



INSTRUCTIONS and FITTING GUIDE

Read Carefully Before Use - Use Only as Directed



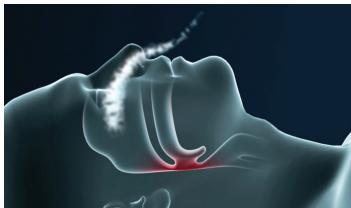
Discover the PureSleep® Solution—tonight!

www.puresleep.com

How does PureSleep® work?

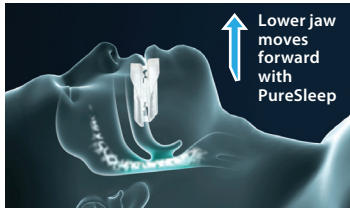
The PureSleep anti-snoring mouthpiece is designed to reduce snoring by holding your lower jaw slightly forward of its normal position while you sleep. This tends to open the upper airway so air isn't forced through such a narrow opening. Instead, airflow is improved and tissue vibration is reduced or even eliminated.

Airway narrowed - causing snoring



The soft tissue at the back of the throat relaxes during sleep, partially blocking the airway. Air passing through causes vibration - and the sound of snoring.

Airway opened with PureSleep



The principle of PureSleep is simple: it moves your jaw forward, opening the airway so that air moves through unobstructed, reducing the vibration.

Should You Use PureSleep®?

Do Not Use PureSleep If:

- You are under 18 years of age.
- You have been diagnosed with central sleep apnea which is different from obstructive sleep apnea and far less common.
- You have chronic asthma, emphysema, COPD or any other serious breathing or respiratory disorder.
- You have loose, damaged or weakened teeth, fillings or caps.
- You have an abscess, mouth sores, bleeding gums or severe gum disease.
- You have had a dental implant within the last 3 months.
- You have braces, full dentures or sleep using another dental appliance.
- You have been diagnosed with temporomandibular joint disorder (TMD) or have symptoms of TMD such as clicking, popping, grating or locking of your jaw or jaw pain when you open your mouth, yawn or chew.
- You experience jaw or tooth pain from clenching your jaw or grinding your teeth.

Important Warnings

- ⚠ • Use of this device may cause tooth movement, bite change, gum or tooth soreness, pain or soreness of the temporomandibular (jaw) joint or a worsening of TMD symptoms, excessive salivation, and you won't be able to breathe through your mouth as easily.
- If you experience difficulty breathing or if other respiratory disorders exist or continue, stop using PureSleep® and consult a physician immediately.
- Keep out of reach of children.
- PureSleep is not indicated for the treatment of obstructive sleep apnea.

We recommend you review this instruction booklet before you prepare your PureSleep mouthpiece. This will ensure that you are familiar with the procedures and time-critical actions for each step, prior to starting the process. After your review, please follow the instructions step-by-step as you perform the preparation procedure.

Prepare PureSleep® for First Use

Step 1: Identify What Type of Bite You Have

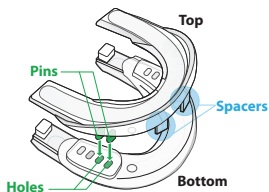
- **Typical Bite:** Your upper front teeth slightly overlap your lower front teeth.
- **Mild Underbite:** Your upper front teeth meet evenly with or slightly behind your lower front teeth.
- **Severe Underbite:** Your upper front teeth are farther behind your lower front teeth.
- **Overbite:** Your upper front teeth are substantially forward of your lower ones.

Note: If you're not sure if you have an overbite or a typical bite, proceed to Step 2 and try placing your PureSleep mouthpiece in your mouth using the settings for both types of bite to see which allows the mouthpiece to best align with your teeth while you hold your jaw as far forward as you comfortably can.

Step 2: Connect the Top and Bottom Parts Based on Your Bite Type

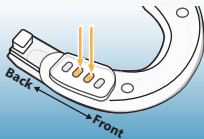
The top and bottom parts of the mouthpiece are designed to fit together by inserting the plastic pins on the top part into the holes on the bottom part.

Note: The spacers are there to make sure the parts stay the right distance from each other during the fitting process.

