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
Address	1320 N. 300 W., Lehi, UT 84043, United States
Contact / Website	www.meetdandy.com
Complaints	complaints@meetdandy.com

DEVICE IDENTITY

Device Identity

Device Family	Surgical Guide, STD Abutment Insertion Guide
GMDN / EMDN Code	57949
Product Code(s)	SAIG
Device Type	Custom-made dental device (CMD) / Patient Matched Medical Device (PMMD)
Sterility	Not supplied sterile
Single-use / Reuse	Single-use
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	57949
Product Code(s)	SAIG

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	Single use

1) Intended Purpose (Intended Use)

The Insertion Guide is intended for use with single or multiple abutments during placement. It is intended for short-term use and is then discarded.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Abutment placement on a dental implant or on multiple implants in the correct orientation, performed by a dental professional.
- Material: Acrylic - monomer and powder

Lucitone 199
Monomer
Powder

3) Contraindications

Allergy to or hypersensitivity to the used materials

4) Warnings / Precautions / Potential Risks

⚠ WARNING

Surgery in the oral cavity and oral rehabilitation include general risks.

These include (but are not limited to):

- Small components accidentally dropped in the patient's mouth can be swallowed or aspirated.
- Allergy or hypersensitivity to the chemical ingredients of the material used.

⚠ CAUTION

- The Abutment Insertion Guide should not be exposed to thermal treatment such as steam or dry heat sterilization.
- This product is intended for single use and may not be reused. Reusing the product introduces:
- The risk of infection and complications due to a loss of accuracy of fit and the precision of the components.
- Performance failure of the device.
- Infection, inflammation, or allergy related to the device.
- Swallowing or inhalation of the device or a part thereof.

5) Cleaning and Care

Do not autoclave or use dry heat sterilization as these may affect the mechanical properties. Chemical disinfection is recommended before use.
E.g.. Cidex OPA Solution - 0.55% ortho-phthaldehyde
Use

1) Check the osseointegration of the implant/implants to be restored
2) Try in the Insertion Guide
3) Before placing the abutment/abutments, try the guide in the patient's mouth. Ensure a tight fit and a secure fit.
4) Placement of the abutment in the guide
5) Place the abutment/abutments in the insertion guide and ensure proper fit and orientation (timing). There should be a slight resistance while inserting the abutment /abutments into the guide, and it should hold them securely.
6) Abutment insertion
7) Make sure to hold the guide gently.
8) Place the guide on the patient's teeth and seat it in place.
9) Each abutment should adapt to the implant's orientation.
10) Insert each abutment/abutment into the appropriate implant.
11) If resistance is felt, ensure abutment/abutments are aligned with the implant.
12) Abutment Screw Tightening
13) While holding the guide in place, insert the Abutment Screw (should be located in the model) and tighten.
14) Take a radiograph to confirm seating.
15) Final tightening
16) Tighten the abutment screw using a torque wrench according to the implant manufacturer's torque specifications.
17) If the soft tissue creates hard resistance and blanches during seating, it is recommended that you proceed slowly before final torquing of the screw.
18) Cover the screw head
    a) Use your preferred method.
    b) Dandy recommends:
        i) Either a material similar to plumber's tape or a cotton pellet.
19) Then cover with a material similar to Cavit.

20) Cementation
    a) Cement the final restoration to the abutment using your preferred method (make sure that the cement method is consistent with the restoration type).

6) Storage

The products should be stored in their packaging in a dry place at a normal temperature (18–25°C/64–77°F). Use the sterilized components within the stated time period from the sterile bag.

7) Expected Life / Service

The dental abutment placement guide itself is a single-use or short-term tool for precise implant placement

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

Comply with the current applicable national waste disposal regulations.

EUROPEAN UNION (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

European Union — Custom-Made Device (CMD)

GMDN / EMDN	Q010399- Surgical Dental Devices - Other
Product Code(s)	SAIG

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	Single use

1) Intended Purpose (Intended Use)

The Insertion Guide is intended for use with single or multiple abutments during placement. It is intended for short-term use and is then discarded.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Abutment placement on a dental implant or on multiple implants in the correct orientation, performed by a dental professional.
- Material: Keyguide

KeyGuide

3) Contraindications

Allergy to or hypersensitivity to the used materials

4) Warnings / Precautions / Potential Risks

⚠ WARNING

Surgery in the oral cavity and oral rehabilitation include general risks.

