

Snoring



Obstructive
Sleep Apnea

Optimizing Compliance and Efficacy

O.R.M type Device®

Optimized Retention of the Mandible

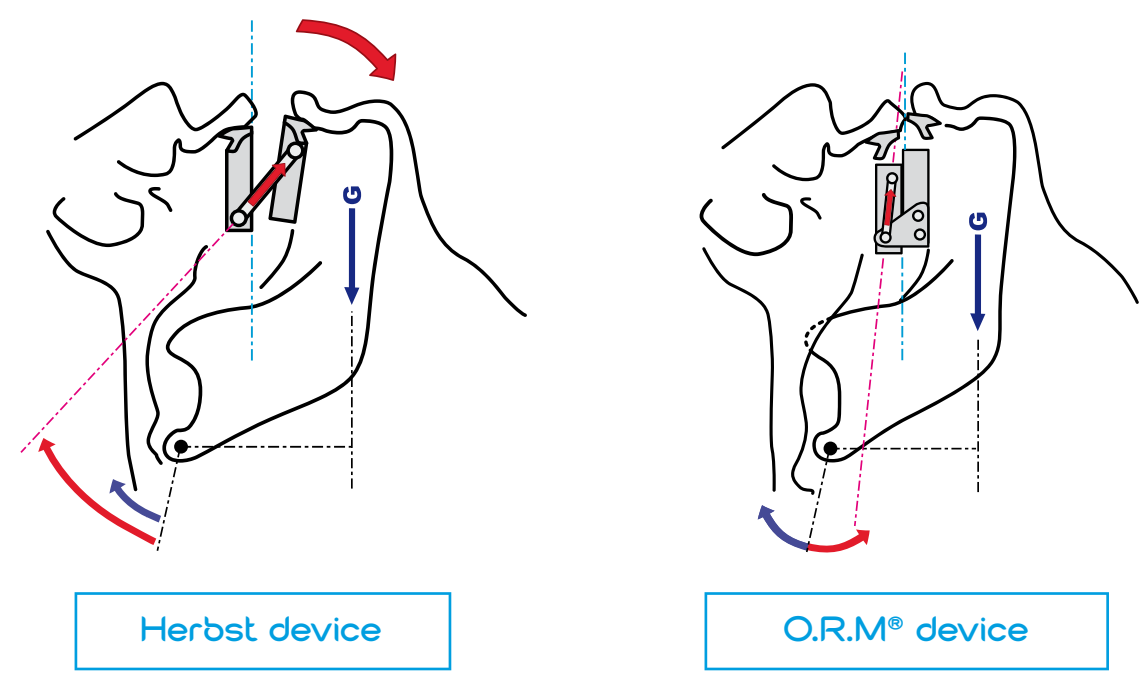
The reference MRD powered
by CAD/CAM technology



 **NARVAL**
LABORATOIRES

Patient-friendly therapeutic solution

Specifically developed for adult OSAS...

