NOTE:
If you plan to use the SRI component to increase the vertical opening, it is important that you carefully fuse the SRI into the slot of the upper appliance. This can be done by placing a thin wash of standard clear acrylic in the receptacle on the base of the upper appliance, then inserting the SRI component. Build a slight bead of acrylic (for extra strength) along the seam of the SRI - being extra careful not to allow acrylic to flow into the top half of the SRI that is to accept the PE insert.

Communications:
Always send the patient's sleep physician's (and any other treating physician's) follow-up communication regarding patient status.

LAMBERG PROTOCOL FOR TITRATION

DELIVERY VISIT:
• Patient Instructions: No Advancement for ONE week.

WEEK 1 VISIT:
• Evaluate patient comfort, side effects, and condition of appliance.
• Review advancement protocol with patient.
• Advance appliance by putting in the next insert (.5 mm advance), once per week until: Resolution of symptoms, Snoring, Nocturnal Awakenings, Unrefreshed Sleep (ESS) OR Appliance becomes uncomfortably advanced.

MONTH 1 VISIT:
Evaluate patient comfort, side effects, and condition of appliance.
• Weight • Blood Pressure • ESS score

MONTH 2 VISIT:
Evaluate patient comfort, side effects, and condition of appliance.
• Weight • Blood Pressure • ESS score

MONTH 3 VISIT:
Evaluate patient comfort, side effects, and condition of appliance.
• Weight • ESS score
• Blood Pressure taken
• AEQ (Appliance Experience Questionnaire)
... and Schedule a H.S.T (Home Sleep Test)

HOME SLEEP TEST CONSULTATION:
Fax nPSG Titration Protocol to sleep lab as necessary. Adjust appliance in 1mm increments at 30 minute intervals, if respiratory events persist. Do not advance during REM. Do not advance more than 3mm.

User Assistance Contact Information: Dr. Steven Lamberg, 631-261-6014, your dentist, or SML™, 800-423-3270.

SML™
SPACE MAINTAINERS LABORATORIES
9129 Lurline Avenue
Chatsworth, CA 91311
Phone: 818-998-7460 or 800-423-3270
Fax: 818-341-4684

SML™
SPACE MAINTAINERS LABORATORIES

APPLIANCE INSTRUCTIONS FOR THE DENTIST

OVERVIEW
The LSW-S is a two piece appliance which advances the mandible to alleviate snoring and mild-to-moderate sleep apnea. It is adjustable in .5mm increments, by the patient or doctor, utilizing the inserts which come with your case.

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. A copy of the Consent Document may be downloaded from www.LambergSleepWell.com

The dentist will evaluate how the patient is doing and make necessary adjustments to the device at scheduled follow-up visits until subjective reporting indicates an effective response to the device. When subjective reporting is positive, the patient must be evaluated with an attended PSG or a home sleep test device to objectively validate the efficacy of the treatment position.

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Upon obtaining satisfactory objective data, the patient is referred back to his/her physician for evaluation because OSA is a medical condition. Only a physician can make a diagnosis or evaluate treatment efficacy.

OFFICE PROTOCOL

Oral Health and Medical Health History Assessment:
The dentist must perform a complete oral health assessment as well as a medical health history assessment – including a full medical and dental health history, dental radiographs, clinical oral evaluation, and a general interview with the patient. **Precaution:** Dentists should evaluate the medical health history of the patient, including history or asthma; breathing or respiratory disorders; or other relevant health problems, and refer the patient to the appropriate healthcare provider *before prescribing the device*.

Impressions:
Dental impressions of the upper arch of teeth and palate (and the lower teeth) should be taken using a high quality alginate such as Kromopan or PVS impression material. The models are then poured and need to be carefully evaluated for any defects. Accepted models are trimmed and dried in preparation for packing and shipping.

Bite Records:
In order for the laboratory to construct the appliance so that it positions the jaws in the proper relationship to one another, it is necessary to record this relationship (in the patient's mouth) with a hard wax or elastomeric material. The following steps are recommended:

Measure the range of motion of the mandible along its anterior-posterior travel. Use the George Gauge (or Andra Gauge) to measure this. Both are available from SML™: (1-800-423-3270) or visit their website: www.SMLsleep.com

Set the gauge at a fixed position approximately 70% protruded from the most retruded position. Try it in the mouth and have the patient practice closing into the notches on the bite forks. 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. Check to see that the models fit into the bite record without rocking. (This is important!!) The bite record is then wrapped in bubble wrap and must

accompany the models to the lab.

The 70% protruded position is a widely accepted starting point for therapy. Patient comfort and appliance efficacy will guide you in adjusting the protrusiveness to the optimal treatment position at subsequent visits.

Shipping the Case:
Models and bite records should be wrapped with bubble wrap material and shipped to our certified laboratory in a box - along with a prescription for the LSW-S.

Disinfection prior to dispensing appliance to patient:
Once the appliance is back from the laboratory, it should be properly washed and disinfected. Disinfect the appliance using Cavicide according to the manufacturer's instructions. Spray Cavicide directly onto the pre-cleaned appliance, thoroughly wetting all sides. Allow the surface to remain visibly wet for 3 minutes at room temperature. A thorough rinse with high quality potable water is required before dispensing the appliance to a patient. All warnings and precautions should be strictly observed.

Delivery of the Appliance to the patient:
The delivery visit should validate the fit of the appliance and the comfort as well as the patients' ability to insert and remove it properly and without difficulty. It may be necessary to adjust the Adams Clasps with three prong pliers in order to affect a comfortable level of retention. The upper front teeth should feel comfortable with the appliance in place and 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 to have freedom of movement side to side, vertically, and protrusively.

IMPORTANT NOTE: Patient Use Instructions – including risks and benefits, care, maintenance, and warnings – must be dispensed and reviewed with the patient at this visit. (See the enclosed "Patient Instructions" for more information)

OBSERVATION VISITS FOR DEVICE (FIT AND PROTRUSIVENESS) ADJUSTMENTS:

Schedule observation visits (summarized below) to make sure that the appliance is comfortable and etffective and that no dental problems have developed.

Week 1: "Comfort Check." Make any necessary adjustments for the fit of the appliance and the jaw position. Adjustments are made to the appliance in increments of .5 mm, or as necessary when using inserts, follow titration protocol document instructions.

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

6 months: Check on the patients' progress with the appliance.

Yearly: See your patient at least once a year to inspect their teeth and the appliance. This will allow you to make any necessary repairs to the appliance and help minimize any side effects.

IMPORTANT NOTE: THE PATIENT MUST BE TESTED WITH AN ATTENDED OVERNIGHT PSG OR HOME SLEEP TEST TO VALIDATE TREATMENT POSITION EFFICACY.

Special Warning:
The situation where the protrusive element is not sufficient in length, causing the lower plate of the appliance to "fall off" the protrusive element, has not been reported clinically. It is still important to ask the patient if they have experienced this. It is a physical possibility. The protrusive element is easily lengthened, if necessary, by inserting the SRI component which increases the vertical distance between the jaws.