INSTRUCTIONS FOR USE (IFU)

Dandy / Zima International, Inc. | AUS · NZ · UK

MANUFACTURER

Manufacturer	Zima International, Inc. Also DBA Dandy
Address	22 Cortlandt St, 30th Floor, New York, NY, 10007, US
Contact / Website	www.meetdandy.com
Complaints	complaints@meetdandy.com

DEVICE IDENTITY

Device Identity

Device Family	Inlay – Resin
GMDN / EMDN Code	GMDN: 38649 (Resin Dental Inlay) EMDN: Q010206 (Dental prostheses)
Product Code(s)	PMMAINL
Device Type	Custom-made dental device (CMD) / Patient Matched Medical Device (PMMD)
Sterility	Supplied non-sterile
Single-use / Reuse	Single use
Intended User	Prescribing dental professional / dental practice

TABLE OF CONTENT

AUSTRALIA (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

Australia — Patient Matched Medical Device (PMMD)

GMDN / EMDN	GMDN: 38649 – Resin Dental Inlay EMDN: Q010206 – Dental prostheses
Product Code(s)	PMMAINL

Manufacturer	Zima International, Inc. Also DBA Dandy 22 Cortlandt St, 30th Floor, New York, NY, 10007 US
Australian Sponsor	**Name:** DANDY Labs AUS Pty Ltd **ABN:** 33 693 955 761 **Address:** Tower One – International Towers, Level 46, 100 Barangaroo Avenue, Sydney, New South Wales 2000, Australia

Intended User	Prescribing dental professional / dental practice
Device Type	Patient Matched Medical Device (PMMD)
Sterility	Supplied non-sterile (where applicable)
Single-use / Reusable	Single use

1) Intended Purpose (Intended Use)

Dandy inlay/onlay restorations are made to restore worn, decayed, fractured, and aesthetically unappealing dentition.

They:

- Restore individual permanent teeth that are fractured, decayed, discoloured, or severely worn.
- Restore the shape, function, and aesthetics of the natural dentition.
- Provide occlusal stability and help maintain a healthy interarch relationship.
- Require a more conservative preparation compared with crowns and bridges.

2) Device Description / Key Specifications

- Custom-made, patient-specific device, manufactured according to the dentist's prescription and digital input data.
- Configuration: Dandy restorations are manufactured using digital technology (CAD/CAM), achieving a precise fit and adaptation to the patient's specific needs. They are milled from a highly filled, biocompatible composite resin block for good aesthetics and a tooth-friendly modulus of elasticity.
- Material: Polymethyl methacrylate (PMMA) block

Material Safety Data Sheet: https://help.meetdandy.com/hc/en-us/articles/27911516419341-Temporary-Crown-and-Bridge-Safety-Data-Sheet

3) Contraindications

- Do not use in patients with a known hypersensitivity or allergy to PMMA.
- The device is intended for temporary use only and should not remain in the patient for more than 30 days.

4) Warnings / Precautions / Potential Risks

The use of inlays/onlays may carry potential risks, including failure, poor fit, fracture, wear, marginal discolouration/staining, and recurrent caries (the most commonly reported reason for failure of resin restorations).

⚠ WARNING

Sensitivity:

This device is manufactured from a composite resin based on (meth)acrylate monomers. Patients with a known sensitivity or allergy to acrylates, methacrylates, or related substances should be informed of this by the treating clinician prior to treatment. In rare cases, allergic or irritant reactions may occur in sensitized individuals. The material used is fully cured (polymerized) by the manufacturer; however, trace residual monomer may occasionally be present.

Irritation:

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

Wear and discolouration:

Compared with ceramic restorations, composite resin is more susceptible to surface wear and discolouration/staining from food, tobacco, and certain beverages (e.g. coffee, tea, red wine), particularly with inadequate oral hygiene. Periodic polishing by the dental professional may be required to maintain aesthetics.

⚠ CAUTION

Patient conditions:

Inlays/onlays should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, or oral lesions.

5) Cleaning and Care (Patient care instructions – as directed by the dental professional)

Daily cleaning

Oral hygiene:

Toothbrushing:

- Advise brushing teeth twice daily with a soft toothbrush and a fluoride toothpaste.

Flossing:

- Advise daily flossing to remove plaque and debris between teeth and around the fixed restoration. A floss threader may be needed for hard-to-reach areas.

Mouth rinse:

- Alcohol-based mouth rinses often dry out the mouth, leading to increased plaque and tartar build-up.

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 Service Life / Maintenance

This device is intended for use for less than 30 days.

8) Reporting Incidents / Complaints

Report suspected serious incidents associated with this device to:

- The Manufacturer and/or Dandy Australia entity using the contacts above, and
- Therapeutic Goods Administration (TGA)

In Australia, serious incidents involving medical devices must be reported to the TGA in accordance with the Therapeutic Goods Act 1989.

