

## SomnoDent COAT® Continuous Open Airway Therapy



Comfortable and effective



SomnoDent® Flex on a typodont model  
to facilitate patient education

**SomnoDent®** – The comfortable and effective  
treatment for sleep apnea

### Clinically validated, proven and patented

- Clinically demonstrated to be effective in the treatment of OSA
- Recommended by insurance companies in many countries
- SomnoDent® devices are CE compliant

### Permits normal mouth opening and closing

- Allows speech and drinking during use
- No feeling of claustrophobia
- Permits full lip seal
- Comfortable to wear
- Discreet when worn
- Easy to travel with

### Comfortable, precise and effective

- Incremental precision adjustment to provide optimum fine-tuning
- Highly comfortable with SMH B-Flex
- High level of patient tolerance

### Gentle distribution of forces over all teeth

- Better protection for teeth because forces are evenly distributed over the two plates

### Custom-made quality construction

- Maximum comfort
- Durable, long life

### Customizable to suit the individual needs of patients

- Available with additional features to suit the individual requirements of patients.

### Patients confirm high effectiveness

- 96 % of patients with proven OSA stated that they would like to continue to use the SomnoDent® sleep apnea device.<sup>1) 2)</sup>
- 91 % of patients reported substantial improvement in sleep quality with the SomnoDent® sleep apnea device.<sup>2)</sup>

1) Mehta A, et al: A Randomized, Controlled Study of a Mandibular Advancement Splint for Obstructive Sleep Apnea. Am J Respir Crit Care Med 2001; 163: 1457–1461

2) Gotsopoulos H, et al: Oral Appliance Therapy Improves Symptoms in Obstructive Sleep Apnea. A Randomized, Controlled Trial. Am J Respir Crit Care Med 2002; 166: 743–748

## SomnoDent COAT® Sleep Apnea Device

### SomnoDent® sleep apnea devices are:

- scientifically validated
- clinically tested
- patented
- certified
- carry the CE mark
- manufactured in compliance with EN ISO 13485
- Class 1 custom-made medical devices



SomTabs – oral device cleaning tablet recommended by SomnoMed.



Order online at [www.somnomed.eu](http://www.somnomed.eu)



Training and further education  
in dental sleep medicine

**J J Thompson  
(Orthodontic Appliances) Ltd.**  
95 Hill Street - Sheffield, S2 4SP  
Tel: +44 (0)114 2759585  
Fax: +44 (0)114 2758385  
email: [info@jjthompson.co.uk](mailto:info@jjthompson.co.uk)  
[www.somnomed.eu](http://www.somnomed.eu)



When complete, the SomnoDent® sleep apnea device is carefully inspected and delivered to your practice, including a storage case, bite tab, titration tool and a set of User and Care Instructions.

### SomnoMed® – operates worldwide to promote a good night's sleep!

SomnoMed® is a company that operates worldwide in the field of medical technology, specializing in the development, manufacture and marketing of oral sleep devices to treat sleep-related breathing disorders.

Founded in 2004, SomnoMed® is headquartered in Sydney, Australia. In addition, the company has subsidiaries in Switzerland, Germany, France, Benelux, Sweden, Spain, USA, Japan, Singapore and the Philippines. In the UK, Italy, Canada and Hong Kong, SomnoMed collaborates with certified licence partners.

### Clinically validated, worldwide patented and with warranty

The SomnoDent® sleep apnea device is worldwide patented. Its clinical development began as early as twelve years ago. Since the company's foundation in 2004, the SomnoDent® sleep apnea device has been used for clinical treatment. In the meantime, more than 220,000 patients in over 20 countries have been treated with a SomnoDent® device. The SomnoDent® sleep apnea device offers a SomnoMed® warranty of 2 years ([www.somnomed.eu](http://www.somnomed.eu)).

SomnoMed AG is ISO-certified  
SomnoMed products are registered:  
EU, Switzerland, United States, Canada,  
Australia, South Korea, Japan, Hong Kong

SomnoMed products are  
patented and CE-compliant



**SomnoMed AG Europe**  
Baarerstrasse 125  
CH-6300 Zug  
Switzerland  
T +800-766-66-633  
[info@somnomed.eu](mailto:info@somnomed.eu)  
[www.somnomed.eu](http://www.somnomed.eu)

**SomnoMed**  
The Leader In COAT™  
(Continuous Open Airway Therapy)

# Open Your Airways – Start Breathing



**SomnoDent COAT®** Sleep Apnea Device.  
The comfortable and effective treatment for  
Obstructive Sleep Apnea (OSA) and snoring.

