



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	Orthodontic Retainer
GMDN / EMDN Code	35310
Product Code(s)	RTRNLNGF, RTRNZEND, RTRNHLWY, THERMOER
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	35310
Product Code(s)	RTRNLNGF, RTRNZEND, RTRNHLWY, THERMOER
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)

An orthodontic retainer is a dental device designed to maintain the position of teeth following orthodontic treatment. It is used to prevent teeth from shifting and ensure orthodontic treatment results are maintained.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: The retainer is a custom-made dental device that fits over(or behind) the teeth. It is designed to be comfortable and easy to wear.
- Material: Zendura A, Phase Ortho, Stainless Steel

[Retainer Material Safety Data Sheets](#)[Fixed Wire Material Safety Data Sheet](#)**3) Contraindications**

The retainer should not be used if the user has a known allergy to plastic/metal or if they have an existing dental condition that makes it difficult to wear the device

4) Warnings / Precautions / Potential Risks

WARNING

The use of retainers may have potential risks, including breakage. They can be prone to breakage or cracking, especially if they are not handled or cared for properly. Chewing on the retainer or exposing it to excessive heat can increase the risk of damage.

CAUTION

NA

5) Cleaning and Care

Directions for Use

- To ensure the proper use of removable retainers, dental professionals and patients should follow these steps:
- Wash your hands thoroughly before handling the device.
- Carefully insert the device into the patient's teeth, starting from the back of the patient's mouth and working forward.
- Use your fingers to gently press the device onto the patient's teeth to ensure a snug fit.

Cleaning instructions

1. To clean the removable retainer, patients should follow these steps:
2. Use a soft-bristled toothbrush and non-abrasive toothpaste to brush the device gently.
3. Rinse the device thoroughly with cool water.
4. Do not use hot water, as it can warp the device.
5. Do not use mouthwash, as it can discolor the device.
6. Clean the device daily..

Recommended Wear Time

- Wear times for removable retainers can differ based on the clinician and clinical experience.
- Dandy recommends:
 - First 3-6 Months:
 - Retainers should be worn for 22 hours a day or more. The only time they should be removed is to brush and floss or to eat.
 - First 2 Years:
 - The patient will be able to start wearing their retainers only during sleep.
 - Third Year to the Rest of the Patient's Life:
 - Retainers do not have to be worn as frequently; the goal is to attempt to wear them about every other night.

6) Storage

When not in use, store the removable retainer in the provided case. Keep the case in a cool, dry place, away from direct sunlight.

7) Expected Life / Service

Orthodontic retainer life expectancy varies by type, with clear plastic ones lasting 1-3 years, traditional Hawley (wire/acrylic) retainers lasting 5-10 years, and fixed (bonded wire) retainers potentially lasting 10+ years or even decades with excellent care, though all need replacement due to wear, damage, or dental changes; proper cleaning, storage, and avoiding heat/abrasive foods are crucial for longevity.

8) Incident / Complaint Reporting

Report suspected serious incidents associated with this device to:

Document State: Effective (Simple)

Confidential

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- 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

Orthodontic retainers, especially clear plastic ones, are tough to recycle in regular bins due to multi-layer plastics and medical classification, so the best disposal is through dentist programs for specialized recycling, or as medical/sealed waste if necessary, preventing landfill/ocean pollution.

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

European Union — Custom-Made Device (CMD)

GMDN / EMDN	Q010499 - Orthodontic devices - other
Product Code(s)	RTRNLNGF, RTRNZEND, RTRNHLWY, THERMOER
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)

An orthodontic retainer is a dental device designed to maintain the position of teeth following orthodontic treatment. It is used to prevent teeth from shifting and ensure orthodontic treatment results are maintained.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: The retainer is a custom-made dental device that fits over(or behind) the teeth. It is designed to be comfortable and easy to wear.
- Material: Zendura A, Phase Ortho, Stainless Steel

[Retainer Material Safety Data Sheets](#)

[Fixed Wire Material Safety Data Sheet](#)

3) Contraindications

The retainer should not be used if the user has a known allergy to plastic/metal or if they have an existing dental condition that makes it difficult to wear the device

4) Warnings / Precautions / Potential Risks

WARNING

The use of retainers may have potential risks, including breakage. They can be prone to breakage or cracking, especially if they are not handled or cared for properly. Chewing on the retainer or exposing it to excessive heat can increase the risk of damage.

