



INSTRUCTIONS FOR USE (IFU)

Dandy / Zima International, Inc. | AUS · EU/EN · EU/ES · EU/FR · EU/DE · EU/IT · UK

MANUFACTURER

Manufacturer	Zima International, Inc. Also DBA Dandy
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Contact / Website	www.meetdandy.com
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DEVICE IDENTITY

Device Identity

Device Family	Inlay - Ceramic
GMDN / EMDN Code	38647
Product Code(s)	EMXLPSINP, EMXSINA, EMXSINP, ZIRHTSINA, ZIRHTSINP, ZIRMOSINA, ZIRMOSINP
Device Type	Custom-made dental device (CMD) / Patient Matched Medical Device (PMMD)
Sterility	Not supplied sterile
Single-use / Reuse	Reusable
Intended User	Prescriber: Dental professional / dental practice

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AUSTRALIA (ENGLISH)**INSTRUCTIONS FOR USE (IFU)**

Australia — Patient Matched Medical Device (PMMD)

GMDN / EMDN	38647
Product Code(s)	EMXLPSINP, EMXSINA, EMXSINP, ZIRHTSINA, ZIRHTSINP, ZIRMOSINA, ZIRMOSINP
Manufacturer	Zima International, Inc. Also DBA Dandy 1320 N. 300 W., Lehi, UT 84043 United States
Australian Sponsor	Name: DANDY Labs AUS Pty Ltd Company No.: ABN: 33693955761 Address: Tower One - International Towers, Level 46, 100 Barangaroo Avenue, Sydney, New South Wales 2000, Australia
Intended User	Prescriber — Dental professional / dental practice
Device Type	Patient Matched Medical Device (PMMD)
Sterility	Not supplied sterile
Single-use / Reusable	Reusable

1) Intended Purpose (Intended Use)

Dandy's Inlay/Onlay restorations are made to restore worn, carious, broken, and aesthetically displeasing dentition.

They:

- Restore single, permanent teeth that are fractured, carious, discolored, or severely worn.
- Restore the form, function, and esthetics 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: Zirconia Monolithic (3Y & 4Y), Porcelain-Fused-To-Zirconia (PFZ), E.Max (full contour), E.Max (layered)

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

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

WARNING

The use of Inlays/Onlays 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. Patients with sensitivity or allergy to cobalt or chromium 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 any signs of irritation, inflammation, or discomfort should be evaluated by the treating clinician.

CAUTION

NA

5) Cleaning and Care

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, 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, Inlays/Onlays) generally last 10 to 20 years, with modern materials like zirconia potentially exceeding this lifespan, 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

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

- 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.

EUROPEAN UNION (ENGLISH)**INSTRUCTIONS FOR USE (IFU)**

European Union — Custom-Made Device (CMD)

GMDN / EMDN	Q010206 - Dental Prostheses
Product Code(s)	EMXLPSINP, EMXSINA, EMXSINP, ZIRHTSINA, ZIRHTSINP, ZIRMOSINA ZIRMOSINP
Manufacturer	Zima International, Inc. Also DBA Dandy 1320 N. 300 W., Lehi, UT 84043 United States
EU authorized representative (EURP)	Name: Dandy Labs Europe Company No.: Registration No.: 989857065 Address: 3, boulevard de Sebastopol, 75001 Paris, France
Intended User	Prescriber — Dental professional / dental practice
Device Type	Custom-made dental device (CMD)
Sterility	Not supplied sterile
Single-use / Reusable	Reusable

1) Intended Purpose (Intended Use)

Dandy's Inlay/Onlay restorations are made to restore worn, carious, broken, and aesthetically displeasing dentition.

They:

- Restore single, permanent teeth that are fractured, carious, discolored, or severely worn.
- Restore the form, function, and esthetics 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: 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

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

4) Warnings / Precautions / Potential Risks

WARNING

The use of Inlays/Onlays 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. Patients with sensitivity or allergy to cobalt or chromium 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 any signs of irritation, inflammation, or discomfort should be evaluated by the treating clinician.

CAUTION

na

5) Cleaning and Care

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, 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, Inlays/Onlays) generally last 10 to 20 years, with modern materials like zirconia potentially exceeding this lifespan, 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

Report suspected serious incidents associated with this device to:

- The Manufacturer and/or Dandy EU entity using the contacts above, and corresponding local requirements
- The Competent Authority of your Member State, in accordance with Regulation (EU) 2017/745 (MDR).

Competent Authorities:

- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Spain : Spanish Agency for Medicines and Health Products (AEMPS)
- Germany : Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (BfArM)
- Italy : Ministero della Salute / Istituto Superiore di Sanità (ISS)
- Spain: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) for Spain
- Netherlands: Inspectie Gezondheidszorg en Jeugd (IGJ)
- Austria: Bundesamt für Sicherheit im Gesundheitswesen (BASG)
- Sweden: Läkemedelsverket
- Denmark: Lægemiddelstyrelsen
- Portugal: Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)

INFO

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

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.