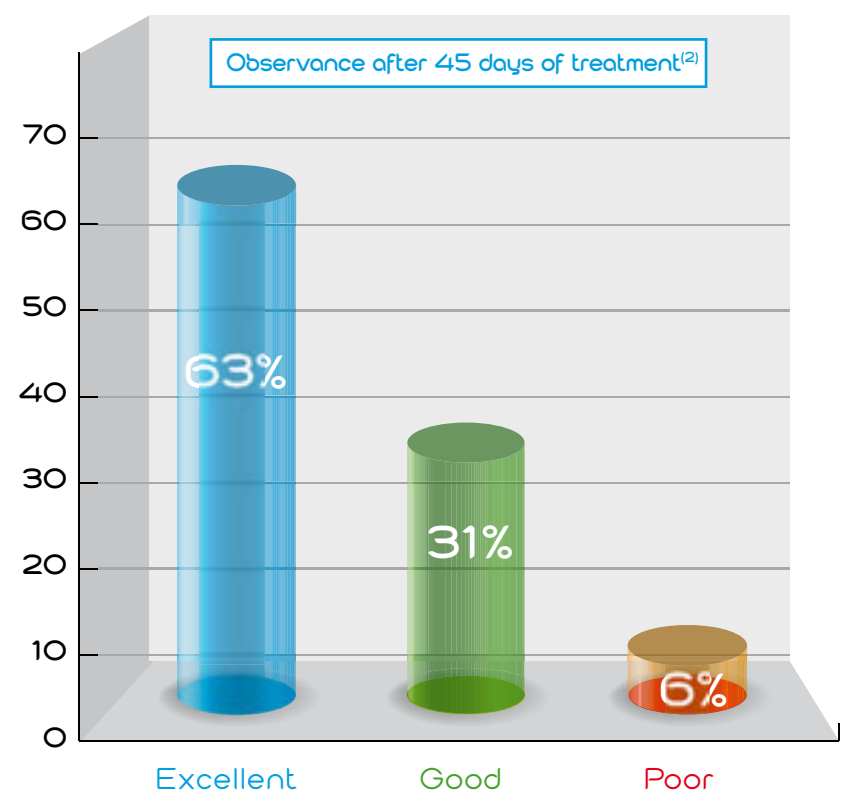


« The results on studied parameters (mouth opening, TMJ contact strength) tend to demonstrate a better clinical profile in terms of compliance and side effects of traction-based mandibular repositioning devices rather than compression-based mandibular repositioning devices” Cheze Study ⁽¹⁾

... enabling rapid treatment adoption

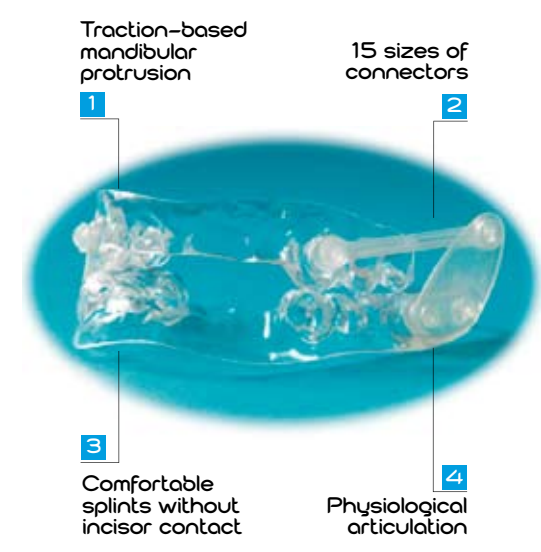
Observance definition :
Excellent: Wear device 7 nights a week all night
Good : Wear device > 4 nights a week and > 4 hrs/night
Poor : Wear device < 4 nights a week or < 4 hrs/night

“This good tolerance led to high reported observance, with 80% of patients wearing the MRD every night compared to a mean of 68% across 7 studies analyzed by Ferguson” Multicentric study⁽²⁾



O.R.M.® Device by Narval CADCAM Technology

The innovations of the O.R.M.® Device...



Objective Safety and Efficacy	Solution	Innovations O.R.M.® type Device
Maximize real efficacy	▶ Tongue can lodge itself against lingual side of incisors	▶ Lingual side of incisors not covered by splint
Minimize dental impact	▶ Exert pressure on most robust teeth	▶ Specific cut-out of the splint with no pressure on incisors
Preserve muscle and articulation comfort	▶ Mandibular advancement respecting occlusal plane	▶ Articulation with elevated attachment point

...powered by CADCAM technology



Optimize customization with CAD software

- ▶ Bite plane parallel to occlusal plane
- ▶ Protection areas over sensitive teeth
- ▶ Splint retention optimization