These include (but are not limited to):

- Small components accidentally dropped in the patient's mouth can be swallowed or aspirated.
- Allergy or hypersensitivity to the chemical ingredients of the material used.

⚠ CAUTION

- The Abutment Insertion Guide should not be exposed to thermal treatment such as steam or dry heat sterilization.
- This product is intended for single use and may not be reused. Reusing the product introduces:
- The risk of infection and complications due to a loss of accuracy of fit and the precision of the components.
- Performance failure of the device.
- Infection, inflammation, or allergy related to the device.
- Swallowing or inhalation of the device or a part thereof.

5) Cleaning and Care

Do not autoclave or use dry heat sterilization as these may affect the mechanical properties. Chemical disinfection is recommended before use.
E.g.. Cidex OPA Solution - 0.55% ortho-phthaldehyde
Use

21) Check the osseointegration of the implant/implants to be restored
22) Try in the Insertion Guide
23) Before placing the abutment/abutments, try the guide in the patient's mouth. Ensure a tight fit and a secure fit.
24) Placement of the abutment in the guide
25) Place the abutment/abutments in the insertion guide and ensure proper fit and orientation (timing). There should be a slight resistance while inserting the abutment /abutments into the guide, and it should hold them securely.
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40) Cementation
    a) Cement the final restoration to the abutment using your preferred method (make sure that the cement method is consistent with the restoration type).

6) Storage

The products should be stored in their packaging in a dry place at a normal temperature (18–25°C/64–77°F). Use the sterilized components within the stated time period from the sterile bag.

7) Expected Life / Service

The dental abutment placement guide itself is a single-use or short-term tool for precise implant placement

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 the full contact information of the local Authorized Representative, see: Authorized Representatives — at the end of the document.

9) Disposal

Comply with the current applicable national waste disposal regulations.

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UNIÓN EUROPEA (ESPAÑOL)

INSTRUCCIONES DE USO (IFU)

Unión Europea — Producto Sanitario a Medida (CMD)

GMDN / EMDN	Q010399 - Productos sanitarios quirúrgicos dentales - Otros
Código(s) del producto	SAIG

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	Un solo uso

1) Finalidad prevista (uso previsto)

La guía de inserción está destinada a su uso con uno o varios pilares durante su colocación. Está destinada a un uso de corta duración y posteriormente debe desecharse.

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: Colocación del pilar sobre un implante dental o sobre varios implantes en la orientación correcta, realizada por un profesional dental.
- Material: KeyGuide

KeyGuide

3) Contraindicaciones

Alergia o hipersensibilidad a los materiales utilizados

4) Advertencias / Precauciones / Riesgos potenciales

⚠ ADVERTENCIAS

La cirugía oral y la rehabilitación oral conllevan riesgos generales.

Entre ellos se incluyen, entre otros:

- Se pueden tragar o aspirar componentes pequeños que se hayan caído accidentalmente en la boca del paciente.
- Alergia o hipersensibilidad a los ingredientes químicos del material utilizado.

⚠ **PRECAUCIONES**

- La guía de inserción del pilar no debe exponerse a tratamientos térmicos como esterilización con vapor o calor seco.
- Este producto está diseñado para un solo uso y no se puede reutilizar. La reutilización del producto presenta:
- Riesgo de infección y de complicaciones derivadas de la pérdida de precisión en el ajuste y en los componentes.
- Fallo de funcionamiento del dispositivo.
- Infección, inflamación o alergia relacionada con el dispositivo.
- Ingestión o inhalación del dispositivo o de una parte del mismo.

