

# ONIRIS<sup>®</sup> ORTHOSIS

**SIMPLE AND EFFECTIVE**  
IN SNORING AND OSA TREATMENT



**The first thermoplastic adjustable mandibular advancement device (MAD), equivalent to a custom made device**

**Form Follows Function**

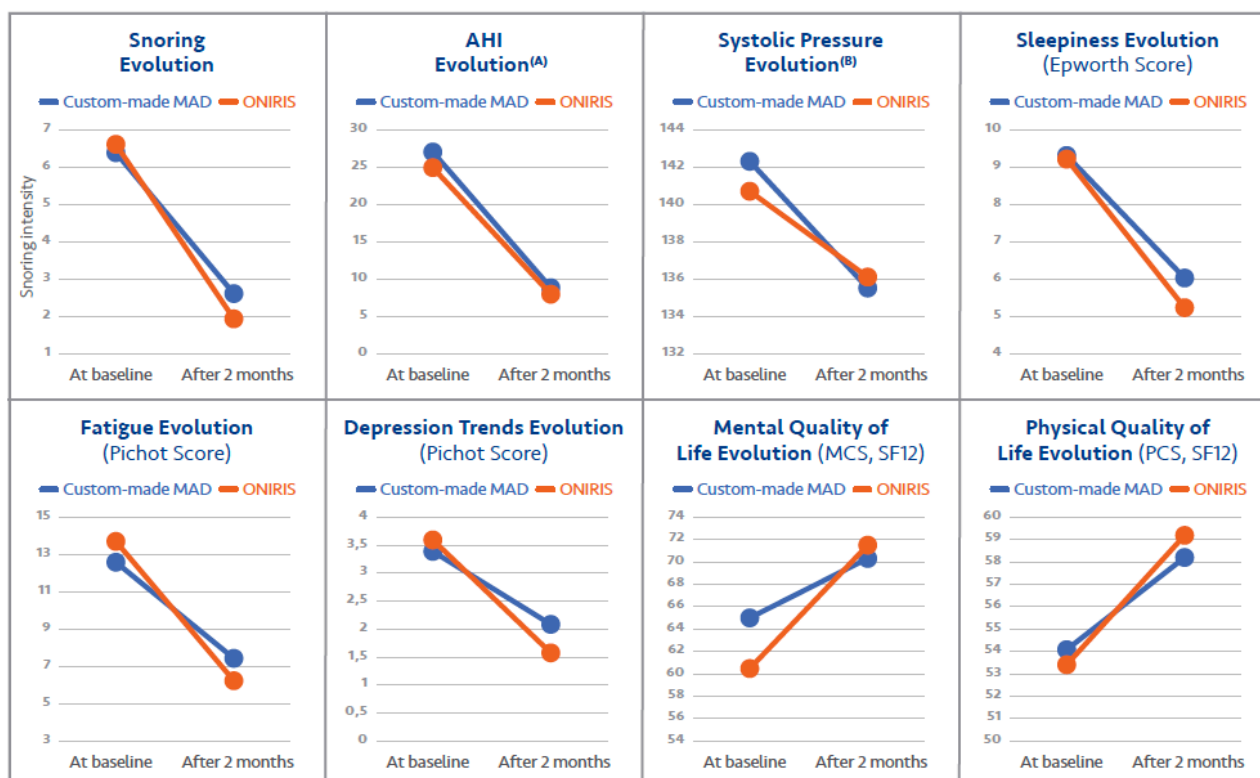
– Louis Sullivan, 1896

# The first thermoplastic adjustable mandibular advancement device (MAD), equivalent to a custom made device

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 follow-up
- 7 recruiting centres
- In intention to treat (ITT) and per protocols (PP) analysis

The results show ONIRIS® was equivalent at 1 year and 2 months of follow-up, regardless of the investigation centre, 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 addition to a CPAP treatment.

# 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 OSA
- **Mild and Moderate OSA**
  - 60-70% of diagnosed OSA patients
  - Patients not eligible for CPAP
- **As an Alternative to Custom MAD**
  - To validate the safety and efficacy of a MAD
  - For patients under long term dental treatment

## SECOND LINE TREATMENT

- **SEVERE OSA, APNEA (30-40% of the PSG):**
  - In cases of CPAP refusal
  - In substitution of CPAP for short travel or vacation.
  - For the second part of the night for patients who fail to keep their CPAP on all night long.
  - In combination with CPAP to reduce CPAP pressures and improve comfort and compliance.

