


Comfort Stabilizer™ Bite Splint

R_x Only

Instructions for Use

ENGLISH

IMPORTANT: PLEASE READ

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

Do not discard instructions during product use.

Description of the Product

Comfort Stabilizer™ Bite Splints are designed to alleviate the pain and damage caused by bruxism (clenching or grinding of the teeth). Severe teeth and jaw or facial muscle pain are common side effects of bruxism. These patient-specific devices fit over the upper and lower teeth during sleep and can offset the effects of bruxism while protecting teeth from daily wear and tear. The upper and lower components mechanically engage to ensure consistent positioning during use. This engagement supports a stable mandible in the patient's habitual occlusal position, resulting in an airway-friendly jaw relationship during wear.

Comfort Stabilizer Bite Splints are shipped non-sterile. The bite splints are available in either a hard material or hard material with a soft inner surface (Comfort H/S™).

Indications for Use

Comfort Stabilizer Bite Splints are indicated for protection against bruxism and nighttime teeth grinding. They create a barrier between the upper and lower dentition to protect the patient's overall occlusion.

Contraindications

Not to be used for the treatment of sleep apnea or other sleep-related breathing disorders. The device is not intended to diagnose any medical condition. If patients have or suspect they have sleep apnea or another sleep-related breathing disorder, they should consult a physician or qualified healthcare provider. This product is not shock absorbent and must not be used as an athletic sports guard.

Cleaning Precautions

- Use only clear, cool water to wash the device. A soft toothbrush may be used.
- Do NOT clean or soak in mouthwash.
- Do NOT use denture cleanser or toothpaste.
- Do NOT use hot water (for cleaning).
- Do NOT use alcohol or hydrogen peroxide.
- Do NOT place in direct sunlight. Keep away from heat sources.

Cleaning Instructions

- Brush and floss your teeth before use.
- Rinse the mouth well with clean water before inserting the device.
- If patient uses mouthwash, rinse the mouth thoroughly with water to remove all residue.
- Rinse the bite splint well with clean, cool water before and after use.
- Clean the bite splint with clean, cool water ONLY and let air dry.

General Safety Precautions

If the bite splint becomes loose, tight, causes you any discomfort, or any part is broken or delaminated, contact your dentist immediately.

Comfort Stabilizer Bite Splints are intended for single-patient use only. Reuse of the device on another patient is not recommended due to the risks of improper fit and cross-contamination/infection. Comfort Stabilizer Bite Splints may only be used for their intended purpose in accordance with general rules for dental treatment. If the indications for use are not clearly specified, use should be suspended until those considerations have been clarified. Irritation of the mouth, tongue and lips may occur. Regular dental follow-ups are recommended to review any side effects to avoid device breakage, allergic reaction, irritation, or discomfort.

Comfort Stabilizer Bite Splints shall only be prescribed by dentists or practitioners licensed by law.

Precautions During Use

- Do not bite hard onto the device.
- When inserting, start in the anterior; then, seat on both sides evenly. Do not bite into place.
- If gagging, coughing or yawning, remove the device from position.
- Comfort Stabilizer MUST be worn in conjunction with both upper and lower trays.
- It is normal to experience soreness within the first week of use.

Storage

The bite splint should be stored in its case after rinsing. Allow the bite splint to air dry at room temperature, out of direct sunlight. The case lid may be kept partially open to facilitate complete drying and to reduce moisture buildup and help avoid the formation of mold or mildew.









Disclaimer of Liability

Bite splints are warranted for six months with proper care. All warranty claims must include return of the bite splint.


Glidewell is not liable for damages resulting from treatment outside of its control, including modification or misuse of the bite splint other than the Indications for Use. The responsibility rests with the provider.

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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 15223-1, 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.

Comfort Stabilizer is a trademark of Glidewell.

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