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

Device Family: Crown - Polymer
GMDN: 17609
Product Code(s): PMMASCRA, PMMASCRP, PRINTTEMP

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 crowns are made to provisionally restore worn, carious, broken, and aesthetically unpleasing dentition.
- They:
    - Restore single, permanent teeth (crowns) that are fractured, carious, discolored, or severely worn.
    - Replace one or more missing permanent teeth by spanning the edentulous space and supporting them with 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 crowns (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 stands for polymethyl methacrylate and is not intended to be used long-term.

- 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 fixed restorations may have potential risks, including failure, misfit, breakage, and recurrent caries.
- ***Warning** – Irritation:
    - Localized irritation of surrounding oral tissues may occur in certain individuals due to individual variability in tissue response. Patients should be monitored post-placement, and any signs of irritation, inflammation, or discomfort should be evaluated by the treating clinician.
    - 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
- 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 crowns 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.

Crown (PMMA) IFU

Jon M, DDS
Updated 2 days ago

Dandy’s temporary crowns (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 stands for polymethyl methacrylate and is not intended to be used long-term.

Indications for Use

Dandy’s temporary crowns are made to provisionally restore worn, carious, broken, and aesthetically unpleasing dentition.

They:

- Restore single, permanent teeth (crowns) that are fractured, carious, discolored, or severely worn.
- Replace one or more missing permanent teeth by spanning the edentulous space and supporting them with 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.

Contraindication

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

Potential Risks and Benefits of PMMA Crowns

Advise patients of the following

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

- ***Warning** – Irritation:
- *Localized irritation of surrounding oral tissues may occur in certain individuals due to individual variability in tissue response. Patients should be monitored post-placement, and any signs of irritation, inflammation, or discomfort should be evaluated by the treating clinician.*

However, the benefits include improved speech, comfort, appearance, chewing, and digestion.

Restoration and Cementation

- Test fit all restorations to ensure adequate fit and aesthetics
- Inspect the margins to ensure proper adaptation
- Adjust high spots (using articulating paper to mark areas)
- Reline with acrylic, if necessary
- Cementation of restoration
    - Clean thoroughly
    - Cement using a provisional cement
    - Excess cement should be cleaned once it has set.
- Cement recommendations

Adjustment recommendations

- Operate the bur at high speed, applying minimal pressure while using water.

    - It's important to maintain the temperature using water and air spray. This method helps prevent the formation of micro-fractures. A fine-grit diamond is advisable for adjustments, and air-only handpiece adjustments are not recommended.
    - For shaping different surfaces, specific tools are best:
        - A football-shaped bur is effective for the occlusal and lingual surfaces, especially on anterior teeth
        - A tapered bur is better suited for the buccal and lingual surfaces.

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 and lead 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: where new cavities can form or cause premature decay of the restorative margins.
- Stay hydrated: Drinking plenty of water will help keep your patient's mouth clean and prevent gum disease.
- Avoid bad habits: Refrain from using teeth to open packages or bite on hard objects.

Additional Information

- If the patient experiences any adverse events, such as pain or irritation, they should contact your practice immediately.
- Fixed restorations have a limited warranty, which may vary depending on the manufacturer.
- Smoking with restorations can cause discoloration

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.
- **Chemical Recycling:** PMMA can be chemically recycled (depolymerized) back to MMA, making it sustainable.
- **Key Considerations:**
    - **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.

ADA Codes

- Multiple codes are available
- Please consult with a CDT for recent information.

Material Safety Data Sheets (MSDS)

Attached are the Material Safety Data Sheets for our Fixed Materials.

- Temporary Crown and Bridge Material Safety Data Sheet

Laboratory Supplied IFUs:

- Here