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	Dental Occlusal Splint
GMDN / EMDN Code	43025
Product Code(s)	TMJNTI, TMJAD, TMJDBS, TMJGA
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	43025
Product Code(s)	TMJNTI, TMJAD, TMJDBS, TMJGA

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 (if applicable)
Single-use / Reusable	Single-use

1) Intended Purpose (Intended Use)

Dandy TMJ Appliances are intended to reduce pain and discomfort in the TMJ and sometimes help re-train muscles to avoid these movements.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: The devices are worn while sleeping to support patients' TMJ in the position prescribed by the dentists. The appliances are removable by the patient.
- Material: Erkodent Disc

Night Guard Material Safety Data Sheets

3) Contraindications

For the select subset of patients who have surgery to treat TMD or any TMJ issues, any further treatment with TMJ appliances or splints should be prescribed by the surgeon.

4) Warnings / Precautions / Potential Risks

⚠ WARNING

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Obstruction of oral breathing
- Excessive salivation

⚠ CAUTION

Dentists should consider the medical history of their patients. Including history of arthritis, surgery, impact trauma, any previous TMJ treatment, respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.

5) Cleaning and Care

Appliance Fit & Adjustments

- The dental staff or dentist should remove the appliance from its packaging and rinse it under water. Then, place the device in the patient's mouth, checking for the proper fit and function of the appliance. The prescribing dentist should always perform the appliance adjustments. Any adjustments in the fit of the device should easily be made chairside to ensure that the patient is pleased with the fit and function of their new appliance.

Operating Instructions

CLEANING

- Brush with a soft-bristle toothbrush before each use.

FIT ADJUSTMENT

- The prescribing dentist or physician should make all adjustments.

REMOVAL INSTRUCTIONS

- To remove the appliance properly, use both index fingers to pull down the front area of the upper appliance.

For Dawson B-splint,

- Do this for the upper first; second, for the lower, pull up in the front area.
- To avoid breakage, do not pull down the back of the appliance.

6) Storage

Dry and store in the provided case when not in use..

7) Expected Life / Service

Expect a 2-3 year product life with the appliance.

Appliance replacement signs are cracks in the acrylic and failure of the device to maintain retention in the patient's mouth.

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

Disposing of a TMJ appliance depends on its material and your location, but generally involves treating it as a small electronic/medical item, focusing on local rules for special waste.

If the item requires refabrication, Dandy requests that the item be returned so the hardware can be retrieved.

EUROPEAN UNION (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

European Union — Custom-Made Device (CMD)

GMDN / EMDN	Q0199: ODONTOLOGY DEVICES - OTHER
Product Code(s)	TMJNTI, TMJAD, TMJDBS, TMJGA

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)

Dandy TMJ Appliances are intended to reduce pain and discomfort in the TMJ and sometimes help re-train muscles to avoid these movements.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: The devices are worn while sleeping to support patients' TMJ in the position prescribed by the dentists. The appliances are removable by the patient.
- Material: Erkodent Disc

Night Guard Material Safety Data Sheets

3) Contraindications

For the select subset of patients who have surgery to treat TMD or any TMJ issues, any further treatment with TMJ appliances or splints should be prescribed by the surgeon.

4) Warnings / Precautions / Potential Risks

⚠ WARNING

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Obstruction of oral breathing
- Excessive salivation

⚠ CAUTION

Dentists should consider the medical history of their patients. Including history of arthritis, surgery, impact trauma, any previous TMJ treatment, respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.

5) Cleaning and Care

Appliance Fit & Adjustments

- The dental staff or dentist should remove the appliance from its packaging and rinse it under water. Then, place the device in the patient's mouth, checking for the proper fit and function of the appliance. The prescribing dentist should always perform the appliance adjustments. Any adjustments in the fit of the device should easily be made chairside to ensure that the patient is pleased with the fit and function of their new appliance.

Operating Instructions

CLEANING

- Brush with a soft-bristle toothbrush before each use.

FIT ADJUSTMENT

- The prescribing dentist or physician should make all adjustments.

REMOVAL INSTRUCTIONS

- To remove the appliance properly, use both index fingers to pull down the front area of the upper appliance.
- For Dawson B-splint,
- Do this for the upper first; second, for the lower, pull up in the front area.
- To avoid breakage, do not pull down the back of the appliance.

