

Nightguard (Thermoformed) Instructions for Use (IFU)

Overview: This guide provides instructions for use, adjustment, and cleaning for Hard, Soft, and Dual-Laminated Thermoformed Nightguards to protect against bruxism..

Indications and Contraindications

Indications for Use

Hard, Soft, and Dual-Laminated Thermoformed Nightguards are dental devices designed to protect teeth from nighttime grinding and clenching (bruxism).

Contraindications

Patients with loose or damaged teeth, or with temporomandibular joint disorder (TMD), should not use this device without first consulting a dental professional.

Risks and Benefits

Nightguard Benefits

- Protects against tooth damage caused by bruxism.
- Provides relief from discomfort associated with grinding.

Potential Risks

- Mouth or tooth soreness may occur during initial use.
 - Soreness typically resolves after a few days of consistent use.
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Instructions for Use

Applying the Nightguard

1. Wash your hands thoroughly before handling the nightguard.
2. Place the nightguard over the upper or lower teeth as instructed by your dentist.
3. Bite down gently to ensure the nightguard fits comfortably and securely.

Removing and Storing the Nightguard

1. Remove the nightguard in the morning.
 2. Rinse the nightguard immediately with warm water.
 3. Store the nightguard in a dry, clean container when not in use.
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Adjustment Recommendations

Technical Adjustment Steps

Dental professionals should follow these steps to prevent micro-fractures during adjustment:

- Operate the bur at high speed with minimal pressure.
 - Use constant water and air spray to maintain a safe temperature.
 - Use a fine-grit diamond for adjustments.
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- **Note:** Do not use air-only handpiece adjustments.

Bur Selection by Surface

- **Occlusal and Lingual Surfaces (Anterior):** Use a football-shaped bur.
 - **Buccal and Lingual Surfaces:** Use a tapered bur.
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Cleaning and Disinfection

Daily Cleaning Process

Clean the nightguard daily before and after every use:

1. Use warm water (no hotter than **45°C/113°F**) and a soft, antibacterial liquid dish soap.
2. Remove all saliva and debris from the device.
3. Rinse thoroughly with cool water.

Cleaning Restrictions

- **Do not** use hot water, as it can warp the nightguard.
- **Do not** use mouthwash, as it can discolor the material.
- **Do not** use flavored, scented, or heavily dyed soaps.

Periodic Maintenance and Disinfection

- Use a soft-bristle brush to clean the inside of the appliance.
 - You may use antibacterial solutions like Polident or Efferdent for 10–15 minutes.
 - **Avoid Submerging In:** Sodium hypochlorite (bleach), hydrogen peroxide, or alcohol-based products.
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Additional Information

- Patients should consult with their practice if they experience tooth pain or sensitivity, as this may be a sign of a more severe underlying issue.
- Patients may experience mouth or tooth soreness when first using the device, which should resolve after a few days.
- Hard, Soft, and Dual-Laminated nightguards have a limited warranty, which may vary depending on the manufacturer.

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Approve	Garvin Tran	Manager, Operations - QMS	09-Sep-2026 15:45

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