

TOMED



Dr. Toussaint GmbH

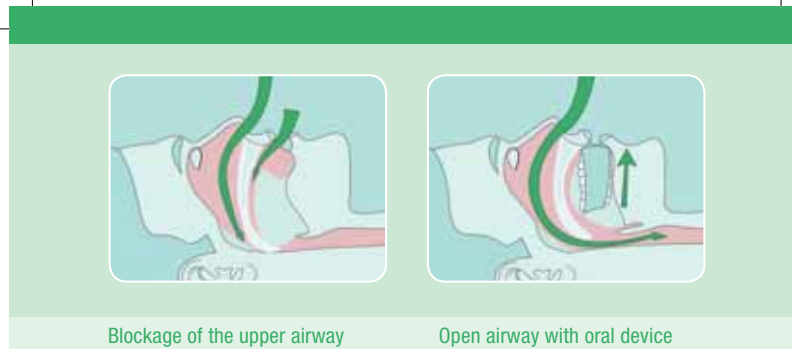
*Dedicated to
Customer Value*



**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 therefore easy to travel with

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 before and after fitting

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 approx. 10 millimetres depending on the length of the adjusting screw used
- 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 and bruxists



Scale on lower tray



Side view of the appliance



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 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.

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 indestructible, 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 Somno-Guard® AP Pro provides the additional benefit that even patients with missing teeth or dentures can wear it.



SomnoGuard® SP Soft before and after fitting

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 thermoplastic impression materials; Soft and Hard. 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 10mm. This type of mandibular positioner can be worn by patients with a retrognathic bite.



SomnoGuard® SP Combination of Soft and Hard trays

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.



SomnoGuard® SP Hard before and after fitting

Specific features:

- Minimum size for maximum comfort
- Incremental advancement of the lower jaw from about -3 to +10 millimetres
- Very low bite opening, i.e., the distance between the upper and lower incisors is only about 2 or 3 mm
- Design allows side-to-side movement of the lower jaw
- Limited mouth breathing is possible
- No metal components
- Lightweight and durable construction
- For use preferably by patients having a smaller jaw size (i.e. mainly women) or having a retrognathic or 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®

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 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 SomnoGuard® with success rates between 50 to



SomnoGuard® before and after fitting

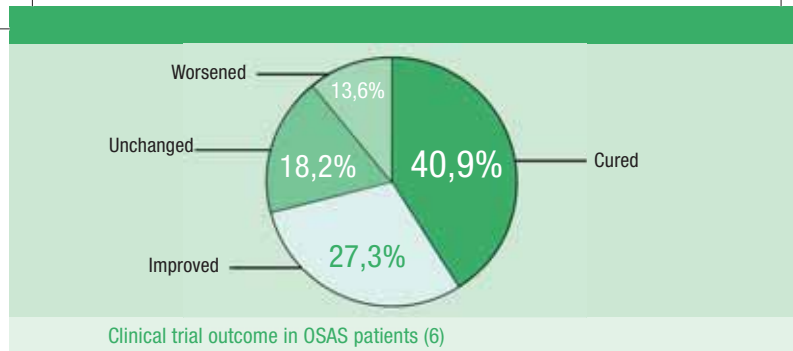
80% in reducing snoring and RDI (Respiratory Disturbance Index). Literature references can be found at the end of this brochure. The detailed clinical trial data is published on www.tomedcare.com

- Normally very well tolerated but minor, temporary side-effects such as hypersalivation and morning discomfort are sometimes noted
- Average life of about one year, and therefore good for short to medium term use
- 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

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 centre. The authors report classic cure in 56% of patients with severe OSAHS (i.e. obstructive sleep apnoea hypopnoea 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® 2.0 (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).

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 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 cases.



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 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/hr to 8.2/hr in the whole group. 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/hr (1). Comparable results have also been published in a study by Schoenhofer, Hochban et al. (2).

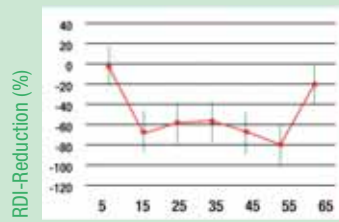
Comfort

When wearing SomnoGuard® for the first time side-effects like short-term toothaches in the morning, temporary jaw joint pains or hypersalivation 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% (1).

Side Effects (N = 20)	1-Month	6-Months
Hypersalivation	11	2
Morning discomfort	9	3
Loss of device	2	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)

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).



