SomnoGuard®
Mandibular Advancement Devices

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

...to make you and others sleep well!
Basics

Snoring and obstructive sleep apnoea

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 are important alternatives to nCPAP in the treatment of snoring and obstructive sleep apnoea. 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 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 oral appliances have the following advantages:

• highly cost effective
• easy handling and care
• lightweight and ideal for travel

In brief the SomnoGuard® oral appliances are a good choice for mobile active men and women to cope with snoring and obstructive sleep apnoea.
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 moulds easily to the teeth and jaws allowing any medical doctor to fit the device chair side.

Specific features:

- Infinite adjustment of the lower jaw advancement from 0 to about 10 mm depending on the length of the adjusting screw selected
- 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
- For use preferably by patients with a normal or larger jaw size
- Suitable for bruxists, however life span may be reduced considerably
SomnoGuard® AP Pro Stainless steel components

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 outside the mouth 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.

Sleep Nasendoscopy
A specific tool kit is available for sleep labs to monitor effectiveness of mandibular advancement devices during sleep nasendoscopy. It consists of a 40 mm long adjustment screw and both a lock - and knurled nut. The kit enables adjustment of lower jaw protrusion from outside the mouth with the device in place.

SomnoGuard® AP Pro
Custom made two-part infinitely adjustable mandibular positioner

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, almost indestructable, inexpensive and can generally be reused when the oral appliance has to be re-made for any reason.

As well as the advantages of the SomnoGuard® AP, the SomnoGuard® AP Pro has the added benefit that even patients with missing teeth or dentures can wear it.
The SomnoGuard® AP Pro is likely to last several years. 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.

**SomnoGuard® SP**
Two-part incrementally adjustable mandibular positioner

This oral appliance is available with two different soft and hard thermoplastic impression materials. The lining of the identical trays of SomnoGuard® SP Soft is made from a soft, transparent copolymer. On the other hand, SomnoGuard® SP Hard’s lining is made from a hard white copolymer. After the fitting process teeth are embedded firmly either into the soft or hard thermoplastic material. Two connectors of equal length combine laterally the upper and lower jaw trays and enable the advancement of the lower jaw. Depending on the length of the connector pair chosen the mandible can be advanced up to 10 mm in 1 mm increments. This type of mandibular positioner can be worn by patients with a retrognathic bite.

The SomnoGuard® SP Soft offers the greatest comfort, and the SomnoGuard® SP Hard the ultimate grip on the teeth. It is sometimes desirable to combine the benefits of both SomnoGuard® SP Hard and SomnoGuard® SP Soft, by using one tray of the SomnoGuard® SP Hard on the lower teeth, and one tray of the SomnoGuard® SP Soft on the upper teeth.
Specific features:

- Minimum size for maximum comfort
- Incremental advancement of the lower jaw from about -3 to +10 mm in 1 mm steps
- Very low bite opening, i.e., the distance between the upper and lower incisors is only about 2 or 3 mm
- Design allows lateral movement of the lower jaw
- Limited mouth breathing is possible
- No metal components
- Lightweight and durable construction
- Often preferred by women with a small jaw, a retrognathic or a deep bite

Important: The SomnoGuard® SP Hard or even a single tray of this oral device should only be fitted by medical professionals or dentists experienced in the use of this mouldable dental impression material. For further information please refer to the user instructions, downloadable from www.tomedcare.com.

SomnoGuard® 3
One-part mandibular advancement appliance

SomnoGuard® 3, the improved successor of the classic SomnoGuard® and the SomnoGuard® 2.0, consists of a hypoallergenic thermoplastic body. Compared to its earlier versions it has an improved retention resulting from a new design. After heating the appliance in boiled water the thermoplastic copolymer becomes soft and mouldable. While soft, the appliance is fitted to the patients’ 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.
Specific features:
- Easily fitted in minutes, preferably by physicians or their trained staff
- Clinical efficacy well proven by several clinical trials performed with the predecessor SomnoGuard® with success rates between 50 to 80% in reducing snoring and RDI (Respiratory Disturbance Index).
- Normally very well tolerated but minor, temporary side-effects such as hypersalivation and morning discomfort are sometimes noted
- Average life of about one year
- Fitting possible to any jaw size
- The most cost-effective option to treat snoring and sleep apnoea