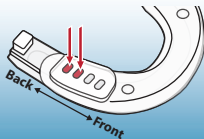


Make sure you are using the correct setting based on your bite. Refer to the illustrations to choose the correct setting for your bite.

Mild Underbite: Use the two center holes.

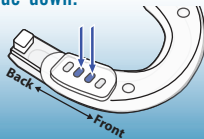


Severe Underbite: Use the two holes closest to the back of the mouthpiece.



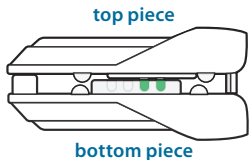
Typical Bite: Use the two holes closest to the front of the mouthpiece.

Overbite: Use the two center holes, but then turn the assembled mouthpiece over and **use it upside-down.**

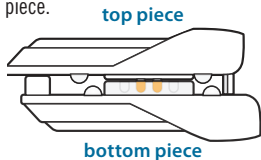


Step 3: Confirm Mouthpiece Connection

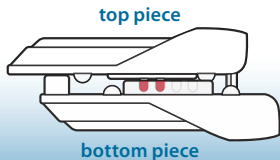
Typical Bite: The front of the two pieces should be even with each other.



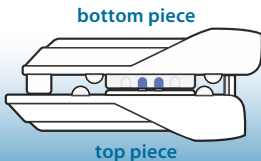
Mild Underbite: The front of the top piece should be slightly behind the front of the bottom piece.



Severe Underbite: The front of the top piece should be behind the front of the bottom piece.



Overbite: The front of the top piece should be slightly behind the front of the bottom piece and the assembled mouthpiece should be turned upside-down so the bottom piece is on the top.



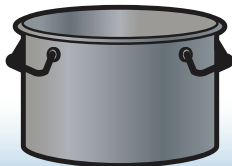
Step 4: Gather Supplies for Custom Fitting Your Mouthpiece

Gather the following supplies:

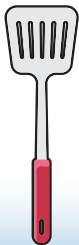
- Your mouthpiece (with the two parts connected based on your bite type)
- A toothbrush and toothpaste
- Medium size pot for heating 1-2 quarts of water
- A slotted spatula or spoon
- A timer that counts seconds
- Small point-tipped scissors



**Toothpaste &
Toothbrush**



**Medium Sized Pot
(1-2 Quarts of Water)**



Spatula



**Timer
(Counts Seconds)**



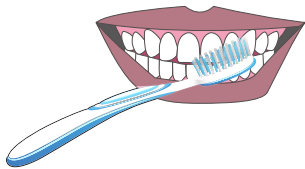
**Small
Point-Tipped
Scissors**



**Mouthpiece
(With the Two Parts Connected)**

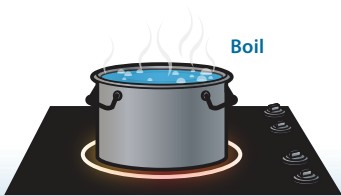
Step 5: Brush Your Teeth

- Having clean teeth means that food particles won't get trapped in the mouthpiece during fitting.
- If you have partial dentures remove them.



Step 6: Boil Water

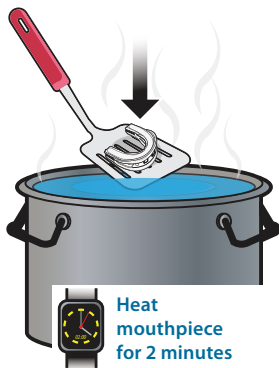
- Bring 1 to 2 quarts of water to a boil in a medium sized pot. The water should be deep enough to submerge the entire mouthpiece.
- Once the water is boiling, turn off the heat source (burner) and wait for the boiling to stop.



Step 7: Heat the PureSleep® Mouthpiece in Hot Water for 2 Minutes

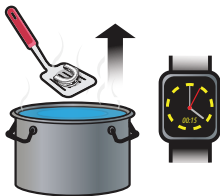
- Using the slotted spatula or spoon, lower the mouthpiece into the water.
- Allow the mouthpiece to heat in the water for 2 minutes. Avoid moving the mouthpiece during this time as the top and bottom parts of the mouthpiece can separate.

