

Intended use of the Oral Appliance

- By prescription only
- Use as directed by your dentist
- Do not use longer than 30 nights; intended as a temporary device
- As a low cost introduction to oral appliance therapy
- Worn at night during sleep
- As a spare oral appliance for travel

Contraindications

The oral appliance should not be used where the following is present:

- Central sleep apnea
- Loose teeth or periodontal disease
- Active TMJ disorder
- Severe respiratory disorders
- Under 18 years of age



Warnings

Use of the oral 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
- Use of the oral appliance for longer than 30 nights may increase the risk that the denture reline material will break down which could lead to swallowing or aspiration of the denture reline material

The SnoreByte® Kit includes:

The following items for the preparation of the oral appliance:

- The Silent Sleep™ tray
- The GC Reline™ universal mixing tip



The following items for the patient to take home:

- The custom oral appliance (after custom-fit)
- Carrying case
- Brush
- Ortho Fresh® Cold Water Cleaner



SNOREBYTE®

Patient Kit



SnoreByte® is a temporary or trial oral appliance used for the treatment of snoring and obstructive sleep apnea.

SnoreByte® Composition

The SnoreByte® consists of the Silent Sleep™, a clear resilient biocompatible tray filled with GC Reline™ a chair side vinyl polysiloxane (VPS) denture liner that is molded to the patient's teeth.

SnoreByte® Custom-fit

The SnoreByte® is custom-fit in minutes. After applying the denture reline material to the Silent Sleep™ tray you fit the oral appliance to the patient's posterior teeth while the patient protrudes his lower jaw slightly.

SnoreByte® Use

The SnoreByte® creates a slight protrusion and limits the posterior movement of the mandible during sleep. This protrusion helps to maintain an open oropharyngeal airway thus reducing snoring and/or non central obstructive sleep apnea.

BRAEBON

For Today's Business of Sleep™

Fitting the SnoreByte®

Before prescribing the SnoreByte® featuring the Silent Sleep™ tray, consider your patient's medical history, including history of asthma, breathing or respiratory disorder, or other relevant health problems. Ensure you arrange for appropriate health care before prescribing the oral appliance as a trial or temporary device.

Step 1

Check the fit of the Silent Sleep™ tray over the patient's teeth or partial denture. Like an impression tray, the Silent Sleep™ should fit over the patient's posterior teeth without interference or painful contact with the tissues of the mouth. If the borders of the tray are irritating to the patient's gingiva due to contact, modify the tray as needed (see figure 1).

NOTE You may trim the Silent Sleep™ tray to fit most dental arches. However, if you are not able to comfortably fit the tray, the Silent Sleep™ should not be used.

Step 2

Determine the initial protrusion position using your preferred bite registration method. There are four different Silent Sleep™ Bite Gauges available, allowing for seven different levels of protrusion. Alternatively, a George gauge may also be used.

WARNING Excessive protrusion of the mandible is NOT necessary and is NOT recommended.

Step 3

Syringe the GC Reline™ denture material into the Silent Sleep™ tray. Syringe the material well through the retention holes of the Silent Sleep™ tray (see Figure 2).

Legal Notices

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Once the tray is filled, place the tray in the patient's mouth, guiding the lower portion onto the mandibular teeth (see Figure 3).

Guide the patient's bite to the predetermined position. Allow the material to set, for the amount of time recommended by the GC Reline™ manufacturer, usually 5 to 7 minutes (see Figure 4).

NOTE Blocking out significant undercuts or under bridges is generally not necessary due to the soft nature of the set lining material; however, this should also be considered.

Step 4

Once the GC Reline™ material is fully set, remove the appliance from the patient's mouth. Trim excessive material, if necessary (see Figure 5).

- Remove any thin material or material which could easily separate from the tray.
- Check for good extrusion of the denture reline material through the retention holes.
- Ensure the denture reline material is firmly seated in the tray.
- Check for areas that could cause irritation to the tissues.

Step 5

Seat the oral appliance and allow the patient to wear it for several minutes (see Figure 6).

If the patient feels significant pressure in the jaw from excessive protrusion, remove the material from the Silent Sleep™ tray and repeat steps 3 to 4 with the patient bringing the jaw into a more comfortable position.

Reposition the appliance as needed:

- Position the jaw more forward, if there is continued snoring with the initial position.
- Position the jaw less forward, if there is soreness due to jaw or TMJ pain or soreness with the initial position.



Figure 1 Initial insertion of the Silent Sleep™



Figure 2 Syringe the GC Reline™



Figure 3 The filled tray is placed over the mandibular teeth

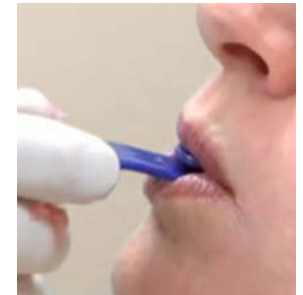


Figure 4 The patient's bite is at the predetermined position as the lining material sets



Figure 5 Trim excess lining material

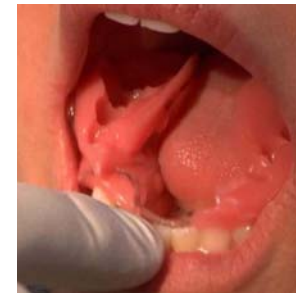


Figure 6 Check the final fit of the SnoreByte®

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