



## Narval CC: Treat obstructive sleep apnoea (OSA) and snoring with a digitally made oral appliance

- Clinically proven alternative to continuous positive airway pressure (CPAP)<sup>1,2,3</sup>
- Custom-made for improved patient comfort and compliance<sup>4</sup>
- High-precision technology
- 100% digital pathway available\*
- Collaborative follow-up platform with Narval Easy

# OSA and mandibular advancement devices (MADs)

## Upper airways in OSA

Healthy patient  
(airway open)



Patient with  
untreated snoring  
(airway partially closed)



Patient with  
untreated OSA  
(airway closed - apnoea)



Patient treated  
with Narval CC  
appliance



The Narval CC appliance maintains the lower jaw (mandible) in a forward position, which in turn draws the base of the tongue forward and widens the airways in the pharyngeal area behind the tongue.

It is designed to open up the space behind the tongue and increase the tension of relaxed soft tissues to help reduce snoring and decrease the number of apnoeas and hypopnoeas that may disturb the physiological sleep cycle.

**Narval CC is indicated to treat adults with snoring or mild to moderate obstructive sleep apnoea (OSA). In case of severe OSA, it is indicated after continuous positive airway pressure (CPAP) therapy failure, non-compliance or refusal.**

## MAD: a treatment solution recommended by international guidelines<sup>5,6</sup>

The American Association of Dental Sleep Medicine (AADSM) and European Respiratory Society (ERS) recommend that sleep physicians consider prescription of oral appliances, rather than no treatment:

- For adult patients with OSA who are intolerant of CPAP therapy or prefer alternate therapy.
- For adult patients with mild to moderate OSA.
- For adult patients who request treatment of primary snoring (without OSA).



# An innovative CAD/CAM\* oral appliance

## Thin and light

CAD/CAM manufacturing helps minimise the bulk of the device to create more space for the tongue. Yet Narval CC splints are strong and can resist forces similar to those generated by jaw clenching (bruxism).<sup>7</sup>

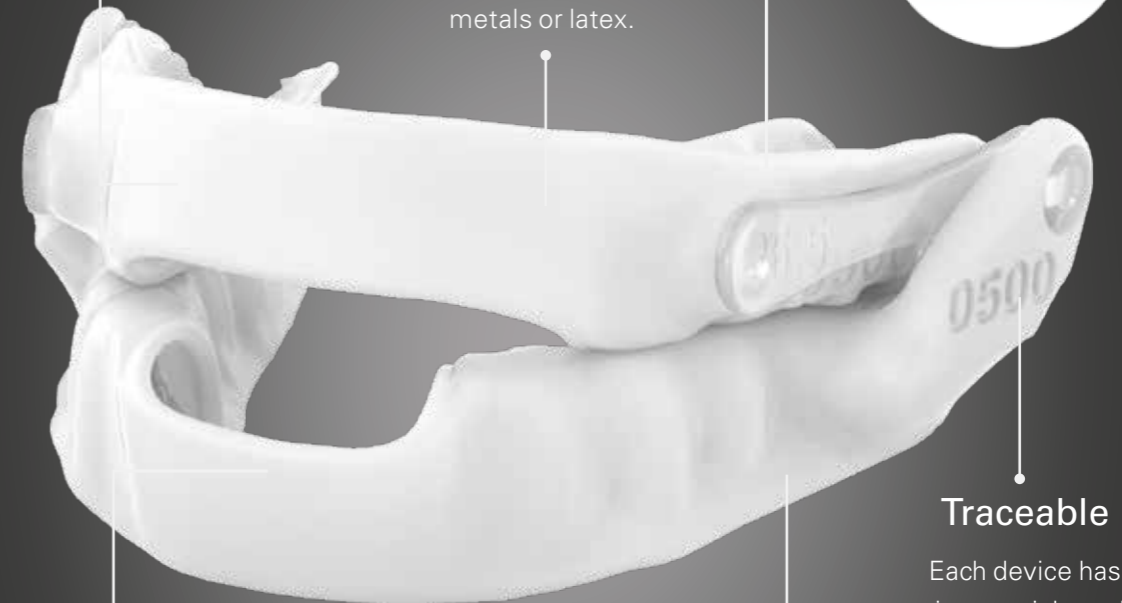
## Ease of titration

Narval CC allows for quick and easy titration.



## Biocompatible

Narval CC appliances are made of polyamide to limit the risk of allergies and do not contain metals or latex.