**SomnoMed**  
The Leader In COAT™  
(Continuous Open Airway Therapy)

### SomnoDent®

The SomnoDent® sleep apnea device is a mandibular advancement splint that provides highly effective treatment of Obstructive Sleep Apnea (OSA) and is very comfortable to wear for patients.

From making a diagnosis to assessing the treatment outcome, the interdisciplinary collaboration between sleep physicians (chest specialists, ENT specialists) and certified SomnoMed® dentists is essential for the successful treatment of OSA with a SomnoDent®.

#### Interdisciplinary diagnostics

If a sleep-related breathing disorder is suspected, initial patient assessment can be carried out with the help of questionnaires (Epworth Sleepiness Scale, Berlin questionnaire). A differential diagnosis by a sleep physician is required to establish if the patient is a sleep apneic.

If the results show that the patient is suitable for treatment with a SomnoDent® sleep apnea device, a certified SomnoMed® dentist will perform the measures necessary for obtaining a custom-made SomnoDent®.

**Note:** Only certified SomnoMed® dentists and/or dentists trained in sleep medicine can treat patients with a SomnoDent® device.

Please visit [www.somnomed.eu](http://www.somnomed.eu) to find out about how to receive certification.

#### Bite registration

SomnoDent® requires a protrusive bite registration. The degree of protrusion is a patient dependent variable; however, it should be approx. 70 % of maximum

protrusion. Use of a George Gauge® is recommended for bite taking. This simple instrument allows accurate recording of the patient's protrusive bite.

#### Increased effectiveness due to incremental precision adjustment

The mandibular advancement of the SomnoDent® sleep apnea device can be incrementally adjusted (titrated) with ease. This improves the efficacy and comfort level of the treatment. The jaw is moved only as far as required to alleviate the condition.

#### Gentle distribution of forces throughout the dentition

The SomnoDent® device incorporates all existing teeth. Over-eruption is prevented and oral forces are evenly distributed throughout the dentition. It is therefore essential that the impressions created by the dentist include all teeth.

#### Long life span

With proper care, the SomnoDent® sleep apnea device will have a life span of 3 to 5 years, even when used every night.

#### Evidence-based treatment method for patients with sleep-related breathing disorders

- \* Interdisciplinary diagnostic assessment and treatment recommendation by sleep physician and dentist
- \* Patient is treated by SomnoMed® dentist
- \* Dentist takes impression and bite registration
- \* SomnoMed® creates a custom-made device
- \* Fitting by SomnoMed® dentist
- \* Fine adjustment by SomnoMed® dentist
- \* 3- and 6-month follow-up appointment with sleep physician and/or SomnoMed® dentist

### That's how COAT® works

SomnoDent® is a custom-made oral device that is created on the basis of the patient's bite registration and consists of upper and lower dental plates.

A patented wing-coupling mechanism moves the jaw gently forward into the desired therapeutic position. This forward movement prevents the tongue from dropping back and tightens the soft tissues and muscles of the upper airway: the airways remain open effectively and reliably during sleeping. The tightening created by the forward movement also prevents the soft tissues of the upper airway from vibrating as air passes over them – the most common cause of loud snoring.

Patients particularly appreciate the fact that they can open and close the mouth and talk and drink as normally when they are wearing the device.

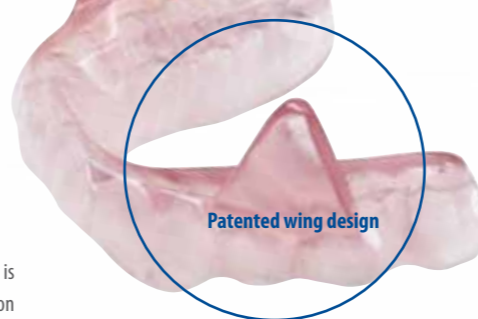


#### SomnoDent® Fusion with exchangeable wings

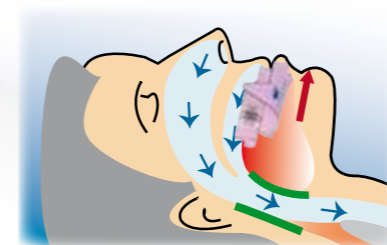
- wing components offering four adjustment levels for ergonomic comfort
- reduced lateral movement even at high levels of protrusion
- improved therapeutic adjustment of the mandibular advancement position

#### Recommended treatment method

The use of sleep apnea devices to treat sleep apnea (OSA) is recommended and prescribed not only by several specialist societies but also by insurance companies in many countries.