CAUTION

NA

5) Cleaning and Care

Directions for Use

- To ensure the proper use of removable retainers, dental professionals and patients should follow these steps:
- Wash your hands thoroughly before handling the device.
- Carefully insert the device into the patient's teeth, starting from the back of the patient's mouth and working forward.
- Use your fingers to gently press the device onto the patient's teeth to ensure a snug fit.

Cleaning instructions

1. To clean the removable retainer, patients should follow these steps:
2. Use a soft-bristled toothbrush and non-abrasive toothpaste to brush the device gently.
3. Rinse the device thoroughly with cool water.
4. Do not use hot water, as it can warp the device.
5. Do not use mouthwash, as it can discolor the device.
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Recommended Wear Time

- Wear times for removable retainers can differ based on the clinician and clinical experience.
- Dandy recommends:
 - First 3-6 Months:
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 - Third Year to the Rest of the Patient's Life:
 - Retainers do not have to be worn as frequently; the goal is to attempt to wear them about every other night.

6) Storage

When not in use, store the removable retainer in the provided case. Keep the case in a cool, dry place, away from direct sunlight.

7) Expected Life / Service

Orthodontic retainer life expectancy varies by type, with clear plastic ones lasting 1-3 years, traditional Hawley (wire/acrylic) retainers lasting 5-10 years, and fixed (bonded wire) retainers potentially lasting 10+ years or even decades with excellent care, though all need replacement due to wear, damage, or dental changes; proper cleaning, storage, and avoiding heat/abrasive foods are crucial for longevity.

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

Orthodontic retainers, especially clear plastic ones, are tough to recycle in regular bins due to multi-layer plastics and medical classification, so the best disposal is through dentist programs for specialized recycling, or as medical/sealed waste if necessary, preventing landfill/ocean pollution.

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

Unión Europea — Producto Sanitario a Medida (CMD)

GMDN / EMDN	Q010499 - Dispositivos ortodónticos - otros
Código(s) del producto	RTRNLNGF, RTRNZEND, RTRNHLWY, THERMOER
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)

Un retenedor ortodóntico es un dispositivo dental diseñado para mantener la posición de los dientes después del tratamiento ortodóntico. Se utiliza para evitar que los dientes se muevan y para garantizar que los resultados del tratamiento ortodóntico se mantengan.

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: el retenedor es un dispositivo dental hecho a medida que se adapta sobre (o detrás) los dientes. Está diseñado para ser cómodo y fácil de usar.
- Material: Zendura A, Fase Ortho, acero inoxidable

[Fichas de datos de seguridad del material de retención](#)[Fichas de datos de seguridad del material de alambre fijo](#)**3) Contraindicaciones**

El retenedor no debe utilizarse si el usuario tiene una alergia conocida al plástico/metál o si tiene una afección dental existente que dificulte el uso del dispositivo.

4) Advertencias / Precauciones / Riesgos potenciales

⚠ ADVERTENCIAS

El uso de retenes puede entrañar riesgos potenciales, incluida la rotura. Pueden ser propensos a romperse o agrietarse, especialmente si no se manejan o cuidan adecuadamente. El uso de retenedores puede conllevar riesgos potenciales, incluida la rotura.

⚠ PRECAUCIONES

Ninguna

5) Limpieza y cuidado

Instrucciones de uso

- Para garantizar el uso adecuado de los retenedores extraíbles, los profesionales dentales y los pacientes deben seguir estos pasos:
- Lávese bien las manos antes de manipular el dispositivo.
- Inserte con cuidado el dispositivo sobre los dientes del paciente, comenzando por la parte posterior de la boca y avanzando hacia delante.
- Con los dedos, presione suavemente el dispositivo sobre los dientes del paciente para asegurarse de que ajuste correctamente.

