

Provider Instructions for Serena Sleep Nightguard and Occlusal/Orthotic Appliances

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Device Description:

The Serena Sleep Nightguard/Occlusal Appliance are custom-made intraoral orthotics used for protecting teeth and restorations against the forces of bruxism and alleviating temporomandibular joint, jaw, and muscle and tension headache pains. These appliances are made of durable, medical grade, Nylon PA2200 (polyamide 12) unless otherwise noted.

Indication for Use:

The Serena Sleep Nightguard/Occlusal Appliance is a removable medical device that is fitted to the patient's mouth and is intended to protect teeth and restorations against the forces of bruxism and alleviating temporomandibular joint, jaw, and muscle and tension headache pains

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

Contraindications

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

Use of the Serena Sleep protecting teeth and restorations against the forces of bruxism and alleviating temporomandibular joint, jaw, and muscle and tension headache pains 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 Nightguard/Occlusal Appliances while eating, drinking, chewing gum, or using tobacco products.
4. Serena Sleep devices should be cleaned daily by using a toothbrush, antibacterial soft soap and warm water.

5. Device should be kept away from children or pet

Sleep Appliance Provider Instructions

Complications

Serena Sleep Nightguard/Occlusal Appliance 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

Nightguard/Occlusal Appliance Model

1. Remove from the package and examine the Nightguard/Occlusal Appliance.
2. Instruct your patients which is the upper tray, and which is the lower tray (if both are included) and when to wear the appliances.
3. Rinse the appliance thoroughly with warm water and clean with a toothbrush and anti-bacterial soap.
4. The appliance should remain on your patients' teeth for the entire time of use.
5. Inserting the appliance: If an upper appliance is used, insert it into the mouth and press up on the appliance with both thumbs to ensure that it fits securely and comfortably. If a lower appliance is used, place it in the mouth and press down on both sides of the

appliance using index fingers to ensure it fits comfortably. Patient should gently bite down on the appliances to insure they are seated and comfortable on the teeth.

Removing the Appliances

To remove the appliances(s), use thumb or fingernail on the edge of the appliance near the back of the mouth and push away from the teeth then peel the appliance from the rest of the teeth.

Period of Use

From the time the patient receives the appliance, the appliance(s) should be worn as instructed by the healthcare provider. 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 or as directed by the fitting healthcare professional.

Cleaning and Storage

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

- Clean the device immediately after using.
- Each day clean the 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 Nightguard/Occlusal Appliance 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 used for protecting teeth and restorations against the forces of bruxism and alleviating temporomandibular joint, jaw, and muscle and

tension headache pains source. Serena Sleep does not make any guarantees regarding the outcome of the treatment.

- The Serena Sleep Nightguard/Occlusal Appliance 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, bite resets, damages not caused by fabrication defects, damage caused by improper cleaning, device modifications made by unauthorized personnel etc.