UNIÓN EUROPEA (ESPAÑOL)**INSTRUCCIONES DE USO (IFU)**

Unión Europea — Producto Sanitario a Medida (CMD)

GMDN / EMDN	Q010206 - Prótesis dentales
Código(s) del producto	EMXLPSINP, EMXSINA, EMXSINP, ZIRHTSINA, ZIRHTSINP, ZIRMOSINA ZIRMOSINP
Fabricante	Zima International, Inc. Also DBA Dandy 1320 N. 300 W., Lehi, UT 84043 United States
Persona Responsable de la UE (EURP)	Nombre: Dandy Labs Europa N° empresa: Número de empresa: 989857065 Domicilio: 3, boulevard de Sebastopol, 75001 París, Francia
Usuario previsto	Prescriptor: profesional dental / consulta dental
Tipo de dispositivo	Dispositivo dental a medida (CMD)
Esterilidad	No se suministra estéril
De un solo uso / Reutilizable	Reutilizable

1) Finalidad prevista (uso previsto)

Las restauraciones tipo inlay/onlay de Dandy están diseñadas para restaurar dentición desgastada, cariada, fracturada o estéticamente insatisfactoria.

Los puentes:

- Restauran dientes permanentes individuales que presentan fracturas, caries, decoloración o desgaste intenso.
- Restauran la forma, la función y la estética de la dentición natural.
- Proporcionan estabilidad oclusal y mantienen unas relaciones interarcales adecuadas.
- Preparación más conservadora en comparación con coronas y puentes.

2) Descripción del dispositivo / Especificaciones clave

- Dispositivo a medida y específico para el paciente, fabricado según la prescripción del profesional dental y los datos digitales de entrada.
- Configuración: Las restauraciones de Dandy se fabrican mediante tecnología digital, lo que permite un ajuste preciso y una personalización adaptada a las necesidades específicas del paciente. Están fabricados con un material altamente duradero y biocompatible, lo que garantiza confort y funcionalidad a largo plazo.
- Material: zirconia monolítica (3Y y 4Y), porcelana fusionada sobre zirconia (PFZ), E.max (contorno completo), E.max (estratificado)

[Ficha de datos de seguridad del material de zirconia](#)

[Ficha de datos de seguridad del material PFZ](#)

3) Contraindicaciones

Las incrustaciones inlay/onlay deben utilizarse con precaución en pacientes con enfermedad periodontal no controlada, reabsorción ósea severa o lesiones orales.

4) Advertencias / Precauciones / Riesgos potenciales

ADVERTENCIAS

El uso de incrustaciones inlay/onlay puede conllevar riesgos potenciales, como fracaso, desajuste, fractura y caries recurrente.

****Advertencia – Sensibilidad:**

Este dispositivo contiene trazas de óxidos de cobalto y cromo utilizados como colorantes en el material cerámico. Los pacientes con sensibilidad o alergia al cobalto o al cromo deben ser informados por el clínico responsable del tratamiento de la presencia de estos compuestos en el dispositivo antes del tratamiento. En casos raros, pueden producirse reacciones alérgicas en individuos sensibilizados.

****Advertencia – Irritación:**

En determinadas personas puede producirse irritación localizada de los tejidos orales circundantes debido a la variabilidad individual en la respuesta tisular. Los pacientes deben ser controlados tras la colocación, y el clínico responsable del tratamiento debe evaluar cualquier signo de irritación, inflamación o molestia.

PRECAUCIONES

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5) Limpieza y cuidado

Limpieza diaria

- Higiene bucal:
 - Cepillado:
 - Se recomienda cepillarse los dientes dos veces al día con un cepillo de cerdas suaves y un dentífrico fluorado.
 - Uso de hilo dental:
 - Recomiende el uso diario de hilo dental para eliminar la placa y los restos entre los dientes y alrededor de la restauración fija. Puede ser necesario utilizar un enhebrador de hilo dental en zonas de difícil acceso.
 - Enjuague bucal:
 - Los enjuagues bucales a base de alcohol tienden a secar la boca, lo que provoca un aumento de la placa y la acumulación de sarro.

Recomendaciones alimentarias y de hábitos

- Evite los alimentos abrasivos: Limite los alimentos duros, crujientes o pegajosos que puedan dañar la restauración o hacer que se afloje.
- Evite los alimentos azucarados: ya que pueden favorecer la aparición de nuevas caries o el deterioro prematuro de los márgenes de la restauración.
- Manténgase hidratado/a: Beber abundante agua ayudará a mantener limpia la boca del paciente y a prevenir la enfermedad periodontal.
- Evite los malos hábitos: Absténgase de usar sus dientes para abrir paquetes o morder objetos duros.

6) Almacenamiento

Utilice estuches específicos para coronas o carillas dentales con insertos de espuma blanda o silicona para evitar astillamientos, arañazos o desplazamientos, asegurándose de que se mantengan limpios, secos y protegidos durante el transporte o mientras esperan su colocación en la clínica o el laboratorio.

7) Vida esperada / Servicio

Las restauraciones dentales cerámicas (coronas, obturaciones, carillas e incrustaciones inlay/onlay) suelen durar entre 10 y 20 años, y los materiales modernos como la zirconia pueden incluso superar esa vida útil. No obstante, su duración varía considerablemente en función de los cuidados, la localización (los dientes posteriores se desgastan más rápidamente) y el tipo de restauración (los implantes suelen ser más duraderos que las coronas sobre dientes). Una excelente higiene bucal (cepillado y uso de hil o dental) y evitar alimentos duros o el rechinar dental (bruxismo) son factores clave para maximizar su longevidad, aunque pueden producirse pequeños desconchados o desgaste.

