

- After cleaning, the patient should rinse the appliance under cool water and air dry before storing.
- Recommend that the patient clean appliance after every use with an appropriate appliance cleaner. Approved appliance cleaners can be purchased by calling 800-423-3270 or order online through www.certifiedsmile.com.
- Do not soak the appliance in bleach, mouthwash, or alcohol. Doing so may weaken or damage the appliance.
- Patient should be instructed to examine the appliance and connectors often for signs of wear and tear. If there is a suspicion or indication that damage has occurred, patient should not wear appliance until the dentist can inspect it.
- Patient should place the appliance in the retainer case provided whenever it is not in use... and keep the appliance out of reach of children and pets.

OBSERVATION/ADJUSTMENT VISITS:

Schedule observation visits (as summarized below) to ensure that the appliance is comfortable and effective and that no dental problems have developed.

NOTE: If the appliance has been fabricated to the prescribed repositioned bite relationship, the dentist may find it beneficial to have the patient wear the appliance for several days before changing the polymer straps.

Week 1-4: Initial Seating & Follow-Up

- Fit the appliance, and instruct the patient in its use and care.
- Ask the patient to sit with the appliance in place for about five minutes. This will assure that the patient is comfortable at this advanced position. If more protrusion is desired, change the connector rods to a smaller size. Please review CONNECTING RODS INSTRUCTION GUIDE to see how to take off connecting rods and to put new rods on. (Seperate Attachment)
- IMPORTANT: A properly taken Bite Record typically places the mandible in the most advantageous position. If this is carefully done, the need to change the rods is rarely necessary.
- Fit the SML™ Good Morning Positioner to the patient's existing centric occlusion relationship. Follow the included fitting instructions, and instruct the patient in its use.

- Deliver the appliance and make any necessary adjustments. If additional mandibular jaw advancement is necessary, have the patient remove their appliance. To advance the mandible replace the existing bilateral connectors with shorter ones. The sizes are clearly marked for each connector. Simply select a shorter connector and replace both sides at the same time. Be sure to record the number and millimeters of the adjustments. The connectors are provided in 1mm increments.

Month 1: Teeth/Appliance Evaluation

- Check the appliance for comfort and fit.

Month 6: Progress Check

- Assess progress with the appliance and address any patient concerns. Consider additional follow-up sleep test to evaluate efficacy and address potential need for further titration.

Year 1: Teeth/Appliance Inspection

- Assess progress with appliance and address any patient concerns. Address the need for any appliance repairs. Consider additional follow-up sleep test to evaluate efficacy and need for further titration of the jaw position.

IMPORTANT: The importance of adhering to this regimen cannot be overemphasized. The follow-up visits listed above are the minimum number of visits necessary to assure the best possible experience for your patient. We recommend that every doctor repeat Week 1 – Year 1 visit scheduling as needed throughout course of patient's lifetime treatment.

FABRICATED BY:



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CAUTION: Federal law requires a written prescription, signed by a licensed medical professional.

CLINICAL DIRECTIONS FOR USE: CLEAR SLEEP™

The Clear Sleep™ is used for reducing nighttime snoring and mild-to-moderate Obstructive Sleep Apnea in adults. Two-piece construction allows for patient comfort. Each appliance is customized for the patient by prescription and is adjustable. Interchangeable connectors of different sizes can be changed to move the mandible forward in 1mm increments during adjustments. The connectors must be secured to the device before delivering to the patient.



INDICATIONS

The Clear Sleep™ is worn while sleeping to support the mandible in a forward position prescribed by the dentist.

CONTRAINDICATIONS

This appliance is contraindicated in the following instances:

- Central Sleep Apnea (CSA)
- Severe respiratory disorders
- Loose teeth or advanced periodontal disease
- Patients under 18 years of age
- Edentulous or insufficient number of teeth to retain the device
- Inadequate mandibular range of motion
- Myofacial dysfunction
- Anthroopathy of the TMJ
- Patient is undergoing dental work that requires temporary crowns