Clinical experience with the SomnoGuard® series of oral appliances

Banhiran et al. had assessed outcomes of a SomnoGuard® AP treatment including efficacy, adverse effects and quality of life in 64 patients (1). Inclusion criteria were patients with OSA (obstructive sleep apnoea) who had failed or refused CPAP and surgery. Exclusion criteria were insufficient teeth, active intraoral disease, and temporomandibular joint (TMJ) disorders. Outcomes were measured using polysomnography, symptom questionnaires, Epworth sleepiness scale (ESS) before treatment and 4 to 6 months thereafter. Mean Apnoea Hypopnoea Index (AHI) and ESS scores decreased from 17.7 ± 14.6 to 7.5 ± 10.9 and from 8.7 ± 4.9 to 6.5 ± 4.4 respectively after treatment (p < 0.001). 39 patients (60.9%) achieved post-treatment AHI of < 5 with the highest success rate in those with mild OSA (75%). A good response defined as post-treatment AHI < 5 plus an AHI reduction of > 50% from baseline was seen in another 13 (20.3%) patients. Adherence to treatment was considered good. Most adverse effects observed such as excessive salivation, dry mouth, temporary TMJ discomfort were mild to moderate and tolerable. Just 4 patients discontinued treatment due to the observed adverse effects.
Doctors conclude that OSA treatment with the SomnoGuard® AP provides good outcomes including improved quality of life. The ready-to-use nature and low cost of the therapy are major advantages.

Other clinical trials with the application of the SomnoGuard® AP had been performed in the U.S. by Friedman et al. providing largely similar outcomes (2 - 4). In a prospective, non-randomized comparative cohort study enrolling altogether 87 patients with OSA, who had tried and failed both CPAP and surgical therapy, had been treated with three different prefabricated oral devices (4). Thereby, objective response defined by a 50% or greater reduction in AHI and AHI < 20 regarding the SomnoGuard AP (N=41) was 66%. Mean AHI of this device dropped from 45.1 to 12.8, and mean SpO2 value increased from 81.1% to 90.5%.

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 Respiratory Disturbance Index (RDI), Apnoea Index (AI) and Hypopnoea Index (HI) (5). This leads to an improvement in sleep quality. The symptoms of obstructive sleep apnoea, consistent with the success criteria of the trial, were classified as „improved“ or „cured“ in 68% of patients.

Similar outcome results had been reported in two clinical trials performed in Belgium by Vanderverken, Braem, van de Heyning (6, 7). The authors reported an RDI reduction of 65% in the SomnoGuard® pilot study of 20 patients (6). In both clinical trials (20 and 36 patients respectively) a major outcome was a significant reduction of daytime sleepiness and snoring.

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 to 8.2 in the whole group (8). Total snoring time dropped from 16.3 to 6.6%. 59.1% of the sleep apnoea patients were successfully treated as their RDI dropped below 10. Comparable results had also been published in a study by Schoenhofer, Hochban et al. (9).
Comfort

When wearing SomnoGuard® for the first time side-effects like short-term toothaches in the morning, temporary jaw joint pains or excessive salivation were reported sporadically. The device can trigger a gag reflex, but this is rare. In the trial with the predecessor habituation time was between 0 and 21 days, the average was 4 days and the compliance rate 74.4% (8). 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 (5, 6). A similar incidence of side-effects had been reported for all clinical trials performed to date (1 - 9).

Conclusion: From the extensive clinical investigations with the SomnoGuard® AP, the one-part classic SomnoGuard® and its predecessor model as well as from 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 mild and moderate obstructive sleep apnoea (OSA).

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. The table on the following page highlights the differences among the various prefabricated SomnoGuard® oral appliances and the custom made SomnoGuard® AP Pro.
Comparision of the SomnoGuard® series of oral appliances

