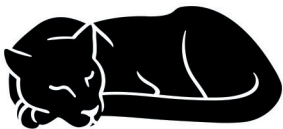


THE PANTHERA ANTI-SNORING DEVICE

PATIENT INSTRUCTIONS FOR USE



PANTHERA
SLEEP

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Definitions

Mandible: The lower jaw bone.

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): Full or partial 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 airflow is thus reduced and hindered. This creates vibrations in the soft structures of the mouth, causing 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, affect your relationships and lower your quality of life.

15% of men and 52% of women are affected by their spouse's snoring².

¹ *Teculescu et al. (2009).*

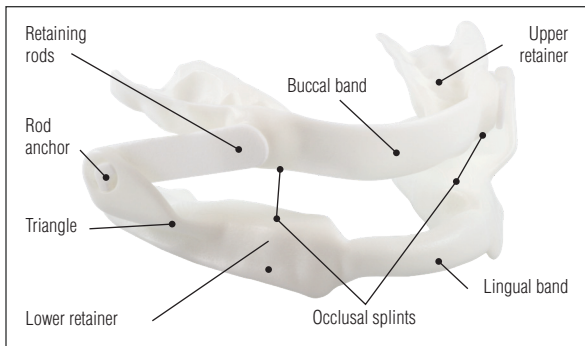
² *Norton et al. (1983).*

GENERAL INFORMATION

Description of Your Anti-Snoring Device

The Panthera device is a customized prescription device, tailored to your specific needs. It has two splints and a retaining system. The upper and lower splints are adapted for the upper and lower teeth, respectively. The retaining system has the shape of a triangle and includes 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.

When the device is worn during sleep, it pulls the lower jaw forward. This advancement clears the back of the tongue, which helps to open the upper airway. Opening the airway facilitates the passage of air.



Material Used

The anti-snoring device is made from a biocompatible plastic material. Highly resistant to wear and flexible, it can resist to 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 mandibular 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 (as 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 aching might be caused by an improper adjustment. 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 mandibular 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 side effects, contact your dental professional.

Recommended Jaw Exercises

Helpful Morning Exercises

The Panthera Anti-Snoring Device is placed on the teeth and the jaw. Its action stresses the joints connecting the jaw to the skull. It is normal to experience some difficulties in placing your jaw in its usual position after use, especially at the beginning of the treatment.

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 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; position the upper splint (the one with no triangles) on the upper teeth. Press on the splint using your fingers so it fits perfectly on the teeth.

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

In some cases, it might be easier to insert the lower splint first (see *Figure 1*). 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 2*).

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

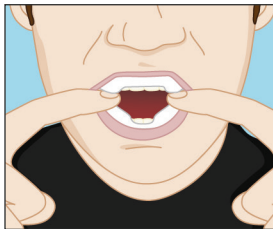


Figure 1



Figure 2

To Remove the Device

First, unclip the lower splint.

To do so, place each thumb on the sides of the lower retainer, near the gum in front of the longest teeth (lower canines), and lift the device (see *Figure 3*).

Then, place your fingers on each side of the upper splint, near the gum, and pull down the splint (see *Figure 4*).

Remove the device from mouth, clean it, dry and store in the case provided.
NEVER PRESS OR PULL on the retaining rods.

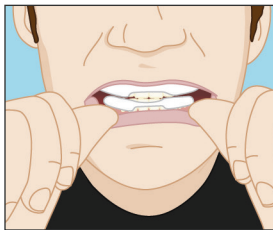


Figure 3

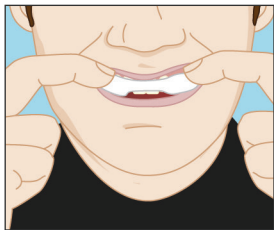


Figure 4

When to Change the Rods

The rods must be changed by your dental practitioner.

At the beginning of treatment, the advancement of the device will be of about 70% of the maximum possible advancement. The jaw advancement must be done progressively and according to your tolerance limit, so it does not result in joint problems. To do so, your dental practitioner will gradually change the rods of your device for shorter ones, thus slowly increasing the advancement of your mandible.

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 have reached your maximum mandibular advancement.

Please follow the directions of your dental professional. Do not hesitate to consult him/her for any questions.



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

Use an antibacterial chlorine-free orthodontic cleaning solution twice a week. Follow manufacturer's instructions.

Approved chlorine-free cleaning solutions are available in most drug-stores.



**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.**

Warranty

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. The useful life of the Panthera Anti-Snoring Device depends on the care provided, its storage, and its 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 joint pain might be due to an improper adjustment. It is recommended to consult the clinician or dentist who provided you with the device for adjustments.

On very rare occasions, the seal on existing dental restoration may become loose. In such event, consult your dental clinician so he/she can adjust the device and/or firmly fix the dental restoration.

Regular follow-ups with the physician who treats your respiratory sleep problem are highly recommended.

Additional Information

Risks of Snoring

Snoring may lead to small scar formation on the walls of the pharynx. The scar tissue reduces the flexibility of the airway and makes it narrower. Therefore, the upper airway ages much more rapidly.

Gaining weight and aging may also influence the development of snoring. If left untreated, snoring problems can worsen and result in obstructive sleep apnea.

4% of men and 2% of women suffer from sleep apnea³.

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

³. *Young et Al., (1993)*



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.

If you have any questions or concerns, you may speak with your dental professional or consult our website.

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