5) Limpieza y cuidado

No esterilice en autoclave ni utilice esterilización con calor seco, ya que pueden afectar a las propiedades mecánicas. Se recomienda la desinfección química antes de su uso.
Por ejemplo. Solución Cidex OPA - ortoftalaldehído al 0,55 %
Uso

1) Solución Cidex OPA - ortoftalaldehído al 0,55 %
2) Pruebe la guía de inserción
3) Antes de colocar el pilar/pilares, pruebe la guía en la boca del paciente. Solución Cidex OPA - ortoftalaldehído al 0,55 %
4) Colocación del pilar en la guía
5) Coloque el pilar o los pilares en la guía de inserción y asegúrese de que el ajuste y la orientación sean correctos (timing). Debe notarse una ligera resistencia al insertar el pilar o los pilares en la guía, que deberá sujetarlos firmemente.
6) Inserción del pilar
7) Asegúrese de sujetar la guía con suavidad.
8) Coloque la guía sobre los dientes del paciente y aséntela correctamente.
9) Cada pilar debe adaptarse a la orientación del implante.
10) Inserte cada pilar en el implante correspondiente.
11) Si nota resistencia, asegúrese de que los pilares estén alineados con el implante.
12) Apriete del tornillo del pilar
13) Mientras mantiene la guía en posición, inserte el tornillo del pilar (que debe estar situado en el modelo) y apriételo.
14) Tome una radiografía para confirmar el asentamiento.
15) Apriete final
16) Apriete el tornillo del pilar con una llave dinamométrica de acuerdo con las especificaciones de par del fabricante del implante.
17) Si el tejido blando ofrece una resistencia importante y blanquea durante el asentamiento, se recomienda proceder lentamente antes de aplicar el par final al tornillo.
18) Cubra la cabeza del tornillo
    a) Utilice su método preferido.
    b) Dandy recomienda:
        i) Utilice un material similar a la cinta de PTFE o una torunda de algodón.
19) A continuación, cúbralo con un material similar a Cavit.
20) Cementación
    a) Cemente la restauración definitiva al pilar utilizando el método que prefiera (asegúrese de que el método de cementación sea compatible con el tipo de restauración).

6) Almacenamiento

Los productos deben almacenarse en su envase, en un lugar seco y a temperatura ambiente (18–25 °C/64–77 °F). Utilice los componentes esterilizados dentro del periodo de tiempo indicado en la bolsa estéril.

7) Vida esperada / Servicio

La propia guía de colocación del pilar dental es una herramienta de un solo uso o de uso a corto plazo para la colocación precisa del implante.

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
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- 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

Cumpla la normativa nacional vigente aplicable en materia de eliminación de residuos.

UNION EUROPÉENNE (FRANÇAIS)

INSTRUCTIONS D'UTILISATION (IFU)

Union Européenne — Dispositif sur Mesure (CMD)

GMDN / EMDN	Q010399 - Dispositifs dentaires chirurgicaux - Autres
Code(s) produit	SAIG

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	Usage unico

1) Usage prévu (utilisation prévue)

Le gabarit d'insertion est destiné à être utilisé avec un ou plusieurs pivots lors de la mise en place. Il est destiné à une utilisation à court terme et est ensuite jeté.

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 : Mise en place d'un pivot sur un implant dentaire ou sur plusieurs implants dans l'orientation correcte, réalisée par un professionnel dentaire.
- Matériel : Keyguide

KeyGuide

3) Contre-indications

Allergie ou hypersensibilité aux matériaux utilisés

4) Avertissements / Précautions / Risques potentiels

⚠ **AVERTISSEMENTS**

La chirurgie de la cavité buccale et la rééducation buccale comportent des risques généraux.

Ceux-ci comprennent (sans toutefois s'y limiter) :

- Les petits composants tombés accidentellement dans la bouche du patient peuvent être avalés ou aspirés.
- Allergie ou hypersensibilité aux ingrédients chimiques du matériau utilisé.

⚠ **PRÉCAUTIONS**

- Le gabarit d'insertion du pivot ne doit pas être soumis à des traitements thermiques tels que la stérilisation à la vapeur ou à la chaleur sèche.
- Ce produit est destiné à un usage unique et ne peut pas être réutilisé. La réutilisation du produit comporte les risques suivants :
- Un risque d'infection et de complications dû à une perte de précision de l'ajustement et des composants.
- Défaillance de performance de l'appareil.
- Infection, inflammation ou allergie liée à l'appareil.
- Ingestion ou inhalation de l'appareil ou d'une partie de celui-ci.