RDI without oral appliance

Influence on RDI (2)

Conclusion: 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 apnoea.

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.

Comparison of the SomnoGuard® series of oral appliances

Feature	SomnoGuard (prefabricated)	SomnoGuard AP (prefabricated)	SomnoGuard SP Hard (prefabricated) <i>New!</i>	SomnoGuard SP Soft (prefabricated) <i>New!</i>	SomnoGuard AP Pro (custom-made)
Efficacy ¹	good (when fitted correctly)	even better than SomnoGuard	pres. comparable to SomnoGuard AP	pres. comparable to SomnoGuard AP	comparable to SomnoGuard AP
Comfort	good	good	good	good	good
Ease of fitting ²	relatively easy	very easy	medium (fitting by medical specialists only)	very easy	Fabrication by dental labs
Refits possible	1 - 3	> 5	> 5	> 5	By dental labs only
Nose breathing required	yes	no	yes	yes	no
Lateral lower jaw movement possible	no	yes	slightly	slightly	yes
Mouth breathing possible	no	yes	yes with restrictions	yes with restrictions	yes
Retention ³ (grip to teeth)	fair	good	very good	good at upper jaw, fair at lower jaw	very good
Lower jaw advancement adjustable	0 - 5 mm	0 to 10 mm, infinite adjustability	stepwise from -3 to +10 mm	stepwise from -3 to +10 mm	0 to 12 mm, infinite adjustability
Average longevity ⁴ (subject to normal use)	12 months	≥ 18 months	approx. ≥ 18 months	approx. ≥ 18 months	≥ 18 months
Vertical bite opening ⁵	2 to 3 mm	7 to 8 mm, normal bite conditions	2 to 3 mm	2 to 3 mm	7 to 8 mm, normal bite conditions

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® is 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.

I 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 fidget in your sleep and/or is your bed rumpled in the morning?				

The publication of this questionnaire was gratefully authorised by the Federal Sleep Apnoea Association of Germany e.V. (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: quite probable

> 25: very probable

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 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.

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

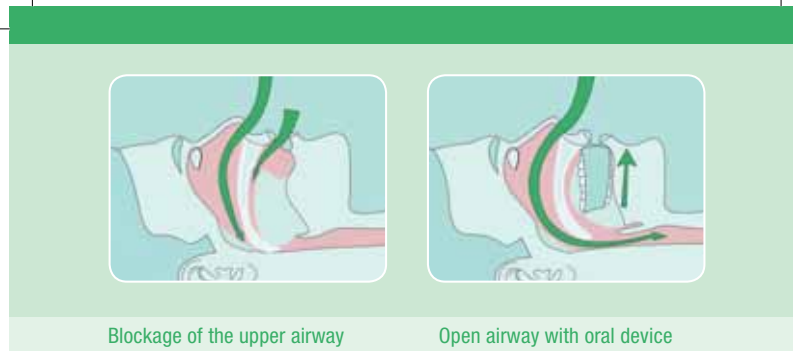
TOMED has implemented a quality management system which complies with the following standards and regulations: - 21 CFR Part 820, Quality System Regulations - DIN EN ISO 13485:2007, Harmonized Medical Devices QMS Standard - MDD 93/42/EEC and 2007/47/EC, Medical Device Regulation of the EC

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Basics

Snoring and obstructive sleep apnoea

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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.

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- highly cost effective
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- lightweight and therefore easy to travel with

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 before and after fitting

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 approx. 10 millimetres depending on the length of the adjusting screw used
- 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 and bruxists



Scale on lower tray



Side view of the appliance



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 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.

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 indestructible, 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 Somno-Guard® AP Pro provides the additional benefit that even patients with missing teeth or dentures can wear it.



SomnoGuard® SP Soft before and after fitting

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 thermoplastic impression materials; Soft and Hard. 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 10mm. This type of mandibular positioner can be worn by patients with a retrognathic bite.



SomnoGuard® SP Combination of Soft and Hard trays

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.



