

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

Device Family: Complete Lower Denture

GMDN:

Lower - 38589

Product Code(s) :ACRFDENT, DENTCOPY, DENTFLRLN, DENTMDTRY, DENTSMOTRY, DENTSPRPR, FDAOMF, FDAOMM, FDAOOCG, MILLDCR, MILLDENT

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)

Dandy's full dentures are designed/fabricated using digital technology, allowing for a precise fit and customization to the patient's specific needs. They are made of highly durable and biocompatible materials, ensuring long-term comfort and function.

2) Device Description / Key Specifications

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

- Configuration: Dandy's Dentures are removable prostheses intended for the replacement of missing natural teeth and associated oral structures. They are indicated for fully edentulous and partially edentulous patients requiring prosthetic restoration.

- Material:

- **HIPHA:** High-impact resistance, lifelike esthetics
- **199 Resin:** Lightweight, digitally accurate
- **PMMA:** Seamless monolithic finish

[Full Denture MSDS](#)

3) Contraindications

Do not use in patients with:

- Uncontrolled periodontal disease
- Severe residual ridge resorption
- Untreated oral lesions
- Known hypersensitivity to acrylic or PMMA-based materials

Avoid in patients allergic to methacrylate monomers.

4) Warnings / Precautions / Potential Risks

- Gingival irritation, mucosal soreness, ulceration
- Poor adaptation may cause instability or trauma
- Allergic response to base or teeth materials

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

To ensure proper use of final dentures, dental professionals and patients should follow these steps:

Insertion Protocol:

- Clean oral tissues with a soft-bristle brush or rinse
- Hold the denture by the edges; insert using a gentle rocking motion
- If it is a partial denture, gently place it in the mouth and use your fingers to guide it into position.
- Avoid using excessive force or pushing the partial denture too far.
- Instruct the patient to bite and swallow to seat
- If it is a partial denture, instruct the patient to gently bite down on the partial denture to ensure proper fit and stability.
- Use adhesive if retention is insufficient
- Use carbon articulation paper to adjust any heavy occlusion points.

Cleaning and Care **

DAILY CLEANING

- Dandy recommends cleaning your dentures 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

USING CLEANING AGENTS

- For periodic debris removal and maintenance, use a soft-bristle brush to clean the inside of your appliance. The denture should be cleaned with antibacterial denture 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 denture 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

When not in use, store final dentures in a clean, dry place. Avoid exposing the dentures to excessive heat or pressure, which may cause warping or other damage.

7) Expected Life / Service

Final dentures are designed to last for several years with proper care and maintenance. Patients should contact their treating dentist/practice for evaluation and repair if dentures become damaged or lose their fit.

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

- Denture disposal typically involves handling it as a regulated biohazardous waste or general waste, often through specialized handlers for incineration or secure landfill disposal.
- Always avoid putting them in regular trash without checking local rules.
- Biohazard/Infectious Waste: Treat used or unclaimed dentures as biohazardous due to saliva/blood; use red bags and authorized carriers.
- Incineration: A common method for final destruction.
- Metal Recovery: If the denture has precious metals (gold/silver), return it to a dental lab or scrap refiner for recycling, as it can be profitable and prevents pollution.
- Confidentiality: Redact or destroy patient info on lab boxes and bases before disposal.