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	Composite Stent
GMDN / EMDN Code	47906 (GMDN) – Custom-made dental composite resin kit *
Product Code(s)	CLSTENT
Device Type	Custom-made dental device (CMD) – mold/matrix only; supplied without composite resin
Sterility	Not supplied sterile
Single-use / Reuse	Single-use
Intended User	Prescriber: Dental professional / dental practice

**Note on classification: this GMDN term covers a resin "kit," but Dandy supplies the custom-made mold/stent component only — the composite resin is not manufactured, supplied, or included by Dandy.*

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AUSTRALIA (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

Australia — Patient Matched Medical Device (PMMD)

GMDN / EMDN	47906 – Custom-made dental composite resin kit *
Product Code(s)	CLSTENT

**Note on classification: this GMDN term covers a resin "kit," but Dandy supplies the custom-made mold/stent component only — the composite resin is not manufactured, supplied, or included by Dandy.*

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) – mold/matrix only; supplied without composite resin
Sterility	Not supplied sterile (if applicable)
Single-use / Reusable	Single use (per patient, per treatment session)

1) Intended Purpose (Intended Use)

The Composite Stent is a custom-made, patient-specific mold manufactured from the patient's accepted digital treatment plan (e.g. digital wax-up / smile design). It reproduces the planned final tooth contours and acts as a positioning and shaping guide for the chairside, direct application of composite resin restorative material by a dental professional. The stent is placed over the patient's existing dentition, with or without prior tooth preparation, to help the clinician reproduce the intended tooth morphology while placing and sculpting composite restorations.

Scope of supply: This device consists of custom-made mold/stent only. It does not include, and is not supplied with, composite resin restorative material. The composite resin is a separate material, selected and supplied by the treating dental professional or a separate manufacturer, and is outside the scope of this device and this IFU. Refer to the chosen resin's own manufacturer instructions for use, safety data sheet, and regulatory clearance/marking before use.

2) Device Description / Key Specifications

- Custom-made, patient-specific device, manufactured according to the dental professional's prescription and digital input data (e.g. intraoral scan, digital smile design/wax-up).

- Configuration: The Composite Stent is thermoformed from the patient's approved digital design. It is typically clear/translucent to allow visualization and light-curing of the composite resin through the stent during placement.
- Material: Erkoflex.
- Scope of supply: Mold/stent only. Composite resin restorative material is NOT included and must be sourced separately by the treating dental professional; see Section 1.

3) Contraindications

- Patients with active (untreated) caries, heavily restored teeth, or significant parafunctional habits (e.g. bruxism) should be evaluated by the dental professional before proceeding – teeth should be assessed to confirm suitability for stent-guided composite restoration.
- Do not use with any composite resin, bonding agent, or etchant that is not appropriately CE/UKCA marked or otherwise cleared for intraoral, direct restorative use.
- Do not use in patients with a known hypersensitivity or allergy to the stent material (Erkoflex).
- Not to be used as a substitute for proper case selection, tooth preparation, or isolation technique.

4) Warnings / Precautions / Potential Risks

Composite stent techniques require meticulous planning to avoid overhangs, voids, and bonding defects. Confirm the stent is rigid, clear, and of adequate thickness for stability before use; create adequate venting for material outflow; and protect adjacent teeth separately during placement.

⚠ WARNING

Isolation:

Use a rubber dam or equivalent isolation technique to prevent contamination of the working field and to protect adjacent soft tissues.

Insertion pressure:

Maintain consistent, low insertion/injection pressure to avoid distortion of the stent and excessive flash/overhang of composite material.

Sensitivity:

Inform patients that post-operative sensitivity is common following composite bonding procedures and is typically temporary; persistent sensitivity should be evaluated by the dental professional.

Material limitations:

Avoid exposing the stent to heat sources or solvents that may distort or degrade the mold material prior to or during use.

⚠ CAUTION

N/A

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

The stent itself is a single-use chairside device and is discarded after the procedure; it is not retained or cleaned by the patient.

6) Storage

Prior to use, store the Composite Stent in a clean, dry container, away from direct heat or sunlight, until the scheduled chairside appointment.

7) Expected Life / Service

The Composite Stent itself is a single-use device, used only during the chairside placement procedure and discarded immediately afterward; it has no in-mouth service life.

