

THE PANTHERA ANTI-SNORING DEVICE
PATIENT INSTRUCTIONS FOR USE



Rx Only

PANTHERA
DENTAL

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The medical device patient labeling adheres to the guidance recommended for: readability, writing for increase comprehension

“**CAUTION:** United States Federal Law restricts this device to use by or on order of a physician.”

Definitions

Mandible. A bone in the lower jaw.

Mandibular Repositioning Device (MRD). An oral appliance that maintains the lower jaw in a forward and closed position during sleep, which allows the airway to stay open.

Obstructive Sleep Apnea (OSA). An almost full collapse of the upper airway caused by the relaxing of the muscles that control the soft palate and the tongue.

Snoring: A loud noise you make when trying to breathe while sleeping.

BEFORE SLEEPING ...



CAUTION PLEASE READ INSTRUCTIONS BEFORE USING THE DEVICE

When you are sleeping, the throat muscles relax. The jaw and the tongue move backward, narrowing the upper airway.

The snorer must try to open the airway. The airflow is reduced and is forced the passage. This creates vibrations in the soft structures in the mouth, provoking snoring.

60% OF MEN AND

40% OF WOMEN SNORE¹

Loud snoring can wake the husband or wife of the snorer and disturb his/her sleep. Generally, the spouse will adjust his/her bedtime schedule or sleep in a different room. Snoring can change your mood and can affect your relationships and can lower your quality of life.

15% of men and 52% of women are affected by their spouse's snoring.²

General Information:

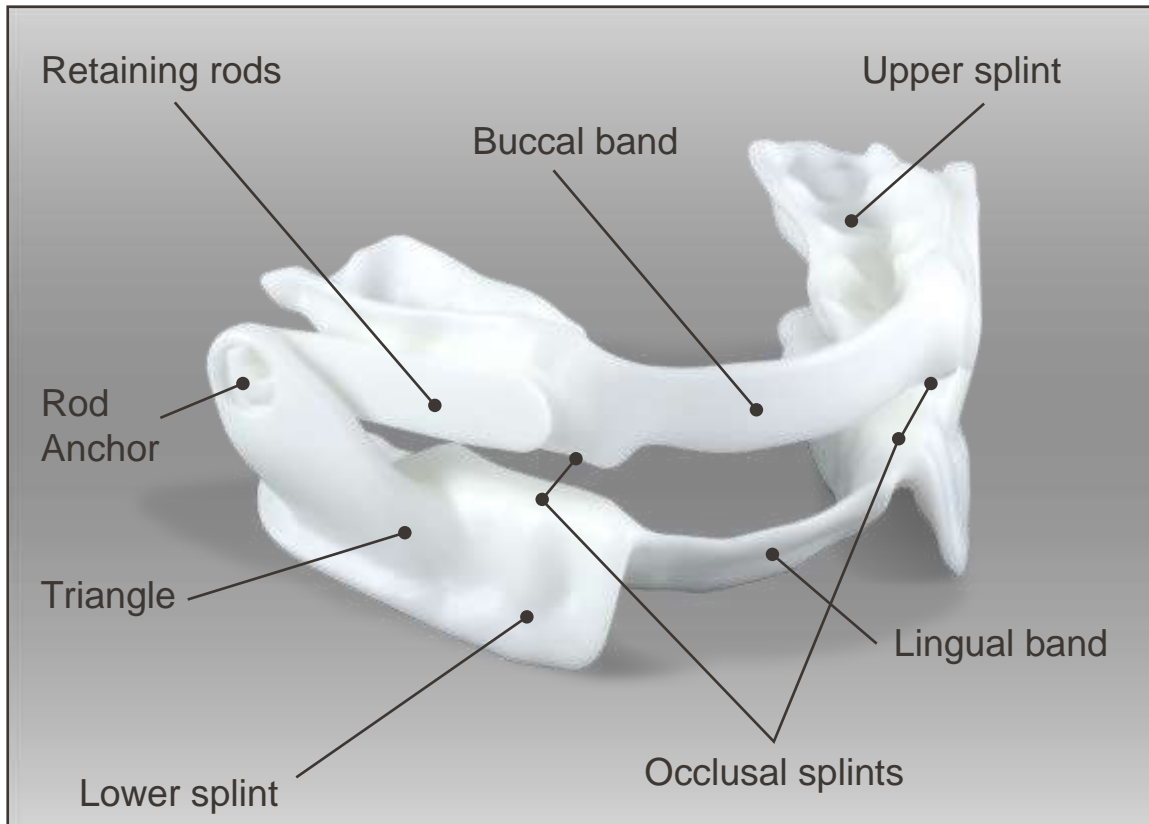
Description of your Anti-Snoring Device

The Panthera device is a prescription customized device for you and tailored to your specific needs. It has two splints and a retaining system. The upper splint is adapted for the upper teeth and the other for the lower teeth. The retaining system is in the form of a triangle and has rods used to move the lower jaw forward by pulling it towards the front. The Panthera device is made from a dental impression. It is to be used only by the person it was made for.

¹. *Teculescu et al. (2009)*;

². *Norton et al. (1983)*.

The device pulls the lower jaw to the front when wearing it during sleep. This clears the back of the tongue, which help to open the upper airways. Opening the airways eases the passage of air.



Material used

The anti-snoring device is made from a biocompatible plastic material. Very resistant to wear and flexible, it supports temperature changes. It must always be handled at room temperature.

Indications for use

The Panthera Anti-Snoring Device is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Contraindications

The Panthera Anti-Snoring Device is a jaw-repositioning device. It is available under medical prescription and intended to treat mild to moderate OSA in adults.

The Panthera anti-snoring device is contraindicated for patients who:

- Have central sleep apnea
- Have severe respiratory disorders
- Have loose teeth or advanced periodontal disease
- Are under 18 years of age

Precautions

Dentists should consider the medical history of the patients. This includes history of asthma, breathing, or respiratory disorders, or other relevant health problems. In the case of such problems, the dentist must refer the patient to a specialized healthcare provider before prescribing the device (per FDA Guidance: Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA).

The Panthera Anti-Snoring Device is for adults. It must be used exclusively during sleep: at night or when taking a nap.

Check the condition of the device on a regular basis. It is recommended to consult a dental professional for an annual check-up.

The development of new aching might be because of maladjustments. It is then recommended to stop wearing the device and consult a dental professional.

The device is made using high quality material. In rare cases, allergies or inflammation may occur. If so, you must stop wearing the device and consult your dental professional.

The device is resistant to temperature changes. It must be handled at room temperature. If the device is left in severe cold or severe heat (for example in a car), it must return to room temperature before being handled.

Note: Wearing a jaw repositioning device is not recommended for people suffering from osteoarthritis of the temporomandibular joints.

The Panthera device should not change the bite (occlusion) in a permanent manner. If you experience this, rapidly consult your dental practitioner.

Warnings

Use of the device may cause:

- Tooth movement or changes in dental occlusion.
- Gingival or dental soreness.
- Pain or soreness of the temporomandibular joint.
- Excessive salivation.
- Obstruction of oral breathing.

If you notice any secondary effects, communicate with your dental professional.

Recommended Jaw Exercises

Helpful morning exercises

The Panthera Anti-Snoring Device is fixed on the teeth and the jaw. This stresses the joints linking the jaw to the skull. It is normal to have some difficulties in placing your jaws in their usual position after use, especially at the beginning.

It is suggested to perform the following exercises to help reposition the lower jaw:

- Move the chin backwards and close molars together while biting. Repeat 5 to 10 times.
- Eat breakfast or chew sugar-free gum; it will help jaws to return to a normal bite.

How to use the device:

To insert the device

Brush your teeth. Place the Panthera device into your mouth; move the upper splint (the one with no triangle) on the upper teeth. Press with fingers on the splint so it fits perfectly on the teeth.

Move the lower jaw forward in order to position the lower splint on the lower teeth. Press with fingers on the splint to put it in place.

In some cases, it might be easier to insert the lower splint first (see Figure 1 Figure 2). If so, after inserting the lower splint, you must move the lower jaw forward in order to insert the upper splint on the upper teeth (see Figure 1 Figure 2).



Figure 1



Figure 2

Note: Initially, it may be easier to insert the device in front of a mirror.

To remove the device

First, unclip the lower splint.

To do so, place thumbs on the sides of the lower retainer near the gum in front of the longest teeth (lower canine teeth), and lift the device (see Figure 3 Figure 4).

Then, place the fingers on the sides of the upper splint, near the gum, and pull down the splint (see Figure 3 Figure 4).

