

Comfort3D™ 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

Comfort3D™ Bite Splint is a digitally-designed, 3D-printed nightguard intended to alleviate the pain and damage caused by bruxism and nighttime teeth grinding. Severe tooth, jaw or facial muscle pain is a common side effect of bruxism. This patient-specific device is a full-coverage nightguard that fits over all of the upper or lower teeth. The Comfort3D Bite Splint tray consists of a single-layer, firm material that provides durability and bonds with acrylic. A lower or upper bite splint can be worn alone or in combination with another bite splint to offset the effects of bruxism while protecting existing healthy teeth and dental restorations from daily wear and tear.

Indications for Use

Comfort3D Bite Splint is indicated for protection against bruxism and nighttime teeth grinding.

Contraindications

Not to be used as an athletic sports guard. Product is not shock absorbent.

Warning

- 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.
- Do NOT use hot water.
- Do NOT use alcohol or hydrogen peroxide.
- Do NOT place in direct sunlight. Keep away from heat sources.

If Comfort3D Bite Splint becomes loose, tight, fractured or broken, or causes any intraoral discomfort, please contact your dentist immediately. If any changes occur to your dentition, please contact your dentist.

Comfort3D Bite Splint is intended to be used on a single patient only. The reuse of the nightguard on another patient is not recommended due to the risk of improper fit and cross-contamination/infection. Comfort3D Bite Splint may only be used for its intended use, in accordance with general rules for a dental treatment.

General Safety and Precautions

Cleaning Procedures:

- Brush and floss your teeth before use.
- Rinse mouth well with clean water before inserting the nightguard.
- Rinse appliance well with clean, cool water before and after use.
- Clean Comfort3D Bite Splint with clean, cool water ONLY, and let it air dry.

Storage:

Comfort3D Bite Splint should be stored in its case after rinsing and allowing the nightguard to air dry.










Disclaimer of Liability


Comfort3D Bite Splint is warranted for six months with proper care. All warranty claims must include a return of the warranted appliance.

The laboratory is not liable for damages resulting from treatment outside of its control: including modification or misuse of the appliance other than the Indication 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 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 5.1.4	Use by Date - Indicates the date (YYYY-MM-DD) after which the medical device is not to be used.
	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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