



# ResMed Mandibular Repositioning Device Instructions

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**ResMed Mandibular Repositioning Device**

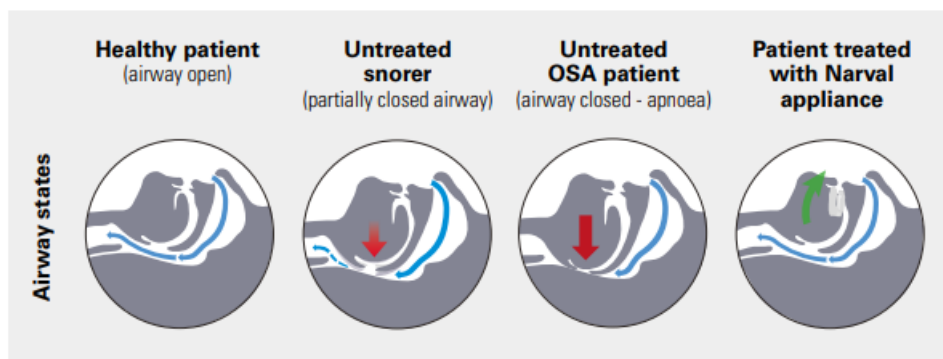


## Introduction

Thank you for choosing the Narval CAD/CAM (computer-aided design and manufacturing) appliance. This document provides user instructions for Narval CC, Narval O.R.M\*, and Narval Equinox\* referred to collectively as your Narval appliance. Please read the entire manual before using your device.

### Mechanism of action

Your Narval 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 aid in opening 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.



## 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 apnoea (OSA) in adults. In the case of severe apnoea, Narval CC is recommended as a second-line intervention after continuous positive airway pressure (CPAP) failure, non-compliance or refusal.

### Narval O.R.M\*

Narval O.R.M is a custom-made medical device, available under medical prescription and intended to treat OSA in adults. In the case of severe apnoea, Narval O.R.M is recommended as a second-line intervention after CPAP failure, non-compliance or refusal.

### Narval Equinox\*

Narval Equinox is a custom-made medical device, available under medical prescription and intended to treat snoring and/or OSA in adults. In the case of severe apnoea, Narval Equinox is recommended as a second-line intervention after CPAP failure, non-compliance or refusal.

## Contraindications

The Narval appliance is contraindicated for patients who:

- have central sleep apnoea;
- have severe respiratory disorders (other than OSA);

- have loose teeth or advanced periodontal disease;
- are under 18 years of age;
- have a completely edentulous arch;
- have a complete lower denture (not an overdenture);
- have short teeth and/or insufficient undercuts to retain the device

## **General warnings and precautions**

### **CAUTION**

- Prior to providing your Narval appliance, the dental sleep specialist needs to:
  - Check for relevant issues in the 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.
  - Perform a dental, periodontal, prosthetic, and temporomandibular joint (TMJ) examination. The following dental issues must be treated by the patient's regular dentist before MRD treatment: periodontal disease, Cysts, and mouth ulcers, Teeth that need to be extracted, Prosthodontics – such as crown or bridge, Orthodontics. Temporomandibular pain needs to be further assessed by the patient's treating physician as well as any other TMJ disorder.
  - Check if the teeth (natural or dental implant) anchoring value and retentive morphology are sufficient to ensure the efficacy of MRD without the significant side effects of treatment.
- 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.
- Regular dental review is recommended.
- Check your Narval appliance on a regular basis. If there is any visible damage or cracking of a component, discontinue use and consult your dental clinician.

### **WARNING**

- 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 irritations in the mouth.

If you experience any persistent side effects or aggravation of existing dental conditions with the use of your Narval appliance, contact your dental clinician or sleep therapist. In case of allergy, inflammatory reaction, persistent irritations, or obstruction of oral breathing, discontinue using your Narval appliance and contact your dental clinician or your sleep therapist.

- You may experience some tooth pain most likely to happen upon awakening when using your Narval appliance. The pain usually disappears. If pain persists, consult your dental clinician.

- On very rare occasions, your fixed prosthetics (crown, bridge, veneer,...) may detach. If this occurs please consult your dental clinician to reattach the prosthetics and to adjust your Narval appliance to minimize the risk of further detachment.
- If you wear an upper removable denture that is not sufficiently retained or well-adjusted, it is essential to visit your dental clinician to adjust or relin the denture.

