

Instructions for Use and Care



 **VitalSleep**[®]
Stop Snoring Mouthpiece



Intended Use

VitalSleep® is intended to reduce simple snoring in adults

Federal law restricts this device for sale by or on the order of a
dentist or physician.

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Made in the USA.

The Snore Reliever Company, LLC

Enjoy Restful Sleep with VitalSleep!

Everyone Deserves Restful Sleep

VitalSleep can help stop your snoring and allow you and those who are living with you enjoy peaceful sleep.

Treat Your Snoring

Snoring is common. Approximately 700 million people worldwide and 100 million Americans snore. It is estimated that 45% of men and 30% of women snore on a regular basis. Snoring can cause great distress for individuals and between partners. It can cause irritability, excessive sleepiness, and lack of productivity during working hours.

Can VitalSleep Help You?

VitalSleep is a fully customizable FDA cleared intra-oral appliance. It allows for a custom fit and for incremental adjustments for maximum results. It's an effective solution for treating your snoring problem.

Benefits of VitalSleep

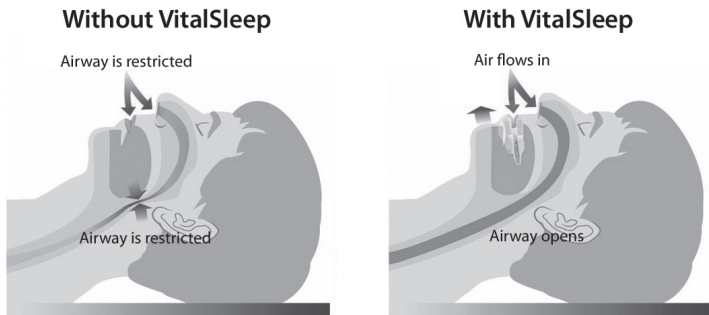
- ★ FDA cleared
- ★ Fully customizable fit
- ★ Low cost
- ★ A non-invasive device
- ★ Latex and BPA free

Treating the Cause of Your Snoring without Surgery

Most snoring is caused by a partial obstruction of the upper airway behind the tongue. When the airway is partially obstructed, the turbulent airflow can cause the tissues of the nose and throat to vibrate. This vibration gives rise to snoring.

How it Works

VitalSleep is intended to be used to reduce or stop simple snoring. It pulls the lower jaw forward and creates an opening between the upper and lower jaw to improve the flow of air into your lungs during sleep. When there is smooth airflow, the snoring stops.



(Fig. 1) The design of VitalSleep keeps the upper airway open allowing smooth airflow for both inhaling and exhaling.

Contraindications

Do not use this device if

- ★ you have, or think you may have central sleep apnea
- ★ you have severe respiratory disorders, such as asthma or emphysema
- ★ you have been diagnosed or may have temporomandibular joint disorder
- ★ you have jaw pain, loose teeth or advanced periodontal disease
- ★ you have dentures or wear braces
- ★ you are less than 18 years old



Instructions

You will need: the (included) separator, the (included) hex key for adjustment, a pot for boiling water, a timer, a spatula.

First Time Fitting

1. Identify the top of the device by locating the triangle ▲ on the backside of the device. The half with the triangle is where your top teeth will bite into.
2. Adjust the device so that the top and bottom halves are aligned as show in the image below. Insert the separator into the mouthpiece. Do not remove the separator until the device has been fitted and cooled.
3. Boil water in a pot. The water must be deep enough to cover the device. When the water boils, turn off the heat and use a spatula to immerse the device in the water. **Heat the device for 10 seconds. Do not over heat. Separator must be in place prior to heating and fitting.**

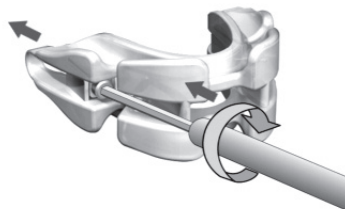


(Fig. 2) Insert the separator into the mouthpiece through the back.
Do not fit the device with the lower portion forward.

4. Place the device in your mouth with triangle (located on the backside of the device) pointing up and bite down gently, keeping it in position for 15 seconds. Avoid having the top and bottom bond to each other by using the separator.
5. Run cool water over the device for 30 seconds to cool the device allowing it to harden. If the device does not fit properly, repeat this procedure until it is comfortable.
6. When the device has been fitted properly remove the separator.

First Time Adjustment

1. Using the hex key, turn the screws clockwise to bring the lower half forward. The indicator mark will move backwards.
2. Check that both sides are equal.
3. Repeat until the lower jaw is in a forward position that does not cause discomfort. Make sure that the indicator markers on both sides are at the same mark when using the device.
If your snoring does not stop slowly increase the forward position of the lower half.



(Fig. 3) Use the hex key to adjust the device.

Everyday Use

Always brush your teeth before using this device. VitalSleep can be used daily. However, if increasing soreness in the jaw or teeth (light soreness is normal) is experienced, either decrease the forward adjustment of the lower half, or stop using the device. If the device does not satisfactorily stop or reduce your snoring, increase the forward position of the lower portion.

Getting Used to the Device

Light soreness is normal for the first 3-5 mornings and after a period without use. You can stretch or massage your jaw after use, or relax tense muscles with a warm washcloth. **Caution:** Pain, difficulty opening your jaw, and clicking or popping noises while opening your jaw are not normal and could be the result of a more serious problem, such as temporomandibular joint disorder (TMD). If you experience these symptoms or believe that you may have TMD, discontinue use immediately.

Storage and Cleaning

Clean the device with a toothbrush and toothpaste after each use, or use cleaning products specially designed for dentures. Store your VitalSleep in the storage case included.

Now Experience the Benefits of Restful Sleep!

You may find that you are better rested and have more energy after a night using VitalSleep. You may also find that your relationships with those living with you are greatly improved.



Warnings

The use of this device may cause:

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

Precautions

Have your dentist or medical doctor perform a complete oral health assessment to ensure the suitability of the appliance. Do not use this device if you have a history of temporomandibular joint disorder, asthma, breathing, or respiratory disorders, or other relevant health problems. Discontinue use immediately if you experience pain in your jaw, teeth or gums, if your snoring becomes worse or if you have difficulty breathing while using VitalSleep.

- * The statements in this manual have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Warranty

VitalSleep is warranted to be free of defects.

Indemnity

The Buyer shall indemnify, defend, and hold harmless the Snore Reliever Company, LLC, its subsidiaries and affiliates (collectively "the Company"), its employees, agents, successors, officers, managers, members and assigns, from any law suits, losses, claims, demands, liabilities, costs and expenses (including attorney and accounting fees) that the Company may sustain or incur arising from (a) the Buyer's improper use of the products, including without limitation to storage, handling, and transportation of products, (b) use of the products by a third party with the Buyer's authorization, (c) use of the products by a third party without the Buyer's authorization, where such unauthorized use is due to the Buyer's negligent act or omission, or willful misconduct, (d) the Buyer's failure to comply with any applicable laws and regulations or to obtain any licenses or approvals necessary to purchase and use the products, or (e) the Buyer's breach of any of its obligations set forth in these terms and conditions, in the instructions for use and care, or in this Agreement.

The Company will provide the Buyer with: (i) prompt written notice of such claim of which the Company is aware; (ii) control over the defense and settlement of such claim; and (iii) proper and full information and assistance at the Buyer's expense to settle and/or defend any such claim. Notwithstanding the foregoing, Buyer shall not settle any such claim, suit or proceeding without the written consent from the Company, which shall not be unreasonably withheld.

Now Experience the Benefits of Restful Sleep!



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