

SomnoGuard[®] by TOMED GmbH

Family of Airway Stabilization Devices

In-office turn-key oral appliance solutions for
SNORING & OBSTRUCTIVE SLEEP APNEA

First Line Medical therapy solution now available
as an integral part of your practice

Improve Access · Lower Cost · Expedite Care · Optimize Outcomes

***Prefabricated,
Custom Fit***

SomnoGuard[®] AP2



SomnoGuard[®] SPX



*Appliances before and after:
15 minute, single-visit,
custom fitting process*

- Custom fit
- Precisely titratable
- FDA cleared for **both** OSA & snoring
- Fully engage Mandible and Maxilla
- Same day therapy initiation
- Unprecedented efficiency

74%
Reported
compliance

SomnoGuard[®] FDA registered prescription based devices are clinically proven in the treatment of snoring and mild to moderate OSA in adults and are eligible for insurance coverage

Lab-Manufactured

SomnoGuard[®] AP Pro

*Lab-manufactured appliance
from scan or impressions
Allow 4-6 weeks*

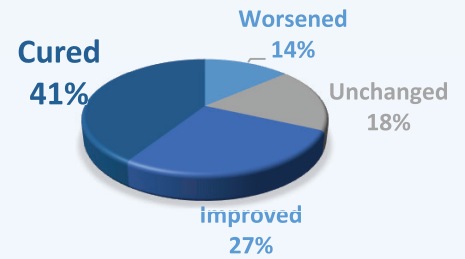


65%
AHI
Reduction

Part #	Description	Price*
03050200	SomnoGuard® AP 2 low profile titratable two-part thermoformed mandibular advancement device, prefabricated, custom fitted-indefinitely adjustable by titrating screw	\$259*
0309000	Somnoguard® SPX ultra low profile, two piece, two part thermoformed mandibular advancement device, high retention copolymer, custom fitted, precision turnbuckle titration	\$279*
0306000	SomnoGuard® AP Pro custom fabricated titratable oral appliance	\$395
SS031000P	Professional Fitting Kit warming kettle, bowl, scissors, timer and instructional practice support literature	\$175

*Professional and volume discounts available

Clinical trial outcome in OSAS patients

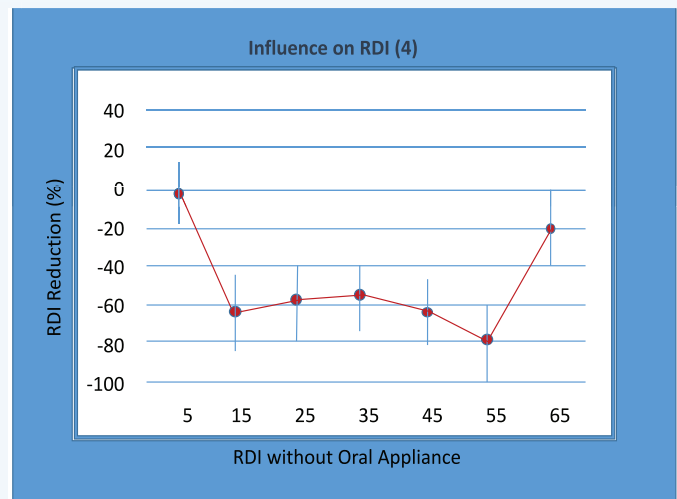


Summary: 1) Friedman M, Pulver zzzz, Wilson M, When OSA surgery Fails: Adjunctive treatment with MADS

- 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%

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/Teeth	6	2
Breathing Problems	4	2
Device to Large	4	0
Nausea	1	1
Suffocation	1	0
Altered Bite	0	0



Insurance coding recommendations

Codes	Description
EO485 (HCPCS)	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, pre-fabricated, includes fitting and adjustment
EO486 (HCPCS)	Custom fabricated appliance (SomnoGuard® AP Pro)
21085 (CPT)	Impression and custom preparation, oral surgical splint, orthognathic code, coverage subject to specific plan inclusion, precertification recommended

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, Willems, 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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