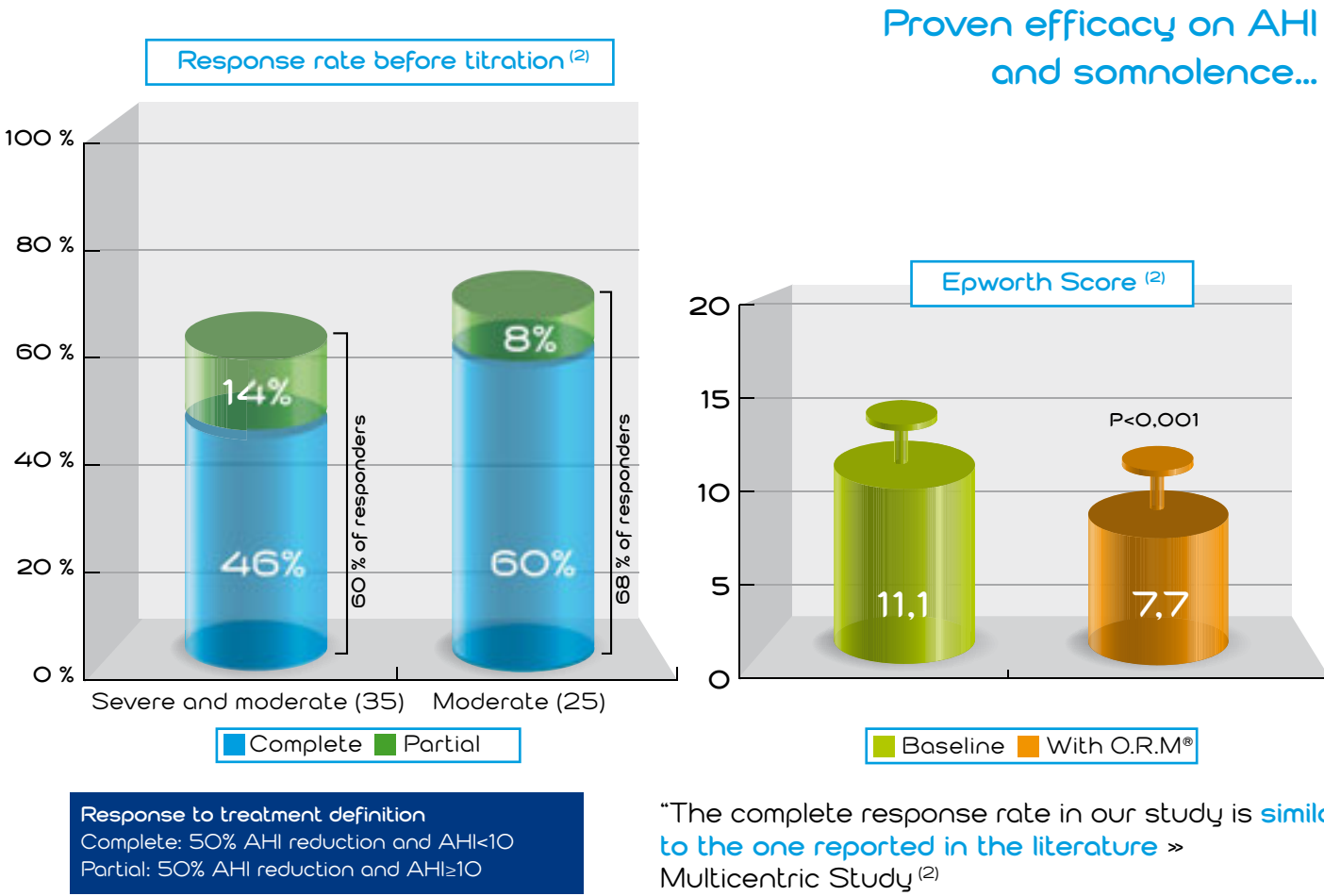


Ensure quality with CAM production

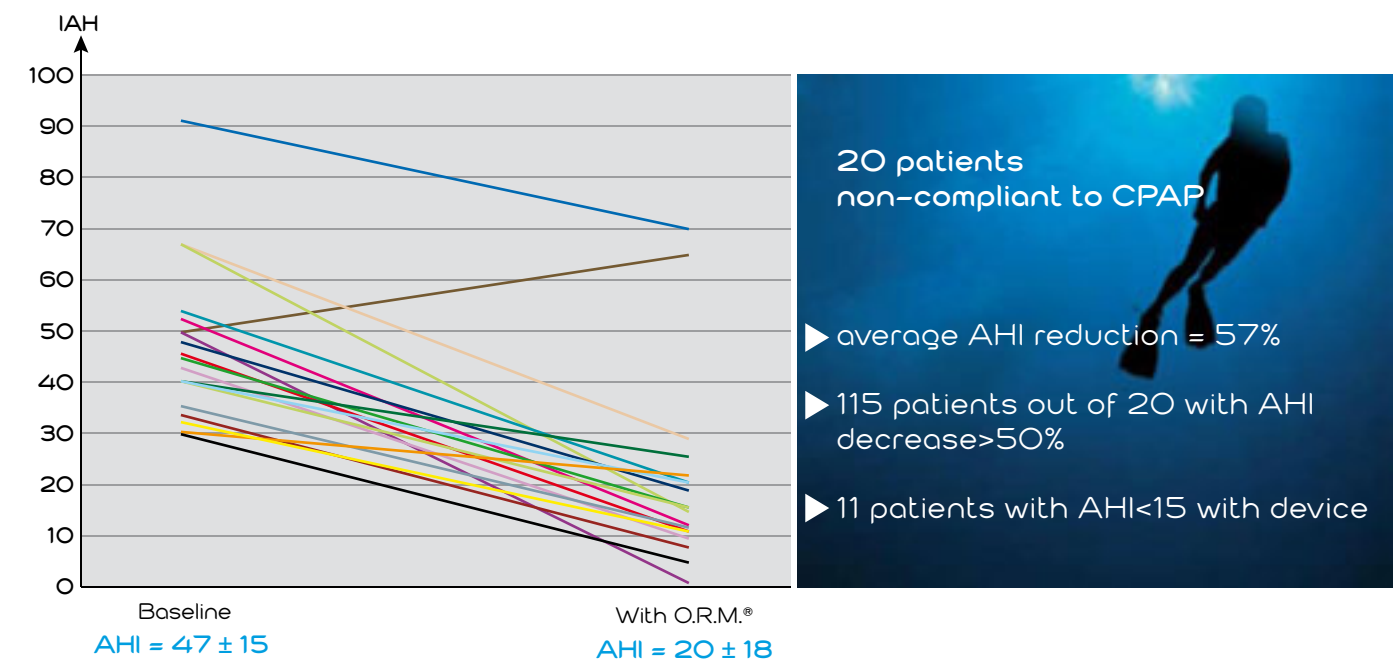
- ▶ Triangle integrated in splint
- ▶ Comfortable silicone coating
- ▶ Easily interchangeable connectors

(1) Cheze L. and col. « Impact on temporomandibular joint of two mandibular advancement device designs », ITBM – RBM 27 (2006) 233.237
(2) Vecchierini MF and col. « Efficacy and compliance of mandibular repositioning device » Sleep Med (2007) doi:10.1016/j.sleep.2007.09.007