5) Nettoyage et entretien

Ne pas stériliser à l'autoclave ni par chaleur sèche, car cela pourrait altérer les propriétés mécaniques.
Une désinfection chimique est recommandée avant utilisation.
Par ex. Solution Cidex OPA – ortho-phtaldéhyde à 0,55 %
Utilisation

1) Vérifier l'ostéo-intégration de l'implant/des implants à restaurer.
2) Essayer le gabarit d'insertion.
3) Avant de placer le ou les pivots, essayer le gabarit dans la bouche du patient. Garantir un ajustement parfait et une bonne tenue.
4) Mise en place du pivot dans le gabarit.
5) Placer le ou les pivots dans le gabarit d'insertion et vérifier qu'ils sont correctement orientés (alignement). Une légère résistance devrait se faire sentir lors de l'insertion du/des pivots dans le gabarit, qui doit les maintenir fermement en place.
6) Insertion du pivot.
7) Veiller à tenir délicatement le gabarit.
8) Placer le gabarit sur les dents du patient et mettre en place.
9) Chaque pivot doit s'adapter à l'orientation de l'implant.
10) Insérer chaque pivot dans l'implant approprié.
11) En cas de résistance, s'assurer que le ou les pivots sont alignés avec l'implant.
12) Serrage de la vis du pivot.
13) Tout en maintenant le gabarit en place, insérer la vis du pivot (doit être située dans le modèle) et serrer.
14) Prendre une radiographie pour vérifier le bon positionnement.
15) Serrage final.
16) Serrer la vis du pivot à l'aide d'une clé dynamométrique, en respectant les valeurs de couple indiquées par le fabricant de l'implant.
17) Si les tissus mous créent une résistance dure et des blanches pendant la mise en place, il est recommandé de procéder lentement avant le serrage final de la vis.
18) Couvrir la tête de vis
    a) Utiliser votre méthode préférée.
    b) Dandy recommande :
        i) Soit un matériau similaire au ruban de plombier, soit une boulette de coton.
19) Puis recouvrir d'un matériau similaire au Cavit.
20) Scellement
    a) Sceller la restauration finale du pivot en utilisant la méthode de votre choix (s'assurer que la méthode de scellement correspond au type de restauration)

6) Stockage

Les produits doivent être conservés dans leur emballage d'origine, dans un endroit sec et à température ambiante (18 à 25°C/64 à 77°F). Utiliser les composants stérilisés dans le délai indiqué après leur sortie du sachet stérile.

7) Durée de vie / Service attendu

Le gabarit de mise en place du pivot dentaire lui-même est un outil à usage unique ou à court terme pour une mise en place précise de l'implant

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 aplicables
- 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

Respecter les réglementations nationales en vigueur en matière d'élimination des déchets.

EUROPÄISCHE UNION (DEUTSCH)

GEBRAUCHSANWEISUNG (IFU)

EU-SONDERANFERTIGUNG (CMD – Sonderanfertigung)

GMDN / EMDN	Q010399 – Produkte für die zahnärztliche Chirurgie – Sonstige
Produktcode(s)	SAIG

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)

Die Einsetzhilfe ist zur Verwendung bei der Platzierung von einzelnen oder mehreren Abutments bestimmt. Es ist für den kurzzeitigen Gebrauch bestimmt und wird anschließend entsorgt.

2) Produktbeschreibung / Hauptspezifikationen

- Maßgefertigte, patientenspezifische Sonderanfertigung, hergestellt nach zahnärztlicher Verordnung und digitalen Eingabedaten.
- Konfiguration: Das Einsetzen des Abutments auf einem Zahnimplantat oder auf mehreren Implantaten in der korrekten Ausrichtung, durchgeführt von einer zahnärztlichen Fachkraft.
- Material: Keyguide

KeyGuide

3) Kontraindikationen

Allergie oder Überempfindlichkeit gegen die verwendeten Materialien

4) Warnhinweise / Vorsichtsmaßnahmen / Potenzielle Risiken

⚠ WARNHINWEISE

Chirurgische Eingriffe in der Mundhöhle und die orale Rehabilitation bergen allgemeine Risiken. Dazu gehören (unter anderem):

- In die Mundhöhle des Patienten herabgefallene Kleinteile können versehentlich verschluckt oder aspiriert (eingeatmet) werden.

