

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

Device Family: Denture Reliner - Hard

GMDN: 17609

Product Code(s): ACRFDENTRLN, DENTFLRLN, MILLDENTRLN

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)

This custom-made denture reliner is intended to improve denture fit/retention when a denture no longer fits as intended and requires relining, as prescribed by a licensed dental professional.

2) Device Description / Key Specifications

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

- Configuration: Hard denture reline (full arch) (as applicable)

- Material: Sofreliner (Silicone Dioxide)

[Liner Material Safety Data Sheets \(Paste\)](#)

[Liner Material Safety Data Sheets \(Primer\)](#)

3) Contraindications

Do not use in patients with:

- Known hypersensitivity to the device material

- Untreated oral lesions

4) Warnings / Precautions / Potential Risks

Potential risks associated with denture lining materials may include:

- Gingival irritation, mucosal soreness, ulceration
- Poor adaptation may cause instability or trauma
- Allergic response
- Separation of material

If the patient experiences pain, irritation, or other adverse effects, discontinue use and contact the treating dental professional.

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

Daily cleaning:

- Brush gently using a soft-bristled denture brush or soft toothbrush.
- Avoid abrasive products (e.g., toothpaste, abrasive cleaners, strong soaps).
- Use mild, non-abrasive liquid dish soap as directed by the dental professional.
- Rinse thoroughly under cool or lukewarm running water.
- Avoid high heat; do not use hot or boiling water.

Soaking:

- Store/soak as directed by the dental professional to prevent drying.
- Avoid prolonged soaking in effervescent cleaners if this may damage the material.

Do not use:

- Avoid cleaning/immersing the device in sodium hypochlorite (chlorine bleach), hydrogen peroxide, mouthwash, or alcohol products, as these may damage or discolour the material.

6) Storage

When not in use, store the device as directed by the dental professional. Avoid excessive heat, pressure, or conditions that may deform or damage the device.

7) Expected Life / Service

With appropriate care and maintenance, the device is intended for ongoing use as directed by the dental professional. If the device becomes damaged or fit is no longer acceptable, the patient should contact their treating dental professional for evaluation.

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

Dispose of the device in accordance with local regulations and the dental practice's procedures. If the device is contaminated with bodily fluids, treat it as clinical/infectious waste per local requirements.

