

D. Storing:

Always dry the appliance completely before storing. Place it in a dry plastic case whenever it is not in your mouth. Keep your appliance so that family pets cannot reach it.

E. Maintenance / Observation Visits With Your Dentist

1. Follow-up visits are necessary at the following intervals:

Week 1: "Comfort Check." Make any necessary adjustments for the fit of the appliance and the jaw position.

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

6 months: Check on your progress with the appliance.

Yearly: See your dentists once a year to inspect your teeth and the appliance. This will help minimize any side effects in your mouth and allow the dentist to make any necessary repairs to the appliance. IT IS ESSENTIAL TO UNDERGO SOME TYPE OF OBJECTIVE SLEEP TESTING, EITHER WITH A HOME SLEEP TESTING DEVICE OR AN OVERNIGHT ATTENDED PSG, TO EVALUATE THE EFFICACY OF THE APPLIANCE.

Important Note: The need to adhere to this maintenance care regimen cannot be overstated. The follow-up visits listed above are the minimum amount of visits necessary to assure the best possible experience for you. You should call your dentist for additional visits whenever you feel they may be necessary. To insure the best possible outcome with the appliance it is essential to have a proper fit and to have your mouth evaluated with follow-up visits on a regular basis.

- 2. The appliance should last for 2-3 years – depending on how well you care for it.
- 3. Inspect your appliance regularly. If you notice any chipping or cracking in the appliance, or the clasps are bent (or it seems to fit differently) see your dentist as soon as possible to repair or replace the appliance. These changes could effect its proper functioning and or safety.

5. WARRANTY

The Lamberg Sleep Well Device is custom made for you from materials to ensure comfort and durability. Your device is warranted by the certified laboratory used by your dentist. This is a manufacturers warranty and NOT a claim for stopping snoring or improving your obstructive sleep apnea. If your Lamberg Sleep Well Device is broken, it is very important that you cease using the device and contact your dentist to have it repaired immediately.

FABRICATED BY:

SML™ 9129 Lurline Ave Chatsworth, CA Tel: (800) 423-3270



PATIENT INSTRUCTIONS

1. PURPOSE OF THE LAMBERG SLEEP WELL DEVICE:

The purpose of the Lamberg Sleep Well Device is to reduce or alleviate night time snoring and mild and moderate obstructive sleep apnea.

2. DESCRIPTION OF THE LSW DEVICE:

Description of the Device: The Lamberg Sleep Well Device is a two part device that is worn in the mouth and is used for treating Snoring and Sleep Apnea. It consists of two distinct components, or plates, that engage the teeth of each of the dental arches separately. The upper dental plate and the lower dental plate are in contact only in the front area of the mouth by means of a patented coupling system comprised of a protrusive element on the upper dental plate and its complimentary mate on the lower dental plate. This interface serves to reposition the lower jaw, and therefore the tongue, forward. It is this forward repositioning of the tongue which acts to increase the patients' airway size, thus enhancing breathing while sleeping. Each device is custom made for the patient by prescription only, and is adjustable at the time of delivery and anytime thereafter.

3. CONTRAINDICATIONS, RISKS, WARNINGS, CAUTIONS:

A. Contraindications

The device is contraindicated in the following instances:

Central Sleep Apnea (CSA)

Severe respiratory disorders

Loose teeth or advanced periodontal disease

Under 18 years of age

Edentulous or insufficient number of teeth to retain the device

Inadequate mandibular range of motion

Myofacial dysfunction

Anthropathy of the TMJ

If the patient is undergoing any type of orthodontic treatment

If the patient is undergoing dental work that requires temporary crowns

IMPORTANT NOTE: IF THE APPLIANCE IS BROKEN, DO NOT WEAR IT.

B. Risks

Use of the device may cause:

Tooth movement or changes in the dental occlusion or bite

Gingival irritation or dental soreness

Pain or soreness of the TMJ or facial muscles

Obstruction of oral breathing

Excessive salivation

Loosening and or dislodgment of dental fillings or crowns.

A small percentage of patients actually increase their number of apneic and hypopneic events when using an oral appliance. **Important Note:** Should you experience any of these adverse events, discontinue use of the device and call your dentist.

C. General Warnings

Performance may be adversely affected by: weight gain, obesity, alcohol consumption, sedative use, allergies, smoking, any cold or sickness that compromises nasal breathing, very high altitudes, increased age, and hormonal changes in women such as menopause. DO NOT modify the device and DO NOT share the device. If the appliance is broken, DO NOT wear it.

D. Cautions

The appliance should NOT be used as bleaching trays. DO NOT run or exercise with the appliance in your mouth.

4. USE INSTRUCTIONS

A. What to expect:

Initially, when the appliance is placed in your mouth you will, most likely, find it cumbersome.

First Night: There will be an increase in salivary flow for the first few weeks of use which will slowly subside. Some patients experience minor gagging or awkwardness swallowing, but these sensations are not permanent. After nighttime use, and removal of the appliance, you may feel that your teeth do not bite together as before. If this feeling persists for twenty minutes after removal, use the SML™ Good Morning Positioner. If there is continued discomfort, discontinue use and see your dentist.

Long Term: Contacts between teeth may be less tight. Most patients experience little if any discomfort after a few weeks of adapting to their intra-oral sleep apnea device. If there is continued discomfort, discontinue use and see your dentist.

B. Wearing the Appliance:

1. Prior to Inserting the appliance: Brush and floss your teeth.
2. Insertion: Insert the appliance into your mouth when going to sleep. Place the upper dental plate in your mouth onto the upper arch of teeth first and press up with your thumbs to make sure it is fully seated and secure and it does not rock. Then place the lower dental plate in your mouth on your lower teeth and press down until it is securely seated.
3. While it's in your mouth: DO NOT pop the appliance in and out of your mouth with your tongue.
4. Removal: First the lower dental plate. Then, the upper dental plate. When removing the upper dental plate, pull down slowly on the metal loops by your upper molars.
5. If a tooth feels sore, or you experience muscle / joint soreness, bring the appliance into your dentist for an adjustment.
6. If the appliance is broken, DO NOT wear it. Bring it to your dentist.

C. Cleaning:

Clean your appliance each morning after every use with a denture toothbrush or a regular toothbrush using either toothpaste or a denture cleaning paste e.g. Dentu-Creme or Fresh-n-Brite, which you will find in your supermarket. Use cold water only when cleaning your appliance. Take care to brush all surfaces, inside and out. Approximately once a week, we recommend that you soak the appliance in a denture cleaning solution. There are many commercially available denture cleaning solution products such as Polident or Efferdent or OAP Appliance Cleaner (available from SML™ (1-800-423-3270) or www.SMLglobal.com). Follow the manufacturers instructions when using these products. After cleaning, rinse appliance under cool water. Completely air dry before storing.

CAUTIONS: DO NOT soak the appliance in mouthwash or alcohol, or bleach as these may weaken your appliance, and DO NOT place in hot or boiling water or expose to excessive heat as this could distort the appliance.