- Allergie oder Überempfindlichkeit gegen die chemischen Bestandteile des verwendeten Materials.

⚠ VORSICHTSMASSNAHMEN

- Die Abutment-Einsetzhilfe darf keiner thermischen Behandlung wie einer Dampf- oder Heißluftsterilisation ausgesetzt werden.
- Dieses Produkt ist für den Einmalgebrauch bestimmt und darf nicht wiederverwendet werden. Eine Wiederverwendung des Produkts birgt folgende Risiken:
- Das Risiko von Infektionen und Komplikationen aufgrund eines Verlusts der Passgenauigkeit und der Präzision der Komponenten.
- Ein Funktionsversagen des Produkts.
- Infektionen, Entzündungen oder produktbezogene allergische Reaktionen.
- Das Verschlucken oder Inhalieren des Produkts oder eines Teils davon.

5) Reinigung und Pflege

Nicht autoklavieren oder mittels Heißluft sterilisieren, da dies die mechanischen Eigenschaften beeinträchtigen kann. Vor dem Gebrauch wird eine chemische Desinfektion empfohlen.
Z. B. Cidex OPA-Lösung – 0,55 % Orthophthaldehyd
Anwendung

1. Überprüfen Sie die Osseointegration des zu versorgenden Implantats / der zu versorgenden Implantate.
2. Anprobe der Einsetzhilfe
3. Führen Sie vor dem Einsetzen des Abutments / der Abutments eine Anprobe der Einsetzhilfe im Mund des Patienten durch. Stellen Sie einen spielfreien und sicheren Sitz sicher.
4. Einsetzen des Abutments in die Einsetzhilfe
5. Setzen Sie das Abutment / die Abutments in die Einsetzhilfe ein und gewährleisten Sie den korrekten Sitz sowie die exakte Ausrichtung (Timing). Beim Einsetzen des Abutments / der Abutments in die Einsetzhilfe sollte ein leichter Widerstand spürbar sein, und die Führung muss diese sicher halten.
6. Einsetzen des Abutments
7. Halten Sie die Einsetzhilfe vorsichtig fest.
8. Setzen Sie die Einsetzhilfe auf die Zähne des Patienten auf und bringen Sie diese vollständig in Position.
9. Jeder Abutment muss sich an die Ausrichtung des Implantats anpassen.
10. Führen Sie jedes Abutment in das entsprechende Implantat ein.
11. Falls ein Widerstand spürbar ist, stellen Sie sicher, dass das Abutment / die Abutments korrekt auf das Implantat ausgerichtet sind.
12. Anziehen der Abutment-Fixierschraube
13. Während Sie die Einsetzhilfe in Position halten, setzen Sie die Abutmentschraube (diese sollte sich im Modell befinden) ein und ziehen Sie sie fest.
14. Fertigen Sie eine Röntgenaufnahme an, um den korrekten Sitz zu überprüfen.
15. Abschließende Festziehen
16. Ziehen Sie die Abutmentschraube mit einem Drehmomentschlüssel gemäß den Drehmomentvorgaben des Implantatherstellers fest.
17. Wenn das Weichgewebe einen starken Widerstand erzeugt und beim Einsetzen abblasst, wird empfohlen, langsam vorzugehen, bevor das endgültige Drehmoment auf die Schraube aufgebracht wird.
18. Abdecken des Schraubenkopfes
    1. Verwenden Sie Ihre bevorzugte Methode.
    2. Dandy empfiehlt:
        1. Entweder ein Material ähnlich wie Teflonband (Gewindedichtband) oder ein Wattepellet.
19. Decken Sie den Schraubenkanal anschließend mit einem Material ähnlich wie Cavit ab.
20. Zementierung
    1. Zementieren Sie die endgültige Versorgung mit Ihrer bevorzugten Methode auf dem Implantataufbau fest (stellen Sie sicher, dass die Zementierungsmethode mit der Art der Versorgung kompatibel ist).

6) Lagerung

Die Produkte sollten in ihrer Verpackung an einem trockenen Ort bei normaler Temperatur (18–25 °C / 64–77 °F) gelagert werden. Verwenden Sie die sterilisierten Komponenten innerhalb des angegebenen Zeitraums aus dem Sterilisationsbeutel.