8) Incident / Complaint Reporting

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

- Unused stents may be disposed of as general solid waste (confirm material recyclability locally).
- After clinical use, the stent will typically have been in contact with saliva, bonding agents, and uncured/partially cured composite resin. It should therefore be treated as contaminated clinical waste and disposed of via an appropriate labeled clinical waste stream (e.g. for high-temperature incineration), in accordance with local environmental and clinical waste regulations. Do not dispose of used stents in general/household waste.

NEW ZEALAND (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

New Zealand — Patient Matched Medical Device (PMMD)

GMDN / EMDN	47906 – Custom-made dental composite resin kit *
Product Code(s)	CLSTENT

**Note on classification: this GMDN term covers a resin "kit," but Dandy supplies the custom-made mold/stent component only — the composite resin is not manufactured, supplied, or included by Dandy.*

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) – mold/matrix only; supplied without composite resin
Sterility	Not supplied sterile (if applicable)
Single-use / Reusable	Single use (per patient, per treatment session)

1) Intended Purpose (Intended Use)

The Composite Stent is a custom-made, patient-specific mold manufactured from the patient's accepted digital treatment plan (e.g. digital wax-up / smile design). It reproduces the planned final tooth contours and acts as a positioning and shaping guide for the chairside, direct application of composite resin restorative material by a dental professional. The stent is placed over the patient's existing dentition, with or without prior tooth preparation, to help the clinician reproduce the intended tooth morphology while placing and sculpting composite restorations.

Scope of supply: This device consists of custom-made mold/stent only. It does not include, and is not supplied with, composite resin restorative material. The composite resin is a separate material, selected and supplied by the treating dental professional or a separate manufacturer, and is outside the scope of this device and this IFU. Refer to the chosen resin's own manufacturer instructions for use, safety data sheet, and regulatory clearance/marking before use.

2) Device Description / Key Specifications

- Custom-made, patient-specific device, manufactured according to the dental professional's prescription and digital input data (e.g. intraoral scan, digital smile design/wax-up).

- Configuration: The Composite Stent is thermoformed from the patient's approved digital design. It is typically clear/translucent to allow visualization and light-curing of the composite resin through the stent during placement.
- Material: Erkoflex.
- Scope of supply: Mold/stent only. Composite resin restorative material is NOT included and must be sourced separately by the treating dental professional; see Section 1.

3) Contraindications

- Patients with active (untreated) caries, heavily restored teeth, or significant parafunctional habits (e.g. bruxism) should be evaluated by the dental professional before proceeding – teeth should be assessed to confirm suitability for stent-guided composite restoration.
- Do not use with any composite resin, bonding agent, or etchant that is not appropriately CE/UKCA marked or otherwise cleared for intraoral, direct restorative use.
- Do not use in patients with a known hypersensitivity or allergy to the stent material (Erkoflex).
- Not to be used as a substitute for proper case selection, tooth preparation, or isolation technique.

4) Warnings / Precautions / Potential Risks

Composite stent techniques require meticulous planning to avoid overhangs, voids, and bonding defects. Confirm the stent is rigid, clear, and of adequate thickness for stability before use; create adequate venting for material outflow; and protect adjacent teeth separately during placement.

⚠ WARNING

Isolation:

Use a rubber dam or equivalent isolation technique to prevent contamination of the working field and to protect adjacent soft tissues.

Insertion pressure:

Maintain consistent, low insertion/injection pressure to avoid distortion of the stent and excessive flash/overhang of composite material.

Sensitivity:

Inform patients that post-operative sensitivity is common following composite bonding procedures and is typically temporary; persistent sensitivity should be evaluated by the dental professional.

Material limitations:

Avoid exposing the stent to heat sources or solvents that may distort or degrade the mold material prior to or during use.

⚠ CAUTION

N/A

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

The stent itself is a single-use chairside device and is discarded after the procedure; it is not retained or cleaned by the patient.

6) Storage

Prior to use, store the Composite Stent in a clean, dry container, away from direct heat or sunlight, until the scheduled chairside appointment.

7) Expected Life / Service

The Composite Stent itself is a single-use device, used only during the chairside placement procedure and discarded immediately afterward; it has no in-mouth service life.

8) Incident / Complaint Reporting

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

- Unused stents may be disposed of as general solid waste (confirm material recyclability locally).
- After clinical use, the stent will typically have been in contact with saliva, bonding agents, and uncured/partially cured composite resin. It should therefore be treated as contaminated clinical waste and disposed of via an appropriate labeled clinical waste stream (e.g. for high-temperature incineration), in accordance with local environmental and clinical waste regulations. Do not dispose of used stents in general/household waste.

