

## Dental practitioner guide

Treatment of snoring and obstructive sleep apnea with the Narval appliance.  
A custom-made mandibular repositioning device.

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# Welcome

Thank you for choosing the Narval CAD/CAM (computer-aided design and manufacturing) appliance.

This document provides the necessary information related to the Narval protocol of care. Please read it carefully before ordering and fitting the device.

## Intended use

### Narval CC

Narval CC is a custom-made medical device, available under medical prescription and intended to treat snoring and/or obstructive sleep apnea (OSA) in adults. In the case of severe apnea, Narval CC is recommended as a second-line intervention after continuous positive airway pressure (CPAP) failure, non-compliance or refusal.

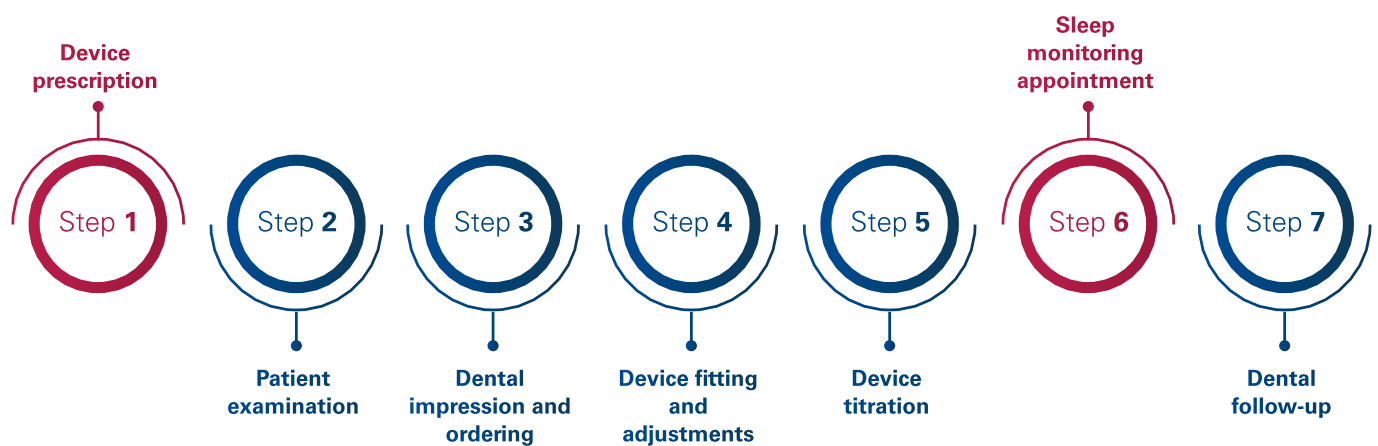


# Clinical protocol of care

The prescription of an oral appliance requires **pluridisciplinary cooperation between a sleep specialist and a dental practitioner**. The clinical protocol of care below summarises the main steps from prescription to device fitting and efficacy monitoring. In the following chapters, the steps requiring dental expertise (steps 2 to 5 and step 7) will be described more specifically.



Sleep specialist



Dental practitioner

## Step 1: Device prescription

AADSM (American Academy of Dental Sleep Medicine) recommend that sleep physicians consider prescribing oral appliances, rather than no treatment, for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy<sup>1</sup>.

## Step 2: Patient examination

## Step 3: Dental impression and ordering

## Step 4: Device fitting and adjustments

## Step 5: Device titration

An European Respiratory Society Task Force recommend that the device should be custom made, evaluated and advance the mandible at least 50% of maximum protrusion. A titration procedure is essential<sup>2</sup>.

## Step 6: Sleep monitoring appointment

AADSM recommend that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conducting follow-up without sleep testing, for patients fitted with oral appliances<sup>1</sup>.

## Step 7: Dental follow-up

AADSM recommend that dental follow-up must be carried out under the supervision of a qualified dentist. Follow-up of oral appliance therapy in adult patients with obstructive sleep apnea is required to survey for dental-related side effects and occlusal changes and reduce their incidence<sup>1</sup>.

# Step 1 Device prescription

Narval appliance prescription is made by a sleep specialist in accordance with the patient's diagnostic and treatment needs. The patient's diagnosis is conducted via a **polygraphy or a polysomnography that assesses Obstructive Sleep Apnea (OSA) severity according to OSA classification.**

AHI (Apnea – Hypopnea index) and daytime sleepiness are the two major indicators that help sleep specialists to choose the appropriate treatment. If the diagnostic result shows an AHI < 5, a Narval appliance can be prescribed to treat snoring.

## AADSM recommendation statement<sup>1</sup>

*We recommend that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy.*

*We recommend that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea).*

# Step 2 Patient examination

## Patient contraindications

The Narval appliance is contraindicated for patients who:

### General contraindications

- Have central sleep apnea
- Have severe respiratory disorders (other than OSA)
- Are under 18 years of age

### Dental contraindications

- Have loose teeth or advanced periodontal disease
- Have a completely edentulous lower arch unless a complete denture mechanically retained is present (e.g. retained by implants)
- Have a completely edentulous upper arch unless a complete upper denture is present
- Have short teeth and/or insufficient undercuts to retain the device.

## Precautions

Before prescribing a Narval appliance:

→ **Check for relevant issues in your patient's medical history, such as respiratory disorders, asthma and breathing problems. Any such problems should be referred to the appropriate healthcare provider before treatment.**

→ **Carry out the following examinations:**

### TMJ examination

Any TMJ (temporomandibular joint) pain or other TMJ disorder must be further assessed by the dental practitioner.

### Periodontal examination

The following dental issues must be treated by the patient's regular dental practitioner before MRD (Mandibular Repositioning Device) treatment:

- Periodontal disease
- Cysts and mouth ulcers
- Teeth that need to be extracted
- Prosthodontics, such as a crown or bridge
- Orthodontics

### Patient identification: oral and prosthetics examination

To establish whether a patient is suitable for MRD treatment, you must perform a dental, periodontal, prosthetic and TMJ examination.

### Anchoring value and number of teeth

The latest dental sleep guidelines<sup>1,3</sup> for OSA management with MRD therapy recommend a sufficient anchoring value and an adequate retentive morphology of teeth without specifying any threshold for the minimum number of teeth. The dental practitioner should check if the teeth (natural or dental implant) anchoring value and morphology are sufficient to ensure the efficacy of MRD without significant side effects from treatment.