Remove the device from mouth, clean it, dry and store in case provided.

NEVER PRESS OR PULL on the retaining rods.



Figure 3

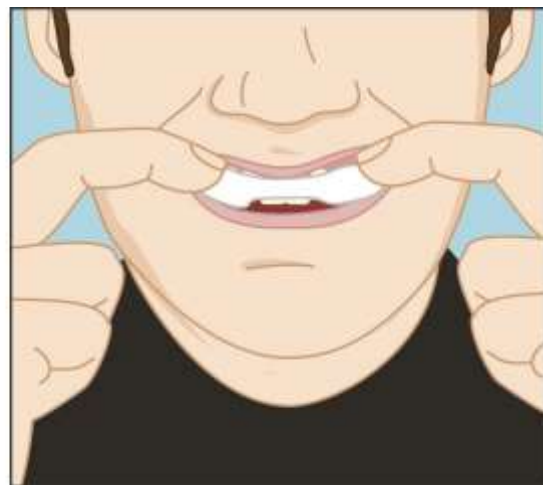


Figure 4

When to change the rod lengths

Your dental professional must change rods.

At the beginning, the advancement of the device will be of about 70 % of the maximum movement possible. The jaw advancement must be done progressively and according to your tolerance limit so it does not result in joint problems.

We recommend a jaw advancement of 1 mm at a time.

According to your comfort and tolerance, the lower jaw will be moved forward until snoring is reduced or alleviated, or until you hit your maximum jaw reach.

**Please respect the directions of your dental professional.
Do not hesitate to consult for any questions.**



To change the rods

Your dental professional must change rods.

Storing the device

Along with your device, you will receive a storing case and a carrying pouch.

When traveling, put the device in the storing case.

Before each use, verify the device for:

Possible damage. The device should not be used if there is visible wear or damage.

Cleanliness. If the device is not clean, it should be cleaned as per the cleaning instructions below.

Comfort. Make sure the device is comfortable and fits on upper and lower teeth snugly.

Recommended storage conditions: In its storage box at room temperature, away from direct heat and humidity.

Keep away from children.

Avoid leaving the device on the night table. **Dogs love it.**

Over time, some parts might change color. This depends on saliva acidity and device maintenance, among other factors. It is recommended to follow the cleaning instructions below.

Cleaning Instructions

Clean daily your device in lukewarm water with a soft toothbrush. Rinse, dry and store in case provided.

Twice a week use an antibacterial chlorine-free orthodontic cleaning solution. Follow manufacturer instructions.

Approved chlorine-free orthodontic cleaning solutions are available in most drugstores



Never use chlorine based products such as denture cleansers, bleach or acetic acid.

Never put the device in water warmer than 45°C or 133°F.

Rx Only



Your Panthera Anti-Snoring Device is guaranteed 5 years against any manufacturing or material defects. This includes device and rods breakage.

The patient and dentist should inspect the device for wear and tear, etc... The life time of the Panthera Anti-Snoring Device depends on the patient's care, storage and utilization.

Troubleshooting Information

This device must be worn during sleep.

To ensure proper oral hygiene, it is essential to brush your teeth before wearing the device. Check the integrity of your device on a regular basis.

Muscle and articulation pain might be due to maladjustments. It is recommended to consult the clinician or dentist who provided you with the device for adjustments.

On very rare occasions, the seal on the existing dental work may become loose. In such event, you need to consult your dental clinician to adjust the device and / or to firmly fix the dental work.

Regular follow-up by the physician who follows you for respiratory sleep problem is highly recommended.

For more information, visit www.snoringpanthera.com

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Additional Information

Risks of Snoring

Snoring may lead to creation of small scars on the walls of the pharynx. The scar tissue lowers flexibility and makes the airway smaller. Therefore, the upper airways age much more rapidly.

Putting on weight and ageing also influences the development of snoring.

Non-treatment increases snoring problems and may turn into obstructive sleep apnea.

4% of men and 2% of women suffer from sleep apnea.³

If you or your relatives have noticed breathing pauses when you sleep, it is recommended you consult a doctor.

NEED HELP?

We hope that you will be satisfied with your new Panthera anti-snoring device and that it will contribute to improve your quality of life.

In case of questions or doubts, you may speak with your dental professional or consult our website.

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www.snoringpanthera.com