8) Notificación de incidentes / Reclamaciones

Comunique cualquier sospecha de incidente grave relacionado con este producto a:

- El fabricante y/o la entidad de Dandy en la UE utilizando los datos de contacto indicados anteriormente, así como conforme a los requisitos locales aplicables
- La Autoridad Competente de su Estado Miembro, de conformidad con el Reglamento (UE) 2017/745 (MDR).

Autoridades competentes:

- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Spain : Spanish Agency for Medicines and Health Products (AEMPS)
- Germany : Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (BfArM)
- Italy : Ministero della Salute / Istituto Superiore di Sanità (ISS)
- Spain: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) for Spain
- Netherlands: Inspectie Gezondheidszorg en Jeugd (IGJ)
- Austria: Bundesamt für Sicherheit im Gesundheitswesen (BASG)
- Sweden: Läkemedelsverket
- Denmark: Lægemiddelstyrelsen
- Portugal: Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)

INFO

Para los datos completos de contacto del Representante Autorizado local, consulte: Representantes Autorizados — fin de este documento.

9) Eliminación

- Las restauraciones totalmente cerámicas (de porcelana) suelen eliminarse como residuo sólido convencional o llevarse a centros de reciclaje específicos que acepten residuos

mixtos de cerámica o escombros de construcción, ya que son difíciles de reciclar como otros materiales habituales.

- Basura doméstica: Deposítelas en el contenedor habitual de residuos, ya que no se descomponen ni se reciclan en los sistemas estándar de reciclaje.
- Consulte siempre con su municipio local o el transportista de residuos para conocer las normas específicas; sin embargo, los artículos cerámicos no suelen aceptarse en los contenedores de reciclaje estándar junto a la acera.
- Centros de reciclaje: Llévelas a un centro de reciclaje local que acepte cerámica mezclada, hormigón o residuos de construcción, ya que en algunos casos pueden reutilizarse.
- Si la restauración ha estado en la boca del paciente o ha entrado en contacto con la saliva, deséchela como residuo biomédico.

UNION EUROPÉENNE (FRANÇAIS)

INSTRUCTIONS D'UTILISATION (IFU)

Union Européenne — Dispositif sur Mesure (CMD)

GMDN / EMDN	Q010206 - Prothèses dentaires
Code(s) produit	EMXLPSINP, EMXSINA, EMXSINP, ZIRHTSINA, ZIRHTSINP, ZIRMOSINA ZIRMOSINP

Fabricant	Zima International, Inc. Also DBA Dandy 1320 N. 300 W., Lehi, UT 84043 United States
Personne Responsable de l'UE (EURP)	Nom : Dandy Labs Europe N° d'enregistrement: Numéro d'enregistrement: 989857065 Adresse : 3, boulevard de Sebastopol, 75001 Paris, France

Utilisateur prévu	Prescripteur : professionnel dentaire/cabinet dentaire
Type de dispositif	Dispositif dentaire sur mesure (DMC)
Stérilité	Non fourni stérile
Usage unique / Réutilisable	Réutilisable

1) Usage prévu (utilisation prévue)

Les restaurations inlay (à l'intérieur de la dent)/onlay (englobant aussi les parois) de Dandy sont conçues pour restaurer une dentition usée, cariée, fracturée ou inesthétique.

- Ils :
 - Restaurer les dents simples et permanentes qui sont fracturées, cariées, décolorées ou gravement usées.
 - Rétablissent la forme, la fonction et l'esthétique de la dentition naturelle.
 - Assurent la stabilité occlusale et préservent les relations interarcades correctes.
 - Une préparation moins invasive que celle requise pour les couronnes et les bridges.

2) Description du dispositif / Caractéristiques principales

- Dispositif sur mesure, spécifique au patient, fabriqué selon les prescriptions des professionnels dentaires et les données d'entrée numériques.

- Paramétrage : Les restaurations Dandy sont fabriquées à l'aide de technologies numériques, ce qui garantit un ajustement précis et une personnalisation adaptée aux besoins spécifiques du patient. Ils sont fabriqués à partir d'un matériau hautement durable et biocompatible, assurant confort et fonctionnalité à long terme.

- Matériau : Zircon monolithique (3Y et amp ; 4Y), porcelaine-fondue à la zircone (PFZ), E.Max (plein contour), E.Max (couche)

[Fiche de données de sécurité du matériau zircone](#)

[Fiche de données de sécurité PFZ](#)

[Fiche de données de sécurité du matériau de contour complet E.MAX](#)

3) Contre-indications

Les inlays/onlays doivent être utilisés avec prudence chez les patients présentant une maladie parodontale non contrôlée, une résorption osseuse sévère ou des lésions buccodentaires.

4) Avertissements / Précautions / Risques potentiels

⚠ Avertissements

- L'utilisation d'inlays/onlays peut présenter des risques potentiels, notamment une défaillance, un mauvais ajustement, une rupture et des caries récurrentes.