→ **If there are no contraindications and you have informed patient consent, you can proceed with treatment according to the clinical protocol described in the next pages.**

# Step 3 Dental impressions and ordering

Before placing an order for a Narval appliance, please contact your local ResMed representative. Narval appliances can be ordered either using **physical impressions** (silicone or alginate) or **digital impressions** (from an intra-oral scanner). In both cases dental impressions and protrusion settings must meet the requirements detailed below:

## 1. Dental impressions

### The dental impressions must:

- Accurately depict both jaws.
- Include full sulcal depth (at least 5mm to the margin).
- Include the most posterior tooth in each arch and, if possible, capture the distal surface, including third molars.
- Capture/scan at least:
  - For the upper arch**
    - 50% of the last present molars;
    - If all molars are missing, 100% of the second premolars AND 15mm of soft tissue extension after distal.
  - For the lower arch**
    - 100% of the second molars AND 5mm of soft tissue extension distal to them;
    - If second molars are missing, 100% of first molars AND 15mm of soft tissue extension after distal.
- Capture details like occlusal surface textures, gingival margins, frenula and every bit of tooth shape, similar to a partial denture impression.
- Be taken with dentures in place (if any) and show the bottom of the sulcus in the full dental arch.
- If the patient has (a) pontic(s) and if
  - They wear it/them during the night, the impressions must be taken with the pontic(s) in place. Please do NOT send the pontic(s) to ResMed. This is not required.
  - They do not wear it/them during the night, the anchoring value of the remaining teeth must be sufficient. If the Narval appliance MRD is not retentive enough, new impressions with the pontic(s) in place could be requested, in which case the patient will need to wear the pontic(s) every time the Narval appliance MRD is used.

## 2. Protrusion setting specifications

ResMed also requires protrusion setting information to produce the Narval appliance. This information can be sent as a **bite registration in desired protrusion** or **measurements in maximum protrusion**.

### Option 1: Bite registration in desired protrusion

The initial mandibular protrusion of the Narval appliance will be set according to the bite registration provided.

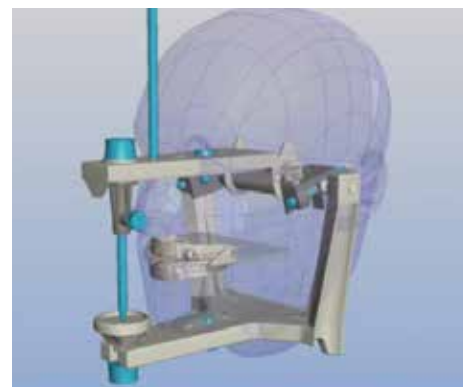
- ResMed recommends reducing the vertical dimension as much as possible, leaving a minimum of 4 mm to allow proper design of the splints. If you would like this option, please tick **"Reduce the vertical dimension to the maximum (ResMed recommended option)"** on the order form.
- If you would like ResMed to reproduce the vertical dimension recorded by your bite registration, tick **"Reproduce the vertical dimension recorded by the bite registration"** on the order form. In this case, the bite registration must be at least 4 mm thick to allow proper design of the splints.
- Consider starting your patient's therapy at approximately 60% of the maximum protrusive range, as long as it is comfortable for the patient. Narval has a wide range of adjustment so you do not need to begin with an aggressively protruded posture.
- Remember to check posterior clearance and be careful of a deep curve of Spee or angled third molars as this may create clearance problems in protrusion.

## Option 2: Measurements in maximum protrusion

You can also choose to provide measurements in maximum protrusion. ResMed's CAD software contains a virtual articulator based on the Quick Master B2 (From Fag) which simulates the mandibular movements.

The initial mandibular protrusion of the Narval appliance will be set at approximately 60% of maximum advancement.

The vertical dimension will be minimised while ensuring no posterior contact during advancement. (Please pay attention to the curve of Spee, which can lead to posterior contacts during advancement).

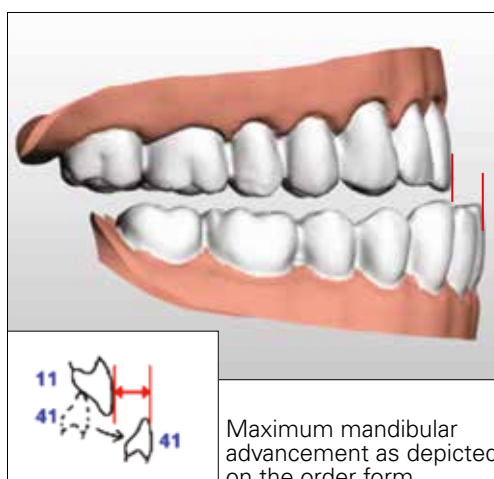


The following two measurements must be made with a ruler and noted on the order form:

### → Measurements of maximum mandibular advancement

Measure your patient's maximum mandibular advancement from the middle of the facial surface of tooth 11 to the middle of the facial surface of tooth 41.

To do this, ask the patient to move the lower jaw as far forward as possible. Place the ruler against the facial surface of tooth 11 and take the measurement directly above the facial surface of tooth 41.



Maximum mandibular advancement as depicted on the order form.

### Tips:

You may find it beneficial to have the patient move the jaw to maximum protrusion a number of times before taking your final measurements or bite recording.

If you have a doubt about maximum protrusion ability, you can ask the patient to open his mouth to the maximum. A rule of thumb indicates that:

$$\text{maximum opening (in cm)} \times 2 \approx \text{maximum advancement (in mm)}$$

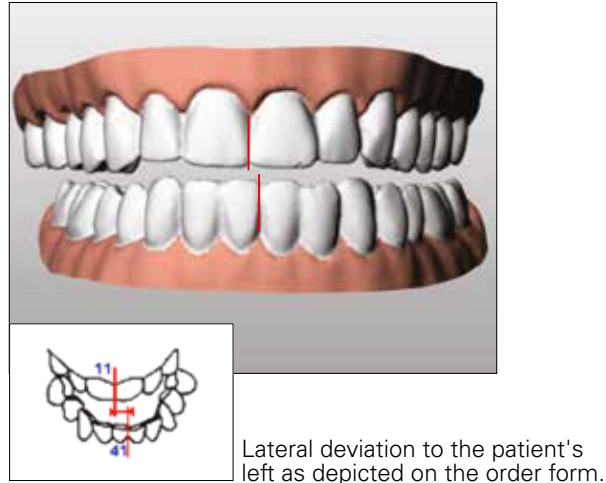
## Precautions

According to the AADSM consensus report<sup>4</sup> for OSA management with MRD therapy, the maximum mandible advancement capability should be  $\geq 5$  mm in order to achieve optimal MRD efficacy. The patient's ability to advance the mandible can evolve over time, especially under MRD treatment. Additionally some patients with limited mandibular advancement before treatment initiation may benefit from MRD therapy. In any case, the dental specialist should assess the efficacy and safety of the treatment during follow-up appointments.