Instrucciones de limpieza

1. Para limpiar el retenedor extraíble, los pacientes deben seguir estos pasos:
2. Utilizar un cepillo de dientes de cerdas suaves y un dentífrico no abrasivo para cepillar suavemente el dispositivo.
3. Enjuague bien el dispositivo con agua fría.
4. No utilice agua caliente, ya que puede deformar el dispositivo.
5. No utilice enjuague bucal, ya que puede decolorar el dispositivo.
6. Limpiar el dispositivo a diario.

Tiempo de uso recomendado

- El tiempo de uso de los retenedores removibles puede variar en función del criterio clínico y de la experiencia del profesional.
- Dandy recomienda:
 - Primeros 3-6 meses:
 - Los retenedores deben llevarse 22 horas al día o más. Solo deben retirarse para cepillarse los dientes, usar hilo dental o comer.
 - Primeros 2 años:
 - El paciente podrá empezar a usar los retenedores únicamente durante el sueño.
 - A partir del tercer año y durante el resto de la vida del paciente:
 - Los retenedores no tienen que usarse con tanta frecuencia; el objetivo es intentar llevarlos en noches alternas.

6) Almacenamiento

Cuando no se utilice, guarde el retenedor removible en el estuche suministrado. Mantenga el estuche en un lugar fresco y seco, alejado de la luz solar directa.

7) Vida esperada / Servicio

Los retenedores ortodónticos, especialmente los de plástico transparente, son difíciles de reciclar en los contenedores convencionales debido a su composición multicapa y a su clasificación como producto sanitario, por lo que la mejor opción es eliminarlos a través de programas dentales de reciclaje especializado o, si es necesario, como residuo sanitario sellado, evitando así la contaminación de vertederos y océanos.

8) Notificación de incidentes / Reclamaciones

Comuniqué 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

Los retenedores ortodónticos, especialmente los de plástico transparente, son difíciles de reciclar en contenedores regulares debido a los plásticos multicapa y la clasificación médica, por lo que la mejor eliminación es a través de programas de dentistas para el reciclaje especializado, o como residuos médicos/sellados si es necesario, evitando la contaminación en vertederos/océanos.

UNION EUROPÉENNE (FRANÇAIS)

INSTRUCTIONS D'UTILISATION (IFU)

Union Européenne — Dispositif sur Mesure (CMD)

GMDN / EMDN	Q010499 - Appareils orthodontiques - autres
Code(s) produit	RTRNLNGF, RTRNZEND, RTRNHLWY, THERMOER
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)

Un dispositif de contention orthodontique est un dispositif dentaire conçu pour maintenir la position des dents après un traitement orthodontique. Il est utilisé pour empêcher les dents de bouger et assurer le maintien des résultats du traitement orthodontique.

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.
- Configuration : Le dispositif de contention est un appareil dentaire sur mesure qui s'adapte sur (ou derrière) les dents. Il est conçu pour être confortable et facile à porter.
- Matériel : Zendura A, Phase Ortho, acier inoxydable

[Fiches de données de sécurité du matériel utilisé pour l'appareil de contention](#)

[Fiche de données de sécurité du fil métallique](#)

3) Contre-indications

L'appareil de contention ne doit pas être utilisé si l'utilisateur présente une allergie connue au plastique ou au métal, ou s'il souffre d'un problème dentaire rendant difficile le port de cet appareil

4) Avertissements / Précautions / Risques potentiels

⚠ Avertissements

L'utilisation d'appareils de contention peut présenter des risques potentiels, y compris la rupture. Ces appareils peuvent se casser ou se fissurer, surtout s'ils ne sont pas manipulés ou entretenus correctement. Mâcher le dispositif de contention ou l'exposer à une chaleur excessive peut augmenter le risque d'endommagement.

⚠ Précautions

NA

5) Nettoyage et entretien

Mode d'emploi

- Afin de garantir une utilisation correcte des appareils de contention amovibles, les professionnels dentaires et les patients doivent suivre les étapes suivantes :
- Se laver soigneusement les mains avant de manipuler l'appareil.
- Insérer avec précaution l'appareil dans les dents du patient, en commençant par l'arrière de la bouche du patient et en progressant vers l'avant.
- Appuyer délicatement avec vos doigts sur l'appareil pour l'ajuster parfaitement sur les dents du patient.

