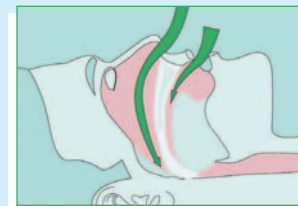


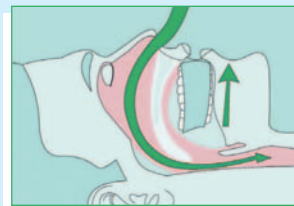
Basics

Obstructive sleep apnoea 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 appliances gain growing importance as treatment alternatives to nCPAP in the treatment of snoring and obstructive sleep apnoea. These appliances advance your lower jaw forward, thereby extending the airway at the base of the tongue and reducing the speed of the inspired air.



Blockage of the upper airway



Open airway with oral device

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.

Tomed offers currently a series of four different oral appliances which all have the following advantages.

Common advantages:

- Highly cost effective
 - Easy handling and care
 - Lightweight and therefore easy to travel with
- In brief a good choice for mobile and active men.

SomnoGuard® and SomnoGuard 2.0®

One-part thermoplastic mandibular advancement devices to treat snoring and mild to moderate obstructive sleep apnoea

Both appliances consist of a hypoallergenic thermoplastic body. After heating the appliance in water that has been boiled 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. SomnoGuard® 2.0 is a modified appliance that accords 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® before and after fitting



SomnoGuard® 2.0

Features and advantages:

- Easy fitting within minutes, preferably by physicians or their trained staff
- Clinical efficacy well proven by several clinical trials performed with the SomnoGuard® with success rates between 50% to 80% in reducing snoring and RDI (i.e. Respiratory Disturbance Index). Literature references can be found at the end of this brochure and the detailed actual clinical trial outcome data is published on www.tomedcare.com
- Normally very well tolerated. Minor and temporary side effects refer mainly to hypersalivation and morning discomfort
- Average life of about one year, and thus considered for short to medium term use
- The most cost-effective option to treat snoring and sleep apnoea

SomnoGuard® AP

Two-part mandibular adjustable positioner with thermoplastic body to treat snoring and mild to moderate sleep apnoea

SomnoGuard® AP is a unique mandibular advancement device. Lateral movement of the 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 tray shells consist of solid clear and transparent medical grade polycarbonate. The inner lining which accommodates the teeth impressions is made of a thermoplastic copolymer as it is similarly used with the SomnoGuard® monobloc appliances. After the oral appliance is heated in a hot water bath its thermoplastic body moulds easily to the teeth and jaws allowing any medical doctor to fit the device chair side.



SomnoGuard® AP before and after fitting

Features and benefits:

- Titratable advancement of the lower jaw from 0 to approx. 12 or more millimetres depending on the length of the adjusting screw used
- Limited lateral movement of the lower jaw
- Unrestricted mouth breathing if necessary
- Fixed and stable retention by deep teeth and jaw impressions
- Lightweight and durable construction
- Easy fitting within minutes by any doctor or even the patients themselves
- Highly cost-effective
- Considered for medium term use up to two years

An adjusting screw made of stainless steel allows the anterior adjustment of the lower tray against the upper tray between 0 and about 12 mm or even more 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 exactly control the adjustment with an accuracy of about 0.5 mm. Upper and lower trays can be moved laterally.



Scale on lower tray

Important:

The appliance fits jaw impression tray sizes S (small), M (medium) and L (Large). 90% to 95% of the total population are covered by these impression tray sizes. In case of very small (S) or very large (XL) jaw sizes your dentist may be able to trim off parts of the hard transparent outer shell tray to fit the device. If you are not aware of your personal impression tray size please ask your dentist for advice.

SomnoGuard® AP Pro

Dental lab made two-part mandibular adjustable positioner to treat snoring and mild to moderate sleep apnoea

The SomnoGuard® AP Pro can easily be constructed from common acrylic/elastomeric thermoform dental materials in any dental lab after taking impressions of the lower and upper jaws and producing plaster models. The components used to connect the upper and lower trays of the dental appliance and enable the infinite advancement of the lower jaw are made from stainless steel.

The components' technology is based on the preceding development of the SomnoGuard® AP. The components are very durable, more or less indestructible, inexpensive and can most often be reused when the oral appliance has to be re-made for some reason.



SomnoGuard® AP Pro



Stainless steel components

As well as the advantages of the SomnoGuard® AP, the dental device SomnoGuard® AP Pro provides the additional benefit that even patients with missing teeth or dentures can wear it.

SomnoGuard® AP Pro is considered for long term use between about three to five years or longer. However, as with any oral appliance, regular checkups with your dentist are recommended.

We supply the metal components for the fabrication of the SomnoGuard® AP Pro only to dentists and dental labs.

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

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 sleep jerkily and/or is your bed disordered in the morning?				

The publication of the questionnaire was gratefully authorised by the Federal Sleep Apnoea Association of Germany e.V.; 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

Date of information: 01.10.2005



TOMED

Dr. Toussaint GmbH

*Dedicated to
Customer Value*

SomnoGuard® Mandibular Advancement Devices

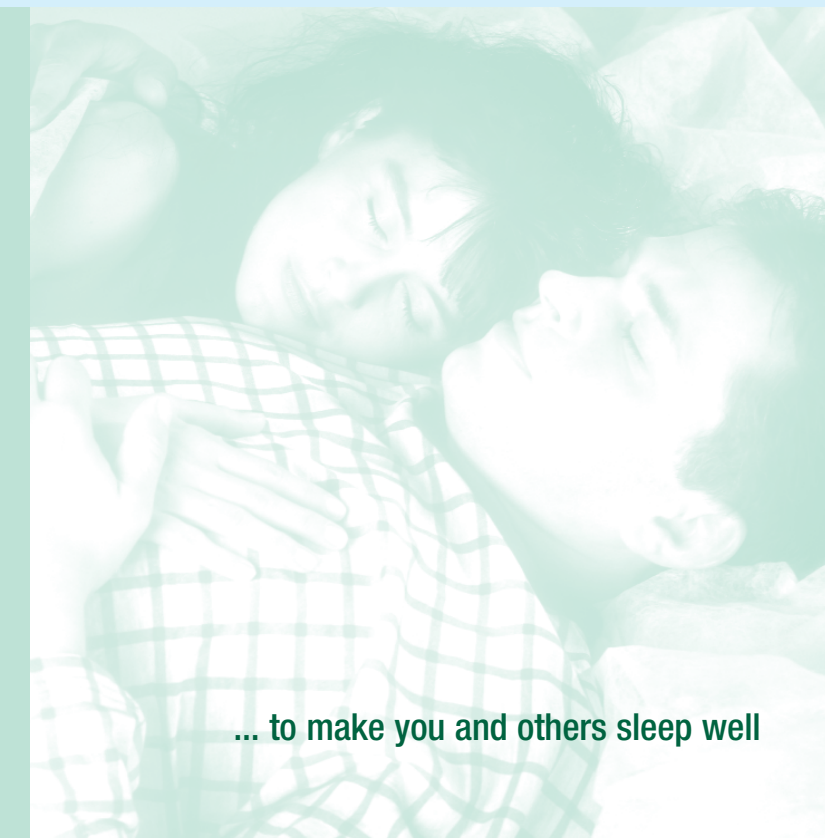
effectively stop annoying snoring, and reduce nocturnal respiratory arrests due to sleep apnoea.



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... to make you and others sleep well