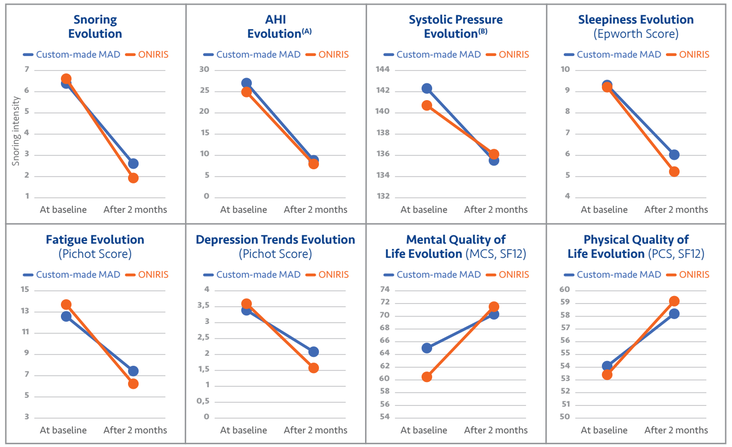
ONIRIS® is the first "boil and bite" MAD not inferior to custom-made MAD [2]

The IRIS clinical study is the largest multi-centric randomized controlled study in the field:

- 200 patients refusing or not tolerating CPAP
- Control MAD: Custom-made MAD TALI type (LPPR : 2455325)
- 1 year of follow-up
- 7 recruiting centers
- In Intention to Treat (ITT) and Per Protocole (PP) analysis.

The results show ONIRIS'® non-inferiority at 1 year and 2 months of follow-up, regardless of the investigation center, analyzed population (ITT or PP), gender, BMI or OSA severity.



(A) Evolution of AHI for responding patients (B) Evolution of systolic blood pressure for patients having high blood pressure

These results are consistent with the Haute Autorité de Santé (HAS) report on custom-made MAD [3] and the latest meta-analysis on custom-made MADs [4][5].

In the patients' case of CPAP refusal or intolerance, the ONIRIS® MAD is not inferior to custom-made MAD.

Because they have a reasonable price and a quick and easy fitting, ONIRIS® devices are particularly interesting prior to custom-made MADs' treatment or in addtition to a CPAP treatment.

For more information, to receive order forms or a sample, please contact us:
By phone: +33 1 47 16 17 17, **By email:** contact@oniris-snoring.com

ONIRIS
Dental Sleep Medicine

A complete line of device against snoring and OSAS

It is a significant challenge to treat successfully patients that are suffering from snoring and sleep apnea while taking into account their difficulties and economic realities. This is why it is essential to offer them the most appropriate and efficient treatment (efficiency / price).

Our devices TALI, ONIRIS and ONIRIS PRO are the subject of several multicentric clinical studies [1; 2; 6-9], proving their efficiency in the long run over snoring and mild, moderate and severe sleep apnea.

	ONIRIS	ONIRIS Pro™	TALI
Snoring	✓	✓	✓
Sleep Apnea	✓	✓	✓
Freedom of movement	✓	✓	✓
Personalized mm advancement	✓	✓	✓
Personalized print	✓	✓	✓
Dentist fitting		✓	✓
Validated by the French Haute Autorité de Santé		✓	✓
Custom-made device			✓
Fitting timing	**24 to 48 hours**	**15 to 30 days**	**3 to 4 months**
Lifetime duration	**18 to 24 months**	**18 to 24 months**	**5 years**
Price range excluding reimbursement (fitting fee included)	**60 to 80 €**	**200 to 300 €**	**600 to 800 €**
Price fixed by the LPP		**69 € (LPP 2465967)**	**459 € (LPP 2455325)**
Reimbursement Conditions by the French Social Security System	**OSAHS patients with at least 3 of the following symptoms: daytime somnolence, daily severe snoring, chocking and suffocation feeling during sleep time, daytime tiredness, nocturia, morning cephalgias. • As first line treatment, if 15 ≤ AHI ≤ 30 with no serious sign associated • As second line indication in case of CPAP refusal or intolerance : - If AHI > 30; - If 15 ≤ AHI ≤ 30 with serious sign associated**		

Do you have a question? A patient in need of advice? Contact our specialists!
By phone: + (33) 1 47 16 17 17 - By email: contact@oniris-snoring.com

Today, with more than a 10-year experience and more than 100, 000 patients treated with our devices, we offer our knowhow to provide you with quality devices, enabling a custom-made, innovative and easy-to-use treatment agai nst snoring and sleep apnea for your patients.