<table>
<thead>
<tr>
<th>Feature</th>
<th>SomnoGuard® AP Pro (custom-made)</th>
<th>SomnoGuard® AP (prefabricated)</th>
<th>SomnoGuard® SP Soft (prefabricated)</th>
<th>SomnoGuard® SP Hard (prefabricated)</th>
<th>SomnoGuard® 3 (prefabricated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>good</td>
<td>very good</td>
<td>comparable to SomnoGuard® AP</td>
<td>comparable to SomnoGuard® SP Soft</td>
<td>good</td>
</tr>
<tr>
<td>Comfort</td>
<td>good</td>
<td>good</td>
<td>good</td>
<td>good</td>
<td>good</td>
</tr>
<tr>
<td>Ease of fitting</td>
<td>very easy</td>
<td>easy</td>
<td>medium (fitting by medical specialists)</td>
<td>very easy</td>
<td>easy</td>
</tr>
<tr>
<td>Refits possible</td>
<td>yes</td>
<td>yes</td>
<td>yes with restrictions</td>
<td>yes with restrictions</td>
<td>yes</td>
</tr>
<tr>
<td>Nose breathing</td>
<td>no</td>
<td>no</td>
<td>yes with restrictions</td>
<td>yes with restrictions</td>
<td>yes</td>
</tr>
<tr>
<td>Mouth breathing</td>
<td>no</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Retention</td>
<td>good to fair</td>
<td>good</td>
<td>good at upper jaw, fair at lower jaw</td>
<td>good at upper jaw, fair at lower jaw</td>
<td>good</td>
</tr>
<tr>
<td>Lower jaw advancement (lip to teeth)</td>
<td>0 to 10 mm, infinite adjustability</td>
<td>0 to 5 mm</td>
<td>0 to 10 mm, infinite adjustability</td>
<td>0 to 10 mm, infinite adjustability</td>
<td>0 to 10 mm, infinite adjustability</td>
</tr>
<tr>
<td>Vertical bite opening</td>
<td>2 to 3 mm</td>
<td>2 to 3 mm</td>
<td>2 to 3 mm</td>
<td>2 to 3 mm</td>
<td>2 to 3 mm</td>
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<tr>
<td>Average longevity</td>
<td>&gt; 18 months</td>
<td>&gt; 18 months</td>
<td>&gt; 18 months</td>
<td>&gt; 18 months</td>
<td>&gt; 18 months</td>
</tr>
<tr>
<td>Vertical bite opening</td>
<td>7 to 8 mm, normal bite conditions</td>
<td>7 to 8 mm, normal bite conditions</td>
<td>7 to 8 mm, normal bite conditions</td>
<td>7 to 8 mm, normal bite conditions</td>
<td>7 to 8 mm, normal bite conditions</td>
</tr>
</tbody>
</table>

Comments: 1) Efficacy is what counts predominantly. Efficacy is characterised by reduction of snoring and breathing arrests due to obstructive sleep apnoea to a normal or safe level. 2) Fitting quality determines treatment outcome. Even inexperienced people can obtain good fitting results with the 2-part SomnoGuard® AP or the SomnoGuard® SP Soft, fitting of the 1-part SomnoGuard® 3 is a little bit more difficult, and fitting quality depends more on experience. Due to its extraordinary retention SomnoGuard® SP Hard should only be fitted by experienced medical specialists. 3) If necessary mouth breathers can use a chin-up strip to keep the mouth closed when sleeping. 4) Longevity of SomnoGuard® SP’s connectors, as opposed to that of the trays, may be reduced considerably depending on usage patterns. 5) Vertical bite opening means the distance between the incisors with the device in place. A larger level of bite opening may influence tolerability and comfort using the oral appliance especially if the jaw size is quite small.
Self-check questionnaire for snorers

The Ruhrland-Hospital in Essen-Heidhausen (Germany), Dept. 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.

<table>
<thead>
<tr>
<th>Questions</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
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</thead>
<tbody>
<tr>
<td>1. Are you sleepy during the day?</td>
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<tr>
<td>2. Do you close off during the day spontaneously?</td>
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<td>3. Do you find it difficult to concentrate for long periods?</td>
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<td>4. Do you feel less efficient than you used to?</td>
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<tr>
<td>5. Do you snore loudly or do others say you do?</td>
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<tr>
<td>6. Has your partner witnessed you stopping breathing during your sleep?</td>
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<tr>
<td>7. Do you wake up in the morning with headache?</td>
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<tr>
<td>8. Do you feel tired and dizzy in the morning?</td>
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<td>9. Do you fall asleep when watching TV, reading, working at the office, driving car or talking to others?</td>
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<tr>
<td>10. Do you have difficulties getting off to sleep at night?</td>
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<tr>
<td>11. Do you wake up during the night?</td>
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<tr>
<td>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?</td>
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<tr>
<td>13. Do you fidget in your sleep and/or is your bed rumpled in the morning?</td>
<td></td>
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</tbody>
</table>

The publication of this questionnaire was gratefully authorised by the Federal Sleep Apnoea Association of Germany e.V. (wwwbsd-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: quite probable
> 25: very probable
References

5) Maurer JT, Hörmann K, Huber K et al., A mandibular device for the ENT office to treat obstructive sleep apnea, Otolarngol Head Neck Surg 2007, 136: 231 – 235  
7) 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, lecture at the „7th World Congress on Sleep Apnea“ in Helsinki on 2 July 2003, published in “das schlafmagazin”, 2003, 3: 9–10  

Detailed and continuously updated clinical trial data as well as the user instructions are published on www.tomedcare.com

TOMED has implemented a quality management system which complies with the following standards and regulations:
– 21 CFR Part 820, Quality System Regulations
– MDD 93/42/EEC and 2007/47/EC, Medical Device Regulation of the EC

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