Instructions de nettoyage

1. Pour nettoyer le dispositif de contention amovible, les patients doivent suivre les étapes suivantes :
2. Utiliser une brosse à dents à poils souples et du dentifrice non abrasif pour broser délicatement l'appareil.
3. Rincer soigneusement le dispositif à l'eau froide.
4. Ne pas utiliser d'eau chaude, car elle peut déformer l'appareil.
5. Ne pas utiliser de bain de bouche, car il peut décolorer l'appareil.
6. Nettoyer le dispositif tous les jours.

Durée de port recommandée

- La durée de port des appareils de contention amovibles peut varier en fonction du praticien et de son expérience clinique.
- Dandy recommande :
 - Premiers 3 à 6 mois :
 - Les appareils de contention doivent être portés au moins 22 heures par jour. Il ne faut les retirer que pour se brosser les dents, passer du fil dentaire ou manger.
 - 2 premières années :
 - Le patient pourra commencer à porter ses appareils de contention uniquement pendant son sommeil.
 - De la troisième année jusqu'à la fin de la vie du patient :
 - Il n'est pas nécessaire de porter les appareils de contention aussi souvent ; l'objectif est d'essayer de les porter environ une nuit sur deux.

6) Stockage

Lorsqu'il n'est pas utilisé, ranger l'appareil de contention amovible dans le boîtier prévu à cet effet. Conserver le boîtier dans un endroit frais et sec, à l'abri de la lumière directe du soleil.

7) Durée de vie / Service attendu

La durée de vie des appareils de contention orthodontiques varie selon leur type : les appareils en plastique transparent durent entre 1 et 3 ans, les appareils Hawley traditionnels (fil métallique/résine) entre 5 et 10 ans, et les appareils fixes (fil métallique collé) peuvent durer plus de 10 ans, voire plusieurs

décennies, s'ils sont très bien entretenus. Cependant, tous doivent être remplacés en raison de l'usure, des dommages ou des changements dentaires ; un nettoyage et un rangement appropriés, ainsi que le fait d'éviter la chaleur et les aliments abrasifs, sont essentiels pour garantir leur longévité.

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 appareils de contention orthodontiques, en particulier ceux en plastique transparent, sont difficiles à recycler dans les poubelles ordinaires en raison de leur composition en plusieurs couches de plastique et de leur classification comme déchets médicaux ; il est donc préférable de les éliminer via les programmes de recyclage spécialisés mis en place par les dentistes, ou, si nécessaire, de les traiter comme des déchets médicaux ou des déchets sous emballage hermétique, afin d'éviter la pollution des décharges et des océans.

EUROPÄISCHE UNION (DEUTSCH)**GEBRAUCHSANWEISUNG (IFU)**

EU-SONDERANFERTIGUNG (CMD – Sonderanfertigung)

GMDN / EMDN	Q010499 – Kieferorthopädische Produkte – andere
Produktcode(s)	RTRNLNGF, RTRNZEND, RTRNHLWY, THERMOER

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:	Wiederverwendbar

1) Zweckbestimmung (Verwendungszweck)

Ein kieferorthopädischer Retainer ist ein zahnmedizinisches Produkt, das dazu dient, die Position der Zähne nach einer kieferorthopädischen Behandlung stabil zu halten. Es dient dazu, ein Verschieben der Zähne zu verhindern und den dauerhaften Erhalt des kieferorthopädischen Behandlungsergebnisses zu gewährleisten.

2) Produktbeschreibung / Hauptspezifikationen

- Maßgefertigte, patientenspezifische Sonderanfertigung, hergestellt nach zahnärztlicher Verordnung und digitalen Eingabedaten.
- Konfiguration: Der Retainer ist eine maßgefertigte zahnmedizinische Apparatur, die auf (oder hinter) den Zähnen platziert wird. Er ist so konzipiert, dass er einen hohen Tragekomfort bietet und einfach anzuwenden ist.
- Material: Zendura A, Phase Ortho, Edelstahl

[Sicherheitsdatenblätter für Retainer](#)

[Sicherheitsdatenblatt für festsitzenden Retainerdraht](#)

3) Kontraindikationen

Der Retainer darf nicht verwendet werden, wenn eine bekannte Allergie gegen Kunststoff/Metall vorliegt oder wenn eine bestehende Zahnerkrankung das Tragen des Produkts erschwert.