### → Measurements of lateral deviation

Measure and indicate on the order form any lateral deviation of the mandible in maximum protrusion (midline deviation: in mm).



## 3. Specific requirements for physical impressions

### Impressions

The more precise the impressions, the more comfortable the MRD will be for your patient. If an impression is damaged, inadequate or inaccurate, the MRD will not provide proper fit and retention.

Narval appliance packaging includes a transportation box specifically conceived to help protect impressions. The box includes a cardboard box together with two plastic bags to help protect impressions from events that could damage the shape and precision of the impressions. It aims at reducing humidity level variation.

Please disinfect your impressions before shipment.



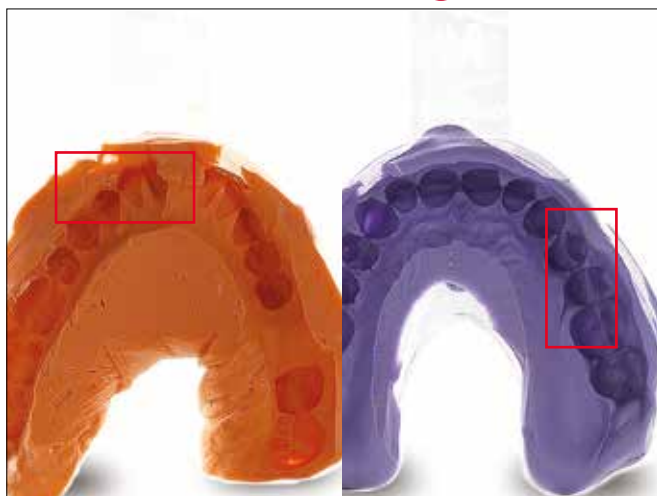
#### Tips and tricks:

- Consider using Rim-Lock® impression trays which allow for full impression of the gingival sulcus and posterior molar area.
- Consider using the double-mix impression technique in which two impression materials of PolyVinyl Siloxane (PVS) with different viscosity (low and high) can capture the necessary details.
- Ask the patient to rinse his mouth with water to remove excess saliva.
- Dry occlusal surfaces.
- Choose the most appropriate impression material. ResMed recommends silicone for long distance and/or weekend transportation. Consider using a high quality silicone impression material, as you would for making a crown or bridge impression, allowing for multiple pours.
- Alginate should only be used for short distance transportation. If using alginate impression material, please use a tray adhesive and/or a specific alginate impression tray.

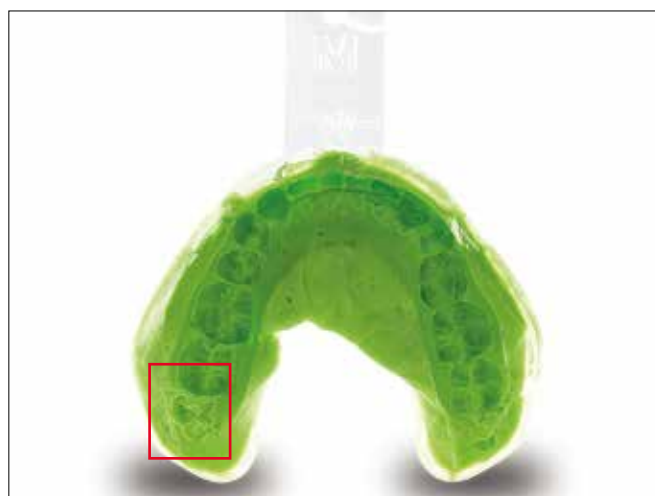
**Note:** Impressions may be discarded following the production process.



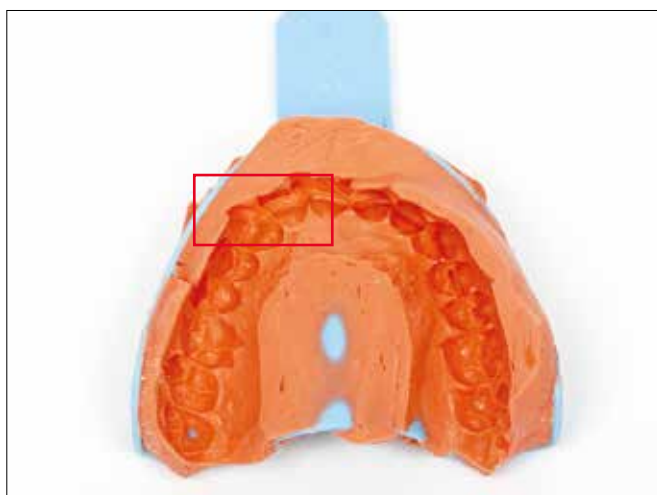
## Examples of unusable impressions ✗



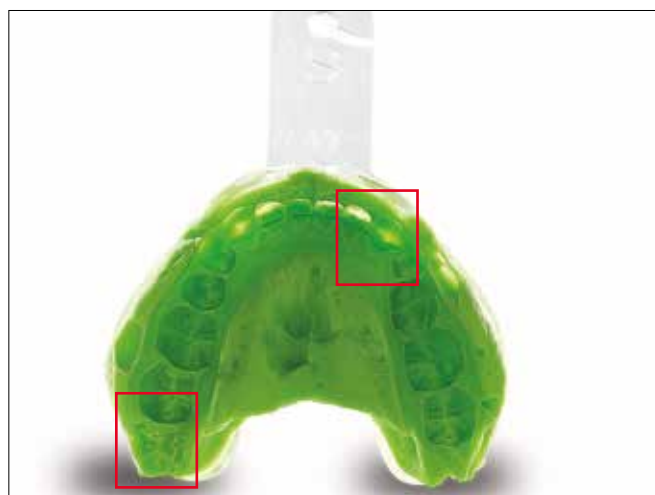
Deformation of the impression due to insufficient setting time of the material.



