

Contraindications

The Silent Sleep™ oral appliance 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



Intended Use

The Silent Sleep is intended for use as a temporary or trial oral appliance in the diagnosis and treatment of snoring and non-central obstructive sleep apnea, by prescription only and under the direction of a physician or dentist. The Silent Sleep is not intended for use longer than 30 days.

Warnings

Use of the Silent Sleep™ appliance may cause:

- tooth movement or changes in dental occlusion
- gingival or dental soreness
- pain or soreness of the temporomandibular joint(s)
- obstruction of oral breathing
- excessive salivation

Precautions

Patients should be instructed to check the Silent Sleep appliance for any signs of breakdown prior to nightly use and to discontinue use if breakdown is noticed until the appliance can be evaluated by the dentist/physician. Dentists, physicians and qualified healthcare providers should always consider the medical history of the patient, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and arrange for appropriate healthcare before prescribing the Silent Sleep appliance.

**Dentists, physicians and qualified healthcare providers prescribing the Silent Sleep appliance are encouraged to maintain proper continuing education in the areas of sleep disordered breathing and temporomandibular joint disorders.

Fitting Instructions for The Silent Sleep™

Description of Use

The Silent Sleep oral appliance consists of a one-piece tray which is customized to the patient's teeth using GC Reline, a chairside vinyl polysiloxane resilient denture liner. The Silent Sleep is fit to the posterior teeth of the patient while the patient protrudes their lower jaw slightly. This slight protrusion, and the limiting of posterior movement of the mandible during sleep, helps to maintain a patent oropharyngeal airway and thus reduce snoring and/or non central obstructive sleep apnea in patients who respond to this type of device.



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FDA approved oral appliance for
snoring and obstructive sleep apnea



Fitting Instructions

Step 1: Gather Needed Materials

- GC Reline™ Soft cartridge
- Silent Sleep bite gauges
- Slow speed hand piece with cross cut acrylic bur
- MixPac Dispenser
- Watch or stopwatch
- MixTips
- Sharp scissors
- Silent Sleep tray
- Patient case

Step 2: Check the fit of the Silent Sleep™ tray over the patient's teeth or partial denture. Place the longer channel facing downward.

Modify the tray as needed if the borders of the tray are irritating to the patient's gingiva due to contact. Just like an impression tray, the Silent Sleep should be able to fit over the patient's posterior teeth without interference or painful contact with the soft or hard tissues. If the tray does not fit the patient's dental arches or causes discomfort, the Silent Sleep should not be used.

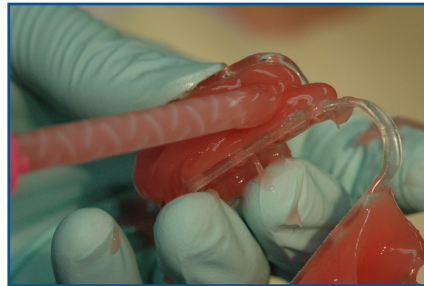
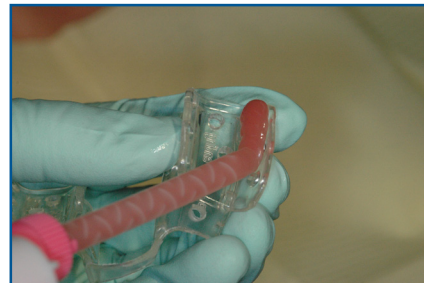


Step 3: With the Silent Sleep™ tray in the patient's mouth, have the patient practice closing onto the Silent Sleep bite gauge to check comfort level and ability to snore audibly. Choose the best one.

There are 4 different Silent Sleep bite gauges, allowing for 7 different levels of protrusion.

Excessive protrusion of the mandible is not necessary and is not recommended. Other bite registration methods may be used to determine the initial position.

Step 4: Completely dry off the Silent Sleep tray, and then apply the GC Reline™ impression material into the Silent Sleep™ tray, paying special attention to syringing the material at the retention holes through the middle of the appliance and at the sides.



Step 5: Once the tray is filled, place the tray in the patient's mouth with the longer change facing downward, and guide the lower portion onto the mandibular teeth.



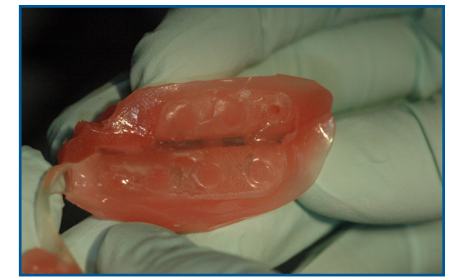
Step 6: Have the patient bite onto the chosen bite gauge. Note the time, and allow the Reline to set fully, about 5 minutes. IMPORTANT: When the patient bites into the Reline with the bite gauge, instruct the patient to close and push forward and outward with the tongue (i.e. "Make your tongue bigger in your mouth").

Blocking out significant undercuts or under bridges is generally not necessary due to the soft nature of the set VPS; however this should always be considered.



Step 7: Once the GC Reline™ material is fully set, remove the appliance from the patient's mouth. Excessive material may be trimmed.

Use a cross cut acrylic burr at maximum speed on a slow speed hand piece, or GC Reline finishing burs, to smooth the GC Reline for a comfortable fit. Care should be taken to remove any material that is thin or appears as if it would easily separate from the tray. Check to determine that there has been good extrusion of the VPS material through the retention holes and that the material is firmly seated in the tray. Check for any areas that could cause irritation to the tissues.



Step 8: Seat the appliance and allow the patient to wear it for several minutes.

If the patient feels significant pressure in their jaw from excessive protrusion, you may remove the material from the Silent Sleep™ tray, prime the tray with GC Primer, and repeat steps 2 through 6. Repositioning of the appliance may also be performed in this way if it is desirable to bring the lower jaw into a more forward position, such as in the case of continued snoring with the initial position, or less forward position, such as in the case of jaw or TMJ pain or soreness with the initial position.