UNITED KINGDOM (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	47906 – Custom-made dental composite resin kit *
Product Code(s)	CLSTENT

**Note on classification: this GMDN term covers a resin "kit," but Dandy supplies the custom-made mold/stent component only — the composite resin is not manufactured, supplied, or included by Dandy.*

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) – mold/matrix only; supplied without composite resin
Sterility	Not supplied sterile (if applicable)
Single-use / Reusable	Single use (per patient, per treatment session)

1) Intended Purpose (Intended Use)

The Composite Stent is a custom-made, patient-specific mold manufactured from the patient's accepted digital treatment plan (e.g. digital wax-up / smile design). It reproduces the planned final tooth contours and acts as a positioning and shaping guide for the chairside, direct application of composite resin restorative material by a dental professional. The stent is placed over the patient's existing dentition, with or without prior tooth preparation, to help the clinician reproduce the intended tooth morphology while placing and sculpting composite restorations.

Scope of supply: This device consists of custom-made mold/stent only. It does not include, and is not supplied with, composite resin restorative material. The composite resin is a separate material, selected and supplied by the treating dental professional or a separate manufacturer, and is outside the scope of this device and this IFU. Refer to the chosen resin's own manufacturer instructions for use, safety data sheet, and regulatory clearance/marking before use.

2) Device Description / Key Specifications

- Custom-made, patient-specific device, manufactured according to the dental professional's prescription and digital input data (e.g. intraoral scan, digital smile design/wax-up).

- Configuration: The Composite Stent is thermoformed from the patient's approved digital design. It is typically clear/translucent to allow visualization and light-curing of the composite resin through the stent during placement.
- Material: Erkoflex.
- Scope of supply: Mold/stent only. Composite resin restorative material is NOT included and must be sourced separately by the treating dental professional; see Section 1.

3) Contraindications

- Patients with active (untreated) caries, heavily restored teeth, or significant parafunctional habits (e.g. bruxism) should be evaluated by the dental professional before proceeding – teeth should be assessed to confirm suitability for stent-guided composite restoration.
- Do not use with any composite resin, bonding agent, or etchant that is not appropriately CE/UKCA marked or otherwise cleared for intraoral, direct restorative use.
- Do not use in patients with a known hypersensitivity or allergy to the stent material (Erkoflex).
- Not to be used as a substitute for proper case selection, tooth preparation, or isolation technique.

4) Warnings / Precautions / Potential Risks

Composite stent techniques require meticulous planning to avoid overhangs, voids, and bonding defects. Confirm the stent is rigid, clear, and of adequate thickness for stability before use; create adequate venting for material outflow; and protect adjacent teeth separately during placement.

⚠ WARNING

Isolation:

Use a rubber dam or equivalent isolation technique to prevent contamination of the working field and to protect adjacent soft tissues.

Insertion pressure:

Maintain consistent, low insertion/injection pressure to avoid distortion of the stent and excessive flash/overhang of composite material.

Sensitivity:

Inform patients that post-operative sensitivity is common following composite bonding procedures and is typically temporary; persistent sensitivity should be evaluated by the dental professional.

Material limitations:

Avoid exposing the stent to heat sources or solvents that may distort or degrade the mold material prior to or during use.

⚠ CAUTION

N/A

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

The stent itself is a single-use chairside device and is discarded after the procedure; it is not retained or cleaned by the patient.

6) Storage

Prior to use, store the Composite Stent in a clean, dry container, away from direct heat or sunlight, until the scheduled chairside appointment.

7) Expected Life / Service

The Composite Stent itself is a single-use device, used only during the chairside placement procedure and discarded immediately afterward; it has no in-mouth service life.

8) Incident / Complaint Reporting (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

- Unused stents may be disposed of as general solid waste (confirm material recyclability locally).
- After clinical use, the stent will typically have been in contact with saliva, bonding agents, and uncured/partially cured composite resin. It should therefore be treated as contaminated clinical waste and disposed of via an appropriate labeled clinical waste stream (e.g. for high-temperature incineration), in accordance with local environmental and clinical waste regulations. Do not dispose of used stents in general/household waste.

AUTHORIZED REPRESENTATIVES

The table below lists the local 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 20:40

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