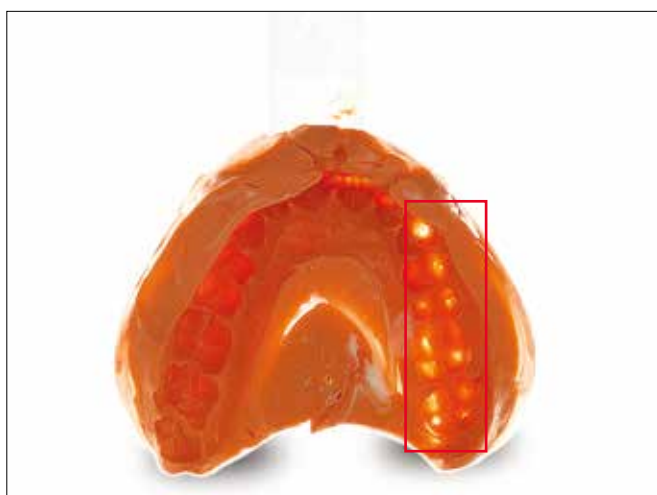
The gingival margins are not visible and a portion of a tooth is missing.



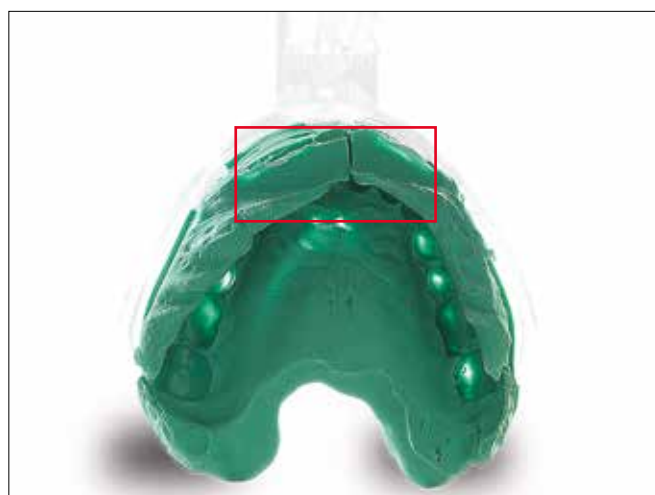
The impression was moved before the material had time to set causing significant deformation in the anterior region.



The impression shows a lack of depth and width of material and the impression failed to capture the posterior molar.



The impression material was not mixed properly and shows evidence of bubbles and lack of material in the tray.



The impression material is delaminating from the tray and has excess material in the labial region yet is too shallow in the occlusion region.

### Examples of good impressions

A complete, well defined upper and lower impression of all visible teeth, especially the molars. Each tooth is well defined with at least 5 mm of material above the gingival margin. A good homogeneous mixture of the material:

- ✓ no powder, bubbles or colour differences
- ✓ no deformation, pulls or tears
- ✓ no delamination from the tray



Upper



Lower

### Plaster models



If you send plaster/stone models, please:

- Only use a Type IV high strength material, low expansion crown and bridge die stone that produces smooth, hard and accurate surfaces.
- Use plaster that can be scanned by CAD/CAM systems (matt and light colour).
- Prepare the plaster model in order to:
  - ensure that all the teeth can be read by the scanner used by our production facility
  - provide utmost accuracy (e.g. remove bubbles).

### Bite registration in desired protrusion

- The patient's bite registration in the desired protrusion must be supplied in a material of your choice. A positioning device, like a ProGauge or George Gauge, with a heavy body or fast-setting silicone (PVS) bite registration material should be used. ResMed does not recommend using wax as it distorts easily.
- Please disinfect bite registrations before sending them to ResMed or your dental laboratory.



A plaster model in centric occlusion



The same model but with the bite recorded with a George Gauge in desired protrusion

### Measurements in maximum protrusion

- Consider providing a bite in centric occlusion in case of special condition (prognathy, retrognathy) and/or unstable occlusion.

## 4. Specific requirements for digital impressions

If you have an intra oral scanner and you want to send a digital imprint for Narval manufacturing, please contact your local ResMed representative or ResMed customer service ([narvalCC@resmed.com](mailto:narvalCC@resmed.com)) to check that your scanner is compatible. We will send you a user guide containing the information you need to order a Narval appliance from digital impressions.



## 5. Ordering

### Important

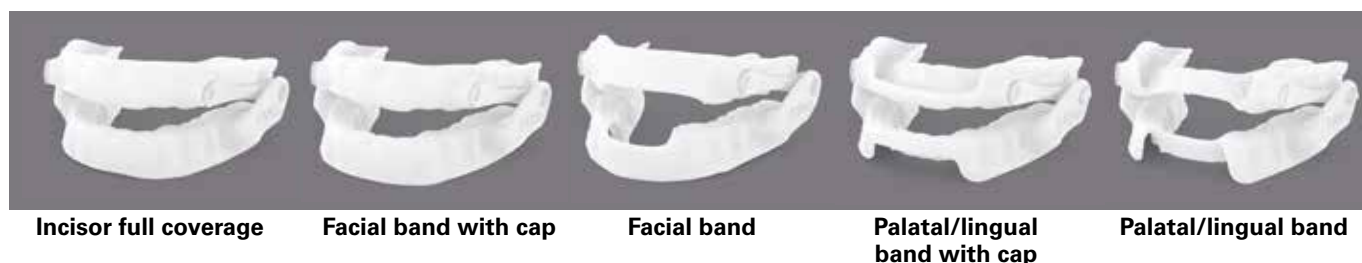
Always use the latest order form to ensure that the most up-to-date information is recorded and sent to the production facility. Comments and additional information should only be in English or French.

Once you have all the necessary information, please complete, sign and date the prescription order form, including your patient's name, your practice address and your contact details. Ensure the patient acknowledges the data privacy statement on the front of the order form.

### → Focus on design preferences

This section on the order form enables you to select one of five Narval design variations.

The variations cover a broad range of patient needs and anatomical constraints, as band design plays an important role when it comes to the fit, comfort and retention of the device.