Note: If the two parts separate, remove the mouthpiece from the water and let it cool. Then repeat the process starting with Step 2.

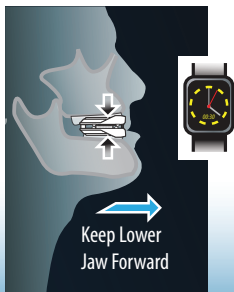


Important: During this time, please review Step 8 on the next page. The actions in Step 8 require specific timing so it's important that you become familiar with them before you continue.

Step 8: Let Mouthpiece Cool, Hold Jaw Forward and Bite Down



Take out and let cool
for 15 seconds



Keep Lower
Jaw Forward

Bite down for 30 seconds

Timing is critical for the following steps:

- Using the slotted spatula or spoon, remove the mouthpiece from the hot water.
- Let the mouthpiece cool for 15 seconds.
- Slide your lower jaw forward to a point that does not cause discomfort.
- Insert the mouthpiece into your mouth.
- **Note:** If you have an overbite, remember to turn the mouthpiece upside-down.
- Bite down firmly, while holding your jaw forward.
- Hold your bite for 30 seconds. It's normal for your teeth and gums to feel very warm during this time. If it gets too uncomfortable, remove the mouthpiece and replace it after a few seconds.

Step 9: Remove and Rinse the Mouthpiece

- Remove your PureSleep® mouthpiece from your mouth.
- Then place it under cool running tap water. This will harden the plastic and lock-in the impression you made of your teeth and jaw position.



Step 10: Test Mouthpiece

Now put PureSleep® back into your mouth to test the fit. Your teeth should fit deeply into the impression you just made, and the mouthpiece should feel like it's holding your lower jaw slightly forward when you relax your jaw. The pressure should not be concentrated along the edges of your front teeth.



- **If your mouthpiece feels right:** You made a good, even, deep impression. Continue to Step 11.
- **If your mouthpiece does not feel right:** You may have waited too long to make the impression after removing the mouthpiece from the hot water or you may not have held your lower jaw forward while biting down. Repeat Steps 5-9 while paying careful attention the timing and jaw position of each step.

Note: If you repeat this process too many times, it can destroy the mouthpiece.

Step 11: Trim Away Excess Material for Greater Comfort As Needed

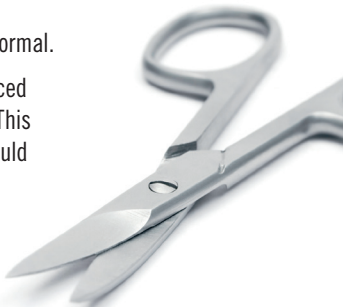
Some of the soft plastic has melted together. This is normal.

However, some soft plastic may also have been displaced by your teeth as you bit down to make an impression. This excess plastic may have formed in a location which could bother your tongue or cause irritation.

If desired, hold your mouthpiece with a towel, and carefully cut away any excess plastic using small pointed scissors.

Do not cut off the plastic in the rear of the mouthpiece as it holds the upper and lower components together. You may also cut off the spacers which protrude down from the front of the upper component as they are only necessary for the fitting process.

You are now ready to use your PureSleep® mouthpiece. If you have partial dentures, remove them before use.



Your First Night with PureSleep®

PureSleep works best if you sleep on your side or stomach. When sleeping on your back, you're more likely to open your mouth which can cause your PureSleep device to fall out. If you breathe through your mouth during sleep because of nasal congestion, we recommend using medication to allow for unobstructed nasal airflow.



If you feel discomfort or are bothered by your mouthpiece and it causes you to wake up, remove the mouthpiece and go back to sleep. Likewise, if in the morning you discover that it fell out of your mouth during the night, continue to use it the following night. You should be able to wear it longer each night.

Note: Mouth-breathing will disrupt your sleep and cause a dry mouth, bad breath and poor oral health. A chinstrap may also be used to prevent your jaw from opening during sleep. We make medical-grade chinstraps available at a reduced cost to PureSleep customers, and they may be obtained by contacting our customer support department. If you have chronic nasal congestion or blockage, we recommend that you consult an ear, nose and throat specialist.

