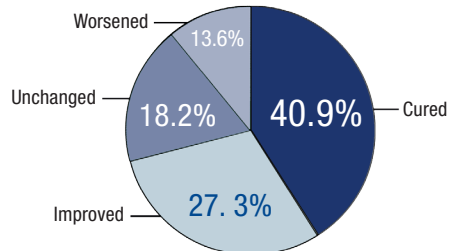
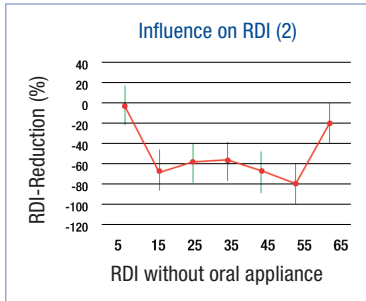


snoring and the respiratory parameters RDI, AI and HI (6). This leads to an improvement in sleep quality. The symptoms of obstructive sleep apnea, consistent with the success criteria of the trial, were classified as “improved” or “cured” in 68% of cases.



Clinical trial outcome in OSAS patients (6)

Similar outcome results have been reported in two clinical trials performed in Belgium by Vanderverken, Braem, van de Heyning (4, 5). The authors reported an



RDI reduction of 65% in the SomnoGuard pilot study of 20 patients (4). In both clinical trails (20 and 36 patients respectively) a major outcome was a significant reduction of daytime sleepiness and snoring.

Comparable results have also been published in a study by Schoenhofer, Hochban et al. (2).

Side Effects (N = 20)	1-Month	6-Months
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

Side-effects of SomnoGuard® observed in the pilot study (4)

Comfort

Studies show (1) that patients, on average, become accustomed to the SomnoGuard® device within 4 days (compliance rate of 74.4%). SomnoGuard® mandibular advancement devices are commonly very well tolerated as the table at the left demonstrates. Side-effects reported from all clinical trials performed to date 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 the SomnoGuard® AP, the classic SomnoGuard®, its predecessor model as well as direct customer feedback we conclude that the various SomnoGuard® oral appliances provide a very inexpensive, safe and effective mode for the treatment of snoring and also, under strict medical guidance, for obstructive sleep apnea.

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

Your prescribing physician:

Provided in the US by



854 US Route 3 • Holderness, NH 03245 • 866.720.8080 • Fax 800.918.7860  
Web: www.1stlinemedical.com • Email: customerservice@1stlinemedical.com

A Proud Member of



Manufactured by Tomed Dr. Toussaint GmbH  
Wiesenstr. 4 D-64625 Bensheim (Germany)



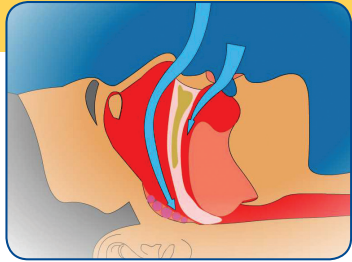
**References** 1) Maurer JT, Hormann K et al.: Einsatz eines intraoralen Schnarchtherapiegerätes aus thermolabilem Kunststoff, HNO 2000, 48: 302 – 308 2) Schoenhofer B, Hochbahn W, Köhler D et al.: Immediate Intraoral Adaptation of Mandibular Advancing Appliances of Thermoplastic Material for the Treatment 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, Willemsen, 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 Nec Surg. 2007, 136: 231 - 235. 7) Friedman M, Pulver T, Wilson M, When OSAHS surgery fails: Adjunctive treatment with MADs, lectured on the occasion of the “AAO-HNSF Annual Meeting” at San Diego on 7 October 2009, abstract published in: Otolaryngol Head Nec Surg. 2009, 141 (3S1): 123-124.

SomnoGuard®  
Mandibular Advancement Devices

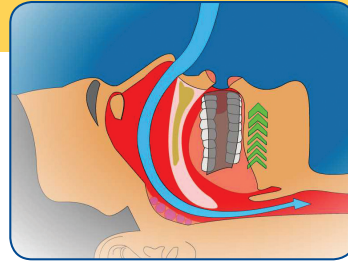
Clinically proven in the treatment of snoring and mild to moderate obstructive sleep apnea in adults.