## Traceable

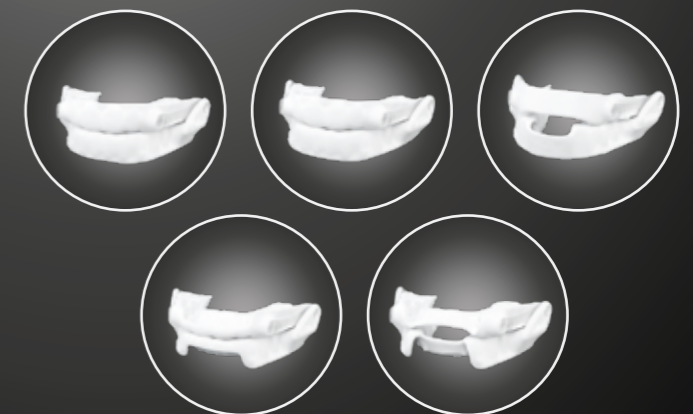
Each device has a unique serial number.

## Patented traction-based articulation

The Narval CC articulation system is designed to generate, on average, 10% less stress on the temporo-mandibular joint (TMJ) than compression-based devices.<sup>8</sup> It is also designed to discourage mouth opening.

## Various design choices

A range of options increase the potential to respond to the specific needs and anatomical constraints of each patient.



\*Computer-aided design / computer-aided manufacturing

# 100% digital pathway available, from IOS to CAD/CAM

ResMed pioneered the use of computer-aided design and manufacturing with laser sintering in Europe. This commitment to innovation and accuracy has now led us to integrate digital scanning technologies into our manufacturing process.

## Advantages of CAD/CAM

- High degree of customisation

Different design variations to fit patients' specific needs and anatomical constraints.
- Consistent accuracy

Standardised processes and digital technology to result in high-quality appliances.
- Smart clipping retention method


For each patient, our CAD software determines the retention area available to grip the teeth.
- A virtual articulator

CAD software includes a simplified model simulating relevant mandibular movements based on Quick Master B2 from Fag (France).




**In blue**, undercuts zone used to obtain the amount of retention needed to grip the teeth.  
**In grey**, undercuts zone available for increased retention but not used to avoid excessive retention.

## Advantages of intra-oral scanning

- 

Reliable scans

Digital impressions eliminate the risk that imprint material will distort during transport.
- 

ResMed assistance

ResMed will provide assistance for your first 3 cases to ensure you have good quality scans before your patients even leave the chair.
- 

Time/cost efficiency

Combination of scanning accuracy and digital record stability to improve device fitting and reduce adjustment time.<sup>9</sup>
- 

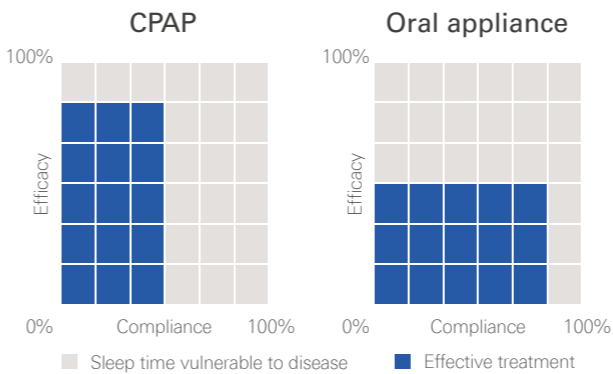
Faster turnaround

Receive your Narval CC appliance in just 10 working days!

Our partners :    

# A clinically proven alternative to CPAP<sup>1</sup>

## Comparable effectiveness of oral appliance and CPAP<sup>10</sup>



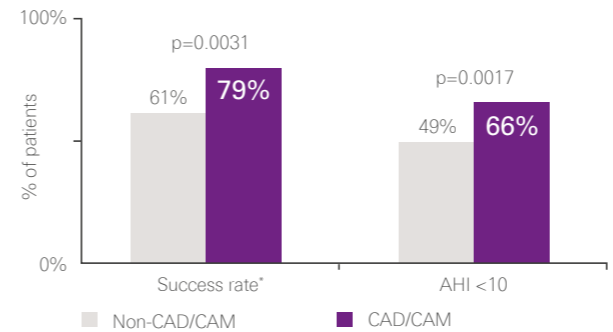
Head-to-head trials confirm that CPAP is superior to MAD in reducing OSA parameters on polysomnography. However, this greater efficacy does not necessarily translate into better health outcomes in clinical practice.