Efficacy validated by clinical studies

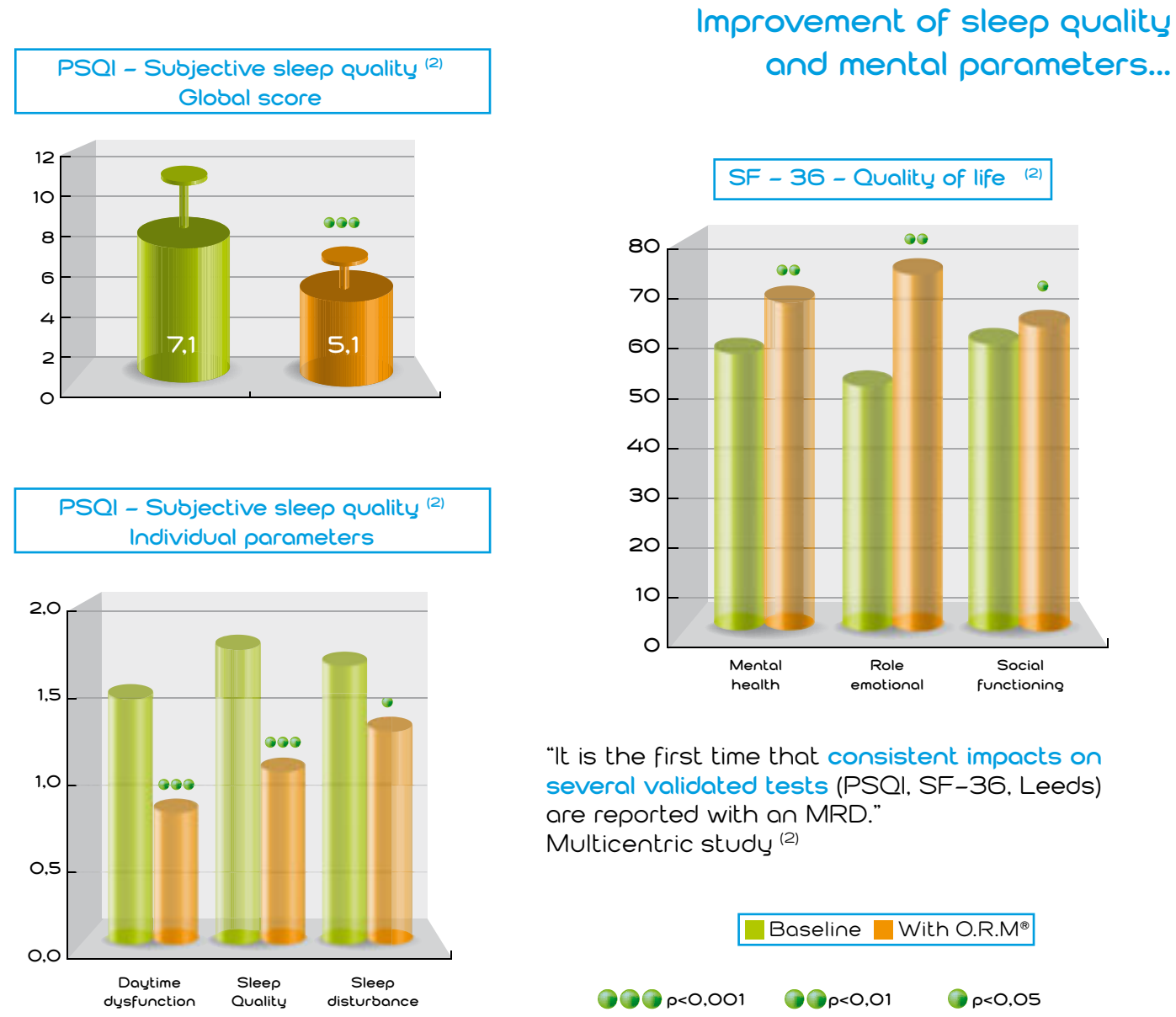


... even in severe OSAS patients



«The cohort study shows efficacy of the MRD on respiratory parameters including for most of severe OSAS patients » Navailles Study ⁽³⁾

Significant quality of life improvement



...associated to long term efficacy and observance

- ▶ 83% efficacy on snoring
- ▶ 94% of patients still under treatment after 15 months
- ▶ 69% of patients wear the O.R.M.® every night
- ▶ 20% of patients suffer from transitory discomfort at wake up (20 min. on average)

« Following this cohort of 108 patients over 15 months has convinced us that the O.R.M.® type device is the most efficient and the less invasive solution to treat light to moderate OSAS. For severe OSAS it might be prescribed in case of CPAP intolerance or in association with the latter » Navailles Study ⁽⁴⁾

(3) Navailles B. and col. « Innovative mandibular advancement splint in the treatment of obstructive sleep disorders » IFOS 2005 Rome

(4) Navailles B. and col. « Prothèse d'avancée mandibulaire et troubles du sommeil obstructifs » SFORL 2004