4) Warnhinweise / Vorsichtsmaßnahmen / Potenzielle Risiken

⚠️ WARNHINWEISE

Die Anwendung von Retainern kann potenzielle Risiken bergen, einschließlich Produktbruch. Sie können anfällig für Brüche oder Risse sein, insbesondere wenn sie nicht ordnungsgemäß gehandhabt oder gepflegt werden. Das Kauen auf dem Retainer oder übermäßige Hitzeeinwirkung kann das Risiko von Beschädigungen erhöhen.

⚠️ VORSICHTSMASSENNAHMEN

NA

5) Reinigung und Pflege

Gebrauchsanleitung

- Um die ordnungsgemäße Anwendung von herausnehmbaren Retainern zu gewährleisten, sollten zahnmedizinisches Fachpersonal und Patienten folgende Schritte befolgen:
- Waschen Sie sich vor der Handhabung des Produkts gründlich die Hände.
- Setzen Sie das Produkt vorsichtig auf die Zähne des Patienten auf, beginnend im hinteren Bereich des Mundes und nach vorne arbeitend.
- Drücken Sie das Gerät mit den Fingern vorsichtig auf die Zähne des Patienten, um einen festen Sitz zu gewährleisten.

Reinigungsanleitung

1. Zur Reinigung des herausnehmbaren Retainers sollten die Patienten folgende Schritte befolgen:
2. Eine Zahnbürste mit weichen Borsten und eine nicht-abrasive Zahnpasta verwenden, um das Produkt vorsichtig abzubürsten.
3. Spülen Sie die Apparatur gründlich mit kaltem Wasser ab.
4. Verwenden Sie kein heißes Wasser, da sich die Apparatur dadurch verziehen kann.
5. Verwenden Sie kein Mundwasser, da dies zu Verfärbungen des Produkts führen kann.
6. Die Apparatur täglich reinigen.

Empfohlene Tragedauer

- Die Tragedauer für herausnehmbare Retainer kann je nach Behandler und klinischer Erfahrung variieren.
- Dandy empfiehlt:
 - Für die ersten 3–6 Monate:
 - Die Retainer sollten mindestens 22 Stunden am Tag getragen werden. Sie sollten ausschließlich zum Zähneputzen, zur Anwendung von Zahnseide oder zum Essen herausgenommen werden.
 - Für die ersten 2 Jahre:
 - Der Patient kann dazu übergehen, seine Retainer ausschließlich während des Schlafens zu tragen.
 - Drittes Jahr bis zum Lebensende des Patienten:
 - Die Retainer müssen nicht mehr so häufig getragen werden; das Ziel ist es, sie etwa jede zweite Nacht zu tragen.

6) Lagerung

Wenn der herausnehmbare Retainer nicht benutzt wird, bewahren Sie ihn in der Zahnschienen-Box auf. Bewahren Sie die Box an einem kühlen, trockenen Ort und geschützt vor direkter Sonneneinstrahlung auf.

7) Erwartete Lebensdauer / Nutzungsdauer

Die Lebenserwartung von orthodontischen Retainern variiert je nach Typ: Transparente Kunststoffschiene weisen eine Haltbarkeit von 1–3 Jahren auf, traditionelle Hawley-Retainer (Draht/Acrylat) von 5–10 Jahren und festsitzende (geklebte) Drahtretainer bei hervorragender Pflege potenziell von über 10 Jahren oder sogar Jahrzehnten; dennoch müssen alle Typen aufgrund von Verschleiß, Beschädigungen oder dentalen Veränderungen ausgetauscht werden, wobei eine ordnungsgemäße Reinigung, Lagerung sowie das Vermeiden von Hitze und harten Lebensmitteln entscheidend für die Langlebigkeit 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

Orthodontische Retainer, insbesondere transparente Kunststoffschienen, sind aufgrund ihrer Mehrschicht-Kunststoffstruktur und ihrer Einstufung als Medizinprodukt in normalen Abfalltonnen schwer zu recyceln, weshalb die beste Entsorgung über Programme von Zahnarztpraxen für spezialisiertes Recycling oder, falls erforderlich, als versiegelter medizinischer Abfall erfolgt, um eine Umweltbelastung von Deponien und Gewässern zu verhindern.