- ****Avertissement – Sensibilité :**

- Cet appareil contient des traces d'oxydes de cobalt et de chrome utilisés comme colorants dans le matériau céramique. Les patients sensibles ou allergiques au cobalt ou au chrome doivent être informés par le clinicien traitant de la présence de ces composés dans l'appareil avant le traitement. Dans de rares cas, des réactions allergiques peuvent survenir chez les personnes sensibilisées.

- ****Avertissement – Irritation :**

- Une irritation localisée des tissus buccaux environnants peut survenir chez certains individus en raison de la variabilité individuelle de la réponse tissulaire. Les patients doivent être surveillés après la mise en place et le médecin traitant doit évaluer tout signe d'irritation, d'inflammation ou d'inconfort.

⚠ PRECAUTIONS

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5) Nettoyage et entretien

Nettoyage quotidien

- Hygiène buccodentaire :
 - Brossage :
 - Il est recommandé de se brosser les dents deux fois par jour, à l'aide d'une brosse à dents à poils souples et d'un dentifrice fluoré.
 - Utilisation du fil dentaire :
 - Recommander une utilisation quotidienne du fil dentaire pour éliminer la plaque dentaire et les résidus alimentaires entre les dents et autour de la restauration fixe. Un enfile-fil dentaire peut s'avérer nécessaire pour les zones difficiles d'accès.
 - Bain de bouche :
 - Les bains de bouche à base d'alcool ont tendance à sécher la bouche, ce qui entraîne une augmentation de la plaque dentaire et de l'accumulation de tartre.

Recommandations alimentaires et habitudes

- Éviter les aliments abrasifs : Limiter la consommation d'aliments durs, croquants ou collants qui pourraient endommager la restauration ou la faire se desceller.
- Éviter les aliments sucrés : Où de nouvelles cavités peuvent former ou provoquer une dégradation prématurée des marges de restauration.
- Rester hydraté : Boire beaucoup d'eau aidera à garder la bouche de votre patient propre et à prévenir les maladies des gencives.
- Éviter les mauvaises habitudes : Évitez d'utiliser vos dents pour ouvrir des emballages ou de mordre dans des objets durs.

6) Stockage

Utiliser des boîtes spécialement conçues pour les couronnes et les facettes dentaires, dotées d'un rembourrage en mousse souple ou en silicone, afin d'éviter tout éclat, rayure ou déplacement, et de garantir qu'elles restent propres, sèches et protégées pendant le transport ou en attendant leur mise en place en clinique ou en laboratoire.

7) Durée de vie / Service attendu

Les restaurations dentaires en céramique (couronnes, obturations, facettes, inlays/onlays) ont généralement une durée de vie de 10 à 20 ans, celle des matériaux modernes comme la zircone pouvant même dépasser cette durée ; toutefois, leur durée de vie varie considérablement en fonction des soins prodigués, de leur emplacement (les dents postérieures s'usent plus rapidement) et de leur type (les implants sont plus durables que les couronnes posées dessus). Une excellente hygiène bucco-dentaire (brossage, utilisation du fil dentaire) et le fait d'éviter les aliments durs ou de grincer des dents (bruxisme) sont essentiels pour optimiser la durée de vie des facettes, même si un léger ébréchage ou une certaine usure sont possibles.

8) Signalement des incidents / Réclamations

Signaler tout incident grave suspecté lié à cet appareil :

- Au fabricant et/ou à l'entité Dandy EU en utilisant les coordonnées indiquées ci-dessus, et conformément aux exigences locales applicables
- L'autorité compétente de votre État membre, conformément au Règlement (UE) 2017/745 (MDR).

Competent Authorities:

- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Spain : Spanish Agency for Medicines and Health Products (AEMPS)
- Germany : Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (BfArM)
- Italy : Ministero della Salute / Istituto Superiore di Sanità (ISS)
- Spain: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) for Spain
- Netherlands: Inspectie Gezondheidszorg en Jeugd (IGJ)
- Austria: Bundesamt für Sicherheit im Gesundheitswesen (BASG)
- Sweden: Läkemedelsverket
- Denmark: Lægemiddelstyrelsen
- Portugal: Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)

INFO

Pour obtenir les coordonnées complètes du représentant autorisé local, veuillez consulter la section : Représentants autorisés — à la fin du document.

9) Élimination

- Les restaurations tout céramique (en porcelaine) sont souvent jetées avec les déchets solides ordinaires ou apportées dans des centres de recyclage spécialisés qui acceptent les déchets mixtes de céramique et de construction, car elles sont difficiles à recycler comme les objets courants.

- Ordures ménagères : Les placer dans votre poubelle habituelle, car elles ne se dégradent pas dans le recyclage standard
- Toujours vérifier auprès de votre municipalité ou de votre prestataire de collecte des déchets pour connaître les règles spécifiques ; toutefois, les objets en céramique ne sont généralement pas acceptés dans les bacs de recyclage standard en bordure de trottoir.
- Centres de recyclage : Les apporter à un centre de recyclage local qui accepte les déchets mixtes de céramique, de béton ou de chantier, car ils peuvent parfois être réutilisés.
- Si la restauration a été dans la bouche du patient ou a été en contact avec de la salive, jeter comme déchet biomédical.

