

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

Device Family: Inlay - Metal

GMDN: 38648

Product Code(s): GLDHNSINA, GLDHNSINP, GLDNPSINP, GLDNWSINP, GLDNYSINP

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 Inlay/Onlay restorations are designed to restore worn, decayed, or broken dentition.
- They:
 - Restore single, permanent teeth that are fractured, carious, or severely worn.
 - Restore the form and function of natural dentition.
 - Provide occlusal stability and maintain proper interarch relationships.
 - More conservative preparation, compared to Crowns and Bridges.

2) Device Description / Key Specifications

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

- Configuration: Dandy's restorations are fabricated using digital technology, enabling a precise fit and customization tailored to the patient's specific needs. They are made of a highly durable and biocompatible material, ensuring long-term comfort and function.

- Material: High-Noble: Rich Yellow (ArgenMill Au58), Noble White (ArgencoW), Non-Precious (ArgenMillCoCr)

[Full Metal Material Safety Data Sheets](#)

3) Contraindications

Inlays/Onlays 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 a level of metal (including nickel). Patients with sensitivity or allergy to metals should be informed by the treating clinician of the presence of these compounds in the device prior to treatment. In rare cases, allergic reactions may occur in sensitized individuals.

***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.
 - 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 biting on hard objects

6) Storage

Stored in specialized boxes with foam or membranes for protection, often made of ABS plastic. For patients who lose a crown, store it in a sealed bag or a small container with a small amount of water to keep it safe and moist until the dentist's visit.

7) Expected Life / Service

They offer exceptional longevity, typically lasting 20 years or more, often extending to 30 years or even a lifetime with excellent care, thanks to their unmatched durability, resistance to chipping, and precise 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

- Dandy asks that restorations that contain precious metals created by Dandy that need refabrication, be returned to us.
- Disposing of metal dental restorations involves either recycling them as precious metals (especially if gold alloy) through specialized refineries or scrap dealers for value, or general recycling if non-precious (like steel), but never in regular trash.
 - Precious Metal Refining: Many dental restorations contain valuable metals, making them a valuable asset for recycling.
 - Specialized Refiners: Some companies offer mail-in programs where you send in your scrap in prepaid, insured envelopes for assay and payment.
- How it Works: You send your restorations, they refine the metals, and pay you based on current market prices, often with insured shipping.
- For Non-Precious Metal Restorations
 - Dandy restorations that need refabrication, do not have to be returned to us.
 - Scrap Metal Dealers: various scrap metals, offering pickup or drop-off, though you'd need to confirm if they take small dental items.
 - General Recycling: Check with your local sanitation department for guidelines on disposing of bulk or metal items if it's not a dental office scenario.