



## **Sleep Appliance Patient Instructions**

**Device Description:** The Serena Sleep Appliance is a custom-made intraoral device used for treating snoring and sleep apnea.

**Indication for Use:** The Serena Sleep Appliance is a removable medical device that is fitted to the patient's mouth. It is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

**Caution:** By prescription only. Federal law restricts this device to sold only by or on the order of a physician.

### **Do not use if you meet the following criteria:**

1. You have central sleep apnea or severe obstructive sleep apnea
2. You have a severe respiratory disorder
3. You have loose teeth or advanced periodontal disease
4. You are less than 18 years of age

### **Warnings**

1. If you have an allergic reaction to this product, please discontinue use and contact your doctor.
2. Use of the Serena Sleep Appliance may cause:
  - Tooth movement or changes in dental occlusion
  - Gingival or dental soreness
  - Pain or soreness to the temporomandibular joint
  - Obstruction of oral breathing
  - Excessive salivation

### **Precautions**

1. Your dentist should consider your medical history, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer you to the appropriate healthcare provider before prescribing the device.
2. Devices are non-sterile, clean before use.
3. Do not wear Serena Sleep devices while eating, drinking, chewing gum, or using tobacco products.

4. Clean your Serena Sleep devices after use, by using a toothbrush, antibacterial soap, and warm water.
5. Keep your Serena Sleep devices away from children or pets

## **Complications**

Serena Sleep devices can cause serious side effect: however, these side effects occur in only a small number of people. Your doctor will monitor you for them. Some side effects include:

- Sore jaw joints
- Increased salivation
- Dry mouth
- Sore teeth
- Tissue irritation
- Change in bite alignment

These possible side effects should diminish within an hour of removing the device. If any of these side effects continue, contact your dentist immediately.

## **Recommended Procedure**

### **Elevate Model**

1. Remove the Serena Sleep appliances from the package and examine them.
2. Working with your dental healthcare professional, select the proper upper and lower appliances as indicated by the letter code on the side of the appliances. Codes A, B and C are designed for your upper teeth and Codes X, Y and Z are designed for your lower teeth. You may have one, two or three upper appliances and one, two or three lower appliances.

Use the upper and lower appliances as instructed by your dental healthcare professional.

- a. Upper and lower appliances have step placements for different advancements to optimize the effectiveness and comfort of your Serena Sleep Appliance.
  - b. Each upper and lower appliance has notches for elastics to help train your teeth to stay together through the night. Use these elastics as instructed by your dental healthcare professional.
  - c. When using elastics, make sure both sides of your appliances are using matching elastics.
  - d. It can take several weeks of use to achieve the optimal effectiveness and comfort.
3. Rinse the appliance thoroughly with cool water and clean with a toothbrush.
  4. Prior to sleeping, insert the appliance in your mouth. The appliance should remain on your teeth for the entire sleep period.

Inserting the Elevate appliance when not using elastics:

Place the upper appliance in your mouth. Press up on the appliance with both thumbs to ensure that it fits securely and comfortably. Place the lower appliance in your mouth. Press down on both sides of the appliance using your index fingers to ensure it fits comfortably.

Inserting the Elevate appliance when using elastics:

Connect the elastics to the notches BEFORE placing in mouth. Place upper and lower appliances in your mouth and press up on the appliance with both thumbs to ensure that the upper appliance fits securely and comfortably on your upper teeth. Position the lower appliance so that it is aligned with your teeth and press down on the appliance to ensure that the lower appliance fits securely and comfortably on your lower teeth. With the upper and lower appliance fitted on your teeth, gently bite down and slide your bottom jaw forward and then relax your jaw and your bite

Serena Nylon EMA® Model

1. Remove the Serena Sleep appliances from the package and examine them.
2. Working with your dental healthcare professional, place the proper advancement bands on the posts.

Advancement Bands:

- a. Use the bands as instructed by your dental healthcare professional.
  - b. Bands have different lengths and elasticity to optimize the effectiveness and comfort of your Serena Sleep appliance.
  - c. Make sure both sides of your appliances are using matching bands.
  - d. It can take several weeks of use to achieve the optimal effectiveness and comfort.
3. Rinse the appliance thoroughly with cool water and clean with a toothbrush.
  4. Prior to sleeping, insert the appliance in your mouth. The appliance should remain in for the entire sleep period.

Place upper and lower appliances in mouth and press up on the appliance with both thumbs to ensure that upper appliances fit securely and comfortably on to your upper teeth.

Position the lower appliance so that it is aligned with your teeth and press down on the appliance to ensure the lower appliance fits securely and comfortable on your lower teeth.

### **Removing the Device:**

It is suggested to remove the lower device first. Using your thumbs on both sides, gently pull the lower device in an upwards motion to remove. Using both your index fingers and thumbs, gently pull the upper device down and forwards to remove.

## **Period of Use**

From the time the patient receives the appliance, the device should be worn. The patient should not wear the appliance if they have not worn the device within the first year after receiving the appliance. The appliance should be replaced when the appliance cracks or the device fails to stay in your mouth. If one of these problems occurs, please return the appliance to your doctor/dentist for evaluation and potential replacement.

## **Cleaning and Storage**

It is very important to clean the Serena Sleep Appliance daily to ensure the longevity and cleanliness of your appliances. The following steps need to be followed to clean the device.

- Clean the device immediately after using.
- Each day clean your appliance thoroughly with a soft toothbrush, warm water and antibacterial soap
- Do not use toothpaste as it contains abrasives.
- If soaking the appliance in a cleaner, follow the specific cleaner instructions.
- Dry the device and storage case thoroughly.
- When not in use, the device should be stored in a storage case.

## **Warranty**

Serena Sleep warrants all Serena Sleep Appliances supplied to be free from defects in materials and in fabrication for a period of 36 months from the date of delivery to the providing medical practitioner. This device is meant for treating snoring and obstructive sleep apnea at the source. Serena Sleep does not make any guarantees regarding the outcome treatment of obstructive sleep apnea.

- The Serena Sleep warranty is invalidated if the device needs to be remade due to change in the patient's oral anatomy.
- The warranty is invalidated if the patient breaks a particular area on the device that was not a result of fabrication defects.
- Repairs not covered under warranty include, but are not limited to, bite resets, damages not caused by fabrication defects, damage caused by improper cleaning, device modifications made by unauthorized personnel etc.