

INSTRUCTIONS FOR USE (IFU) - UK CUSTOM-MADE DEVICE (CMD - Custom Made Device)

Device Family: MouthGuard

GMDN: 38620

Product Code(s): NIGHTGRDS, THERMONGH, THERMONGS, THERMONGHS, THERMONGA, THERMONGNTI, THERMOSG, THERMOHFA, THERMOHOS, THERMONGS, THERMOHSOS, THERMOHSFA, THERMONGA, THERMONGNTI, THERMOSFA

Manufacturer:

Zima International, Inc. Also DBA Dandy

1320 N. 300 W.

Lehi, UT 84043

United States

Contact:

UK Responsible Person (UKRP):

Name = DANDY LABS GB, LTD

Company Number = 16873608

Registered Address = 5 New Street Square, London EC4A 3TW.

Intended User: Prescriber Dental professional / dental practice

Device Type: Custom-made dental device (CMD)

Sterility: Not supplied sterile (if applicable)

Single-use / Reusable: Reusable

1) Intended Purpose (Intended Use)

The device is made of biocompatible materials and is custom-made for each patient. The nightguard fits comfortably over the upper or lower teeth and provides protection against damage caused by bruxism.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.

- Configuration: Hard, Soft, and Dual-Laminated Night Guards (Thermoformed) are dental devices that protect teeth from nighttime grinding and clenching.

- Material: Hard, Soft, Hard/Soft, Astron, and 3D Printed

[Erkoflex Thermoforming Discs - Soft](#)

[Erkoflex Thermoforming Discs - Hard](#)

[Erkoflex Thermoforming Discs - Hard/Soft](#)

[Clearsplint - Powder](#)

[Clearsplint - Liquid](#)

[Keysplint](#)

3) Contraindications

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

4) Warnings / Precautions / Potential Risks

The potential risks include mouth or tooth soreness, which should resolve after a few days of use.

5) Cleaning and Care (Patient Care Instructions — as directed by the dental professional)

Directions for Use

- Wash your hands before handling the nightguard.
- Place the nightguard over the upper or lower teeth as the dentist instructs.
- Bite down gently to ensure a comfortable fit.
- Remove the nightguard in the morning and rinse with warm water.

Cleaning instructions

- Dandy recommends cleaning your device daily before and after every use. Immediately after removal,
- Use warm water (not to exceed 45°C/113°F) and dishwashing soap to remove remaining saliva and debris from the device.

Only use soft, antibacterial dish soap (liquid)

- Do not use flavored or scented soaps
- Do not use soaps with heavy dyes and colors
- Rinse the device thoroughly with cool water.
- Do not use hot water, as it can warp the device.
- Do not use mouthwash, as it can discolor the device.

Clean the device daily.

USING CLEANING AGENTS

- For periodic debris removal and maintenance, use a soft bristle brush to clean the inside of your appliance for debris removal.
- The product should be cleaned with antibacterial cleaning solutions like Polident and Efferdent.
- These cleaners are designed for use in brief sessions of 10–15 minutes.
- Always make sure to follow the manufacturer's instructions for proper use.

Do not use:

- Avoid immersing the product in, or cleaning it with, any of the following substances: sodium hypochlorite (chlorine bleach), hydrogen peroxide, mouthwash, or alcohol products. Using these can lead to discoloration and damage to the material.

6) Storage

The device should be stored in a dry, clean container when not in use.

7) Expected Life / Service

.A mouthguard's life expectancy varies by type: 1-5 years for durable custom-fit guards, depending heavily on usage, material, and care, with heavy grinding or poor cleaning shortening their lifespan significantly and making them less protective. Regular checks for cracks, fit, odor, or damage are key indicators for replacement, ensuring consistent protection against sports impacts or teeth grinding (bruxism).

8) Incident / Complaint Reporting (UK)

Report suspected serious incidents associated with this device to:

- The Manufacturer and/or UK Responsible Person (UKRP) using the contacts above, and
- The UK Medicines and Healthcare products Regulatory Agency (MHRA) in accordance with local requirements.

9) Disposal

Specialized services handle biohazardous waste, but for home users, standard household disposal is key. This involves keeping it out of landfills whenever possible, and definitely out of sewers and recycling facilities.