

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

Device Family: Bridge - Polymer
GMDN: 37542
Product Code(s): PMMASBRA, PMMASBRP

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: Single-use

1) Intended Purpose (Intended Use)

Dandy's temporary bridges are made to provisionally restore worn, carious, broken, and aesthetically displeasing dentition.

They:

- Replace one or more missing permanent teeth (bridges) by spanning the edentulous space and being supported by natural teeth or dental implants
- Restore the form, function, and esthetics of natural dentition.
- Provide occlusal stability and maintain proper interarch relationships.
- Provide a preview of the final restoration.

2) Device Description / Key Specifications

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

- Configuration: Dandy's temporary bridges (PMMA) are fabricated using digital technology, allowing for a precise fit and customization to the patient's specific needs. They are made of a highly durable and biocompatible material, ensuring long-term comfort and function. PMMA, which stands for polymethyl methacrylate, is not intended for short-term use.

- Material: Argen PMMA

[Temporary Crown and Bridge Material Safety Data Sheet](#)

3) Contraindications

Temporary crowns should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, active caries, or oral lesions.

4) Warnings / Precautions / Potential Risks

The use of temporary bridges may have potential risks, including failure, misfit, breakage, and recurrent caries.

*Warning – Irritation:

- Localized irritation of surrounding oral tissues may occur in specific individuals due to individual variability in tissue response. Patients should be monitored after placement, and the treating clinician should assess any signs of irritation, inflammation, or discomfort.

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

Daily Cleaning

- Oral Hygiene:
 - Brushing:
 - Recommended brushing teeth twice a day, using a soft-bristled toothbrush and a fluoride toothpaste.
- Flossing:
 - Recommend daily flossing to remove plaque and debris from between the teeth and around the fixed restoration. A floss threader may be needed for hard-to-reach areas (for bridges). Care must be taken to prevent the dislodging of the restoration.
- Mouthwash:
 - Alcohol-based mouthwashes tend to dry out the mouth, leading to increased plaque and tartar buildup.

Dietary and Habit Recommendations

- Avoid abrasive foods: Limit hard, crunchy, or sticky foods that can damage the restoration or cause it to loosen.
- Avoid sugary foods, as they can form new cavities or cause premature decay of the restorative margins.
- Stay hydrated: Drinking plenty of water helps keep your patient's mouth clean and prevents gum disease.
- Avoid bad habits: Refrain from using teeth to open packages or biting on hard objects.

6) Storage

Requires a cool, dry place, protected from direct sunlight, extreme heat (above 77°F/25°C), moisture, dust, and contamination, as these conditions can degrade the material or compromise its integrity, affecting temporary use and ultimately impacting shelf life and performance.

7) Expected Life / Service

PMMA (polymethyl methacrylate) dental bridges generally last 3 to 5 years, but often require more frequent attention than other materials, depending heavily on oral hygiene, habits (avoiding hard/sticky foods), bridge design, and location (front vs. back teeth).

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

Disposal of PMMA (Polymethyl Methacrylate) dental restorations involves recycling, often through specialized dental waste handlers who can chemically break it down into its monomer (MMA) or manage it as plastic. However, it should not be placed in the general trash due to environmental concerns.

- Fully cured PMMA might also be treated like general plastic waste if not mixed with metals or hazardous components.
- No Regular Trash: Do not dispose of PMMA dental waste in the regular garbage or medical waste streams.
- Hazardous Components: If mixed with solvents or other hazardous materials, it requires specific hazardous waste handling.