The following Narval design guide will help you select the appropriate design for your patients:

		Teeth morphology						Particular focus		
		Low retentive canines & molars (short or no undercut)	Proclined or highly retentive incisors	Retroclined incisors	Significant overbite	Significant overlap of the incisors	Frenulum close to gingival margins	Reduce tongue pressure on incisors	Maximise tongue space	Foster anterior teeth alignment <sup>5</sup>
WITHOUT ANTERIOR CONTACT	Facial band			●	●	●			●	
	Facial band with cap	●		●					●	
	Incisor full coverage	●						●		
	Lingual band with cap	●	●				●	●		
	Lingual band		●		●	●	●			
WITH ANTERIOR CONTACT	Facial band with cap	●	N/A	●					●	●
	Incisor full coverage	●	N/A	N/A				●		●
	Lingual band with cap	●	●	N/A				●		●

### Important

Without any design specification, ResMed will select a design for you, prioritising a non-contact facial band design unless the dental morphology requires a different design.

Whatever design you choose, with or without contact, the Narval appliance does not take retention from the anterior teeth.

If you choose a specific design, ResMed will try to comply with your preference but might have to change in case the dental morphology requires a different design.

### → Focus on anterior contact option

Three of these designs are also available with contact on the facial and lingual surfaces of the incisors. This option can be used for low retentive cases, as it increases surface contact with the teeth. It can also be used to help maintain anterior teeth alignment into the splints (see adjacent table).<sup>5</sup>

**If you choose a design with anterior contact and we are not able to comply with your preference, we will change for one of the other two designs with anterior contact.**

### → Focus on vertical dimension and molar coverage

Following the AADSM report, the Narval appliance default design will prioritise comfort for the patient by minimising the vertical dimension and the bulk of the device.

**For this same reason, the Narval appliance default design** will not cover all of the molars, especially if canines and premolars are retentive enough to decrease the vertical dimension and bulk of the device. As a consequence, by default, the splints will be designed as follows:

- On the upper, we will cover at least tooth #6
- On the lower, we will cover at least tooth #7

In all cases, low retention might make it necessary to cover more posterior teeth in order to increase retention.

**If this default choice does not fit your needs, you can request that we cover all of the molars by ticking the relevant box on the order form.**

#### AADSM report<sup>4</sup>

*Vertical adjustability has been a controversial subject in the design of oral appliances. Despite anecdotal reports of patients benefiting from an increased vertical dimension, **several studies suggested that increased vertical dimension, measured as inter-incisal distance, resulted in decreased patient acceptance and had no consistent impact on efficacy.***

### → Focus on patient-specific dental particularities

If your examination shows that your patient has any of the following dental conditions, please specify this on the order form:

#### • **Teeth to protect or broken teeth:**

Based on this information, we will create a splint that does not take retention on these specific teeth in order to avoid any further damage.

#### • **Future restoration on teeth:**

The Narval device should be ordered only once dental restorations have been done. However, if a treatment request is urgent, you can specify the teeth to protect in anticipation of a future restoration. In that case, the splints will provide additional space around the specified teeth area in an effort to allow a proper fitting of the device after restoration.

#### • **Complete lower denture mechanically retained (e.g. by implants):**

A complete lower denture is not a contraindication if it is mechanically retained (e.g. by implants). If the patient wears the denture during the night, please tick the box and record the impression of the arch with the lower denture in place. Please note that in this case, the Narval appliance retention will be increased.

#### • **Complete upper denture:**

A complete upper denture is not a contraindication. If the patient wears the denture during the night, please tick the box and record the impression of the arch with the upper denture in place. Please note that in this case, the Narval appliance retention will be increased.

#### • **Presence of removable partial denture(s):**

If the patient wears a removable partial denture during the night, dental impressions must be recorded with the removable partial denture in place. In that case, a specific design shape will be created to optimise the retention provided by the partial denture and allow the device to be clipped on to the denture edges.

If the patient does not wear the removable partial denture during the night, please ensure that the anchoring value and morphology of the remaining teeth are sufficient.

The Narval appliance will be designed on the basis of your expert input and the specific needs of your patient. In order to optimise the design of your patient's appliance, please ensure you provide all relevant information on the Narval order form.

# Step 4 Fitting and adjusting the device

## 1. Instructing your patient

Please find below general warnings and precautions in relation to the use of the Narval appliance.

### Warnings

#### Using the Narval appliance may cause the following expected side effects:

- Tooth movement or changes in dental occlusion.
- Gingival or dental soreness.
- Pain or soreness of the temporomandibular joint.
- Obstruction of oral breathing.
- Excessive salivation or mouth dryness.
- In rare cases, allergy or inflammatory reaction or persistent irritation in the mouth.

#### Your patient should contact you in case of:

- Any persistent side effect or aggravation of an existing dental condition with the use of Narval appliance.
- Allergy, inflammatory reaction, persistent irritation or obstruction of oral breathing. In that case, the patient should discontinue their use of the Narval appliance immediately.
- Persistent tooth pain upon awakening when using Narval appliance.
- Fixed prosthetics (crown, bridge, veneer, etc.) that detach. If this occurs, the prosthetics must be reattached and the Narval appliance must be adjusted to minimise the risk of further detachment.
- Upper removable denture that is not sufficiently retained or well adjusted. If this occurs, the denture must be adjusted or relined.

### Precautions

#### Please instruct your patient about the following precautions:

- Do not eat while wearing your Narval appliance.
- Only wear your Narval appliance during sleep.
- Brush and rinse your teeth before wearing your Narval appliance.
- Attend a regular dental review.
- Check the Narval appliance on a regular basis. If there is any visible damage or cracking of a component, the patient should discontinue use and consult the dental practitioner.

Please make sure that your patient is aware of the above warnings and precautions. Inform the patient that they are written in the Instructions for Use that are delivered with the Narval appliance.



## 2. Fitting the device



- Clean the device.
- Moisten the splints in water and validate the fit of each splint in the patient's mouth.
- In case of insertion difficulty, please read section pp 16-17 "Adjusting retention".



- Position the device in the patient's mouth with the upper splint against the upper teeth.



- Ask the patient to press firmly with his fingers on the upper splint until it's securely in place. You may hear a 'snap' as the device engages the undercuts.



- Bring the patient's jaw forward and let him proceed in a similar way to slide in the lower splint. In some cases, it may be easier to insert the lower splint first, particularly where there is limited protrusive range.



