

# SILENT NITE® SLEEP APPLIANCE

R<sub>x</sub> Only

## Instructions for Use

ENGLISH

### Product Description

Silent Nite® Sleep Appliance is a mandibular advancement device (MAD) intended to treat snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older who prefer it to continuous positive airway pressure (CPAP), or who do not respond to, are not appropriate candidates for, or who fail treatment attempts with CPAP or surgical treatment. Silent Nite holds the mandible in a protrusive position to increase the volume of the nasopharynx and the oropharynx and improves airflow during sleep. It is meant to be worn during sleep by a single patient. It consists of one upper tray, one lower tray, and two connectors and is provided non-sterile.

### Indications for Use

Silent Nite is indicated to reduce snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. Silent Nite is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.

### Contraindications

- Patients who have central sleep apnea
- Patients who have severe respiratory disorders
- Patients who have loose teeth or advanced periodontal disease
- Patients who are under 18 years of age
- Patients who have temporomandibular joint (TMJ) dysfunction

### Description of Label Symbols

The titles and symbol descriptions are in the symbols glossary on page 2 of this document.



### Warning

- Silent Nite usage is by prescription only. Only the prescribed patient should use Silent Nite.
- A qualified dentist should consider patient medical history, including history of asthma, breathing or respiratory disorders, or other relevant health problems before prescribing the device.
- Patients should have a minimum of 8 teeth per jaw.
- Patients should use with caution. Allergic reactions cannot be excluded.

### Use of the device may cause

- tooth movement or changes in dental occlusion
- gingival or dental soreness
- obstruction of oral breathing
- pain or soreness to the temporomandibular joint
- excessive salivation

Regular dental follow-ups are recommended to review any side effects to avoid device breakage, allergic reaction, irritation, or discomfort that leads to frustration or discontinuation of this therapy.

### Guidelines Regarding the Patient Experience

#### First Time Use, Patient Experiences Soreness

Soreness may be felt after using Silent Nite for the first time and several days after. Soreness may be felt in the jaw, teeth, and gums. After several days of using the device, patient's jaw, teeth, and gums should eventually adjust.

#### Patient Experiences Continual Soreness or Long-Term Discomfort

- Silent Nite is contraindicated when there is the possibility of disease or injury to the temporomandibular joint.
- If patient temporomandibular joints are healthy, then use the next longer connector to reduce the forward advance of the mandible. (See Instructions for Replacing Connectors section.) Reducing the mandible advance should prevent soreness.

#### Patient Still Snoring

Further forward advancement of the mandible is required. Use the next shorter connector to advance the mandible forward and increase airway opening. (See Instructions for Replacing Connectors section.)

#### Patient Experiences Malocclusion in the Morning, After Appliance Removal

- When the mandible remains in the forward position after appliance removal, the patient should gently push and hold the mandible into its natural position for a few moments. Holding the mandible in place will stretch the masticatory muscles back into position.
- Chewing sugar-free gum immediately after appliance removal should also reduce the duration of the malocclusion. Chewing or biting helps relax the muscles back into their natural position.

#### Patient's Teeth Shift During Sleep

Teeth movement is a rare side effect of wearing the Silent Nite. Store models or data of the initial impression in case teeth movement occurs. Ensure that the splint covers all teeth, and the connectors are working as intended. Adjustments by the dentist may be necessary.

#### Patient Experiences Tightness or Pressure on Teeth

Using an acrylic carbide bur, relieve any internal areas identified by the patient. If the situation is not remedied, new impressions must be made in order to remake the appliance. Follow the stone manufacturer's instructions carefully. When pouring an impression, make sure the correct powder/liquid ratio has been used and that the impressions are free of bubbles and voids when pouring.

#### Patient's Upper or Lower Piece Pops Out

If the appliance is popping off the teeth, the patient could be trying to force his/her mouth open.

The appliance should restrict opening the mouth, but if forced, the appliance will release from the undercut on teeth. If there is minimal undercut on the teeth, this appliance should not be used for that patient.

### Maintenance Care and Storage Guidelines

#### Hygiene and Maintenance Procedures

##### Before Inserting the Device

- Brush and floss the teeth, then thoroughly rinse the mouth and the device with clean water.

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- If the patient uses mouthwash at bedtime, patient must thoroughly rinse the mouth with water afterward. All traces of mouthwash must be rinsed out of the mouth.

## After Using the Device

1. Clean by using a 3.8% or less, peroxide-based appliance cleaner, according to instructions on box.
2. Thoroughly wash the inside and exterior of the upper and lower splints with cool, clear water.
3. Shake off excess water and allow to air dry.
4. After the cleaned device is completely dry, store the device in its storage case.

## Precautions

- **DO NOT** soak the device in mouthwash, denture cleanser, hot water (> 50 °C) or alcohol.
- **DO NOT** wash the device with soap, toothpaste, or mouthwash.
- **DO NOT** dry the device with a blow dryer.
- **DO NOT** store in direct sunlight.









## Storage

Silent Nite should be stored completely dry, at room temperature, out of direct sunlight, in a clean, dry storage case.

## Disclaimer of Liability

Silent Nite Sleep Appliance is warranted for two years with proper care. All warranty claims must include return of the appliance. Prismatic Dentalcraft, Inc. is not liable for damages resulting from treatment outside of its control: including modification or misuse of the appliance other than the Indications for Use, the responsibility rests with the provider.

## Symbols Glossary

Symbol	Reference No. 21 CFR Part 801, Section	Title – Symbol Description
	Sec. 801.109(b)(1)	By Prescription Only – Caution: Federal law restricts this device to sale by or on the order of a dentist or physician.
Symbol	Reference No. EN ISO 15233-1, Section	Title – Symbol Description
	Sec. 5.1.6	Catalogue Number – Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Sec 5.1.7	Serial Number – Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Sec 5.4.3	Consult Instructions for Use – Indicates the need for the user to consult the instructions for use.
	Sec 5.1.1	Manufacturer – Indicates the medical device manufacturer.
	Sec 5.1.3	Date of Manufacture – Indicates the date (YYYY-MM-DD) when the medical device was manufactured.
	Sec 5.4.4	Caution – Indicates the user needs to consult the instructions for use for important cautionary information such as warnings and precautions.
	Sec 5.3.2	Keep Away from Sunlight – Indicates a medical device that needs protection from light sources.

## Instructions for Replacing Connectors

1. Remove the original connectors on the device.
2. Carefully cut or twist off side (a) of the desired connectors.
3. Remove any sharp edges from side (a) on each connector. Connector side (a) is hinged in the area of the upper jaw canine.
4. Hinge the upper end of each connector (a) onto the anchor of its upper splint (canine).
5. Pull each connector down firmly until it engages with its anchor.
6. If the connector does not firmly engage with the anchor, remove, and engage the other end.
7. Hinge the lower end of each connector (b) onto the anchor of the lower splint.
8. Pull each connector (b) so it slides easily along its anchor.
9. Check that each connector is fully engaged by sliding it forward and backward along its anchor.
10. With both connectors properly engaged, Silent Nite is ready for use.

Silent Nite is a registered trademark  
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