

COLOR CHANGE

Your device can change color under effects of the following:

- Some medicine, amalgam fillings, metal crowns and bridges, for example: may affect saliva properties that may affect your device.
- Coffee, tea, cola and wine: do not wear your device when drinking such beverages.

The color change does not affect your device's performance.

TROUBLESHOOTING INFORMATION

The Panthera X3 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 the existing dental restoration may become loose. In such event, consult your dental clinician for either an adjustment of your device and/or firmly fix the dental restoration.

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

WARRANTY

Your Panthera Device is guaranteed 3 years effective from the month of manufacture. The warranty provided by Panthera Dental will come into force on the date of manufacture and expires at the end of the warranty period, to the nearest months.

The warranty covers the device and the clips against any manufacturing or material defects. This is a manufacturer's warranty. It is not a claim to stop snoring or improve the obstructive sleep apnea.

Warranty repair work may only be performed by Panthera Dental and/or his partners and/or your dental professional. The device replacement will be at the choice of Panthera Dental.

Please note that the warranty does not cover any damages caused by a pet. In no case shall Panthera Dental cover labour fees. Panthera Dental will not be liable for other associated costs either, including but not limited to professional fees, laboratory fees, loss of profit, etc.

If your device is broken, contact your dental professional.

To honor this warranty, the device must be returned to Panthera Dental.

DISPOSAL

To dispose of your device please follow your disposal regulations.

THE PANTHERA ANTI-SNORING X3 DEVICE Description

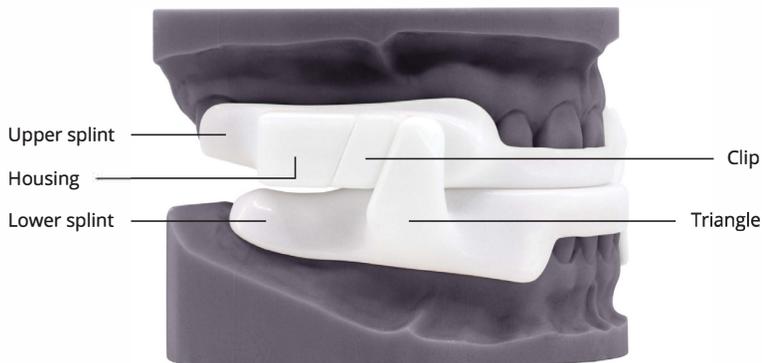


Figure 6: The Panthera Anti-Snoring X3 device parts

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PANTHERA X3 ANTI-SNORING DEVICE
Patient instructions for use

! 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 then make an effort to open his narrowed airways. The air flow is reduced and its forced passage creates vibrations in the soft structures (such as the uvula, the soft palate and the pharyngeal walls), which causes snoring.

60% OF MEN AND 40% OF WOMEN SNORE¹

Loud snoring can wake up the partner and disturb his sleep. Generally, the partner will adjust his 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 partner's snoring.²

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 apnea.³

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

GENERAL INFORMATION

The Panthera devices are prescription customized devices, tailored to your specific needs and composed of two splints and a retaining system. The upper and lower splints are adapted for the upper and lower teeth, respectively. The retaining system moves the lower jaw forward.

When the device is worn during sleep, it moves 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.

The Panthera device is made from a dental impression. It is to be used only by the person it was made for.

MATERIAL USED

The Panthera devices are made from the polyamide type 12, a biocompatible material in the nylon family. This material doesn't contain: resin, latex, bisphenol A, phthalates.

This material is conformed to: ISO 10993: biological evaluation of medical devices

Part 1: Evaluation and testing within a risk management process

Part 5: Tests for in vitro cytotoxicity

Part 10: Tests for irritation and skin sensitization

Allergy and intolerance to this material are extremely rare, if you have doubts, stop using the appliance and consult your dentist or physician.

INDICATIONS FOR USE

The Panthera X3 devices are intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

In case of severe apnea, these devices are recommended as second-line intervention after continuous positive airway pressure (CPAP) failure, non-compliance or refusal.

CONTRAINDICATIONS

They are contraindicated for patients who:

- Have central sleep apnea
- Have loose teeth or advanced periodontal disease
- Have severe respiratory disorders
- 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.

The Panthera devices are 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 Panthera Devices are 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 Panthera Devices are resistant to temperature changes but 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 Devices should not change the bite (occlusion) in a permanent manner. If you experience this, rapidly consult your dental practitioner.

WARNINGS

Use of the Panthera Devices may cause:

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

If you notice any persistent side effects, stop using your device and contact your dental professional.

RECOMMENDED JAW EXERCISES

Helpful morning exercises

The Panthera 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 backward 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 and humidify your device with water. Place the upper splint, (the one without triangle) on the upper teeth. Press on the splint using your fingers so it fits perfectly on the teeth (see Figure 1). Move the lower jaw forward and place the lower splint on the lower teeth. Press on the splint using your fingers to put it in place (see figure 2).



Figure 1



Figure 2



Figure 3



Figure 4

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

TO REMOVE THE DEVICE

First, undclip the lower splint. To do so, place each thumb on the sides of the lower splint, 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).

Clean it, dry thoroughly and store in the case provided.

WHEN TO CHANGE THE ADVANCEMENT

The advancement must be supervised by your dental practitioner.

The jaw advancement must be achieved 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 clips of your device, thus slowly increasing the advancement of your mandible.

We recommend a progressive mandibular advancement of 1 mm at a time. 0.5mm clips are available for smoother advancement.

According to your comfort and tolerance, the lower jaw will be move forward until snoring is reduced or alleviated, or until you have reached your maximum mandibular advancement.

HOW TO CHANGE THE ADVANCEMENT

To remove the clip :

Take the clip between your index and thumb and pull it out of the device.

To insert the clip (Figure 5) :

Simply push the clip with your thumb until it is completely inserted.

The length of the clip is indicated on the inner side of it. To increase protrusion the clips must be longer (ex. 3mm to 4mm) To decrease protrusion the clips must be shorter (ex. 4mm to 3mm)



STORING THE DEVICE

Along with your device, you have received a storing box. When traveling, place 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.**

CLEANING INSTRUCTIONS

Daily

After each use, rinse your device in lukewarm water. Clean it with a denture brush. Used the smaller head of the denture brush to clean inside the device. Rinse.

Dry your device thoroughly with clean tissue or towel.

Inspect your device for cleanliness and soundness. It should not used when visibly damaged.

Put it in its storage box an away from children and pets.

Twice a week or more

Use an antibacterial chlorine-free orthodontic cleaning solution. Follow the manufacturer's instructions. Soak and brush the device with the antibacterial solution. Rinse well and dry with a clean tissue or towel.

Once a week

Remove the clips of the upper, soak in the antibacterial chlorine-free orthodontic cleaning solution and brush the clip and the housing with the solution. Rinse well. Follow the precedents instruction.

PRECAUTION!

Verify that you have **no allergy** to the ingredient of the antibacterial chlorine-free orthodontic cleaning solution.

Do not use chlorine based product, bleach, acetic acid, household cleaning products or alcoholic solutions.

Do not use mouthwash to clean your device, this could stain and induce odor or taste.

Do not put your device in boiling water (100°C or 212°F).

If your water comes from an artesian well, it is recommended to use bottled water to clean your device.

**Always wear both upper and lower arches together.
Never wear individual arches only.**