> **INFO**
> For full contact details of the local Authorized Representative, refer to: Authorized Representatives — end of this document.

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.

NEW ZEALAND (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

New Zealand — Patient Matched Medical Device (PMMD)

GMDN / EMDN	GMDN: 38649 – Resin Dental Inlay EMDN: Q010206 – Dental prostheses
Product Code(s)	PMMAINL

Manufacturer	Zima International, Inc. Also DBA Dandy 22 Cortlandt St, 30th Floor, New York, NY, 10007 US
New Zealand Sponsor	**Name:** DANDY Labs NZ Limited **NZBN:** 9429053758446 **Address:** Quigg Partners, Level 7, 36 Brandon Street, Wellington, NZ 6011

Intended User	Prescribing dental professional / dental practice
Device Type	Patient Matched Medical Device (PMMD)
Sterility	Supplied non-sterile (where applicable)
Single-use / Reusable	Single use

1) Intended Purpose (Intended Use)

Dandy inlay/onlay restorations are made to restore worn, decayed, fractured, and aesthetically unappealing dentition.

They:

- Restore individual permanent teeth that are fractured, decayed, discoloured, or severely worn.
- Restore the shape, function, and aesthetics of the natural dentition.
- Provide occlusal stability and help maintain a healthy interarch relationship.
- Require a more conservative preparation compared with crowns and bridges.

2) Device Description / Key Specifications

- Custom-made, patient-specific device, manufactured according to the dentist's prescription and digital input data.
- Configuration: Dandy restorations are manufactured using digital technology (CAD/CAM), achieving a precise fit and adaptation to the patient's specific needs. They are milled from a highly filled, biocompatible composite resin block for good aesthetics and a tooth-friendly modulus of elasticity.
- Material: Polymethyl methacrylate (PMMA) block

Material Safety Data Sheet: https://help.meetdandy.com/hc/en-us/articles/27911516419341-Temporary-Crown-and-Bridge-Safety-Data-Sheet

3) Contraindications

- Do not use in patients with a known hypersensitivity or allergy to PMMA.
- The device is intended for temporary use only and should not remain in the patient for more than 30 days.

4) Warnings / Precautions / Potential Risks

The use of inlays/onlays may carry potential risks, including failure, poor fit, fracture, wear, marginal discolouration/staining, and recurrent caries (the most commonly reported reason for failure of resin restorations).

⚠ WARNING

Sensitivity:

This device is manufactured from a composite resin based on (meth)acrylate monomers. Patients with a known sensitivity or allergy to acrylates, methacrylates, or related substances should be informed of this by the treating clinician prior to treatment. In rare cases, allergic or irritant reactions may occur in sensitized individuals. The material used is fully cured (polymerized) by the manufacturer; however, trace residual monomer may occasionally be present.

Irritation:

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

Wear and discolouration:

Compared with ceramic restorations, composite resin is more susceptible to surface wear and discolouration/staining from food, tobacco, and certain beverages (e.g. coffee, tea, red wine), particularly with inadequate oral hygiene. Periodic polishing by the dental professional may be required to maintain aesthetics.

⚠ CAUTION

Patient conditions:

Inlays/onlays should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, or oral lesions.

5) Cleaning and Care (Patient care instructions – as directed by the dental professional)

Daily cleaning

Oral hygiene:

Toothbrushing:

- Advise brushing teeth twice daily with a soft toothbrush and a fluoride toothpaste.

Flossing:

- Advise daily flossing to remove plaque and debris between teeth and around the fixed restoration. A floss threader may be needed for hard-to-reach areas.

Mouth rinse:

- Alcohol-based mouth rinses often dry out the mouth, leading to increased plaque and tartar build-up.

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 Service Life / Maintenance

This device is intended for use for less than 30 days.

8) Reporting Incidents / Complaints

Report suspected serious incidents associated with this device to:

- The Manufacturer and/or Dandy New Zealand entity using the contacts above, and
- Medsafe

In New Zealand, serious incidents and quality issues involving medical devices should be reported to Medsafe in accordance with New Zealand's medical device adverse event reporting requirements.

> **INFO**
> For full contact details of the local Authorized Representative, refer to: Authorized Representatives — end of this document.

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.

UNITED KINGDOM (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	GMDN: 38649 – Resin Dental Inlay EMDN: Q010206 – Dental prostheses
Product Code(s)	PMMAINL

Manufacturer	Zima International, Inc. Also DBA Dandy 22 Cortlandt St, 30th Floor, New York, NY, 10007 US
UK Responsible Person (UKRP)	**Name:** DANDY LABS GB, LTD **Company Number:** 16873608 **Address:** 5 New Street Square, London EC4A 3TW, United Kingdom

Intended User	Prescribing dental professional / dental practice
Device Type	Custom-made dental device (CMD)
Sterility	Supplied non-sterile (where applicable)
Single-use / Reusable	Single use

1) Intended Purpose (Intended Use)

Dandy inlay/onlay restorations are made to restore worn, decayed, fractured, and aesthetically unappealing dentition.