... dedicated to making you and others sleep well!



Blockage of the upper airway



Open airway with oral device

## Basics

### Snoring and obstructive sleep apnea

Obstructive sleep apnea results from the temporary blockage of the upper airway during inspiration. 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.

Mandibular advancement devices are important alternatives in the treatment of snoring and obstructive sleep apnea. These appliances advance your lower jaw, extend the airway at the base of the tongue and reduce the speed of the inspired air.

Before treatment, it is important that a proper diagnosis is made by your physician differentiating habitual snoring from obstructive sleep apnea. The treatment your doctor recommends will depend on your test results.

### The SomnoGuard® Advantages:

- Highly cost effective (often covered by insurance)
- Easy handling and care
- Well tolerated by most patients
- Lightweight and therefore easy to travel with
- Easily fitted in minutes by any physician or their trained staff

**In brief the SomnoGuard® oral appliances are a good choice for mobile active men and women to cope with snoring and obstructive sleep apnea.**

## SomnoGuard® AP

### Two-part infinitely adjustable mandibular positioner

SomnoGuard® AP is a unique mandibular advancement device. Lateral movement of the lower jaw and an infinitely adjustable protrusion are key features. SomnoGuard® AP consists of an upper and a lower tray each made of two materials. The outer shell is made from solid, clear and transparent medical grade polycarbonate. The inner lining, which accommodates the teeth impressions, is made from a thermoplastic copolymer. After the oral appliance is heated in hot water its thermoplastic body molds easily to the teeth and jaw allowing any medical doctor to fit the device chair side.



SomnoGuard® AP before and after fitting



SomnoGuard® before and after fitting



### Specific features:

- Infinitely adjustable for improved patient comfort and clinical efficacy
- Permits lateral movement of the lower jaw to address bruxism
- Unrestricted mouth breathing if necessary
- Fixed and stable retention by deep teeth and jaw impressions
- Lightweight and durable construction
- May be refitted to improve comfort
- For use preferably by patients with a normal or larger jaw size and bruxists

An adjusting screw, made of stainless steel, allows the anterior adjustment of the lower tray against the upper tray between 0 and about 10 mm depending on the length of the screw used. The adjustment is only possible extra-orally and when the upper and lower trays are disassembled. Disassembling both trays is also necessary for cleaning.

By using the scale on both sides of the thread you can precisely control the adjustment with an accuracy of about 0.5 mm. Upper and lower trays can be moved laterally.

### Important:

Several years of experience in many markets shows that the dimension of the trays assures a proper fit for almost all patients. In the case of very small or very large jaw sizes a dentist may be able to trim parts off the hard transparent outer tray to fit the device.



Adjustment scale on lower tray



Side view of the appliance

## SomnoGuard®

### One-part mandibular advancement appliance

SomnoGuard® consists of a hypoallergenic thermoplastic body. After heating the appliance in boiled water the thermoplastic copolymer becomes soft and moldable. While soft, the appliance is fitted to the patients' upper and lower jaw and when cooled it is ready to be worn at night. Fitting the appliance can be carried out without special equipment.

### Specific features:

- Fitting possible to any jaw size
- Average life of about one year, and therefore good for short to medium term use

## Clinical experience with SomnoGuard® Oral Appliance Therapy

Clinical efficacy has been well-proven by several clinical trials performed with the SomnoGuard®, with success rates between 50 to 80% in reducing snoring and RDI (Respiratory Disturbance Index). Literature references can be found at the end of this brochure, and clinical trial data is published on [www.tomedcare.com](http://www.tomedcare.com).

Patients who had tried and failed both CPAP and surgical therapy were enrolled by Friedman, Pulver and Wilson in a prospective, non-randomized study in a U.S. tertiary care center. The authors report classic cure in 56% of patients with severe OSAHS (obstructive sleep apnea hypopnea syndrome) and 56% of patients with mild to moderate OSAHS based on an evaluation by polysomnography for both the SomnoGuard® AP (N = 25) and the SomnoGuard® (N = 20). Acceptance of the MADs was >80%. At three months, 73% of patients were still using the device, comparing favorably with reported compliance of dental devices (7).

In a separate clinical trial with 44 sleep apnea 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

(Cont.)