6) Storage

Dry and store in the provided case when not in use..

7) Expected Life / Service

Expect a 2-3 year product life with the appliance.

Appliance replacement signs are cracks in the acrylic and failure of the device to maintain retention in the patient's mouth.

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

- Disposing of a TMJ appliance depends on its material and your location, but generally involves treating it as a small electronic/medical item, focusing on local rules for special waste.
- If the item requires refabrication, Dandy requests that the item be returned so the hardware can be retrieved.

UNIÓN EUROPEA (ESPAÑOL)

INSTRUCCIONES DE USO (IFU)

Unión Europea — Producto Sanitario a Medida (CMD)

GMDN / EMDN	Q0199: DISPOSITIVOS DE ODONTOLOGÍA - OTROS
Código(s) del producto	TMJNTI, TMJAD, TMJDBS, TMJGA

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 (si procede)
De un solo uso / Reutilizable	un solo uso

1) Finalidad prevista (uso previsto)

Los dispositivos para la ATM de Dandy están diseñados para reducir el dolor y las molestias en la ATM y, en algunos casos, ayudar a reeducar la musculatura para evitar esos movimientos.

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: Los dispositivos se usan mientras duermen para apoyar la ATM de los pacientes en la posición prescrita por los dentistas. El paciente puede retirar los aparatos.
- Material: Disco de Erkodent

Hojas de datos de seguridad del material de Night Guard

3) Contraindicaciones

Para el subgrupo concreto de pacientes que se someten a cirugía para tratar trastornos temporomandibulares o cualquier problema de la ATM, cualquier tratamiento posterior con aparatos para la ATM o férulas deberá ser prescrito por el cirujano.

4) Advertencias / Precauciones / Riesgos potenciales

⚠ ADVERTENCIAS

- Movimiento dental o cambios en la oclusión dental
- Dolor gingival o dentario
- Dolor gingival o dentario
- Dolor o molestias en la articulación temporomandibular
- Salivación excesiva

⚠ PRECAUCIONES

Los dentistas deben tener en cuenta el historial clínico de sus pacientes. Deben tenerse en cuenta los antecedentes de artritis, cirugía, traumatismos, tratamientos previos de la ATM, trastornos respiratorios u otros problemas de salud relevantes, y derivar al paciente al profesional sanitario adecuado antes de prescribir el dispositivo.

5) Limpieza y cuidado

Ajuste y adaptación del aparato

- El personal dental o el dentista deben retirar el aparato de su embalaje y enjuagarlo bajo el agua. A continuación, coloque el dispositivo en la boca del paciente, comprobando que el aparato se ajusta y funciona correctamente. El dentista prescriptor siempre debe realizar los ajustes del aparato. Cualquier ajuste del dispositivo debe poder realizarse fácilmente en clínica para garantizar que el paciente quede satisfecho con el ajuste y el funcionamiento de su nuevo aparato.

Instrucciones

LIMPIEZA

- Cepille con un cepillo de cerdas suaves antes de cada uso.

AJUSTE

- El dentista o el médico prescriptor deben hacer todos los ajustes.

INSTRUCCIONES DE RETIRADA

- Para retirar correctamente el aparato, utilice los dos dedos índices para descender la zona frontal del aparato superior.

Para la férula Dawson B,

- haga esto primero en la parte superior; después, en la parte inferior, tire hacia arriba de la zona frontal.
- Para evitar roturas, no tire hacia abajo de la parte posterior del aparato.

6) Almacenamiento

Seque y guarde en el estuche suministrado cuando no esté en uso.

7) Vida esperada / Servicio

Espere una vida útil del producto de 2 a 3 años con el aparato.

Los signos de que el aparato debe sustituirse incluyen grietas en el acrílico y la incapacidad del dispositivo para mantener la retención en la boca del paciente.

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

- Los signos de que el aparato debe sustituirse incluyen grietas en el acrílico y la incapacidad del dispositivo para mantener la retención en la boca del paciente.
- Si el artículo requiere refabricación, Dandy solicita que se devuelva para poder recuperar los componentes.