[1] Marty, M. Lacaze, O. Arreto, C. D. Pierrisnard, L. Bour, F. Chéliout-Héraut, F. and Simonneau, G. (2015), Snoring and Obstructive Sleep Apnea: Objective Efficacy and Impact of a Chairside Fabricated Mandibular Advancement Device. Journal of Prosthodontics. doi: 10.1111/jopr.12401. **[2]** Pepin JL, Raymond N, Lacaze O, et al. Heat-moulded versus custom-made mandibular advancement devices for obstructive sleep apnoea: a randomised non-inferiority trial. Thorax 019;0:1–8. doi:10.1136/thoraxjnl-2018-212726 **[3]** Haute Autorité de Santé. Évaluation clinique et économique des dispositifs médicaux et prestations associées pour la prise en charge du syndrome d'apnées hypopnées obstructives du sommeil (SAHOS). Volet 1 - Volet médico-technique et évaluation clinique. Juillet 2016. **[4]** Sharples LD., et al. Meta-analysis of randomised controlled trials of oral mandibular advancement devices and continuous positive airway pressure for obstructive sleep apnoea-hypopnoea. Sleep Med Rev. 2016; 27:108–24. **[5]** Cammaroto G., et al. Mandibular advancement devices vs nasal-continuous positive airway pressure in the treatment of obstructive sleep apnoea. Systematic review and meta-analysis. Med Oral Patol Oral Cir Bucal. 2017; 22(4):417-24. **[6]** Pépin JL, Raymond N, Lacaze O, et al Orthèses d'avancée mandibulaire (OAM) sur mesure vs. thermoformées pour le traitement d'un SAHOS : résultats à 1 an d'une étude de non-infériorité. Médecine du Sommeil Volume 16, Issue 1, March 2019, Pages 42-43 https://doi.org/10.1016/j.msom.2019.01.064 **[7]** F. Gagnadoux, B. Fleury, B. Vielle, B. Pételle, N. Meslier, X. L. N'Guyen, W. Trzepizur, J. L. Racineux. Titrated mandibular advancement versus positive airway pressure for sleep apnoea. European Respiratory Journal 2009 34: 914-920; DOI: 10.1183/09031936.00168208. **[8]** Fleury B1, Rakotonanahary D, Petelle B, Vincent G, Pelletier Fleury N, Meyer B, Lebeau B. Mandibular advancement titration for obstructive sleep apnea: optimization of the procedure by combining clinical and oximetric parameters. Chest. 2004 May;125(5):1761-7.DOI:10.1378/chest.125.5.1761. **[9]** Multicentric ambispective study on 248 patients treated by the TALI device, whose aim was to evaluate the compliance, tolerance and efficiency of the TALI device after at least 2 years of wearing according to a protocole declared at the ANSM, to the American clinical trials register (clinicaltrials.gov) and validated by the CNIL, a People Protection Committee.

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ONIRIS
Dental Sleep Medicine

ONIRIS® ORTHOSIS

SIMPLE AND EFFECTIVE
IN SNORING AND OSA TREATMENT

The first thermoplastic adjustable MAD not inferior to a custom made device*

TGA FDA Made in France CE ANVISA

* Proven by the largest randomize trial in the field: Pepin JL, Raymond N, Lacaze O, et al. Heat-moulded versus custom-made mandibular advancement devices for obstructive sleep apnoea: a randomised non-inferiority trial. Thorax 019;0:1–8. doi:10.1136/thoraxjnl-2018-212726

ONIRIS Indications

FIRST LINE TREATMENT

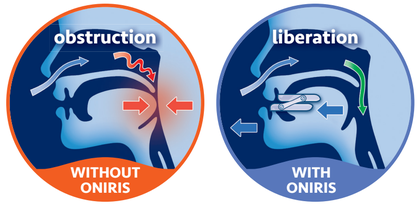
- **SNORING:**
  - A common problem among all ages and both genders
  - 40% of affected people aged 40 and older
  - Strong predictive sign of SAOS
- **MILD and MODERATE OSAS:**
  - 60 à 70% of the diagnosed patients
  - not eligible to CPAP
- **As an ALTERNATIVE to LABORATORY MAS:**
  - to validate the safety and efficacy of a MAS
  - for patients under long term dental treatment (remoulding capacity)

SECOND LINE TREATMENT

- **SEVERE apnoea (30 à 40% of the PSG):**
  - in case of CPAP refusal,
  - in substitution of CPAP for short travels,
  - for the second part of the night for patients who fail to keep CPAP all night long,
  - in combination of CPAP to reduce pressure and improve comfort and compliance.