SomnoGuard® SP Hard before and after fitting

Specific features:

- Minimum size for maximum comfort
- Incremental advancement of the lower jaw from about -3 to +10 millimetres
- Very low bite opening, i.e., the distance between the upper and lower incisors is only about 2 or 3 mm
- Design allows side-to-side movement of the lower jaw
- Limited mouth breathing is possible
- No metal components
- Lightweight and durable construction
- For use preferably by patients having a smaller jaw size (i.e. mainly women) or having a retrognathic or 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®

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 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 SomnoGuard® with success rates between 50 to



SomnoGuard® before and after fitting

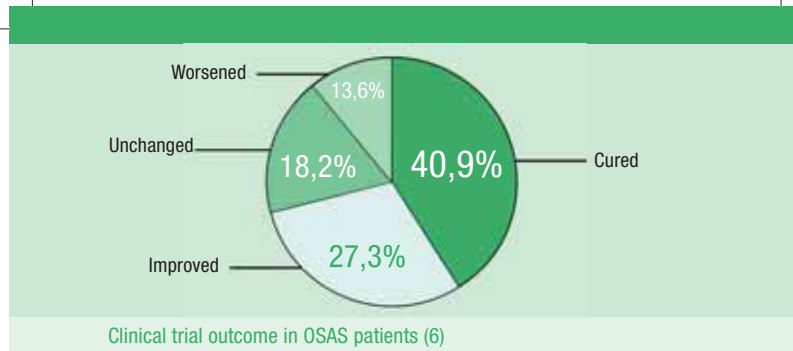
80% in reducing snoring and RDI (Respiratory Disturbance Index). Literature references can be found at the end of this brochure. The detailed clinical trial data is published on www.tomedcare.com

- Normally very well tolerated but minor, temporary side-effects such as hypersalivation and morning discomfort are sometimes noted
- Average life of about one year, and therefore good for short to medium term use
- 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

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 centre. The authors report classic cure in 56% of patients with severe OSAHS (i.e. obstructive sleep apnoea hypopnoea 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® 2.0 (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).

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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 trials (20 and 36 patients respectively) a major outcome was a significant reduction of daytime sleepiness and snoring.

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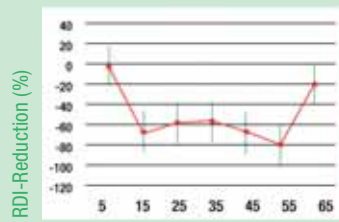
Comfort

When wearing SomnoGuard® for the first time side-effects like short-term toothaches in the morning, temporary jaw joint pains or hypersalivation 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% (1).

Side Effects (N = 20)	1-Month	6-Months
Hypersalivation	11	2
Morning discomfort	9	3
Loss of device	2	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)

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).



RDI without oral appliance

Influence on RDI (2)

Conclusion: 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 apnoea.

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.

Comparison of the SomnoGuard® series of oral appliances

Feature	SomnoGuard (prefabricated)	SomnoGuard AP (prefabricated)	SomnoGuard SP Hard (prefabricated) <i>New!</i>	SomnoGuard SP Soft (prefabricated) <i>New!</i>	SomnoGuard AP Pro (custom-made)
Efficacy ¹	good (when fitted correctly)	even better than SomnoGuard	pres. comparable to SomnoGuard AP	pres. comparable to SomnoGuard AP	comparable to SomnoGuard AP
Comfort	good	good	good	good	good
Ease of fitting ²	relatively easy	very easy	medium (fitting by medical specialists only)	very easy	Fabrication by dental labs
Refits possible	1 - 3	> 5	> 5	> 5	By dental labs only
Nose breathing required	yes	no	yes	yes	no
Lateral lower jaw movement possible	no	yes	slightly	slightly	yes
Mouth breathing possible	no	yes	yes with restrictions	yes with restrictions	yes
Retention ³ (grip to teeth)	fair	good	very good	good at upper jaw, fair at lower jaw	very good
Lower jaw advancement adjustable	0 - 5 mm	0 to 10 mm, infinite adjustability	stepwise from -3 to +10 mm	stepwise from -3 to +10 mm	0 to 12 mm, infinite adjustability
Average longevity ⁴ (subject to normal use)	12 months	≥ 18 months	approx. ≥ 18 months	approx. ≥ 18 months	≥ 18 months
Vertical bite opening ⁵	2 to 3 mm	7 to 8 mm, normal bite conditions	2 to 3 mm	2 to 3 mm	7 to 8 mm, normal bite conditions

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® is 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.

I 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 fidget in your sleep and/or is your bed rumpled in the morning?				

The publication of this questionnaire was gratefully authorised by the Federal Sleep Apnoea Association of Germany e.V. (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: quite probable

> 25: very probable