UNION EUROPÉENNE (FRANÇAIS)

INSTRUCTIONS D'UTILISATION (IFU)

Union Européenne — Dispositif sur Mesure (CMD)

GMDN / EMDN	Q0199 : DISPOSITIFS ODONTOLOGIQUES - AUTRES
Code(s) produit	TMJNTI, TMJAD, TMJDBS, TMJGA

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 (le cas échéant)
Usage unique / Réutilisable	Usage unique

1) Usage prévu (utilisation prévue)

Les appareils Dandy pour l'articulation temporo-mandibulaire (ATM) sont conçus pour réduire la douleur et l'inconfort au niveau de l'ATM et, dans certains cas, aider à rééduquer les muscles afin d'éviter ces mouvements.

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 : Ces appareils sont portés pendant le sommeil afin de maintenir l'articulation temporo-mandibulaire des patients dans la position prescrite par les dentistes. Les appareils sont amovibles par le patient.
- Matériel : Disque Erkodent

Fiches de données de sécurité des matériaux pour gouttières de nuit

3) Contre-indications

Pour le groupe restreint de patients qui subissent une intervention chirurgicale pour traiter un trouble de l'articulation temporo-mandibulaire (ATM) ou tout autre problème lié à l'ATM, tout traitement complémentaire à l'aide d'appareils ou d'attelles doit être prescrit par le chirurgien.

4) Avertissements / Précautions / Risques potentiels

⚠ AVERTISSEMENTS

- Mouvement dentaire ou modifications de l'occlusion dentaire
- Douleurs gingivales ou dentaires
- Douleur ou douleur à l'articulation temporomandibulaire
- Obstruction de la respiration orale
- Salivation excessive

⚠ PRECAUTIONS

Les dentistes doivent tenir compte des antécédents médicaux de leurs patients. Y compris les antécédents d'arthrite, d'interventions chirurgicales, de traumatismes par choc, de traitements antérieurs de l'articulation temporo-mandibulaire, de troubles respiratoires ou d'autres problèmes de santé pertinents, et orienter le patient vers le professionnel de santé compétent avant de prescrire l'appareil.

5) Nettoyage et entretien

Installation et réglage de l'appareil

- Le personnel dentaire ou le dentiste doit retirer l'appareil de son emballage et le rincer à l'eau. Ensuite, placer le dispositif dans la bouche du patient, en vérifiant que l'appareil est correctement ajusté et fonctionnel. Le dentiste prescripteur doit toujours effectuer les réglages de l'appareil. Tout ajustement de l'appareil doit pouvoir être effectué facilement en cabinet afin de s'assurer que le patient est satisfait du confort et du fonctionnement de son nouvel appareil.

Instructions d'utilisation

NETTOYAGE

- Nettoyer avec une brosse à dents à poils souples avant chaque utilisation.

AJUSTEMENT

- Le dentiste ou le médecin prescripteur doit effectuer tous les ajustements.

INSTRUCTIONS DE RETRAIT

- Pour retirer l'appareil correctement, utiliser les deux index pour abaisser la partie avant de l'appareil supérieur.

Pour Dawson B-splint,

- Commencer par le haut ; ensuite, pour le bas, tirer vers le haut au niveau de la partie avant.
- Pour éviter tout risque de casse, ne pas tirer sur l'arrière de l'appareil.

6) Stockage

Sécher et stocker dans le boîtier fourni lorsqu'il n'est pas utilisé.

7) Durée de vie / Service attendu

Prévoir une durée de vie de 2 à 3 ans pour cet appareil.

Les signes indiquant qu'il faut remplacer l'appareil sont la présence de fissures dans l'acrylique et l'incapacité de l'appareil à rester en place dans la bouche du patient.

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)
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- 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

- L'élimination d'un appareil pour l'articulation temporo-mandibulaire dépend de son matériau et de votre lieu de résidence, mais consiste généralement à le traiter comme un petit appareil électronique ou médical, en respectant les réglementations locales relatives aux déchets spéciaux.
- Si l'article doit être refabriqué, Dandy demande qu'il lui soit renvoyé afin de pouvoir récupérer les pièces.

