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

CLINICAL DIRECTIONS 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.

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 prostrusively.

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 removal of the appliance after nighttime use, 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:
If the appliance has been fabricated to the prescribed repositioned bite relationship (as outlined above) the dentist may find it beneficial to have the patient wear the appliance for several days before activating the expansion screws.

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)

- If additional mandibular jaw advancement is necessary, have the patient remove their appliance.
- To advance the mandible, insert the Adjustment Key (in the expansion screws on the upper portion of the appliance) and turn it in the direction of the arrow that is visible on the body of the screw. Each ¼ turn of the key opens the screw by 0.2 mm.
- Be sure to advance the appliance bilaterally.
- Record the number and millimeters of the adjustments.

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

**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.

SML®
SPACE MAINTAINERS LABORATORIES
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Fax: 818-341-4684
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
• Tooth movement or changes in the dental occlusion
• Increased salivation
• Loosening and/or dislodging of dental fillings or crowns
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.

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 hypopneic events when use an oral appliance.

PREPARING THE PRESCRIPTION:
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.

INSTRUCTIONS
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.

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:
The 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
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.