EUROPÄISCHE UNION (DEUTSCH)

GEBRAUCHSANWEISUNG (IFU)

EU-SONDERANFERTIGUNG (CMD – Sonderanfertigung)

GMDN / EMDN	Q010206 – Zahnprothesen
Produktcode(s)	EMXLPSINP, EMXSINA, EMXSINP, ZIRHTSINA, ZIRHTSINP, ZIRMOSINA ZIRMOSINP
Hersteller	Zima International, Inc. auch bekannt als Dandy 1320 N. 300 W., Lehi, UT 84043 Vereinigte Staaten
Bevollmächtigter in der EU (EURP):	Name = Dandy Labs Europe Unternehmensnummer = 989857065 Eingetragene Anschrift = 3, boulevard de Sebastopol, 75001 Paris
Vorgesehener Anwender	Verschreibende(r) Zahnarzt/Zahnarztpraxis
Produkttyp	Zahntechnische Sonderanfertigung (CMD)
Sterilität	Wird nicht steril geliefert
Einmalprodukt/wiederverwendbar:	Einmalgebrauch

1) Zweckbestimmung (Verwendungszweck)

Dandy Inlay/Onlay-Restaurationen sind für die Wiederherstellung von abradertem, kariösem, frakturiertem und ästhetisch unvorteilhaftem Gebiss konzipiert.

- Sie:
 - Zur Wiederherstellung einzelner, bleibender Zähne, die frakturiert, kariös, verfärbt oder stark abgenutzt sind.
 - Zur Wiederherstellung von Form, Funktion und Ästhetik des natürlichen Gebisses.
 - Gewährleisten okklusale Stabilität und erhalten die korrekte Kieferrelation.
 - Konservativere Präparation im Vergleich zu Kronen und Brücken.

2) Produktbeschreibung / Hauptspezifikationen

- Maßgefertigte, patientenspezifische Sonderanfertigung, hergestellt nach zahnärztlicher Verordnung und digitalen Eingabedaten.
- Konfiguration: Die Versorgung von Dandy werden unter Einsatz digitaler Technologien gefertigt, was eine präzise Passform sowie eine exakt auf die spezifischen Bedürfnisse des Patienten abgestimmte Individualisierung ermöglicht. Sie bestehen aus einem hochgradig langlebigen und biokompatiblen Material, was langfristigen Komfort und uneingeschränkte Funktion gewährleistet.
- Material: Monolithisches Zirkondioxid (3Y & 4Y), Zirkonkeramik (Zirkon verblendet) (PFZ), e.max (vollanatomisch), e.max (verblendet)

[Sicherheitsdatenblatt für Zirkondioxid](#)

[Sicherheitsdatenblatt für PFZ](#)

[Sicherheitsdatenblatt für vollanatomisches e.max](#)

3) Kontraindikationen

Inlays/Onlays sollten bei Patienten mit unkontrollierter Parodontalerkrankung, schwerer Knochenresorption oder Läsionen der Mundschleimhaut nur mit Vorsicht angewendet werden.

4) Warnhinweise / Vorsichtsmaßnahmen / Potenzielle Risiken

⚠️ WARNHINWEISE

- Die Verwendung von Inlays/Onlays kann potenzielle Risiken beinhalten, einschließlich Versagen, Passungenauigkeit, Bruch und Sekundärkaries.
- ****Warnhinweis** – Empfindlichkeit:
 - Dieses Produkt enthält Spuren von Kobalt- und Chromoxiden, die als Farbpigmente im Keramikmaterial verwendet werden. Patienten mit einer Überempfindlichkeit oder Allergie gegen Kobalt oder Chrom müssen vor der Behandlung vom behandelnden Arzt über das Vorhandensein dieser Stoffe im Produkt informiert werden. In seltenen Fällen können bei sensibilisierten Personen ggf. allergische Reaktionen auftreten.
- ****Warnhinweis** – Reizung:
 - Aufgrund der individuellen Variabilität der Gewebereaktion kann es bei bestimmten Personen zu lokalen Irritationen des umgebenden oralen Gewebes kommen. Die Patienten sollten nach dem Einsetzen überwacht werden, und jegliche Anzeichen von Reizung, Entzündung oder Missempfinden sollten durch den behandelnden Arzt evaluiert werden.

⚠️ VORSICHTSMASSNAHMEN

NA

5) Reinigung und Pflege

Tägliche Reinigung

- Mundhygiene:
 - Zähneputzen:
 - Empfohlen wird zweimal tägliches Zähneputzen mit einer weichen Zahnbürste und einer fluoridhaltigen Zahnpasta.
 - Zahnseide:
 - Es wird eine tägliche Anwendung von Zahnseide empfohlen, um Plaque und Speisereste aus den Zahnzwischenräumen sowie im Bereich des festsitzenden Zahnersatzes zu entfernen. Für schwer zugängliche Bereiche kann eine Einfädelhilfe für Zahnseide erforderlich sein.
 - Mundspülung:
 - Alkoholhaltige Mundspülungen neigen dazu, den Mund auszutrocknen, was zu einer verstärkten Bildung von Plaque und Zahnstein führt.