- To remove or reposition the device, simply use your fingers evenly on both sides of the mouth to disengage the splints. Do not pull or press on the connectors to adjust the position.



- Instruct the patient not to bite down onto the splint to insert it onto their teeth. Remind them to remove both sides at the same time to avoid putting undue force on the dentition and splint.



### 3. Adjusting retention

If needed, you can add or remove some retention from the device.

#### When retention is too high.

If you want to relieve retention on specific areas of the Narval appliance, you can do so at chairside by simply making **small incremental adjustments** and checking the device on the model and patient along the way.

#### STEP 1: REMOVE MATERIAL



- Use a **scalpel** or a stone bur at low speed to gradually remove excess material from the inside surface.
- Reduce edges in the interdental spaces and remove material corresponding to the side of teeth that have a significant undercut.



#### STEP 2: POLISH



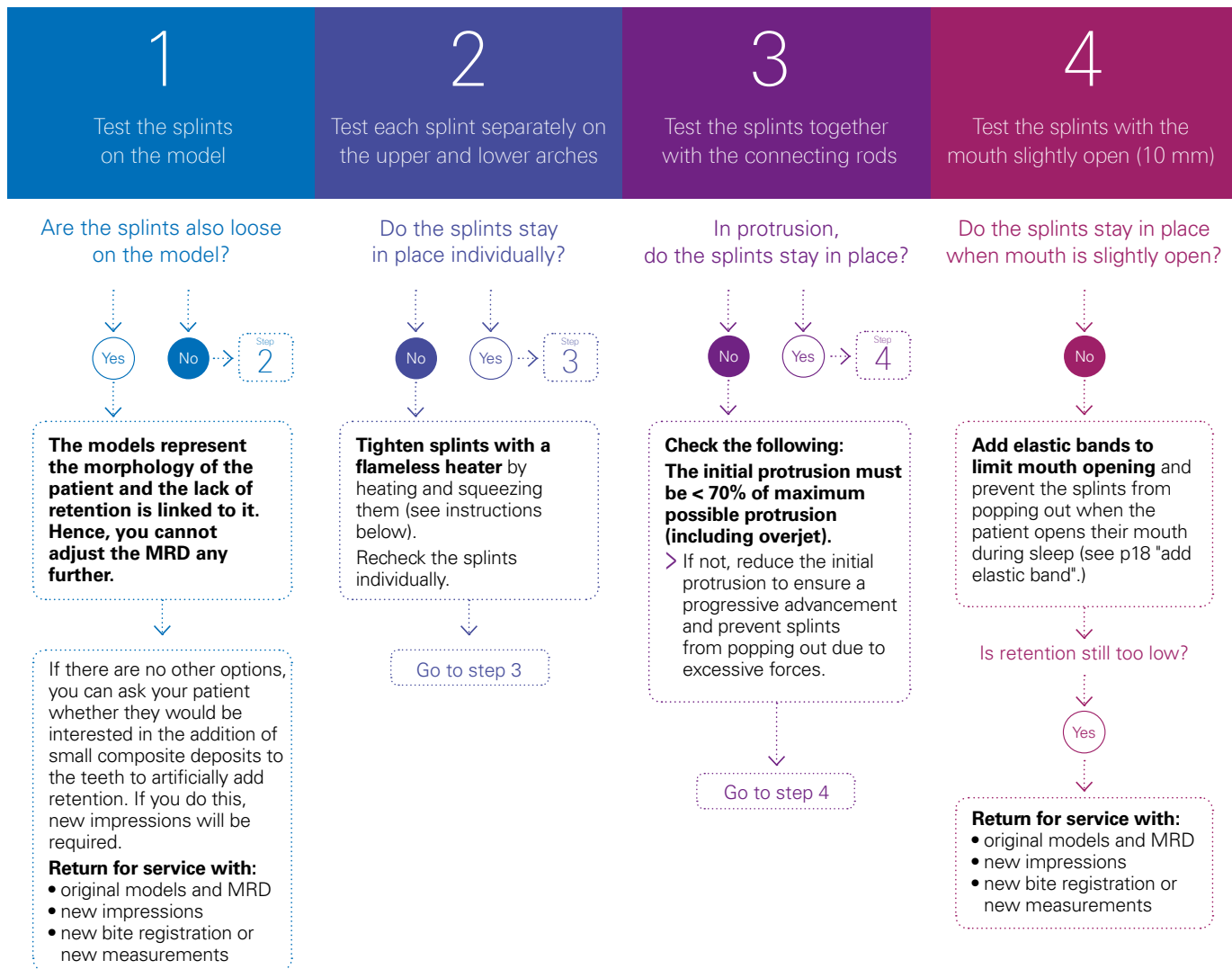
- Finish by polishing spots where material has been removed using a **rubber bur** for polishing.
- You can also use the scalpel to remove flash created by grinding on the appliance.

If you remove material on the band it should not result in a height smaller than 7.5 mm in total (including a cap) or a thickness less than 1.2 mm.

Always remove localised layers step by step in small increments. Try the device on the model and then on patient. Removing material on wide or deep surfaces could weaken the splint. Assess the transparency of the device to estimate the remaining thickness. If in doubt, check with a caliper: the thickness must remain greater than 1.2 mm. If you remove material, always check the splints for possible weakness or breakage before fitting them in the patient's mouth.

## When retention is too low.

If you want to increase retention on specific areas of the Narval splints, you can use the following protocol:



Instructions to increase retention:

Always use lateral movements while applying heat with a flameless heater so as not to burn the splint.



- Heat one side of the relevant quadrant of the device. Focus the heat on the lingual and palatal sides of the splints. Do not heat the internal surfaces or the edges of the splints.
- Squeeze the splint with your fingers to tighten it a bit.
- Cool completely with compressed air.
- Replace the splint on the plaster model, then with the patient to test retention.
- If retention is still too low, repeat the process on the other side of the quadrant.

## 4. Adjusting lateral-deviation

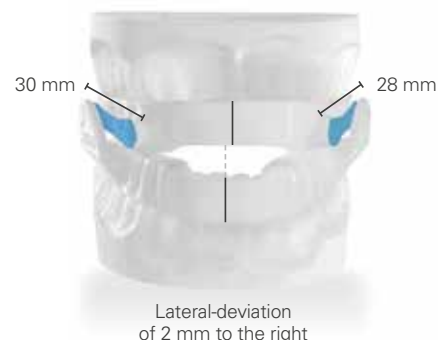
To prevent the splints from popping out due to unbalanced forces, the rod lengths are adjusted to obtain a natural position of the mandible.

