

without difficulty. It may be necessary to adjust the clasps to achieve a comfortable level of retention. **NOTE: The Patients' Directions for Use MUST be dispensed and reviewed with the patient at this visit.**

INSERTION:

1. Place the upper part in the patient's mouth and gently press it up into place with your thumbs.
2. Place the lower part of appliance against the upper part and bring mandible forward so the patient can carefully insert their mandibular teeth into the lower appliance.
3. Complete placement by pressing down with forefingers to finish the seating of the appliance.

The upper front teeth should feel comfortable with the appliance in place. An acrylic lab bur can be used to relieve any pressure spots on the inside of the appliance. The appliance is designed to allow the mandible freedom of movement side-to-side, vertically, and protrusively.

REMOVAL:

1. Remove the lower part of appliance first, using thumbs on both sides to carefully lift it off the teeth.
2. Remove the upper part of appliance by carefully pulling down on the sides of the appliance.
3. Rinse and clean the appliance

AFTER NIGHTTIME USE, (and removal of the appliance), some patients may feel that teeth do not occlude as before. If this persists for twenty minutes after removal, patients should be instructed to use the SML® Good Morning Positioner to restore their customary bite relationship. This is accomplished by:

- Placing it between the upper and lower teeth
- Biting down slowly
- Holding this closed position for several seconds
- Repeating until bite again feels normal.

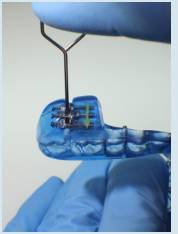
OBSERVATION/ADJUSTMENT VISITS:

IMPORTANT

The expansion screw used on this appliance requires ten ¼ turns to achieve 1mm of expansion. Each ¼ turn (90° rotation) of the turnbuckle equals one-tenth of a millimeter.

Recommended maximum expansion: 5mm.

60% TO 70% PROTRUSIVE CONSTRUCTION BITE REQUIRED (as per standard OSA repositioning)



Schedule observation visits to ensure that the appliance is comfortable and effective and that no dental problems have developed.

If additional mandibular jaw advancement is necessary, have the patient remove their appliance. Be sure to advance the appliance bilaterally. Record the number and millimeters of the adjustments.

Week 1: "Comfort Check." Make any necessary adjustments for the fit and positioning. Adjustments are usually made in increments of 0.5 mm

Months 1, 2, and 3: Evaluate teeth and appliance. Make any necessary adjustments in jaw position.

6 months: Check progress with the appliance and address any patient concerns.

Yearly: Inspect teeth and appliance. This allows you to minimize any side effects and make any necessary appliance repairs.

FABRICATED BY:



SPACE MAINTAINERS
LABORATORIES

SML® - Space Maintainers Laboratories
9129 Lurline Ave, Chatsworth, CA
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www.SMLglobal.com



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

**CLINICAL INSTRUCTIONS FOR USE:
ADJUSTABLE DORSAL APPLIANCE**

The Adjustable Dorsal Appliance is available in two mandibular advancement models: the Dual Laminate Appliance and the Acrylic & Clasp Appliance.

- The Dual Laminate model has a soft, rubbery surface on the inside of each piece and a hard acrylic surface on the outside without metal clasps for retention. The appliance is held in place by the soft, rubbery liner. Patients must have adequate natural undercuts for retention of the Dual Laminate model, because retention cannot be increased during treatment, and the appliance cannot be modified to accommodate new tooth restorations or the loss of posterior teeth.
- The Acrylic & Clasp model has several metal ball clasps, which can be adjusted to increase retention on teeth that have insufficient undercuts. The ball clasps can often be modified, should further dental work be performed and adjustments required.



CONTRAINDICATIONS

This appliance is contraindicated if the patient:

- Has Central Sleep Apnea (CSA)
- Has severe respiratory disorders
- Has loose teeth or advanced periodontal disease
- Is under 18 years of age
- Is edentulous or insufficient number of teeth to retain the appliance
- Has inadequate mandibular range of motion
- Has myofacial dysfunction
- Has anthropathy of the TMJ
- Is undergoing any type of orthodontic treatment
- Is undergoing dental work that requires temporary crowns

WARNINGS

Use of the appliance may cause:

- Tooth movement or changes in the dental occlusion
- Gingival irritation or dental soreness
- Pain or soreness of the TMJ or facial muscles
- Increased salivation
- Loosening and/or dislodging of dental fillings or crowns.

