Indications for Use

The Slide® Sleep Appliance is for use to reduce night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Prescription only

CAUTION: Federal law restricts this device to sale by or on the order of a qualified dentist.

Device Description

The Slide Sleep Appliance is a prescribed intraoral device worn while sleeping in order to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA). Snoring and OSA is caused by partial or complete closure of the muscle in the upper airway (pharyngeal space). The device uses two splints joined by two parallel sliding connectors that position the lower jaw forward and open from its normal location. This forward protrusion opens up the upper airway reducing obstructions during sleep. The prescribing dentist determines the exact repositioning of the lower bite using a George Gauge or equivalent bite registration obtained from the patient in the office. Its simplistic design allows for the forward displacement to be adjusted without the use of specialized tools using different sized spacers. Adjustments are initially made in the prescribing dentist office, further adjustments can be made depending on relief of symptoms and comfort while sleeping.

Contraindications

The Slide is contraindicated for patients who:

- Have central sleep apnea.
- Have severe respiratory symptoms.
- Have loose teeth or advanced periodontal disease.
- Are under 18 years of age.

Warnings

Use of the Slide may cause:

- Tooth movement or changes in dental occlusion.
- Gingival or dental soreness.
- Pain or soreness to the temporomandibular joint.
- Obstruction of oral breathing.
- Excessive Salivation.
- Dry mouth.

Precautions

Dentists should consider the medical history of the patient, including history of asthma, breathing, or respiratory disorders, or other relevant health problems and refer the patient to the appropriate healthcare provider before prescribing these devices.

Device Exam & Prescribing

Sleep Study

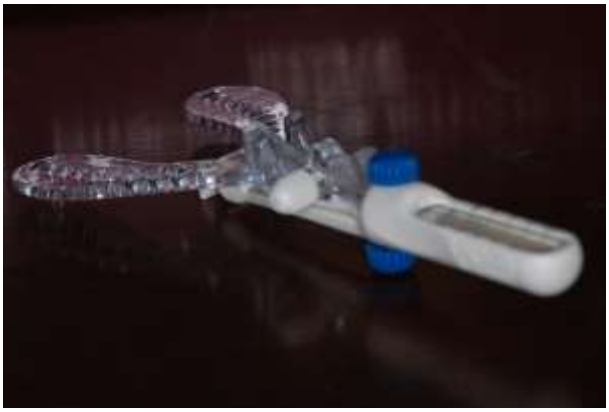
It is imperative that each patient have a sleep study completed prior to prescribing an intraoral appliance for use. The sleep study will determine the level or severity of obstructive sleep apnea (OSA) that the patient is currently experiencing and this information should be used by the prescribing dentist to determine if the patient is even a candidate for an intraoral mandibular repositioning device or would be treated better with a CPAP device.

Dental Exam

Each patient should be subject to a complete and comprehensive dental exam prior to prescribing a snoring or sleep apnea device. Once the patient has undergone a comprehensive dental exam complete with full records and a sleep study the dentist can accurately prescribe a snoring or sleep apnea device.

Guidance on Mandibular Opening

Standard mandibular opening for this snoring/ sleep apnea device is 4-5mm between the maxillary and mandibular posterior teeth. This allows for increased air volume and facilitates airway opening. It also ensures the proper amount of space for the sliding connectors when they are mounted by the lab. Use a George gauge or SOMGauge™ which has a vertical opening adjustment to ensure that the bite has at least 7mm of inter-incisal opening. Use bite registration material to take the final bite at 40-50% maximum forward protrusion. A wax bite is not acceptable. Allow the patient to sit with the desired protrusion for 5-10min to ensure comfort.



Submit Digital Impressions or PVS impression and Bite to Dental Lab

Submit the patient's upper arch, lower arch and bite registration to the lab using a digital scan or send the physical impressions to the lab to create the final device. It is required to use digital scan and a lab with 3D printers using KeySplint Soft® resin or Nylon PA 12 to form the splints to ensure maximum device lifespan and patient comfort. If a digital scan is not available, a detailed PVS impression will be acceptable if it is without voids and captures the distal of the last molars.

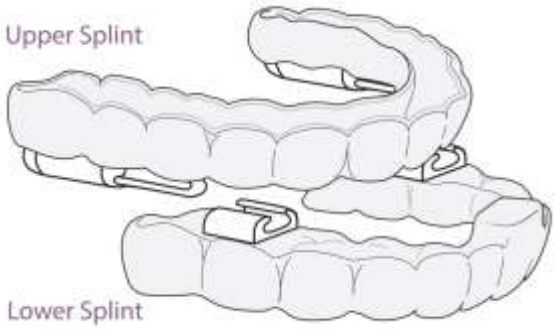
Appliance Fit & Adjustments

Appliance Fit

The dental staff or dentist should remove the Slide from the packaging and rinse the device off with cool water. If required, clean the device using a mild detergent soap, cool water (not to exceed 45°C/113°F) and a soft toothbrush.

Prior to patient fit inspect the device for signs of damage including cracking, part separation from splint, splint deformation, etc. Do not use if there are physical signs of damage. Contact lab if damage is observed.

Device shall be provided with "0" Spacers on the unit so that device creates forward displacement equivalent to the bite registration sent to the lab. Place the Slide in the patient's mouth with the "0" Spacers, checking for proper fit of the device on the patient. Ensure the patient is capable of easily removing the device from their mouth. Instruct the patient to remove the Slide by removing the lower splint first by lifting up with the thumbs and sliding the lower splint forward off the upper splint. Next, the upper splint is removed by pulling down off the upper teeth.