Empfehlungen zu Ernährung und Gewohnheiten

- Vermeidung abrasiver Lebensmittel: Vermeiden Sie nach Möglichkeit harte, knusprige oder klebrige Speisen. Diese können die Restauration beschädigen oder dazu führen, dass sie sich lockert.
- Vermeidung zuckerhaltiger Lebensmittel: Diese begünstigen die Entstehung von neuer Karies und können zu einem vorzeitigen Abbau der Kronen- und Brückenränder führen.
- Hydriert bleiben: Das Trinken von reichlich Wasser trägt dazu bei, die Mundhöhle des Patienten sauber zu halten und Parodontalerkrankungen vorzubeugen.
- Vermeidung schlechter Gewohnheiten: Verzichten Sie darauf, die Zähne zum Öffnen von Verpackungen oder zum Beißen auf harte Gegenstände zu verwenden.

6) Lagerung

Verwenden Sie spezielle Transportboxen für Kronen und Veneers mit weichen Schaumstoff- oder Silikoneinsätzen, um zu verhindern, dass sie abplatzen, zerkratzen oder verrutschen, und stellen Sie sicher, dass sie während des Transports oder während der Wartezeit bis zum Einsetzen in der Klinik oder im Labor sauber, trocken und geschützt gelagert werden.

7) Erwartete Lebensdauer / Zeit der Benutzung

Keramischer Zahnersatz (Kronen, Füllungen, Veneers, Inlays/Onlays) hält in der Regel 10 bis 20 Jahre, wobei moderne Werkstoffe wie Zirkoniumoxid diese Lebensdauer potenziell überschreiten können; die Haltbarkeit variiert jedoch erheblich je nach Pflege, Lokalisation (Zähne im Seitenzahnbereich nutzen sich schneller ab) und Versorgungsart (Implantate sind dauerhafter als die darauf befestigten Kronen). Eine hervorragende Mundhygiene (Zähneputzen, Zahnseide) sowie das Vermeiden von harten Lebensmitteln oder Zähneknirschen (Bruxismus) sind der Schlüssel zur Maximierung der Langlebigkeit, wenngleich leichte Abplatzungen oder Verschleiß möglich sind.

8) Meldung von Vorfällen / Beschwerden

Melden Sie vermutete schwerwiegende Vorkommnisse in Verbindung mit diesem Produkt:

- dem Hersteller und/oder der Dandy EU-Niederlassung unter Verwendung der oben genannten Kontaktdaten und der entsprechenden lokalen Anforderungen
- Die zuständige Behörde Ihres Mitgliedstaats gemäß Verordnung (EU) 2017/745 (MDR).

Competent Authorities:

- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Spain : Spanish Agency for Medicines and Health Products (AEMPS)
- Germany : Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (BfArM)
- Italy : Ministero della Salute / Istituto Superiore di Sanità (ISS)
- Spain: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) for Spain
- Netherlands: Inspectie Gezondheidszorg en Jeugd (IGJ)
- Austria: Bundesamt für Sicherheit im Gesundheitswesen (BASG)
- Sweden: Läkemedelsverket
- Denmark: Lægemiddelstyrelsen
- Portugal: Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)

INFORMATION

Die vollständigen Kontaktdaten des lokalen Bevollmächtigten finden Sie unter „Bevollmächtigte Vertrete am Ende des Dokuments.

9) Entsorgung

- Vollkeramischer Zahnersatz (Keramikrestorationen) wird in der Regel als normaler Restmüll entsorgt oder zu speziellen Recyclinghöfen gebracht, die Mischkeramik oder mineralische Abfälle annehmen, da eine Wiederverwertung wie bei herkömmlichen Wertstoffen schwierig ist.
 - Haushaltsmüll: Entsorgen Sie diese in Ihrer normalen Restmülltonne, da sie im Standard-Recyclingkreislauf nicht verwertet werden können.
- Informieren Sie sich stets bei Ihrer zuständigen Gemeinde oder Ihrem Entsorgungsunternehmen über die spezifischen Vorschriften; keramische Gegenstände werden jedoch im Allgemeinen nicht über die normale Wertstofftonne vor Ort entsorgt.
- Recyclingzentren: Bringen Sie diese zu einem örtlichen Recyclinghof, der Mischkeramik oder mineralische Abfälle annimmt, da sie unter Umständen wiederverwendet werden können.
- Wenn sich die Restauration im Mund des Patienten befand oder mit Speichel in Kontakt gekommen ist, entsorgen Sie diese als infektiösen Abfall (medizinischen Sonderabfall).



UNIONE EUROPEA (ITALIANO)

ISTRUZIONI PER L'USO (IFU)

DISPOSITIVO PERSONALIZZATO UE (CMD = Dispositivo personalizzato)

GMDN / EMDN	Q010206 - Dental Prostheses
Codice(i) prodotto	EMXLPSINP, EMXSINA, EMXSINP, ZIRHTSINA, ZIRHTSINP, ZIRMOSINA ZIRMOSINP

Produttore	Zima International, Inc. Also DBA Dandy 1320 N. 300 W., Lehi, UT 84043 Stati Uniti
Responsabile per l'UE (EURP):	Nome = Dandy Labs Europe Codice azienda = 989857065 Sede legale = 3, boulevard de Sebastopol, 75001 Parigi

Utente previsto	medico odontoiatra prescrittore / studio dentistico
Tipo di dispositivo	dispositivo odontoiatrico personalizzato (CMD)
Sterilità	non fornito sterile
Monouso / Riutilizzabile	Riutilizzabile

1) Destinazione d'uso (uso previsto)

I restauri inlay/onlay Dandy sono realizzati per ripristinare denti usurati, cariati, fratturati ed esteticamente non soddisfacenti.