UNIONE EUROPEA (ITALIANO)**ISTRUZIONI PER L'USO (IFU)**

DISPOSITIVO PERSONALIZZATO UE (CMD = Dispositivo personalizzato)

GMDN / EMDN	Q010499 – Dispositivi ortodontici – Altro
Codice(i) prodotto	RTRNLNGF, RTRNZEND, RTRNHLWY, THERMOER

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)

Il retainer ortodontico è un dispositivo odontoiatrico progettato per mantenere la posizione dei denti dopo il trattamento ortodontico. Questo dispositivo viene utilizzato per prevenire lo spostamento dei denti e garantire il mantenimento dei risultati del trattamento ortodontico.

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: il retainer è un dispositivo dentale personalizzato che si applica sopra (o dietro) i denti. È progettato per essere comodo e facile da applicare.
- Materiale: Zendura A, Phase Ortho, acciaio inossidabile

[Schede di sicurezza dei materiali del retainer](#)

[Scheda di sicurezza del materiale del filo fisso](#)

3) Controindicazioni

Il retainer non deve essere utilizzato se l'utilizzatore è allergico alla plastica/metallo o se ha una patologia dentale esistente che rende difficile l'uso del dispositivo.

4) Avvertenze / Precauzioni / Rischi potenziali

AVVERTENZE

L'uso dei retainer può comportare potenziali rischi, inclusa la rottura. Possono essere soggetti a rotture o crepe, soprattutto se non sono manipolati o curati adeguatamente. Masticare il retainer o esporlo a calore eccessivo può aumentare il rischio di danni.

PRECAUZIONI

NA

5) Pulizia e cura

Istruzioni per l'uso

- Per garantire un uso corretto dei retainer rimovibili, gli odontoiatri e i pazienti devono attenersi alla procedura seguente:
- Lavarsi accuratamente le mani prima di maneggiare il dispositivo.
- Inserire con cautela il dispositivo nei denti del paziente, partendo dalla parte posteriore della bocca e procedendo in avanti.
- Usare le dita per premere delicatamente il dispositivo sui denti del paziente per assicurarsi che aderisca.

Istruzioni per la pulizia

1. Per pulire il retainer rimovibile, i pazienti devono seguire i seguenti passaggi:
2. Per spazzolare delicatamente il dispositivo, utilizzare uno spazzolino a setole morbide e un dentifricio non abrasivo.
3. Sciacquare accuratamente il dispositivo con acqua fredda.
4. Non utilizzare acqua bollente, in quanto è in grado di deformare il dispositivo.
5. Non utilizzare collutorio, poiché può scolorire il dispositivo.
6. Pulire il dispositivo ogni giorno.

Tempo di utilizzo consigliato

- I tempi di utilizzo per i retainer rimovibili possono differire in base al medico e all'esperienza clinica.
- Dandy consiglia:
 - Primi 3–6 mesi:
 - I retainer devono essere indossati per 22 ore al giorno o più. L'unico momento in cui devono essere rimossi è quello per spazzolarli e passare il filo interdentale o per mangiare.
 - Primi 2 anni:
 - Il paziente potrà iniziare ad applicare i retainer solo durante il sonno.
 - Dal terzo anno al resto della vita del paziente:
 - I retainer non devono essere applicati con la stessa frequenza; l'obiettivo è quello di cercare di indossarli a notti alterne.

6) Conservazione

Quando non in uso, conservare il retainer rimovibile nella custodia fornita. Conservare la custodia in un luogo fresco e asciutto, lontano dalla luce solare diretta.