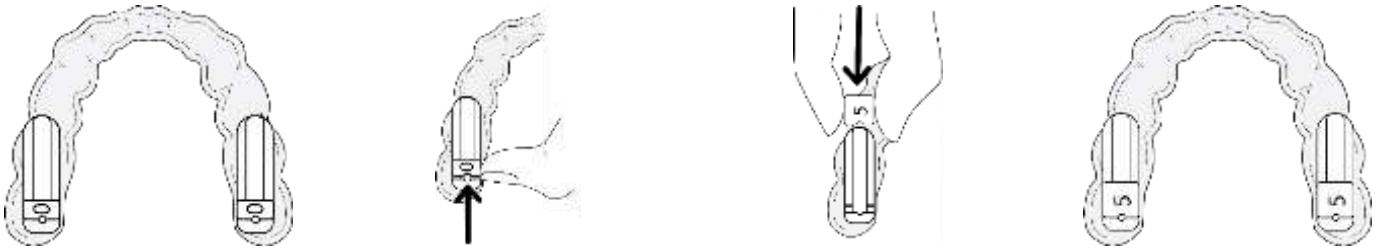
Guidance on Mandibular Advancement

Standard mandibular advancement for a snoring/sleep apnea device is situation dependent. Generally, the mandible is advanced between 50-60% of the patient's maximum mandibular protrusion from the patient's centric occlusion for proper appliance function. The patient may make further adjustments incrementally for jaw comfort and prevent the tongue from falling back and blocking the throat for maximum effectiveness and maximum reduction of the patient's Sleep Apnea Index.

Appliance Adjustments

The Slide adjustments should always be initially performed by the prescribing dentist. The splints can be heated in warm water (not to exceed 45 °C/113 °F) for 30 seconds to ensure a comfortable fit.

The spacers are embossed with the approximate forward advancement ranging from 0mm to 8mm in 1mm increments. The Slide is sent with the "0" spacers on the device. This will match the bite registration position sent to the dental lab. Any adjustments in the fit of the Slide should easily be made chairside to ensure that the patient is pleased with the fit and function of their new device. The patient is shown how to slide the two splints together via the sliding connectors and how to make further adjustments incrementally for jaw comfort and snoring reduction.



Demonstrate to the patient how to adjust the forward mandibular displacement. Ensure the patient understands that spacers should be matching after fit adjustment.

Provide guidance to the patient regarding when an adjustment might be required, how many days they should leave a size on before making further adjustments, and at what point they should stop advancements and contact you if symptoms are still persistent.

Once the patient is familiar with the device function and proper adjustment is achieved, the entire Slide Kit may be sent home with the patient.

Operating Instructions

Directions for Daily Use

Ensure patient understands the daily use of the device:

- Brush and floss teeth before device use.
- Prior to use inspect the device for signs of damage including cracking, sliding component deformation, sliding components separating from splint, splint deformation, etc. Do not use if there are physical signs of damage.
- The Slide should be placed in the mouth prior to the entire sleep period and worn for the entire sleep period duration.
- Slide the upper and lower jaw splints together before use and insert the device into the mouth. Note: Ensure both sides of the appliance are engaged before inserting into the mouth. Ensure both the upper and lower splints fit completely over the teeth.
- Remove the Slide by lifting up on the lower splint with their thumbs and sliding the lower splint forward off the upper splint. Next, the upper splint is removed by pulling down off the upper teeth.

Home Care Instructions

Instruct the patient to clean the device after each use, and to clean the reusable storage as needed. Remind patient of the following:

- Clean the device after each use with mild detergent soap, cool water (not to exceed 45 °C/113 °F) and a soft bristle toothbrush. Do not use warm or hot water as it can lead to device deformation.
    - ALWAYS clean your Slide Sleep Appliance after each use, clean the reusable storage as needed.
    - DO NOT use warm or hot water as it can lead to device deformation.
    - DO NOT use mouthwash or toothpaste as it can lead to material deterioration.
- Ensure the device is dry before storage, shake off residual water.
- Store the device in the provided storage case in a cool, dry location when not in use.

Note: Brushing may cause spacer to come loose while cleaning. Brush along the Rail connector towards the spacer to prevent spacer from coming loose during cleaning.

Appliance Replacement

Appliance replacement signs are cracking, sliding component deformation, sliding components separating from splint, splint deformation, and failure of the device to maintain retention in the patient's mouth. Once you have determined the need for a new appliance, send a new prescription with a new set of impressions and bite.

Lost spacers may be ordered separately by the dentist or by the patient directly at www.slide2sleep.com (SKU 046-1100 Slide 0mm Replacement Spacers – 10 pack or SKU 046-1101 Slide 0-8mm Replacement Spacer set – 2 pack).

Parts and Accessories

Component	Part Number (SKU)
the Slide® Acrylic Sleep Kit	046-1000
the Slide® Nylon Sleep Kit	046-1500
Slide 0mm Replacement Spacers – 10 pack	046-1100
Slide 0-8mm Replacement Spacer set – 2 pack	046-1101

Symbols

REF	Catalogue Number	Rx Only	Perscription Use Only		Single Patient, Multiple Uses		Keep Away From Rain	NON STERILE	Non-sterile Device
LOT	Batch Code (Lot Number)		Consult Instructions for Use		Date of Manufacture		Upper Temperature Limits		

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PATENT PENDING