NOTE: A small percentage of patients actually increase their number of apneic and hypopneic events when use an oral appliance.

Should your patients experience any of these adverse events, instruct them to discontinue use of the appliance and call your office.

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PRECAUTIONS:

- After removal of the appliance after nighttime use, patients may feel that their teeth do not occlude as before. If this feeling persists for twenty minutes after removal, they may use the SML® Good Morning Positioner.
- Be sure the trays are kept clean. Examine them often for signs of wear and tear. If you suspect that damage has occurred, contact your dental laboratory for possible repair.
- Performance may be adversely affected by: weight gain, obesity, alcohol

consumption, sedative use, allergies, smoking, very high altitudes, increased age, hormonal changes such as menopause, a cold, or sickness that compromises nasal breathing.

IT IS ESSENTIAL THAT THE PATIENT BE TESTED WITH A HOME SLEEP TESTING APPLIANCE OR AN OVERNIGHT-ATTENDED PSG (PolySomnoGram-diagnostic sleep test) TO VERIFY THE EFFICACY OF THE TREATMENT.

ALWAYS follow-up with your patient's sleep physician (and any other treating physicians), regarding your patient.

OFFICE PROTOCOL:

Oral Health and Medical Health History Assessment:

Perform a complete oral health assessment as well as a medical health history assessment including:

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

NOTE: Dentists should evaluate the medical health history of the patient, including asthma, breathing, respiratory disorders, or other relevant health problems. Refer the patient to the appropriate healthcare provider for treatment of health problems *before prescribing the appliance.*

IMPRESSIONS:

Dental impressions should be taken of the upper arch and palate and the lower arch using a high quality alginate such as Kromopan® or polyvinyl siloxane (PVS) impression material. We recommend that models be created in your office from the impressions, evaluated for defects, trimmed and dried before shipping to the laboratory.

BITE RECORDS:

A bite record is necessary for the dental laboratory to construct an appliance that positions the jaws in the proper relationship to one another. Record this relationship (in the patient's mouth) with a hard wax or elastomeric material. The following steps are recommended:

- Use an Andra™ or George™ Gauge to measure the range of

motion of the mandible along its anterior-posterior travel. [Both gauges are available from SML® (1-800-423-3270) or www.SMLsleep.com.]

- **Set the gauge** at a fixed position, approximately 70% protruded from the most retruded position. NOTE: The 70% protruded position is a widely accepted starting point for therapy. Patient comfort and appliance efficacy will guide you in adjusting the protrusion of the mandible to the optimal treatment position at subsequent visits.

If your patient cannot comfortably advance to 70%, take the bite record at the most comfortable protruded position. Vertical opening must be a minimum of 4mm at the first molar region.

- **After setting the gauge**, insert it in the mouth and have the patient practice closing into the notches on the bite forks. Then remove the gauge from the mouth and place softened wax or elastomeric material on both sides of the bite fork component. Have the patient bite down into that material until it sets or hardens.

IMPORTANT: Articulate the models (with the bite record). Make sure that the models fit into the bite record without rocking. Ensure the skeletal midline is aligned and the models are properly settled. The bite record should then be wrapped in bubble wrap and sent with the models to the lab.

SHIPPING THE CASE:

Models and bite records should be wrapped separately with bubble wrap and shipped to our certified laboratory with a prescription for the appliance in the box.

PATIENT FITTING:

Prior to patient contact, the new appliance should be properly washed and disinfected with Cavicide®, in accordance with that manufacturer's instructions. Spray Cavicide directly on the pre-cleaned appliance, thoroughly wetting all sides. Allow the surface to remain visibly wet for 3 minutes at room temperature. Rinse thoroughly with high quality potable water.

The delivery visit should confirm the fit and comfort of the appliance, as well as the patients' ability to insert and remove it properly and