7) Erwartete Lebensdauer / Nutzungsdauer

Die Einsetzhilfe für den Implantataufbau selbst ist ein Einwegprodukt oder ein Kurzzeit-Werkzeug für die präzise Platzierung des Implantats.

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

Halten Sie die aktuell geltenden nationalen Vorschriften zur Abfallentsorgung ein.

UNIONE EUROPEA (ITALIANO)

ISTRUZIONI PER L'USO (IFU)

DISPOSITIVO PERSONALIZZATO UE (CMD = Dispositivo personalizzato)

GMDN / EMDN	Q010399 – Dispositivi per chirurgia dentale - Altro
Codice(i) prodotto	SAIG

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)

La guida di inserimento è destinata all'uso con abutment singoli o multipli durante il posizionamento. È destinata all'uso a breve termine e viene quindi smaltita.

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: posizionamento dell'abutment su un impianto dentale o su più impianti con il corretto orientamento, eseguito da un odontoiatra.
- Materiale: KeyGuide

KeyGuide

3) Controindicazioni

Allergia o ipersensibilità ai materiali utilizzati.

4) Avvertenze / Precauzioni / Rischi potenziali

⚠ AVVERTENZE

L'intervento chirurgico nella cavità orale e la riabilitazione orale includono rischi generali.
Questi includono (ma non sono limitati a):

- I componenti di piccole dimensioni caduti accidentalmente nella bocca del paziente possono essere ingeriti o aspirati.

- Allergia o ipersensibilità alle sostanze chimiche del materiale utilizzato.

⚠ **PRECAUZIONI**

- La guida di inserimento dell'abutment non deve essere esposta a trattamenti termici come la sterilizzazione a vapore o a calore secco.
- Questo prodotto è monouso e non può essere riutilizzato. Il riutilizzo del prodotto introduce:
- Il rischio di infezioni e complicanze dovute a una perdita di accuratezza della vestibilità e della precisione dei componenti.
- Prestazioni ridotte del dispositivo.
- Infezione, infiammazione o allergia correlata al dispositivo.
- Deglutizione o inalazione del dispositivo o di una sua parte.

5) Pulizia e cura

Non eseguire la sterilizzazione in autoclave o a calore secco in quanto potrebbe alterare le proprietà meccaniche. Si raccomanda la disinfezione chimica prima dell'uso.
Ad es. soluzione Cidex OPA – 0,55% ortoftaldeide
Utilizzo

1. Controllare l'osteointegrazione dell'impianto/impianti da restaurare.
2. Provare con la guida di inserimento.
3. Prima di posizionare l'abutment/gli abutment, provare la guida nella bocca del paziente. Assicurare una vestibilità aderente e sicura.
4. Posizionamento dell'abutment nella guida
5. Posizionare l'abutment/gli abutment nella guida di inserimento e assicurarsi che la vestibilità e l'orientamento (sincronismo) siano adeguati. Durante l'inserimento dell'abutment/degli abutment nella guida deve essere presente una leggera resistenza, che deve tenerli saldamente.
6. Inserimento dell'abutment
7. Assicurarsi di tenere la guida delicatamente.
8. Posizionare la guida sui denti del paziente e metterla in posizione.
9. Ogni abutment deve adattarsi all'orientamento dell'impianto.
10. Inserire ciascun abutment nell'impianto appropriato.
11. Se si avverte resistenza, assicurarsi che l'abutment/gli abutment siano allineati con l'impianto.
12. Serraggio della vite dell'abutment
13. Tenendo la guida in posizione, inserire la vite dell'abutment (deve essere collocata nel modello) e serrare.
14. Fare una radiografia per confermare la posizione.
15. Serraggio finale
16. Serrare la vite dell'abutment usando una chiave dinamometrica in base alle specifiche di coppia fornite dal produttore dell'impianto.
17. Se il tessuto molle crea molta resistenza e sbianca durante il posizionamento, si consiglia di procedere lentamente prima del serraggio finale della vite.
18. Coprire la testa della vite.
    1. Usare il metodo preferito.
    2. Dandy consiglia:
        1. Materiale simile al nastro idraulico o pellet di cotone.
19. Quindi coprire con materiale simile a Cavit.
20. Cementazione
    1. Cementare il restauro finale sull'abutment utilizzando il metodo preferito (assicurarsi che il metodo del cemento sia coerente con il tipo di restauro).

