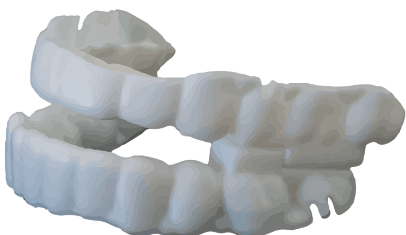




Serenasleep

DURABLE | COMFORTABLE | EFFECTIVE



"Relieving Sleep Apnea"

Instructions for Use

Patient Name: _____

Prescribing

Physician: _____

Dentist: _____

Model: _____

Serial No: _____

Date of Initial Fitting: _____

Notes: _____

Record of Titration:

Date: _____ Adjustment: _____

Date: _____ Adjustment: _____

Date: _____ Adjustment: _____

Date: _____ Adjustment: _____

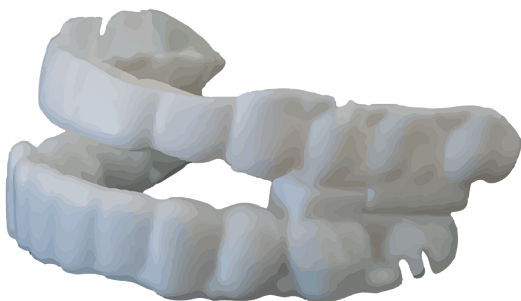
Date: _____ Adjustment: _____

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Congratulations for taking this step in relieving sleep apnea using an affordable, comfortable and effective sleep appliance by **Serena Sleep**.

Your healthcare professional is dedicated to help you improve your obstructive sleep apnea.



Appliance Description

Your new **Serena Sleep** appliance is custom-made to your teeth. It is an intraoral appliance used for treating snoring and sleep apnea. This oral appliance is designed to advance your lower jaw (mandibular) to help open your upper air way while you sleep. Please see your specific model description for further detailed information.

Indication for Use

The **Serena Sleep** appliance is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults.

Caution

Rx only. Federal law restricts this appliance to sale by prescription.

How to Use Your Appliance

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 efficiency 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:

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 insure that the lower appliance fits securely and comfortably on your lower teeth.

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. Note: Always wear the upper appliance and lower appliance when using. Do not wear only one without wearing the other.

Removing the Appliance

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

Period of Use

The appliance can be worn every night.

The appliance should be replaced when the appliance cracks or the appliance fails to stay in the patient's mouth. If one of these problems occur please return the appliance to your doctor/dentist for evaluation and potential replacement.

Morning Activities

The American Academy of Dental Sleep Medicine suggests jaw exercises may reduce jaw discomfort related to using your oral sleep apnea appliance. The American Academy of Dental Sleep Medicine has a 4 minute video that shows a number of jaw exercises. Type in this information to go to the video:

https://www.aadsm.org/patient_jaw_exercises.php

Morning Repositioner

If your dental healthcare professional provided you with a morning repositioner, it is important to use it each morning as instructed by your dental healthcare professional.

Sore jaw muscles are common when first using your sleep appliance. If jaw pain or bite problems persist, contact your dental healthcare professional.

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 appliance. Please follow the steps below to clean your appliance.

- Always clean your appliance in the morning immediately after having removed it from your mouth.
- Use a soft toothbrush.
- Do not use toothpaste as it contains abrasives.
- After having removed the appliance from the storage case, thoroughly brush it with a tooth brush and rinse it under cool running water.
- Dry all parts of the appliance and storage case carefully and thoroughly using a clean towel.
- When not in use, the appliance should be stored in your storage case and kept away from children, pets and out of direct sunlight.

Recommended Deep Cleaning

Deep clean your **Serena Sleep** appliance twice a week. Fill your provided container about ½ full with warm water. Add a compatible cleanser (your appliance is made from Nylon 12 material) and then place your appliances into the container. Submerge your appliances according to the cleanser instructions.

After the cleaning process is complete, rinse off your appliance and dry it. Discard the used cleaning solution and rinse and dry your container.

Note that some cleansers contain allergen ingredients. Be sure to follow the cleaner's instructions and warnings.

Appliance Selection, Sleep Study, Appliance Exam & Prescribing

It is imperative that you have a sleep study completed prior to receiving a prescription for an intraoral appliance. The sleep study will determine the level or severity that you are currently experiencing, and this information should be used by your dentist to determine your prescription. You should receive a complete and comprehensive dental exam prior to receiving a snoring or sleep apnea appliance. Once you have undergone a comprehensive dental exam complete with full records and a sleep study than the dentist can accurately prescribe a snoring or sleep apnea appliance.

Contradictions

Patients who have central sleep apnea or severe obstructive sleep apnea.

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

Warnings

If you have an allergic reaction, please discontinue use and contact your doctor.

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 appliance respiratory disorders, or other relevant health problems, and refer you to the appropriate healthcare provider before prescribing the appliance.
2. Appliances are non-sterile, rinse before use.
3. Do not wear **Serena Sleep** appliances while eating, drinking, chewing gum or using tobacco products.
4. Clean your **Serena Sleep** appliances after use, by using a toothbrush and cool water. Do not soak in water.
5. Keep your **Serena Sleep** appliances away from children or pets.

Complications

Serena Sleep appliances can cause serious side effects: 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 appliance. If any of these side effects continue, contact your dentist immediately.

Warranty

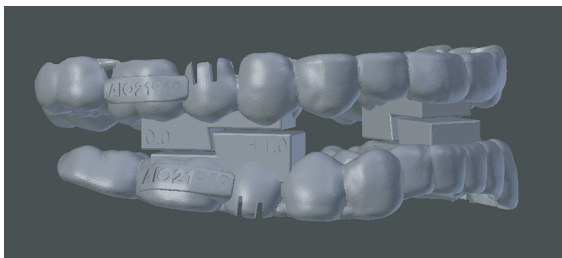
Serena Sleep warrants all **Serena Sleep Appliances** supplied to be free from defects in materials and in fabrication for a period of 36 months from the date of delivery to the providing medical practitioner. This appliance is meant for treating snoring and obstructive sleep apnea at the source. **Serena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

The **Serena Sleep** warranty is invalidated if the appliance needs to be remade due to change in the patient's oral anatomy.

The longevity of the appliance is left up to the patient once received from the providing dentist. The warranty is invalidated if the patient breaks a particular area on the appliance that cannot be repaired and therefore the appliance needs to be remade.

Warranty does not cover bite registration change, improper cleaning, unauthorized modifications or any other non-manufacturing related issues.





"Relieving Sleep Apnea"

Manufactured by Serena Sleep
www.Serenasleep.com

Registered trademarks

US Patent No: 9655695
US Patent No: 9744006
US Patent No: D870894S

Made in the USA – FDA Cleared