## The ONIRIS device's advantages

- Comparability with custom-made devices validated by the Haute Autorité de Santé (HAS) in France.
- Treatment delays reduced
- Decrease in the treatment care inequality: hundreds of dollars instead of thousands
- Readjustable, thus enabling management of patients requiring dental care



The Oniris® orthosis operates by resetting the position 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 as custom laboratory made MAD

- Bi-block shape: total freedom of movement of jaw to open and close mouth
- Patented propulsion strips that adjust the advancement of the jaw from 0-11mm with 1mm accuracy
- Thermoforming: customized, do it yourself, dental impression
- Immediately adaptable



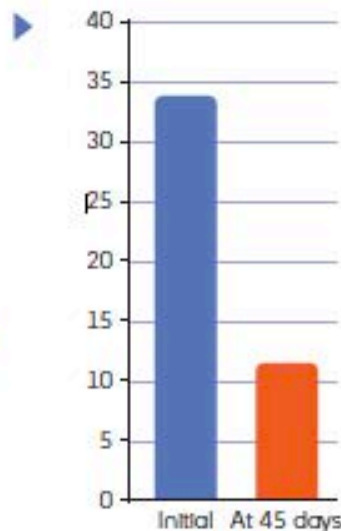
# A recognized efficacy

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.



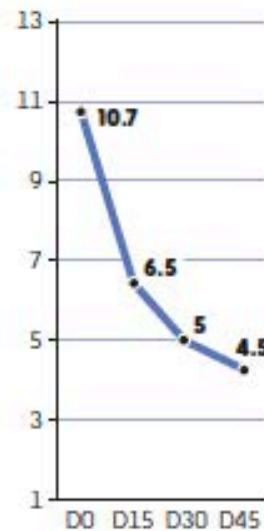
## Apnea Hypopnea Index

- > 77 % complete response on moderate OSA
- > 60 % average diminution of AHI



## Epworth Score

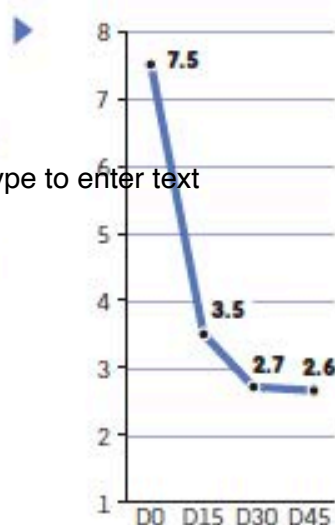
- > 6.2 points reduction in Epworth score (ESS)
- > 97 % of patients have a standardized ESS at 45 days



## Snoring intensity

- > Snoring intensity is divided by 3
- > 83 % of patients report a complete Efficiency

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## 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. Lacase, O., Arreto, C.D., Pierrisnard, L., Bour, 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 <sup>(1)</sup>

- ▶ 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

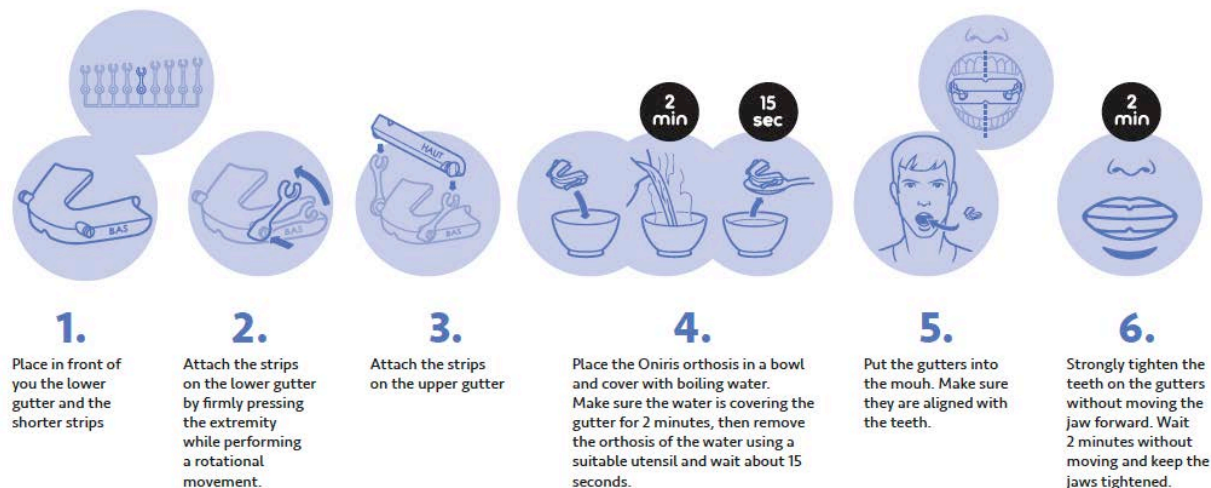
## Strong satisfaction

- ▶ 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.



ONIRIS is distributed in Canada by Novus Medical Inc.



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