

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

Device Family: Crown - Ceramic

GMDN: 38594

Product Code(s): EMXLPSCRA, EMXLPSCR, EMXSCRA, EMXSCR, IMPANTEM, IMPANTHTZ, IMPANTLEMM, IMPANTLVD, IMPANTZIR, IMPOSEMM, IMPOSHTZ, IMPOSLAY, IMPOSLEMM, IMPOSZIR, PFZSCRA, PFZSCR, SHDGLXBASE, SHDGLXDARK, SHDGLXLGHT, ZIRDSSCR, ZIRHTSCRA, ZIRHTSCR, ZIRMOSCRA, ZIRMOSCR

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 ceramic crowns are made to restore worn, carious, broken, and aesthetically displeasing 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.

2) Device Description / Key Specifications

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

- Configuration: Dandy's ceramic crowns 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.

- Material: Zirconia Monolithic (3Y & 4Y), Porcelain-Fused-To-Zirconia (PFZ), E.Max (full contour), E.Max (layered)

[Zirconia Material Safety Data Sheet](#)

[PFZ Material Safety Data Sheet](#)

[Full Contour E.MAX Material Safety Data Sheet](#)

3) Contraindications

Crowns should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, 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** – Sensitivity:
 - This device contains trace levels of cobalt and chromium oxides used as colorants in the ceramic material. The treating clinician should inform patients with sensitivity or allergy to cobalt or chromium of the presence of these compounds in the device before treatment. In rare cases, allergic reactions can occur in individuals who are sensitized.
- ***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 the treating clinician should evaluate 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).
 - 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: 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.

6) Storage

Use dedicated dental crown/veneer boxes with soft foam or silicone inserts to prevent chipping, scratching, or movement, ensuring they are kept clean, dry, and protected during transport or while awaiting placement in a clinic or lab setting..

7) Expected Life / Service

Ceramic dental restorations (crowns, fillings, veneers) generally last 10 to 20 years, with modern materials like zirconia potentially exceeding this, but lifespans vary significantly based on care, location (back teeth wear faster), and type (implants are more permanent than crowns on top). Excellent oral hygiene (brushing, flossing) and avoiding hard foods or teeth grinding (bruxism) are key to maximizing longevity, though some chipping or wear is possible.

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

- All-ceramic (porcelain) restorations are often disposed of as regular solid waste or taken to specific recycling centers that accept mixed ceramics/construction debris, as they're challenging to recycle like typical items.
 - Household Trash: Place in your regular garbage bin, as they don't break down in standard recycling
- Always check with your local municipality or waste hauler for specific rules; however, ceramic items are generally not accepted in standard curbside recycling bins.
- Recycling Centers: Take them to a local recycling center that accepts mixed ceramics, concrete, or construction debris, as they can sometimes be repurposed.
- If the restoration has been in the patient's mouth or has come into contact with saliva, discard it as biomedical waste.