



## Sleep Appliance Provider 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 and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

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

### Contraindications

1. Patients who have central sleep apnea
2. Patients who have severe respiratory disorders
3. Patients who have loose teeth or advanced periodontal disease
4. Patients who are less than 18 years of age

### Warnings

1. 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
  - Allergic reaction

### Precautions

1. Consider the patient's medical history, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.
2. Devices provided are non-sterile and need to be cleaned before use.
3. Patient should not wear Serena Sleep devices while eating, drinking, chewing gum, or using tobacco products.
4. Serena Sleep devices should be cleaned by using a toothbrush, antibacterial soft soap and warm water.
5. Device should be kept away from children or pets



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### Complications

Serena Sleep devices can cause serious side effect. However, these side effects occur in only a small number of people. Monitor your patients for the following possible side effects:

- 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.

### Recommended Procedure

Elevate Model

1. Remove the Serena Sleep appliances from the package and examine them.
2. Working with your patient, select the proper upper and lower appliances to get the desired titration as indicated by the letter code on the side of the appliances. Codes A, B and C are designed for the upper teeth and Codes X, Y and Z are designed for the lower teeth. The 4A comes with two upper appliances and two lower appliances, the 9A comes with three upper and 3 lower appliances.
3. Instruct your patients which upper tray and which lower tray to use.
  - a. Upper and lower appliances have step placements for different advancements to optimize the effectiveness and comfort of the Serena Sleep Appliance.
  - b. Each upper and lower appliance has notches for elastics to help train the jaw stay together through the night. Elastics are optional and to be used at the healthcare providers discretion.
  - c. When using elastics, put the elastics BEFORE the patient inserts and insure both sides of the appliances are using matching elastics.
  - d. It can take several weeks of use to achieve the optimal effectiveness and comfort.
4. Rinse the appliance thoroughly with warm water and clean with a toothbrush and anti-bacterial soap.
5. 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:

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

Inserting the Elevate appliance when using elastics:

Connect the elastics to the elastic notches and then place upper and lower appliances in mouth. Press up on the upper appliance with both thumbs to ensure that the upper appliance fits securely and comfortably on the upper teeth. Position the lower appliance so that it is aligned with the lower teeth and press down on the appliance to ensure that the lower appliance fits securely and comfortably. With the upper and lower appliance placed on the teeth, gently bite down and slide the bottom jaw forward. Then the patient will relax their jaw and bite.

Serena Nylon EMA® Model

1. Remove the Serena Sleep appliances from the package and examine them.
2. Place the selected advancement bands on the posts.

Advancement Bands:

At the healthcare providers discretion, select the bands that are best for your patient.

Bands have different lengths and elasticity to optimize the effectiveness and comfort of the Serena Sleep appliance.

Make sure both sides of the appliances are using matching bands.

It can take several weeks of use to achieve the optimal effectiveness and comfort.

3. Rinse the appliance thoroughly with warm water and clean with a toothbrush and anti-bacterial soap.
4. Prior to sleeping, insert the appliance in your mouth. The appliance should remain in for the entire sleep period.

Inserting the Serena Nylon EMA® Model



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 Appliances**

To remove the lower tray, use both thumbs placed on the band posts and gently move the lower device in an upwards motion to remove. Using both index fingers and thumbs, gently pull the posterior end of the upper device down and forwards to remove.

## **Period of Use**

From the time the patient receives the appliance, the appliances 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 the patient's mouth.

## **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 or cracks the appliance.
- Repairs not covered under warranty include, but are not limited to, accessories, bite resets, damages not caused by fabrication defects, damage caused by improper cleaning, device modifications made by unauthorized personnel etc.

## **Contact**

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