

# SomnoGuard<sup>®</sup> by TOMED GmbH

## Mandibular Advancement Devices

Oral Appliance solutions clinically proven in the treatment of snoring and mild to moderate obstructive sleep apnea in adults.

*... a valuable part of a comprehensive Sleep Practice*

SomnoGuard<sup>®</sup> AP



before and after fitting



SomnoGuard<sup>®</sup>



before and after fitting



**74%**  
reported compliance



**65%**  
AHI reduction

### Adjustable...

**...for optimum patient comfort, compliance and clinical efficacy.**

Easily fitted (10 to 15 minutes) by any physician or trained staff • Permits lateral movement

Highly cost effective - covered by most insurance policies • NO capital investment

***Several Practice Support Models are available.***

***SomnoGuard<sup>®</sup> FDA registered prescription based devices are eligible for insurance coverage.***

Provided in the US by



854 US Route 3 • Holderness, NH 03245 • 866.720.8080 • Fax 800.918.7860  
Web: [www.1stlinemedical.com](http://www.1stlinemedical.com) • Email: [customerservice@1stlinemedical.com](mailto:customerservice@1stlinemedical.com)



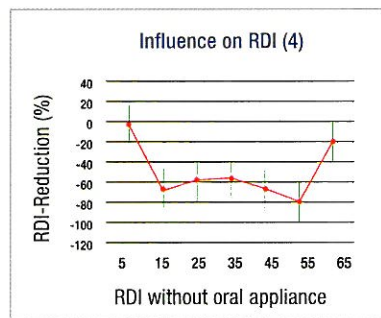
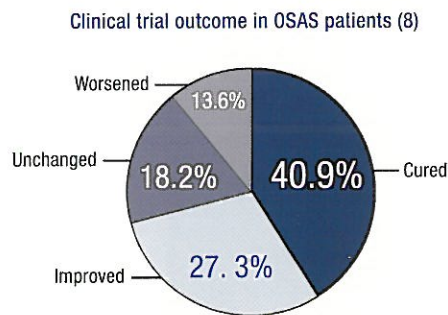
Part #	Description	Price
0302000	SomnoGuard – Unibody, Thermoformed Mandibular Advancement Device – Non-adjustable.	\$119.00*
0305000	SomnoGuard AP – Adjustable (Titratable) two-part Thermoformed Mandibular Advancement Device; Prefabricated; Custom-Fitted.	\$249.00*
031000	Fitting Kit for SomnoGuard Oral Appliances: SS Single Burner Hot Plate, SS Bowls (2), SS Scissors, SS Graspers, Timer.	\$99.00

\*Professional and volume discounts available.

### Insurance coding recommendations

<u>CPT</u> 21085	Impression and custom preparation; oral surgical splint, orthognathic code, coverage subject to specific plan inclusion, precertification recommended
<u>HCPCS</u> EO485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment

### REPORTED CLINICAL RESPONSE



### Comfort/compliance

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

Summary: 1) Friedman M, Pulver zzzz, Wilson M, When OSA surgery Fails: Adjunctive treatment with MADS

- A Prospective non-randomized US based study
  - 45 OSAS patients who had tried and failed CPAP and Surgical intervention
  - Authors report: CURE RATES for patients with mild OSA=100%, Moderate=60%, Severe=58.9%
- Initial acceptance of device=80%, 3 month Compliance rate=73%

**REFERENCES** 1) 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. 2) Marklund M, Franklin K, Persson M, Orthodontic side-effects of mandibular advancement devices during treatment of snoring and sleep apnea. European Journal of Orthodontics 23 (2001) 135-144. 3) Maurer JT, Hormann K et al.: Einsatz eines intraoralen Schnarchtherapiegerätes aus thermolabilem Kunststoff, HNO 2000, 48: 302 – 308 4) 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 5) Maurer JT, Hörmann K et al.: Kom-

binierte operative und prothetische Therapie bei schwerer Schlafapnoe – Ein Fallbericht, Laryngo-Rhino-Otol 2001, 80: 278 – 281 6) 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 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; 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. 8) 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.

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