EUROPÄISCHE UNION (DEUTSCH)

GEBRAUCHSANWEISUNG (IFU)

EU-SONDERANFERTIGUNG (CMD – Sonderanfertigung)

GMDN / EMDN	Q0199: ODONTOLOGY DEVICES - OTHER
Produktcode(s)	TMJNTI, TMJAD, TMJDBS, TMJGA

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)

Dandy TMJ Appliances – Dandy (Kiefergelenkschienen) sind dafür bestimmt, Schmerzen und Beschwerden im Kiefergelenk zu lindern und können in einigen Fällen dazu beitragen, die Muskeln umzutrainieren, um diese Bewegungen zu vermeiden.

2) Produktbeschreibung / Hauptspezifikationen

- Maßgefertigte, patientenspezifische Sonderanfertigung, hergestellt nach zahnärztlicher Verordnung und digitalen Eingabedaten.
- Konfiguration: Die Schienen werden während des Schlafens getragen, um das Kiefergelenk des Patienten in der vom Zahnarzt verordneten Position zu unterstützen. Die Schienen können vom Patienten selbst herausgenommen werden.
- Material: Tiefziehfolie

Sicherheitsdatenblätter für Aufbissschienen

3) Kontraindikationen

Für die ausgewählte Gruppe von Patienten, die sich einem chirurgischen Eingriff zur Behandlung von CMD oder anderen Kiefergelenksproblemen unterziehen, sollte jede weitere Behandlung mit Kiefergelenkschienen oder Aufbissschienen vom Chirurgen verordnet werden.

4) Warnhinweise / Vorsichtsmaßnahmen / Potenzielle Risiken

⚠ WARNHINWEISE

- Zahnbewegungen oder Veränderungen der Okklusion
- Druckschmerzhaftigkeit von Zahnfleisch oder Zähnen
- Schmerzen oder Empfindlichkeit im Kiefergelenk
- Behinderung der Mundatmung
- Übermäßiger Speichelfluss

⚠ VORSICHTSMASSNAHMEN

Die Zahnärzte sollten die Krankengeschichte ihrer Patienten berücksichtigen. Einschließlich einer Vorgeschichte von Arthritis, Operationen, Gewalttrauma, früheren Kiefergelenksbehandlungen, Atemwegserkrankungen oder anderen relevanten Gesundheitsproblemen, und den Patienten vor der Verordnung der Schiene an den entsprechenden Facharzt überweisen.

5) Reinigung und Pflege

Passform und Anpassung der Schiene

- Das Praxispersonal oder der Zahnarzt sollte die Schiene aus der Verpackung nehmen und unter Wasser abspülen. Setzen Sie das Produkt anschließend in den Mund des Patienten ein und überprüfen Sie die ordnungsgemäße Passform und Funktion der Schiene. Die Anpassungen der Schiene sollten immer vom verordnenden Zahnarzt durchgeführt werden. Jegliche Anpassungen der Passform des Produkts sollten problemlos direkt während der Behandlung in der Praxis vorgenommen werden, um sicherzustellen, dass der Patient mit dem Sitz und der Funktion der neuen Schiene zufrieden ist.

Anwendungshinweise
REINIGUNG

- Vor jedem Gebrauch mit einer Zahnbürste mit weichen Borsten abbürsten.

PASSFORM-ANPASSUNG

- Alle Anpassungen sollten von dem verordnenden Zahnarzt oder Arzt vorgenommen werden.

ANLEITUNG ZUM HERAUSNEHMEN

- Um das Gerät ordnungsgemäß zu entfernen, ziehen Sie mit beiden Zeigefingern den vorderen Bereich der oberen Schiene nach unten.
- Bei einer Dawson-B-Schiene:
  - Führen Sie dies zuerst für die obere Schiene durch; ziehen Sie anschließend für die untere Schiene den vorderen Bereich nach oben.
  - **Um einen Bruch zu vermeiden, ziehen Sie die Schiene nicht im hinteren Bereich nach unten.**

6) Lagerung

Trocknen Sie die Schiene und bewahren Sie sie bei Nichtgebrauch in der bereitgestellten Box auf

7) Erwartete Lebensdauer / Nutzungsdauer

Es ist mit einer Produktlebensdauer der Schiene von 2 bis 3 Jahren zu rechnen.

- Anzeichen für einen Austausch der Schiene sind Risse im Acryl sowie ein unzureichender Halt des Produkts im Mund des Patienten.