## Content of the packaging

Your Narval appliance comprises the following components:

1. Lower splint
2. Upper splint
3. Connecting rods



Your Narval appliance is delivered with the following items:

1. A storage container
2. A denture cleaning brush
3. Instructions for use – not shown
4. Elastic bands (optional) – not shown
5. A connecting rod kit to allow the dental clinician to adjust the mandibular advancement – is not shown



## Fitting the appliance



To make it easier, the following steps may be performed in front of a mirror the first few times you position your

Narval appliance:

1. Moisten your Narval appliance with water.
2. Position your Narval appliance in your mouth with the upper splint (smaller one) against your upper teeth.
3. Press firmly with your fingers on the splint until it is securely in place. Do not pull or press on the connectors to adjust the position.
4. Bring the lower jaw forward and proceed in a similar way to slide in the lower splint.

Do not bite into the splint to insert it onto the teeth. In some cases, it may be easier to insert the lower splint first.

### Removing the appliance



1. Use your fingers evenly on each side of the lower splint to gently lift it away from your gums. Ensure you do not pull or press on the connecting rods.
2. Repeat step one with the upper splint.
3. Remove your Narval appliance from your mouth.
4. Clean your Narval appliance according to the cleaning instructions from the Cleaning section.

### Cleaning

#### CAUTION

- Before choosing an antibacterial denture cleanser, you should verify that you are not allergic to any of its ingredients. Always follow the instructions provided with it.
- Do not put the Narval appliance in water warmer than 45°C/113°F.
- Do not use toothpaste or mouthwash to clean your Narval appliance.
- Do not use chlorine-based products, bleach, acetic acid, household cleaning products or alcoholic solutions to clean your Narval appliance.



After each time you use the device:

1. Remove the Narval appliance from your mouth and immerse in lukewarm drinking quality water (e.g. in a clean glass or container).
2. Clean the Narval appliance with a denture brush, making sure to brush the inside surface of the Narval appliance for at least 1 minute. A denture brush typically offers two different brush heads. The smaller brush with angled bristles allows for cleaning the inner surfaces of the Narval appliance, while the larger brush allows for cleaning the outer surfaces.
3. Rinse well with clean, lukewarm drinking quality water.
4. Carefully inspect the Narval appliance to confirm it is visibly clean (e.g. no visible particles remaining on the device). If necessary, clean the device again, repeating steps 1 through 4.
5. Once clean, dry the Narval appliance with a clean tissue or towel and place it back in its storage box.

Twice a week, clean your Narval appliance more thoroughly, using an antibacterial denture cleanser designed for orthodontic appliances:

1. Read the instructions of the antibacterial denture cleanser carefully before use.
2. Clean your Narval appliance following the instructions provided by the cleanser manufacturer.
3. Rinse the Narval appliance well with clean, drinking quality water.
4. Dry the Narval appliance with a clean tissue or towel and place it back in its storage box.

Over time the splints of your Narval appliance might change color. This may be due to the acidity of your saliva and how well you take care of your Narval appliance. This will not affect its performance.

## **Storage**

- Ensure that your Narval appliance is clean and dry before storing.
- To protect your Narval appliance, store it in its storage container at room temperature in a dry place away from direct sunlight.

## Symbols



- Catalog number



- Do not re-use



- Keep away from sunlight



- Batch code



- This way up



- Serial number



- Use by date

- Authorized Representative in



- the European Community

- Keep dry



- Manufacturer



## 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. During the warranty period, ResMed will repair or replace (at the absolute discretion of ResMed) any covered Narval appliance and accessory with a defect in materials and workmanship, subject to the terms, conditions, and exclusions of its warranty.
2. Warranty repair work may only be performed by a ResMed facility or a ResMed authorized partner.
3. ResMed shall not be liable under this warranty for any change of color that might happen over time or any damage that may be caused by pets or any consequential loss resulting from any defect.
4. The warranty period is 24 months from the date of manufacture for Narval appliances and 12 months for any accessories provided with an appliance.
5. For the warranty to be honored, both splints with connecting rods, plaster models, and bite registrations must be returned to ResMed.
6. This warranty shall be void if:
  - the Narval appliance or accessory was modified by a non-accredited ResMed technician or another third party,
  - the Narval appliance or accessory was not used in accordance with the Instructions for Use, and/or,
  - you had dental restorative work or dental modifications during the warranty period.

### ResMed SAS


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See [www.resmed.com](http://www.resmed.com) for other ResMed locations worldwide.

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Documents / Resources

	<p><a href="#">ResMed Mandibular Repositioning Device</a> [pdf] Instructions</p> <p>Narval CC, Narval O.R.M, Narval Equinox, Mandibular Repositioning Device, Mandibular Device, Repositioning Device</p>
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References

- [R Sleep apnea and COPD - learn about symptoms and treatment | ResMed](#)
- [R Sleep apnea and COPD - learn about symptoms and treatment | ResMed](#)