- Questi dispositivi:
 - Restaurano denti singoli e permanenti fratturati, cariati, scoloriti o gravemente usurati.
 - Ripristinano la forma, la funzione e l'estetica della dentatura naturale.
 - Forniscono stabilità occlusale e mantengono le corrette relazioni tra le arcate.
 - Preparazione più conservativa, rispetto a corone e ponti.

2) Descrizione del dispositivo / Specifiche principali

- Dispositivo personalizzato, specifico per il paziente, prodotto in base alla prescrizione dell'odontoiatra e ai dati di input digitali.
- Configurazione: I restauri di Dandy sono realizzati utilizzando la tecnologia digitale, consentendo una precisa vestibilità e personalizzazione su misura in base alle esigenze specifiche del paziente. Sono realizzati in materiale altamente resistente e biocompatibile, garantendo comfort e funzionalità a lungo termine.
- Materiale: zirconia monolitica (3Y e 4Y), porcellana fusa a zirconia (PFZ), E.Max (contorno completo), E.Max (stratificato)

[Scheda di sicurezza del materiale zirconia](#)

[Scheda di sicurezza del materiale PFZ](#)

[Scheda di sicurezza del materiale E.MAX \(contorno completo\)](#)

3) Controindicazioni

Gli inlay/onlay devono essere utilizzati con cautela in pazienti con malattia parodontale non controllata, grave riassorbimento osseo o lesioni orali.

4) Avvertenze / Precauzioni / Rischi potenziali

AVVERTENZE

- L'uso di inlay/onlay può comportare rischi potenziali, tra cui lesioni, malformazioni, rotture e carie ricorrenti.
- ****Avvertenza – Sensibilità:**
 - Questo dispositivo contiene tracce di ossidi di cobalto e cromo utilizzati come coloranti nel materiale ceramico. Prima del trattamento, i pazienti con sensibilità o allergia al cobalto o al cromo devono essere informati dal medico curante della presenza di questi composti nel dispositivo. In rari casi, si possono verificare reazioni allergiche in individui sensibilizzati.
- ****Avvertenza – Irritazione:**
 - In alcuni individui può verificarsi irritazione localizzata dei tessuti orali circostanti a causa della variabilità individuale della risposta tissutale. I pazienti devono essere monitorati dopo il posizionamento e qualsiasi segno di irritazione, infiammazione o disagio deve essere valutato dal medico curante.

PRECAUZIONI

NA

5) Pulizia e cura

Pulizia quotidiana

- Igiene orale:
 - Spazzolamento:
 - Si raccomanda di lavarsi i denti due volte al giorno, utilizzando uno spazzolino da denti a setole morbide e un dentifricio al fluoro.
 - Filo interdentale:
 - Si consiglia di utilizzare ogni giorno il filo interdentale per rimuovere la placca e i detriti tra i denti e intorno al restauro fisso. Può essere necessario una punta passafilo per le aree difficili da raggiungere.
 - Collutorio:
 - I collutori contenenti alcol tendono ad asciugare la bocca, con conseguente aumento della formazione di placca e tartaro.

Consigli sull'alimentazione e sulle abitudini

- Evitare alimenti abrasivi: limitare il consumo di cibi duri, croccanti o appiccicosi che possono danneggiare il restauro o causarne l'allentamento.
- Evitare i cibi zuccherati: laddove possono formarsi nuove cavità o causano un decadimento prematuro dei margini di restauro.
- Rimanere idratati: bere molta acqua aiuterà a mantenere pulita la bocca del paziente e a prevenire le malattie gengivali.
- Evitare cattive abitudini: evitare di usare i denti per aprire pacchetti o mordere oggetti duri.

6) Conservazione

Utilizzare apposite scatole per corone/faccette dentali con inserti in schiuma morbida o silicone per evitare scheggiature, graffi o movimenti, assicurandosi che siano mantenuti puliti, asciutti e protetti durante il trasporto o in attesa di essere applicati in una clinica o in un laboratorio.

7) Durata prevista / Servizio

I restauri dentali in ceramica (corone, otturazioni, faccette, inlay/onlay) durano generalmente da 10 a 20 anni, con materiali moderni come la zirconia che potrebbero superare questo limite, ma la durata varia in modo significativo in base alla cura, alla posizione (usura più rapida dei denti posteriori) e al tipo (gli impianti permangono di più rispetto alle corone nell'arcata superiore). Un'ottima igiene orale (spazzolatura, uso del filo interdentale) ed evitare di consumare cibi duri o digrignare i denti (bruxismo) sono fondamentali per massimizzare la longevità, anche se è possibile qualche scheggiatura o usura.

8) Segnalazione di incidenti / Reclami

Segnalare gli incidenti gravi sospetti associati a questo dispositivo a:

- Produttore e/o entità UE Dandy utilizzando i contatti sopra indicati e i corrispondenti requisiti locali
- L'Autorità Competente del vostro Stato Membro, conformemente al Regolamento (UE) 2017/745 (MDR).

