

Comfort H/S™ Bite Splint

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 Bite Splints are designed to alleviate the pain and damage caused by bruxism (clenching or grinding of the teeth). Severed teeth and jaw or facial muscle pains are common side effects of bruxism. These patient-specific devices fit over upper or lower teeth during sleep and can offset the effects of bruxism while protecting teeth from daily wear and tear. The bite splints are shipped non-sterile.

Comfort Bite Splints are available in four versions: hard, hard with a soft inner surface (Comfort H/S™), semi-soft (ENGRD), soft (NGRD).

Indications for Use

Comfort 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 as an athletic sport guard. Product is not shock absorbent.

Warning

- Use only clear, cool water to wash the device.
- Do NOT clean or soak in mouthwash.
- Do NOT use denture cleanser.
- Do NOT use hot water.
- Do NOT use alcohol or hydrogen peroxide.
- Do NOT place in direct sunlight. Keep away from heat sources.

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

Comfort Bite Splints are 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/infection. Comfort Bite Splints may only be used for their intended use in accordance with general rules for dental treatment. If the indications for use are not clearly specified, treatment 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 Bite Splints shall only be prescribed by dentists or a practitioner licensed by law.

General Safety and Precautions

Cleaning Procedures:

- Brush and floss your teeth 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.
- Rinse bite splint well with clean, cool water before and after use.
- Clean bite splint with clean, cool water ONLY and let air dry.

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 lid of the case can be left partially open to facilitate complete drying.

Disclaimer of Liability

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

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