Using PureSleep®

Soreness or pain in teeth or jaw:

It can take several days to get used to wearing PureSleep. It's normal for the jaw, teeth, and gums to feel moderately sore and fatigued for as long as five (5) days to acclimate to the new jaw position during sleep. Also, if you don't use it for several days, you may need to re-acclimate.

Warning:

- Stop using PureSleep if you feel severe, sharp pain, if you continue to experience soreness beyond the first five days of use, or if you start to experience pain or a clicking or popping sensation when you open your jaw or bite down. These could be symptoms of TMD and continued use of PureSleep could make the problem worse.
- Stop using PureSleep if you experience significantly more sensitivity or discomfort in one or two teeth relative to your other teeth. This means that those particular teeth pushed completely through the soft plastic during the fitting process and are now in contact with the hard plastic shell. This contact is putting stress on those particular teeth which may be harmful. Immediately discontinue use of PureSleep.

Jaw position after removing the PureSleep® mouthpiece:

Each morning your jaw will tend to stay in a “forward” position after PureSleep is removed because the muscles in your jaw have become used to this position during the night. This is normal. An hour or two after removing PureSleep, your jaw should return to its normal position.

You can accelerate this process by performing a simple “jaw stretching” exercise. Gently push your jaw backward while relaxing the muscles in your jaw and holding this position for about a minute, as shown in the image to the right. You may also massage the muscles on each side of your jaw.



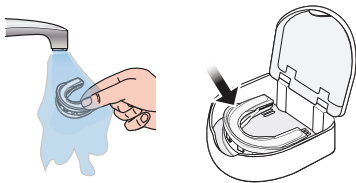
Morning Exercise: Gently push your jaw backward, relax your muscles and hold for about a minute.

⚠ Caution: Do not place PureSleep back in your mouth until your jaw returns to its normal position, otherwise a change in your bite may develop over time.

Taking Care of Your Mouthpiece

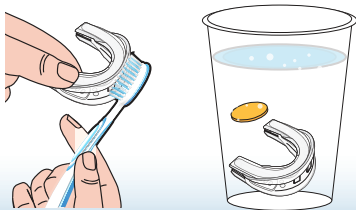
Remove and rinse each morning:

- After removing your PureSleep® mouthpiece in the morning, rinse it off with warm water and let it dry. Your PureSleep storage case is good for this purpose as it allows for proper ventilation.



Deep clean once a week:

- About once per week, clean PureSleep with a toothbrush and toothpaste or soak it in water with cleaning tablets that are intended to clean dental devices such as retainers or dentures. You can get tablets of this kind at your local drug store.
- **Do not use** harsh chemicals or household cleaning products like bleach or ammonia.



Since you (used to) snore . . .

We hope you'll be enjoying peaceful sleep with PureSleep®! Since you snore when you aren't using PureSleep, you may also have sleep apnea, a serious sleep disorder that can reduce the quality of your life and even shorten it. If you answer "yes" to any **2** of the following questions, you are at elevated risk and should get evaluated by a doctor.

- Do you often feel tired, fatigued, or sleepy during the daytime?
- Has anyone observed you stop breathing during sleep?
- Do you have (or are you being treated for) high blood pressure?
- Are you over 50 years old?
- Is your neck circumference greater than 16 inches?
- Are you male?
- Is your body mass index (BMI) greater than 35 kg/m²?

To learn more about sleep apnea and for help finding a doctor who specializes in sleep apnea, visit www.puresleep.com/osa



How do I calculate my BMI?

1. What is your weight in pounds?
2. Divide it by your height in inches.
3. Divide this result by your height again.
4. Multiply the result by 703.
5. The result is Body Mass Index (in kg/m²)



Support

Website:

www.PureSleep.com

PureSleep® Customer Support Helpline:


US and Canada: (866) 879-3777

Outside US and Canada: +1 415 578 3882

Monday through Friday:

8:00 AM – 8:00 PM Eastern Time



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