Competent Authorities:

- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Spain : Spanish Agency for Medicines and Health Products (AEMPS)
- Germany : Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (BfArM)
- Italy : Ministero della Salute / Istituto Superiore di Sanità (ISS)
- Spain: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) for Spain
- Netherlands: Inspectie Gezondheidszorg en Jeugd (IGJ)
- Austria: Bundesamt für Sicherheit im Gesundheitswesen (BASG)
- Sweden: Läkemedelsverket
- Denmark: Lægemiddelstyrelsen
- Portugal: Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)

INFORMAZIONI

Per i recapiti completi del Rappresentante Autorizzato locale, consultare la sezione: Rappresentanti Autorizzati — alla fine del documento.

9) Smaltimento

- I restauri interamente in ceramica (porcellana) vengono spesso smaltiti come rifiuti solidi regolari o portati in centri di riciclaggio specifici che accettano detriti misti di ceramica/costruzione, in quanto sono difficili da riciclare come oggetti tipici.
 - Rifiuti domestici: collocare nel bidone della spazzatura indifferenziata, perché non si decompongono nel riciclaggio standard.
- Verificare sempre le norme specifiche con il proprio comune o con la ditta di trasporto rifiuti; tuttavia, gli oggetti in ceramica di solito non sono accettati nei contenitori di riciclaggio standard.
- Centri di riciclaggio: portarli in un centro di riciclaggio locale che accetta residui misti di ceramica, cemento o costruzione, in quanto a volte possono essere riqualificati.
- Se il restauro è stato nella bocca del paziente o è entrato a contatto con la saliva, smaltirlo come rifiuto biomedico.

UNITED KINGDOM (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	38647
Product Code(s)	EMXLPSINP, EMXSINA, EMXSINP, ZIRHTSINA, ZIRHTSINP, ZIRMOSINA ZIRMOSINP
Manufacturer	Zima International, Inc. Also DBA Dandy 1320 N. 300 W., Lehi, UT 84043 United States
UK Responsible Person (UKRP)	Name: DANDY LABS GB, LTD Company No.: Company Number: 16873608 Address: 5 New Street Square, London EC4A 3TW, United Kingdom
Intended User	Prescriber — Dental professional / dental practice
Device Type	Custom-made dental device (CMD)
Sterility	Not supplied sterile
Single-use / Reusable	Reusable

1) Intended Purpose (Intended Use)

Dandy's Inlay/Onlay restorations are made to restore worn, carious, broken, and aesthetically unpleasing dentition.

They:

- Restore single, permanent teeth that are fractured, carious, discolored, or severely worn.
- Restore the form, function, and esthetics 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: 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

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

4) Warnings / Precautions / Potential Risks

WARNING

The use of Inlays/Onlays 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. Patients with sensitivity or allergy to cobalt or chromium 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 any signs of irritation, inflammation, or discomfort should be evaluated by the treating clinician.

CAUTION

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5) Cleaning and Care

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, 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, Inlays/Onlays) generally last 10 to 20 years, with modern materials like zirconia potentially exceeding this lifespan, 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

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) — www.gov.uk/mhra

In accordance with The Medical Devices Regulations 2002 (as amended).

INFO

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

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.

AUTHORIZED REPRESENTATIVES / REPRÉSENTANTS AUTORISÉS / BEVOLLMÄCHTIGTE VERTRETER / RAPPRESENTANTI AUTORIZZATI / REPRESENTANTES AUTORIZADOS

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

La tabla siguiente enumera el Representante Autorizado o Patrocinador local para cada país. | Le tableau ci-dessous liste le Représentant Autorisé local pour chaque pays. | Die folgende Tabelle enthält die bevollmächtigten Vertreter je Land.

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)
EU — English	Dandy Labs Europe	3, boulevard de Sebastopol, 75001 Paris, France Compliance@meetdandy.com	Reg: 989857065	Competent Authority / EUDAMED
EU — España	Dandy Labs Europa	3, boulevard de Sebastopol, 75001 París, Francia Compliance@meetdandy.com	Reg: 989857065	AEMPS / Autoridad Competente
EU — France	Dandy Labs Europe	3, boulevard de Sebastopol, 75001 Paris, France Compliance@meetdandy.com	Reg: 989857065	ANSM / Autorité Compétente
EU — Deutschland	Dandy Labs Europe	3, boulevard de Sebastopol, 75001 Paris, Frankreich Compliance@meetdandy.com	Reg: 989857065	BfArM / Zuständige Behörde
EU — Italia	Dandy Labs Europe	3, boulevard de Sebastopol, 75001 Parigi, Francia Compliance@meetdandy.com	Reg: 989857065	Min. della Salute / ISS
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. / Les coordonnées sont susceptibles de changer. / Angaben können sich ändern. / I recapiti sono soggetti a modifiche.

**Manufacturer / Hersteller /
Fabbicante / Fabricant /
Fabricante**

Zima International, Inc. Also DBA Dandy
1320 N. 300 W., Lehi, UT 84043, United States
compliance@meetdandy.com



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Signatory Table

Action Name	User Name	Title	Signature Date
Approve	Kasha Lim	Supplier Quality Engineer	12-Jun-2026 01:50

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