



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 in the patient's mouth and 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 sale 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, rinse 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 and cool water. Do not soak in 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

1. Remove the Serena Sleep device from the package and examine them for defects.
2. Rinse the device thoroughly with cool water and a toothbrush.
3. Prior to sleeping, insert the device in your mouth. The appliance should remain in for the entire sleep period.

Inserting the Upper Device: Place the upper device in your mouth. Press up on the device with both thumbs to ensure that it fits securely and comfortably

Inserting the Lower Device: Place the lower device in your mouth. Press down on both sides of the device using your index fingers to ensure it fits comfortably.

4. **Jaw Positioning:** 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
5. **Removing the Device:** Always 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

The device can be worn every night for up to a year. 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 your Serena Sleep Appliance daily to ensure you get the best benefit and longevity from the device. Please follow the steps below to clean your device.

- Always clean your device in the morning immediately after having removed it from your mouth.
- Use a soft tooth brush.
- Do not use toothpaste as it contains abrasives.
- Never use hot water. Hot water damages your device and will invalidate the warranty.
- Never soak your device in a cleaner.
- After having removed the device from the storage case, thoroughly brush it with a tooth brush and rinse it under cool running water.
- Dry all parts of the device and storage case carefully, using a clean towel.
- When not in use, the device should be stored in your storage case.
- To reduce the possibility of discoloration, do not drink coffee or tea while wearing the device.

Warranty

Serena Sleep warrants all Serena Sleep Appliances supplied to be free from defects in materials and in fabrication for a period of 12 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 your oral anatomy.
- The warranty is invalidated if the patient breaks a particular area on the device that cannot be repaired and therefore the device needs to be remade.
- Repairs not covered under warranty include, but are not limited to: clasp repair, bite resets, new device mechanisms, relines, and other damages not caused by fabrication defects (i.e. distorted models, bad bite registration from office, calculus deposits, and device modifications made by unauthorized personnel).