SILENT NITE® SLEEP APPLIANCE WITH THE GLIDEWELL HINGE™

℞ Only

Doctor Instructions for Use

ENGLISH

⚠ **Caution: Federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.**

1. Product Description

Silent Nite® Sleep Appliance with the Glidewell Hinge™ is a patient-specific thermoformed removable intraoral device intended to support the lower jaw in a forward position and is prescribed by the dentist to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adult patients 18 years of age or older. The appliance consists of two patient-specific trays, which are fabricated to conform to the patient's upper and lower dentition and engage by means of adjustable metal bars (i.e., the Glidewell Hinge). This device functions as a mandibular repositioner. It holds the mandible in a protrusive position which increases the patient's ability to exchange air and decreases air turbulence. The device holds the mandible in a position determined by a trained dentist. The hinge is adjusted by the inner adjustment set screw that has a female hex receptor for a hex driver as described in Section 5. The device is shipped non-sterile.

The device is prescribed by a dentist, physician, or licensed practitioner. The usage is by prescription only.

2. Indications for Use

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

3. Contraindications

The device is contraindicated for patients who:

- have central sleep apnea
- are under 18 years of age
- have loose teeth or advanced periodontal disease
- have severe respiratory disorders
- have very small teeth and/or fewer than 8 teeth per arch
- have an acrylic allergy
- have a history of TMJ disorder

4. Warnings and Precautions

Silent Nite Sleep Appliance with the Glidewell Hinge is intended to be used on a single patient only. The reuse of such device on another patient is not recommended due to the risks of improper fit and cross- contamination or infection. The dentist sets the initial mandibular advancement and may train the patient to perform further adjustments, if needed, based on dentist's discretion.

Warnings

Use of the device may cause:

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

Precautions

This device contains nickel in the stainless steel alloy. Dentists should consider the medical history of the patients, including allergic reactions, history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing this device. Irritation of the mouth, tongue, cheeks, and lips may occur. Regular dental follow-ups are recommended to review any side effects, and to avoid device breakage, allergic reaction, or discomfort. Ortho-bands used are latex-free to avoid allergic reaction.

5. Inserting and Fitting of the Appliance

When inserting the device, place the upper splint on the upper teeth first, then slide the lower teeth into the lower splint. To advance the device, place the hex driver into each of the hinge's anterior advancement holes and rotate the hex driver. A half turn in the clockwise direction will advance the device 0.25 mm. A full turn in the clockwise direction will advance the device 0.50 mm and two full turns in the clockwise direction will advance the device 1.00 mm. Turning the set screw counterclockwise will decrease the extension of the lower jaw. Latex-free ortho-bands (5/16 inch) are included and can be used as needed to limit movement, support the lower jaw, and help prevent the mouth from opening. Ortho-bands can be connected from upper to lower hook when protrusion is slight, or from lower hook to upper band lug when more protrusion is used.

Table 1. Advancement

Clockwise Rotation	Advancement (mm)
Half turn	0.25 mm
Full turn	0.50 mm
Two full turns	1.00 mm

6. General Safety

First Time Use: Patient Experiences Soreness

Soreness may be felt after using the device for the first time and several days after. Soreness may be felt in the jaw, teeth, cheeks, and gums. After several days of using the device, the patient's jaw, teeth, cheeks, and gums should eventually adjust. If severe pain persists, the patient should contact the dentist immediately.

Patient Experiences Malocclusion in the Morning, After Appliance Removal

When the mandible remains in the forward position after the appliance's 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. Using the enclosed AM Aligner helps to reposition the bite into centric occlusion. Chewing sugar-free gum immediately after appliance removal should also reduce the duration of the malocclusion. Chewing or biting helps to relax the muscles back into their natural position.

7. Precautions

- Do NOT soak in water.
- Do NOT soak in ammonia.
- Do NOT soak in mouthwash.
- Do NOT soak in bleach.
- Do NOT soak in peroxide.
- Do NOT soak in denture cleaner.
- Do NOT use toothpaste when brushing the device.

8. Hygiene and Cleaning Procedures

Before Inserting the Device

- Brush and floss before use.
- Rinse mouth well with clean water before inserting the device.
- If patient uses mouthwash, all traces of mouthwash should be removed by thoroughly rinsing out mouth with water.

After Using the Device

- Brush the device carefully with a soft toothbrush and cool water.
- Do not use soap to clean appliance.
- Minimize odor by letting the device dry during the day with the container lid open.

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9. Storage

Silent Nite Sleep Appliance with the Glidewell Hinge should be stored in its case after rinsing and allowing the device to air dry at room temperature, out of direct sunlight. The lid of the case can be left partially open to facilitate complete drying.

10. Disclaimer of Liability

The appliance is warrantied for two years with proper care. All warranty claims must include return of the appliance.

Prismatik 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.

11. Symbols Glossary

Symbol	Reference No. 21 CFR Part 801, Section	Title – Symbol Description
℞ Only	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**
REF	Sec. 5.1.6	Catalogue Number – Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	Sec. 5.1.5	Lot Number – Indicates the manufacturer's component lot number so that the lot or batch can be identified.
SN	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 5.2.7	Non Sterile – Indicates the device has not been subjected to a sterilization process.
	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.

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