The SMH B-Flex lining maximizes patient comfort. The resulting high levels of patient satisfaction and acceptance contribute substantially to the therapeutic success of the treatment.



The patented wing-coupling mechanism gently moves the lower jaw into the desired therapeutic position and keeps the airway open during sleeping.

#### Tried, tested and ISO-certified

The SomnoDent® sleep apnea device conforms to the European Directive 93/42/EWG for **Class 1** custom-made medical devices and complies with the Medical Device Directive 93/42/EWG.

The device carries the **CE Mark**, is Swissmedic registered and is approved by the FDA in the USA and by the Japanese authorities as a medical device for the treatment of obstructive sleep apnea. All SomnoDent® devices meet the strict requirements of our QM system.

The devices are manufactured in compliance with the international standard **EN ISO 13485** for medical devices.

#### SomnoDent®: comfortable and effective – particularly in case of CPAP intolerance

	SomnoDent® COAT	CPAP
Permits normal mouth opening	✓	–
Allows speech and drinking	✓	–
Easy to travel with	✓	–
Noiseless	✓	–
Inconvenient face mask	–	✓
Limited sleep positions	–	✓
Complicated cleaning	–	✓
Requires power connection	–	✓

#### Efficacy backed by clinical studies and research results

Evidence of the effectiveness of SomnoDent® has been documented in several research studies.

#### Dental Appliance Treatment for Obstructive Sleep Apnea

Over the last decade, there has been a significant expansion of the evidence base to support the use of oral appliances, with robust studies demonstrating their efficacy. This work has been underpinned by the recognition of the importance of upper airway anatomy in the pathophysiology of OSA. CHEST: Official publication of the American College of Chest Physicians.

#### SomnoDent MAS™ is a viable alternative to CPAP in the treatment of OSA

Research and clinical trials by the Department of Respiratory and Sleep Medicine at St George Hospital, Sydney have found a high level of acceptance and tolerance amongst patients and concluded that the SomnoDent MAS™ is a viable alternative to CPAP in the treatment of OSA in a significant proportion of patients across all grades of OSA severity<sup>1, 2</sup>.

#### Oral Appliances for Snoring and Obstructive Sleep Apnea: A Review

Kathleen A. Ferguson, Rosalind Cartwright, Robert Rogers, Wolfgang Schmidt-Nowara. Division of Respirology, University of Western Ontario, London, Ontario, Canada, Department of Behavioral Sciences, Rush University Medical Center, Chicago, IL, Department of Dental Medicine, St. Barnabas Medical Center, Gibbstown, PA, University of Texas Southwestern, Sleep Medicine Associates of Texas, Dallas, TX.

The studies can be downloaded from [www.somnomed.eu](http://www.somnomed.eu)

### SomnoDent® – a suitable solution for every indication:



#### SomnoDent® Flex

The Flex version features a soft lining, providing an unparalleled fit. The splints are securely anchored with a snug fit and very comfortable to wear.



#### SomnoDent® Fusion

Fusion allows the ergonomic therapeutic advancement position to be determined accurately and precisely by changing the wings and, additionally, by adjusting the screws as necessary. Fusion is available with SMH B-Flex soft layer.



#### SomnoDent® Classic

The classic version is made from high quality acrylic. The acrylic has been specifically designed for splints that have to fulfil superior stability requirements.



#### SomnoDent® Edent Flex

The SomnoDent® Edent is available in the versions Flex and Classic for patients with an edentulous upper jaw.



SMH B Flex is a patented material featuring unique resilient properties that provide tooth- and palate-friendly soft dental surfaces and ensure a snug fit to the teeth and jaw.

SomnoDent® can also be used in combination with implant systems. It can be adjusted to meet the specific needs of the individual patient and employed for therapeutic treatment. Adjustment options include e.g. elastic retention and vertical adaptation.