The ONIRIS device's advantages

- Comparability with custom-made devices validated by the "Haute Authorité de Santé" (HAS)
- Treatment delays reduced
- Decrease in the treatment care inequality : hundreds of euros instead of several thousand euros
- Readjustable thus enabling management of patients requiring dental care



The Oniris® orthosis operates a resetting of the lower jaw, slightly forward during sleep, causing a widening at the level of the oropharynx and thereby preventing obstruction.

A patented system

that offers the same characteristics than laboratory MAS

- Bi-bloc shape: total freedom of movement
- Patented propulsion stripes: adjustment of the advancement from 0 to 11 mm with a 1 mm accuracy
- Thermoforming: customized dental impression
- Immediately adaptable

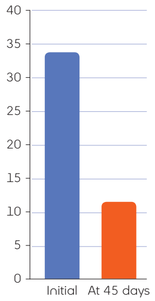
A recognized efficacy

Many general hospitals and doctor's offices have demonstrated the effectiveness of Oniris® orthosis in the treatment of snoring and OSA[1]. This efficiency generally results in a reduction in somnolence and snoring, less fatigue and better sleep quality.

Apnea Hypopnea Index

> 77 % complete response on moderate OSA

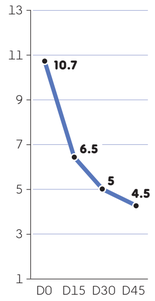
> 60 % average diminution of AHI



Epworth Score

> 6.2 points reduction in Epworth score (ESS)

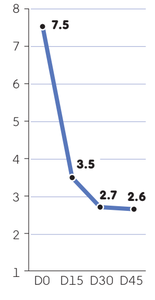
> 97 % of patients have a standardized ESS at 45 days



Snoring intensity

> Snoring intensity is divided by 3

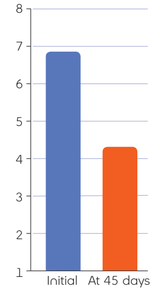
> 83 % of patients report a complete Efficiency



Pittsburg Sleep Quality Index

> 2.6 points of improvement of PSQI

> Sleep subjective quality, sleep disorders and diurnal dysfunction are significantly improved



(1) Marty, M. Lacaze, O. Arreto, C. D. Pierrisnard, L. Bour, F. Chéliout-Héraut, F. and Simonneau, G. (2015), Snoring and Obstructive Sleep Apnea: Objective Efficacy and Impact of a Chairside Fabricated Mandibular Advancement Device. Journal of Prosthodontics. doi: 10.1111/jopr.12401.

A high comfort

The Oniris® orthosis dual-material shape ensures perfect adaptation to the patient's teeth and provides excellent comfort and performance. Its patented propulsion systems provide complete freedom of movement enhancing comfort and total adhesion to the treatment.

Excellent compliance with treatment [1]

- 96 % of patients have a good or excellent compliance with treatment
- 6.5 nights per week average wearing
- 6.2 hours per night i.e. 87 % of sleep time

Few adverse reactions

- 92 % to 98 % of bothers disappear in less than 30 minutes

Strong satisfaction

- Efficiency and high comfort lead to a high patient satisfaction: 94 % report being satisfied or very satisfied

An innovating and easy solution to implement

The Oniris® orthosis uses a thermoforming manufacturing process but at low temperature; thanks to its patented dual-material shape it can be performed directly on the patient's dental arch both with a very precise print resolution and dental covering.

1. Place in front of you the lower gutter and the shorter strips

2. Attach the strips on the lower gutter by firmly pressing the extremity while performing a rotational movement.

3. Attach the strips on the upper gutter

4. Place the Oniris orthosis in a bowl and cover with boiling water. Make sure the water is covering the gutter for 2 minutes, then remove the orthosis of the water using a suitable utensil and wait about 15 seconds.

5. Put the gutters into the mouh. Make sure they are aligned with the teeth.

6. Strongly tighten the teeth on the gutters without moving the jaw forward. Wait 2 minutes without moving and keep the jaws tightened.

YOU ARE GOING TO LIKE NOT TO SNORE ANYMORE

ONIRIS Dental Sleep Medicine