In the example on the right (see picture), the patient has a 2 mm deviation to the right. This means:

- The connecting rod on the right would need to be 1 mm longer (30 mm in length).
- The connecting rod on the left would need to be 1 mm shorter (28 mm in length).

If lateral-deviation **on the right of the patient:**

	Left rod length	Right rod length
<b>1 mm</b>	- 0.5 mm	+ 0.5 mm
<b>2 mm</b>	- 1 mm	+ 1 mm
<b>3 mm</b>	- 1.5 mm	+ 1.5 mm
<b>4 mm</b>	- 2 mm	+ 2 mm



## 5. Adjusting the balance of the slip plane

1. The patient needs to bite with the device in place on a coloured hinged (articulating) paper.
2. Remove the coloured premature contacts with a large, long and abrasive bur in order to increase the stability of planes. Always remove layers step by step with

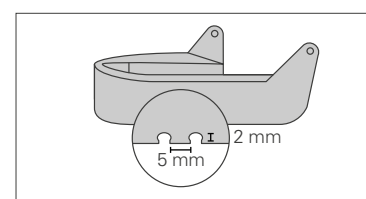
small increments. Try the device on the patient. Removing significant amounts of material could weaken the splint. Hold the device to the light to estimate the remaining thickness and, in case of doubt, check with a caliper: the thickness must remain greater than 1.2 mm.

3. Remove any residual colour left by the hinged paper with unmodified pure alcohol and a polishing bur.
4. Rinse the splints.



## 6. Adding elastic bands

1. If you want to use elastic bands, ResMed recommends orthodontic elastic bands without latex. Make two incisions on the vestibular face of the lower splint between two teeth. Do your best to ensure the incisions are vertically aligned with the rod button. Respect the following dimensions (see picture 1).
  - Height of the slots: 2 to 3 mm. Do not touch the margins.
  - Distance between slots: 5 mm. Do not touch the margins.
2. Connect elastic bands between the rod button of the upper splint and the incision made on the lower splint (see picture 2).



Picture 1



Picture 2

# Step 5



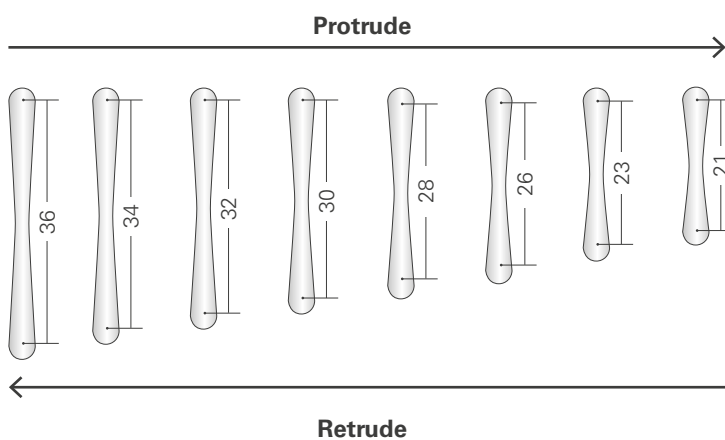
## Device titration

### Important

The Narval appliance is a traction-based appliance. Consequently, the protrusion is increased by shortening the connecting rods.

Titration is the process of adjusting the protrusion of the device and the mandible to find the best balance between efficacy and comfort.

For greater protrusion, you will shorten the connectors. For milder protrusion, you will lengthen the connectors. MRD therapy has a well proven non-linear dose response to the level of protrusion until the efficacy plateau is reached. This means that the greater the protrusion, the more efficient the MRD will be (up to a limit - the efficacy plateau). However, as the protrusion increases it will be less comfortable for the patient, as the pressure on the teeth and the TMJ articulation will increase.



### AADSM recommendation statement<sup>1</sup>

*We suggest that a qualified dentist uses a custom, titratable appliance over non-custom oral devices.*

### ERS task force<sup>2</sup>

*The device should be custom-made, evaluated and advance the mandible at least 50% of maximum protrusion. A titration procedure is essential.*

### How to determine the right protrusion?

The initial mandibular protrusion of the Narval appliance is set at approximately 60% of maximum protrusion, unless you provide a bite registration. In that case, the initial setting corresponds to the position indicated by the registration.

In most cases, the initial setting does not correspond to the optimal protrusion for your patient and you will need to adjust and find the right protrusion based on ongoing symptoms such as:

- snoring frequency and intensity
- tiredness
- daytime sleepiness and tendency to fall asleep
- quality of sleep and nocturia

### What is the recommended titration process with a Narval appliance?

In accordance with recommendations from clinical studies<sup>4</sup>, the Narval appliance can be advanced in increments of 1 mm. It can be fine tuned in 0.5 mm increments.

**Step 1.** At the fitting appointment, there should be no sensation of muscle/TMJ pain. If there is, reduce the protrusion by replacing the connectors with longer ones until the discomfort disappears.

**Step 2.** At the follow-up appointment, once the patient is used to sleeping with the Narval appliance, ask about symptom improvements. If all symptoms are resolved, proceed to step 4.

**Step 3.** If some symptoms persist and the patient can tolerate a greater protrusion, replace the existing connectors with shorter ones to increase protrusion. Protrusion should not be increased by more than 1 mm a week. Set up another follow-up appointment one or two weeks later and repeat step 3 until the symptoms are resolved or you reach the tolerance limit of your patient, whichever happens first. Proceed to step 4.

**Step 4.** For OSA patients, inform your sleep specialist partner of your patient's status and MRD titration. The patient should undertake a controlled sleep recording with their Narval appliance to measure treatment efficacy on breathing parameters such as apnoeas and oxygen desaturation. A controlled sleep recording is usually not required for patients with simple snoring.

## How to adjust Narval appliance protrusion?

Protrusion should not be increased by more than 1 mm a week as adjusting in larger increments may cause undue discomfort.



- Turn the appliance so that the connecting rods are aligned with the bow tie-shaped cut out on the splint.