They:

- Restore individual permanent teeth that are fractured, decayed, discoloured, or severely worn.
- Restore the shape, function, and aesthetics of the natural dentition.
- Provide occlusal stability and help maintain a healthy interarch relationship.
- Require a more conservative preparation compared with crowns and bridges.

2) Device Description / Key Specifications

- Custom-made, patient-specific device, manufactured according to the dentist's prescription and digital input data.
- Configuration: Dandy restorations are manufactured using digital technology (CAD/CAM), achieving a precise fit and adaptation to the patient's specific needs. They are milled from a highly filled, biocompatible composite resin block for good aesthetics and a tooth-friendly modulus of elasticity.
- Material: Polymethyl methacrylate (PMMA) block

Material Safety Data Sheet: https://help.meetdandy.com/hc/en-us/articles/27911516419341-Temporary-Crown-and-Bridge-Safety-Data-Sheet

3) Contraindications

- Do not use in patients with a known hypersensitivity or allergy to PMMA.
- The device is intended for temporary use only and should not remain in the patient for more than 30 days.

4) Warnings / Precautions / Potential Risks

The use of inlays/onlays may carry potential risks, including failure, poor fit, fracture, wear, marginal discolouration/staining, and recurrent caries (the most commonly reported reason for failure of resin restorations).

⚠ WARNING

Sensitivity:

This device is manufactured from a composite resin based on (meth)acrylate monomers. Patients with a known sensitivity or allergy to acrylates, methacrylates, or related substances should be informed of this by the treating clinician prior to treatment. In rare cases, allergic or irritant reactions may occur in sensitized individuals. The material used is fully cured (polymerized) by the manufacturer; however, trace residual monomer may occasionally be present.

Irritation:

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

Wear and discolouration:

Compared with ceramic restorations, composite resin is more susceptible to surface wear and discolouration/staining from food, tobacco, and certain beverages (e.g. coffee, tea, red wine), particularly with inadequate oral hygiene. Periodic polishing by the dental professional may be required to maintain aesthetics.

⚠ CAUTION

Patient conditions:

Inlays/onlays should be used with caution in patients with uncontrolled periodontal disease, severe bone resorption, or oral lesions.

5) Cleaning and Care (Patient care instructions – as directed by the dental professional)

Daily cleaning

Oral hygiene:

Toothbrushing:

- Advise brushing teeth twice daily with a soft toothbrush and a fluoride toothpaste.

Flossing:

- Advise daily flossing to remove plaque and debris between teeth and around the fixed restoration. A floss threader may be needed for hard-to-reach areas.

Mouth rinse:

- Alcohol-based mouth rinses often dry out the mouth, leading to increased plaque and tartar build-up.

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 Service Life / Maintenance

This device is intended for use for less than 30 days.

8) Reporting Incidents / Complaints (UK)

Report suspected serious incidents associated with this device to:

- The Manufacturer and/or UK Responsible Person (UKRP) using the contact details above; and
- The UK Medicines and Healthcare products Regulatory Agency (MHRA), in accordance with local requirements.

> **INFO**
> For full contact details of the local Authorized Representative, refer to: Authorized Representatives — end of this document.

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.

AUTHORIZED REPRESENTATIVES

The table below lists the local Authorized Representative, Sponsor, or Responsible Person for each jurisdiction where this device is marketed. For incident reporting, contact the representative for your country.

Jurisdiction	Authorised Rep / Sponsor	Registered Address / Contact Email	Reg. Number	Regulatory Body
Australia (AUS)	DANDY Labs AUS Pty Ltd	Tower One, Level 46, 100 Barangaroo Ave, Sydney NSW 2000 Compliance@meetdandy.com	ABN: 33693955761	TGA (Therapeutic Goods Administration)
New Zealand (NZ)	DANDY Labs NZ Limited	Quigg Partners, Level 7, 36 Brandon Street, Wellington, NZ 6011	NZBN: 9429053758446	Medsafe
United Kingdom (UK)	DANDY LABS GB, LTD	5 New Street Square, London EC4A 3TW Compliance@meetdandy.com	Co. No.: 16873608	MHRA

NOTE
Contact details are subject to change. Always verify current information on the official product labelling or the manufacturer's website before reporting an incident.

Manufacturer	**Zima International, Inc. Also DBA Dandy** 22 Cortlandt St, 30th Floor, New York, NY, 10007, US compliance@meetdandy.com

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Approve	Garvin Tran	Manager, Operations - QMS	28-Aug-2026 20:28

* Datetime fields are displayed according to the system time zone: (GMT-04:00) Eastern Daylight Time (America/New_York)