6) Conservazione

I prodotti devono essere conservati nella loro confezione in luogo asciutto a temperatura regolare (18–25 °C/64–77 °F). Utilizzare i componenti sterilizzati entro il periodo di tempo indicato dalla busta sterile.

7) Durata prevista / Servizio

La guida per il posizionamento dell'abutment dentale è uno strumento monouso o a breve termine per un posizionamento preciso dell'impianto

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

Rispettare le normative nazionali vigenti in materia di smaltimento dei rifiuti.

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UNITED KINGDOM (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	57949
Product Code(s)	SAIG

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)

The Insertion Guide is intended for use with single or multiple abutments during placement. It is intended for short-term use and is then discarded.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Abutment placement on a dental implant or on multiple implants in the correct orientation, performed by a dental professional.
- Material: Keyguide

Keyguide

3) Contraindications

Allergy to or hypersensitivity to the used materials

4) Warnings / Precautions / Potential Risks

⚠ WARNING

Surgery in the oral cavity and oral rehabilitation include general risks.

These include (but are not limited to):

- Small components accidentally dropped in the patient's mouth can be swallowed or aspirated.
- Allergy or hypersensitivity to the chemical ingredients of the material used.

⚠ CAUTION

- The Abutment Insertion Guide should not be exposed to thermal treatment such as steam or dry heat sterilization.
- This product is intended for single use and may not be reused. Reusing the product introduces:
- The risk of infection and complications due to a loss of accuracy of fit and the precision of the components.
- Performance failure of the device.
- Infection, inflammation, or allergy related to the device.
- Swallowing or inhalation of the device or a part thereof.

5) Cleaning and Care

Do not autoclave or use dry heat sterilization as these may affect the mechanical properties. Chemical disinfection is recommended before use.
E.g.. Cidex OPA Solution - 0.55% ortho-phthaldehyde
Use

41) Check the osseointegration of the implant/implants to be restored
42) Try in the Insertion Guide
43) Before placing the abutment/abutments, try the guide in the patient's mouth. Ensure a tight fit and a secure fit.
44) Placement of the abutment in the guide
45) Place the abutment/abutments in the insertion guide and ensure proper fit and orientation (timing). There should be a slight resistance while inserting the abutment /abutments into the guide, and it should hold them securely.
46) Abutment insertion
47) Make sure to hold the guide gently.
48) Place the guide on the patient's teeth and seat it in place.
49) Each abutment should adapt to the implant's orientation.
50) Insert each abutment/abutment into the appropriate implant.
51) If resistance is felt, ensure abutment/abutments are aligned with the implant.
52) Abutment Screw Tightening
53) While holding the guide in place, insert the Abutment Screw (should be located in the model) and tighten.
54) Take a radiograph to confirm seating.
55) Final tightening
56) Tighten the abutment screw using a torque wrench according to the implant manufacturer's torque specifications.
57) If the soft tissue creates hard resistance and blanches during seating, it is recommended that you proceed slowly before final torquing of the screw.
58) Cover the screw head
    a) Use your preferred method.
    b) Dandy recommends:
        i) Either a material similar to plumber's tape or a cotton pellet.
59) Then cover with a material similar to Cavit.

60) Cementation
    a) Cement the final restoration to the abutment using your preferred method (make sure that the cement method is consistent with the restoration type).

6) Storage

The products should be stored in their packaging in a dry place at a normal temperature (18–25°C/64–77°F). Use the sterilized components within the stated time period from the sterile bag.

7) Expected Life / Service

The dental abutment placement guide itself is a single-use or short-term tool for precise implant placement

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

Comply with the current applicable national waste disposal regulations.

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 / Fabbricante / Fabricant / Fabricante	**Zima International, Inc. Also DBA Dandy** 1320 N. 300 W., Lehi, UT 84043, United States 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	Kasha Lim	Supplier Quality Engineer	12-Jun-2026 12:50

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