7) Durata prevista / Servizio

La durata prevista del dispositivo ortodontico varia a seconda del tipo: quelli in plastica trasparente durano 1–3 anni, quelli tradizionali di Hawley (filo/acrilico) durano 5–10 anni, quelli fissi (filo legato) durano potenzialmente più di 10 anni o addirittura decenni con un'ottima cura. Tutti però hanno bisogno di essere sostituiti a causa di usura, danni o cambiamenti dentali; una corretta pulizia, conservazione ed evitare cibi caldi/abrasivi sono fondamentali per la longevità.

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 retainer ortodontici, in particolare quelli in plastica trasparente, sono difficili da riciclare in contenitori standard a causa della plastica multistrato e della classificazione medica, quindi lo smaltimento migliore avviene attraverso programmi dentistici per il riciclaggio specializzato, o come rifiuti medici/sigillati, se necessario, prevenendo l'inquinamento delle discariche/degli oceani.

UNITED KINGDOM (ENGLISH)**INSTRUCTIONS FOR USE (IFU)**

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	35310
Product Code(s)	RTRNLNGF, RTRNZEND, RTRNHLWY, THERMOER
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 (if applicable)
Single-use / Reusable	Reusable

1) Intended Purpose (Intended Use)

An orthodontic retainer is a dental device designed to maintain the position of teeth following orthodontic treatment. It is used to prevent teeth from shifting and ensure orthodontic treatment results are maintained.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: The retainer is a custom-made dental device that fits over (or behind) the teeth. It is designed to be comfortable and easy to wear.
- Material: Zendura A, Phase Ortho, Stainless Steel

[Retainer Material Safety Data Sheets](#)[Fixed Wire Material Safety Data Sheet](#)**3) Contraindications**

The retainer should not be used if the user has a known allergy to plastic/metal or if they have an existing dental condition that makes it difficult to wear the device

4) Warnings / Precautions / Potential Risks

WARNING

The use of retainers may have potential risks, including breakage. They can be prone to breakage or cracking, especially if they are not handled or cared for properly. Chewing on the retainer or exposing it to excessive heat can increase the risk of damage.

CAUTION

NA

5) Cleaning and Care

Directions for Use

- To ensure the proper use of removable retainers, dental professionals and patients should follow these steps:
- Wash your hands thoroughly before handling the device.
- Carefully insert the device into the patient's teeth, starting from the back of the patient's mouth and working forward.
- Use your fingers to gently press the device onto the patient's teeth to ensure a snug fit.

Cleaning instructions

1. To clean the removable retainer, patients should follow these steps:
2. Use a soft-bristled toothbrush and non-abrasive toothpaste to brush the device gently.
3. Rinse the device thoroughly with cool water.
4. Do not use hot water, as it can warp the device.
5. Do not use mouthwash, as it can discolor the device.
6. Clean the device daily..

Recommended Wear Time

- Wear times for removable retainers can differ based on the clinician and clinical experience.
- Dandy recommends:
 - First 3-6 Months:
 - Retainers should be worn for 22 hours a day or more. The only time they should be removed is to brush and floss or to eat.
 - First 2 Years:
 - The patient will be able to start wearing their retainers only during sleep.
 - Third Year to the Rest of the Patient's Life:
 - Retainers do not have to be worn as frequently; the goal is to attempt to wear them about every other night.

6) Storage

When not in use, store the removable retainer in the provided case. Keep the case in a cool, dry place, away from direct sunlight.

7) Expected Life / Service

Orthodontic retainer life expectancy varies by type, with clear plastic ones lasting 1-3 years, traditional Hawley (wire/acrylic) retainers lasting 5-10 years, and fixed (bonded wire) retainers potentially lasting 10+ years or even decades with excellent care, though all need replacement due to wear, damage, or dental changes; proper cleaning, storage, and avoiding heat/abrasive foods are crucial for longevity.

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

Orthodontic retainers, especially clear plastic ones, are tough to recycle in regular bins due to multi-layer plastics and medical classification, so the best disposal is through dentist programs for specialized recycling, or as medical/sealed waste if necessary, preventing landfill/ocean pollution.

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



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 01:58

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