- Disconnect the lower side first, since the bow tie-shaped cut out is more visible here.
- Firmly push with your thumb at the top of the rod (located on the triangle portion of the splint) to disconnect the rod from the appliance.
- Repeat for the other side of the lower splint, then for both sides of the upper splint.



- Select the appropriate connecting rods:
- To **increase** protrusion, use a **shorter** connecting rod.
- To **decrease** protrusion, use a **longer** connecting rod.



- Hold the connecting rod perpendicular to the splint. Line up the bow tie on the connecting rod with the cut out on the splint.



- Click into place to re-engage the connecting rod.

## Step 6 Sleep monitoring appointment

A monitoring appointment with the sleep specialist can be used to evaluate the efficacy of the Narval appliance via an objective monitoring process (PG or PSG). The results might lead to a new titration follow-up appointment with the dental specialist if treatment results are not sufficient.

### AADSM recommendation statement<sup>1</sup>

*It is recommended that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients fitted with oral appliances*

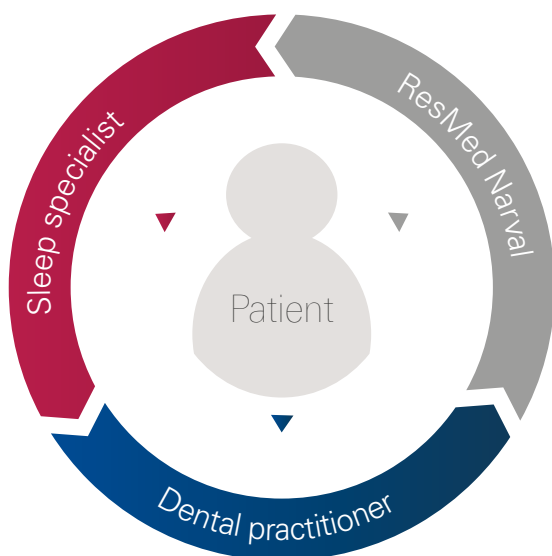
## Step 7 Dental follow up

- Once the titration process is complete, it is important to schedule regular follow-ups with your patient to assess potential side effects and to ensure efficacy and safety in the long term.
- For OSA patients, if a satisfactory improvement in symptoms and an objective sleep recording validation cannot be achieved post titration(s), work with your sleep specialist partner to discuss alternative treatments.

### AADSM recommendation statement<sup>1</sup>

*Dental follow-up must be carried out by qualified dentists providing oversight (rather than no follow-up) of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental related side effects or occlusal changes and reduce their incidence.*

*We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits—as opposed to no follow-up—with a qualified dentist and a sleep physician.*



# Cleaning

The Narval appliance is delivered to your patient with a denture cleaning brush for the daily cleaning. In addition, the Narval appliance must be cleaned more thoroughly twice a week, using an antibacterial denture cleanser designed for orthodontic appliances.

For detailed cleaning instructions with relevant precautions, please refer to the Instructions for Use that are supplied with the appliance.



## Please note

Over time, normal use of a Narval appliance can lead to discolouration or staining. This does not affect the performance of the appliance. Discolouration or staining can be made worse by:

- poor follow-up by patients of the Narval appliance Instructions for Use
- insufficient attention to mouth hygiene by patients
- acidity of saliva

# Whitening protocol

If your patients complain about persistent unaesthetic stains appearing on their device over time, you can follow a specific "Whitening protocol" for the appliance. You can request this protocol from your local ResMed representative.



# Warranty

ResMed acknowledges all consumer rights granted under the EU Directive 1999/44/EC and the respective national laws within the EU for products sold within the European Union.

The warranty below is a voluntary manufacturer's warranty offered by ResMed SAS ("ResMed"). It is in addition and without prejudice to your mandatory rights under applicable law.

- 1.** ResMed guarantees all Narval appliances supplied to be free from defects in materials and workmanship for a period of 2 years from the manufacturing date shown inside the packaging. In specific circumstances, which may vary from region to region, your warranty period may be longer than 2 years. For details, please contact your local ResMed dealer. During the warranty period and at its complete discretion, ResMed will adjust or replace any Narval appliance that is covered by the warranty.
- 2.** Adjustments covered by the warranty may only be performed by a ResMed facility or a ResMed authorised partner.
- 3.** The warranty does not cover:
  - damage that is not caused by manufacturing defects,
  - devices that do not fit due to defective or distorted impressions or defective or distorted bite registrations,
  - dental calculus deposits, stains, changes of colour or odours,
  - damage caused by a pet.
- 4.** The warranty shall be void if:
  - the patient had dental restorative work or dental modifications (e.g. tooth extractions, new crowns, new dental prosthetics) during the warranty period and the defect results from the work or modification,
  - the Narval appliance was not used and cleaned in accordance with the Instructions for Use, or
  - the Narval appliance was modified by a non-authorised party.
- 5.** For the warranty to be honoured, the following elements must be returned to ResMed by the dental sleep specialist: both splints with their connecting rods, storage container and the patient's dental models.



Help your patients get the sleep they deserve!  
Contact your local ResMed representative or email [NarvalCC@resmed.com](mailto:NarvalCC@resmed.com)

For more information, visit [ResMed.com/Narval](https://ResMed.com/Narval)

## References

- 1 Ramar K et al. Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015; An American Academy of Sleep Medicine and American Academy of Dental Sleep Medicine Clinical Practice Guideline. Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine. 2015;11(7):773-827.
- 2 Marie Marklund & al. Non-CPAP therapies in obstructive sleep apnea: mandibular advancement device therapy. European Respiratory Journal 2012 39: 1241-1247; DOI: 10.1183/09031936.00144711 (ERS Task-force report)
- 3 Bettega, G. et al. "Mandibular advancement device for obstructive sleep apnea treatment in adults. July 2014." Revue de stomatologie, de chirurgie maxillo-faciale et de chirurgie orale 116.1 (2015): 28-57.8
- 4 Scherr SC et al. Definition of an effective oral appliance for the treatment of obstructive sleep apnea and snoring: a report of the American Academy of Dental Sleep Medicine. Journal of Dental Sleep Medicine 2014;1(1):39-50.
- 5 Anterior contact European Controlled Product launch (CPL). ResMed Internal Report, data on file (confidential) – September 2017 – 86% of the dental sleep experts chose the anterior contact option with the intent of preventing MRD-related tooth movements.