**Comparable effectiveness of MAD and CPAP has been attributed to higher reported nightly use of MAD, suggesting that inferiority in reducing apnoeic events may be counteracted by greater treatment adherence.**

## Narval CC: High efficacy on AHI<sup>1,2,3</sup>

Narval CC has proven to be an effective solution to treat OSA on both short-term<sup>2,3</sup> and long-term<sup>1</sup> follow up, with good tolerability and compliance. These results were demonstrated during the largest prospective cohort study ever performed on mild to severe OSA patients treated with MAD.

### Efficacy of treatment by type of MAD at 3-6 month follow-up<sup>2</sup>



### Efficacy of treatment at 5-year follow-up

Over the long term, efficacy remains good on CAD/CAM devices with a 52% success rate\* across the three OSA severity groups<sup>1</sup> (mild, moderate and severe). Treatment was particularly effective in the severe OSA group: 62% of severe OSA patients achieved a reduction in AHI >50% at 5 years.<sup>1</sup>

**CAD/CAM Narval MADs are more effective at reducing AHI than non-CAD/CAM Narval MADs, regardless of OSA severity at baseline (79% vs 61% success).**

## Strong results on snoring<sup>2,3</sup>


After 3 months of treatment with Narval CC, 75% of patients said their snoring no longer bothered other people. After 2 years, this applied to 81% of patients, while 90% of patients declared they no longer snored loudly.


To learn more about Narval CC clinical results:


[Visit ResMed.com/Orcades](https://www.resmed.com/orcades)

\*Success rate = % of patient with an AHI reduction >50%

## Strong results on patient satisfaction and compliance<sup>1,3</sup>

- 

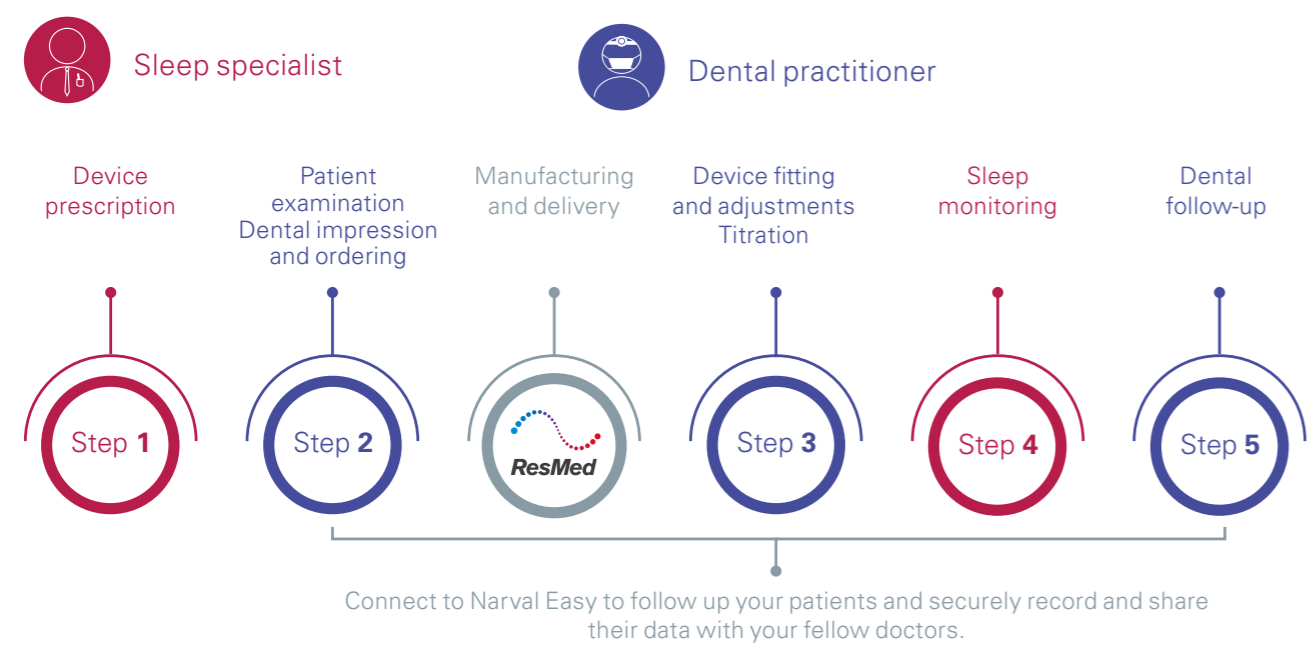
6.7 hours/night usage on average at 5-year follow up<sup>1</sup>
- 

97% of patients want to continue therapy at 2-year follow up<sup>3</sup>
- 

9% dropout due to side effects after 5-year follow up<sup>1</sup>

# A collaborative platform to follow up patients treated with MAD

ResMed's Narval Easy platform makes it easy for sleep specialists and dental practitioners to work together to facilitate MAD patients management. It aims at simplifying collaboration and follow up at all key stages in the clinical protocol of care summarised below.



