/> working at the office? <input type="radio"/> driving car?				
<input type="radio"/> 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 sleep jerkily and/or is your bed disordered in the morning?				

The publication of this questionnaire was gratefully authorised by the Federal Sleep Apnoea Association of Germany e.V., Deipenbecktal 171, 45289 Essen, Phone: 02 01 / 57 06 57, Fax 02 01 / 57 27 98; Internet: www.bsd-web.de

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

- 0 - 14: unlikely, everything appears to be o.k.
- 15 - 25: rather probable
- > 25: very probable

SomnoGuard[®]

effectively stops annoying snoring and reduces nocturnal respiratory arrests



Position-No. in the German Medical Aid Directory:
14.24.07.3001

...to make you and others sleep well

Efficacy clinically proven

*Dedicated to
Customer Safety*

TOMED

Dr. Toussaint GmbH