WARNINGS

- IT IS ESSENTIAL THAT THE PATIENT BE TESTED WITH A HOME SLEEP TESTING DEVICE OR AN OVERNIGHT-ATTENDED PSG TO VERIFY TREATMENT EFFICACY.
- A complete and proper diagnosis must precede treatment. OSA is a medical condition and can only be diagnosed by a physician. Following a diagnosis, explain ALL the options available to the patient and have them sign an informed consent document.
- Use of the device may cause:
 - Gingival irritation or dental soreness
 - Pain or soreness of the TMJ or facial muscles
 - Obstruction of oral breathing
 - Increased salivation
- A small percentage of patients actually increase their number of apneic and hypopneic events when using an oral appliance. Should your patients experience any of these adverse events, instruct them to discontinue use of the appliance and call your office.
- ALWAYS follow-up with your patient's sleep physician (and any other treating physicians) with regard to status of your mutual patient.

PRECAUTIONS:

- Dentists should consider the medical history of the patients, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.
- After removal of the appliance following nighttime use, patients may feel that their teeth do not occlude as before. If this feeling persists for twenty minutes, they may use the SML® Good Morning to restore their customary bite relationship. Follow the included fitting instructions and instruct the patient in its use.
- Patient should be instructed as follows:
 - DO NOT wear the appliance if broken
 - DO NOT use toothpaste to clean the appliance
 - DO NOT run or exercise with the appliance in your mouth
 - DO NOT attempt to modify the appliance
 - DO NOT share the appliance
 - DO NOT expose the appliance to extreme heat or leave in car for prolonged periods
 - DO NOT attempt to pop the appliance in and out of your mouth with your tongue.
 - DO NOT place the appliance in hot or boiling water or expose to excessive heat.

INSTRUCTIONS/OFFICE PROTOCOL:

Perform a complete oral health assessment and medical health history assessment including:

- Full medical and dental health history
- Dental radiographs
- Clinical oral evaluation
- General patient interview

IMPRESSIONS:

Using a high-quality alginate, take dental impressions of the upper and lower arch including the full palate. Please pour the model in your office, evaluate for air bubbles and distortion, trim and dry before shipping to the lab.

BITE RECORDS:

A bite record is necessary for the lab to construct an appliance that positions the mandible and maxilla in proper relationship to one another. The following steps are recommended:

- Use the Airway Materics, Andra™ or George™ Gauge (available from SML at 800-423-3270 or www.SMLglobal.com) to measure the range of motion of the mandible along its anterior-posterior travel.
- Set the gauge – approximately 70% protruded from the most retruded

position. NOTE: If your patient cannot comfortably advance to 70%, take the bite record at the most comfortable protruded position.

- Once the proper position is determined, insert the set gauge into the patient's mouth and instruct the patient to practice closing into the notches on the bite forks. Then remove the gauge and place softened wax or elastomeric material on both sides of the bite fork component and have the patient bite into the protruded position until the bite material sets.

- After you have completed the bite record, ask the patient to sit with the bite plate in place for about five minutes. This will assure that the patient is comfortable at this advanced mandibular position.

NOTE: Make sure that the models fit into the bite record without rocking. Ensure that the skeletal midline is aligned and models properly settled. Then wrap the bite record in bubble wrap and send with models to the lab. Be sure to include the appliance prescription in the box.

DELIVERY DAY/FITTING INSTRUCTIONS:

The delivery visit should confirm the fit and comfort of the appliance, as well as the patient's ability to insert and remove it properly and without difficulty.

- Position the dental chair reclined 30 degrees.
- Insert the appliance in the patient's mouth as one piece. First, push the upper tray into position. Follow this by instructing the patient to bring their mandible forward to engage appliance and have them close into it.
- Have the patient relax and evaluate the comfort of the appliance. NOTE: An acrylic lab bur can be used to relieve any pressure spots.

IMPORTANT: Patient Instructions (including risks and benefits, care, maintenance, and warnings) should be dispensed and reviewed with the patient upon delivery of appliance.

IMPORTANT: A properly taken Bite Record typically places the mandible in the most advantageous position. If this carefully done, the need to change connectors is rarely necessary.

CARE AND CLEANING OF THE APPLIANCE:

[Instruct the patient to follow the manufacturer's instructions for use.]

- After use, the patient should rinse appliance in cold water and gently brush all surfaces clean.
- Patient should be instructed to use a soft-bristled brush. Stiff brushes may scratch or damage the device. DO NOT USE TOOTHPASTE.