## Online digital services to stay informed

Narval Easy is the first online collaborative platform to give sleep doctors the ability to follow up their MAD prescriptions and receive feedback from their dentists partners.

- Communicate directly on the platform
- Share data about common patients
- View clinical assessments and records from your fellow doctors
- Get notified at key stages of the treatment (ie. when ResMed has manufactured the device for your patient)
- Keep track of your patients treated with MAD over the long term

When sleep doctors and dentists use Narval Easy, they can access useful information throughout the treatment process, from **device manufacturing** at ResMed to **device fitting, titration** and **follow-up** with the patient.

To create your account:

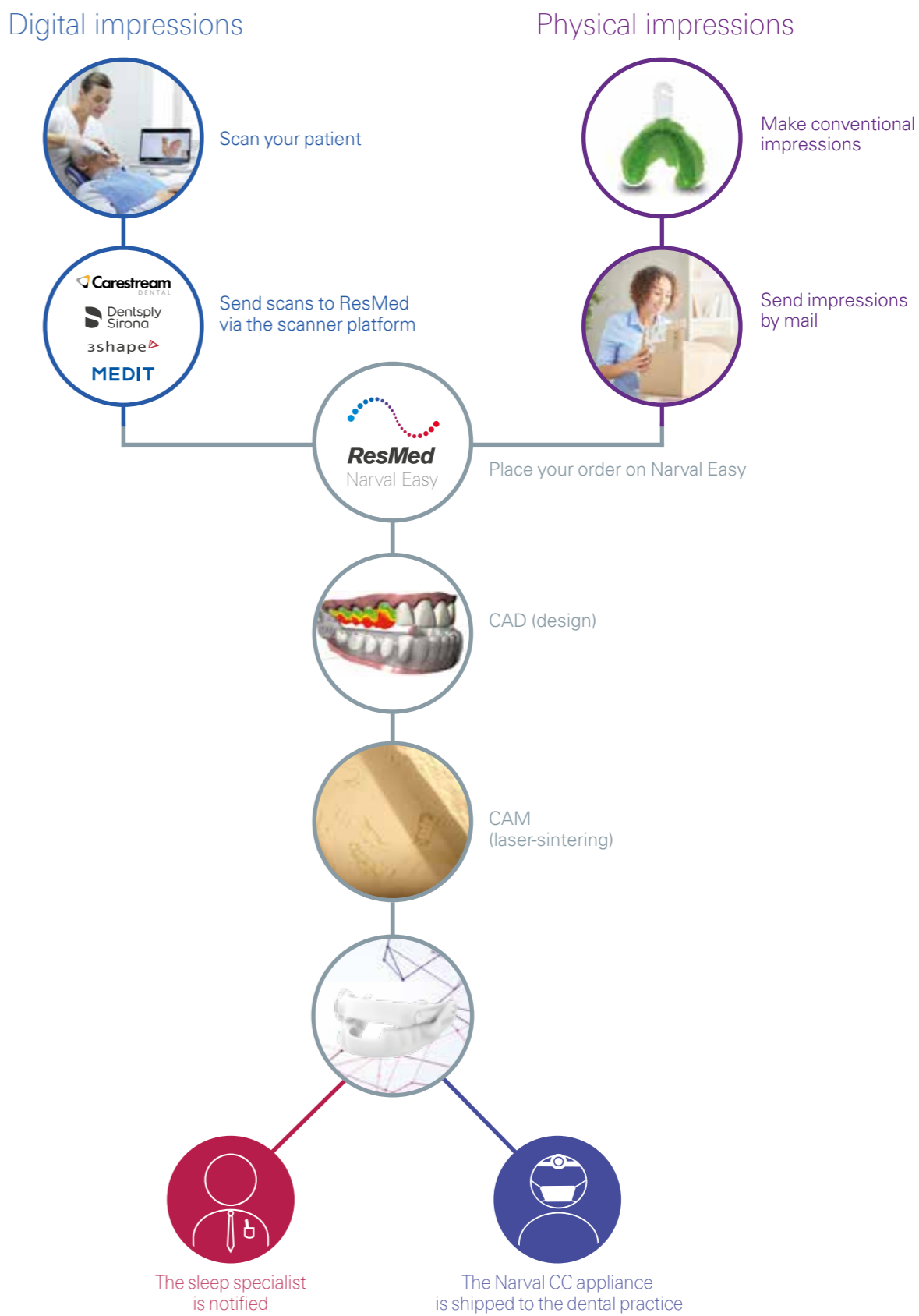
Visit [ResMed.com/NarvalEasy](https://ResMed.com/NarvalEasy)