MRD Indications by the American Academy of Sleep Medicine ⁽⁵⁾

1st Line Treatment

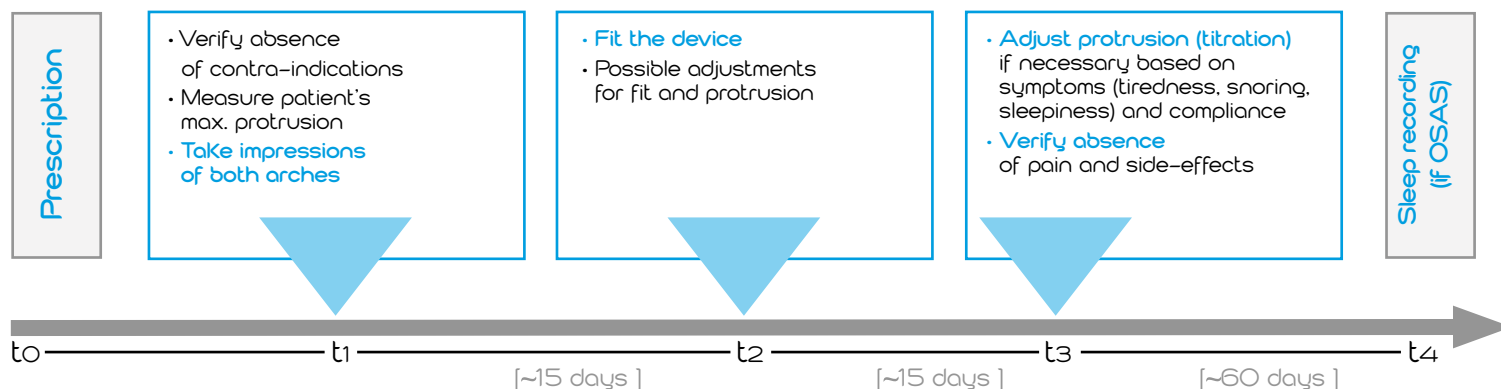
- **Light to Moderate OSAS ($5 \leq \text{AHI} \leq 30$)**
for patients who prefer MRDs over CPAP or who do not respond to or are not appropriate candidates for or fail CPAP or fail behavioural measures treatment
- **Primary Snoring**
for patients who do not respond or are not appropriate candidates for behavioural measures treatment

2nd Line Treatment

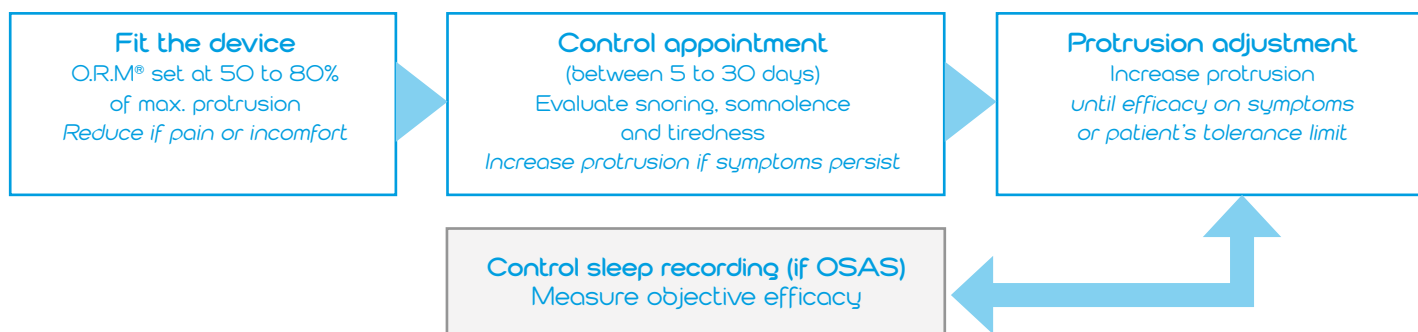
- **Severe OSAS ($\text{IAH} > 30$)**
in case of failure of an initial trial of CPAP

(5) Kushida C. A., et al, Practice parameters for treatment of snoring and OSA with oral appliances Sleep vol 29, N°2, 2006

Protocol of care for patients



Titration : Adjustment of mandibular protrusion



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