Being able to follow up treatment over the long term is key as OSA can evolve over time due to aging or the impact of co-morbidities (cardiovascular diseases, diabetes, etc.).<sup>11</sup> Both specialists should be able to monitor MAD patients closely as changes in AHI are not always associated with a worsening of symptoms.<sup>3</sup>

# Digital manufacturing process

Narval CC appliances can be ordered digitally through the Narval Easy platform or with a paper order form. Narval Easy allows dental sleep specialists to securely place<sup>12</sup>, manage and track Narval CC orders online, whether their practice is equipped with a compatible intra-oral scanner or uses traditional imprints.





# ResMed

For more information, contact your local  
ResMed representative  
or visit [ResMed.com/Narval](https://www.resmed.com/Narval)

1 ORCADES study - 3-6 month, 2 year and 5 year results ppt. Obj ID: C280034.

\*Prospective observational multicentre cohort study on 331 OSA patients. Primary objective of the study was to evaluate the long-term efficacy, tolerance and compliance of ORM Narval Mandibular Repositioning Device (MRD) ClinicalTrials.gov identifier: NCT01326143.

2 Vecchierini MF et al. A custom-made mandibular advancement device for obstructive sleep apnoea-hypopnoea syndrome: the ORCADES study. *Sleep Medicine* 2016 Mar; 19:131-40.

\*A 5-year prospective observational multicentre cohort study on 331 OSA patients. 3-6 months follow-up data analysis. ClinicalTrials.gov identifier: NCT01326143.

3 Attali V et al. Efficacy and tolerability of a custom-made Narval mandibular advancement device for the treatment of obstructive sleep apnea: ORCADES study 2-year follow-up data. *Sleep Med.* 2019 Nov; 63:64-74.

\*A 5-year prospective observational multicentre cohort study on 331 OSA patients. 2-year follow-up data analysis. ClinicalTrials.gov identifier: NCT01326143.

4 Vanderveken OM et al. Comparison of a custom-made and a thermoplastic oral appliance for the treatment of mild sleep apnea. *Am J Respir Crit Care Med.* 2008 Jul 15;178(2):197-202.

\*Randomized controlled cross-over trial, 4 months of treatment, with a 1-month washout interval on 35 OSA patients.

5 Ramar K et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: An update for 2015. *Sleep Medicine* 2015;11(7):773-793. (AASD recommendations).

6 Marklund M et al. Non-CPAP therapies in obstructive sleep apnoea: mandibular advancement device therapy. *European Respiratory Journal* 2012 39: 1241-1247.

Based on the ERS Task Force Report on MAD therapy.

7 Compression tests – ResMed internal report C258999, May 2018 – Chapters 8 & 9: Narval splints withstand compression forces of 500 N.

8 Cheze et al. Impact on temporomandibular joint of two mandibular advancement device designs. *ITBM-RBM, Volume 27, Issues 5–6, November–December 2006, 233-237.*

Computer-simulated biomechanical study.

9 IOS European Controlled Product Launch (CPL/Sirona) - ResMed internal report C258916, May 2018 - Chapters 5.3.1.1 and 7. Extracts:

In 92% of cases, the practitioner was satisfied or very satisfied with the device (N=40).

In 61% of cases the device was judged to fit better than other appliances made with physical impressions (N=36).

81% of the devices fitted well without any adjustment (N=102).

10 Sutherland et al. Efficacy versus Effectiveness in the Treatment of Obstructive Sleep Apnea: CPAP and Oral Appliances. *Journal Dental Sleep Medicine*, 2015.

11 Bonsignore MR & al. Obstructive sleep apnea and comorbidities: a dangerous liaison. *Multidiscip Respir Med.* 2019 Feb 14;14:8.

12 Narval Easy was built to be secure and is hosted by a third-party company that holds the stringent French ASIP Santé certification as well as the ISO 27001 certification to host medical data.

#### ResMed SAS

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