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

- Die Entsorgung einer Kiefergelenkschiene hängt von ihrem Material und Ihrem Standort ab, erfolgt jedoch im Allgemeinen wie bei einem medizinischen oder elektronischen Kleingerät, wobei die örtlichen Vorschriften für Sonderabfall zu beachten sind.
- Falls das Produkt neu angefertigt werden muss, bittet Dandy um Rücksendung des Artikels, damit die Metallteile/Komponenten wiederverwendet werden können.

UNIONE EUROPEA (ITALIANO)

ISTRUZIONI PER L'USO (IFU)

DISPOSITIVO PERSONALIZZATO UE (CMD = Dispositivo personalizzato)

GMDN / EMDN	Q0199: ODONTOLOGY DEVICES - OTHER
Codice(i) prodotto	TMJNTI, TMJAD, TMJDBS, TMJGA

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	Monouso

1) Scopo previsto (uso previsto)

Gli apparecchi per ATM Dandy sono destinati a ridurre il dolore e il disagio nell'articolazione temporomandibolare (ATM) e a volte aiutano a rieducare i muscoli per evitare questi movimenti.

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 dispositivi vengono indossati durante il sonno per supportare l'ATM del paziente nella posizione prescritta dai dentisti. Gli apparecchi sono rimovibili dal paziente.
- Materiale: disco Erkodent

Schede di sicurezza del materiale per night guard

3) Controindicazioni

Per il sottogruppo selezionato di pazienti sottoposti a intervento chirurgico per trattare problemi associati a TMD o ATM, qualsiasi ulteriore trattamento con apparecchi o splint per ATM deve essere prescritto dal chirurgo.

4) Avvertenze / Precauzioni / Rischi potenziali

⚠ AVVERTENZE

- Movimento dei denti o alterazioni dell'occlusione dentale
- Dolore gengivale o dentale
- Dolore o indolenzimento dell'articolazione temporomandibolare
- Ostruzione della respirazione orale

- Salivazione eccessiva

⚠ **PRECAUZIONI**
I dentisti devono considerare l'anamnesi clinica dei loro pazienti, fra cui l'anamnesi di artrite, interventi chirurgici, traumi da impatto, qualsiasi precedente trattamento per ATM, disturbi respiratori o altri problemi di salute pertinenti, e inviare il paziente all'operatore sanitario appropriato prima di prescrivere il dispositivo.

5) Pulizia e cura

Vestibilità e regolazioni dell'apparecchio

- Il personale odontoiatrico o il dentista deve rimuovere l'apparecchio dalla sua confezione e sciacquarlo sotto l'acqua. Quindi, posizionare il dispositivo nella bocca del paziente, verificando il corretto posizionamento e il funzionamento dell'apparecchio. Il dentista prescrittore deve sempre eseguire le regolazioni dell'apparecchio. Eventuali regolazioni del dispositivo devono essere effettuate facilmente alla poltrona per garantire che il paziente sia soddisfatto della vestibilità e del funzionamento del nuovo apparecchio.

Istruzioni per l'uso
PULIZIA

- Spazzolare con uno spazzolino a setole morbide prima di ogni utilizzo.

REGOLAZIONE DELLA VESTIBILITÀ

- Il dentista o il medico prescrittore deve apportare tutte le regolazioni necessarie.

ISTRUZIONI PER LA RIMOZIONE

- Per rimuovere correttamente l'apparecchio, usare gli indici per abbassare l'area anteriore dell'apparecchio superiore.
- Per lo splint Dawson B,
  - Seguire questa procedura prima per la parte superiore; poi, per quella inferiore, tirare verso l'alto nell'area anteriore.

Per evitare rotture, non tirare verso il basso il retro dell'apparecchio.

6) Conservazione

Asciugare e conservare nella custodia fornita quando non in uso.

7) Durata prevista / Servizio

Prevedere una durata di 2–3 anni.

- Le crepe nell'acrilico sono segni che indicano la necessità di sostituzione dell'apparecchio che impediscono al dispositivo di rimanere fermo nella bocca del paziente.

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

- Lo smaltimento di un apparecchio per ATM dipende dal suo materiale e dalla sua posizione, ma in genere prevede il trattamento come piccolo prodotto elettronico/medico, basandosi sulle norme locali per rifiuti speciali.
- Se l'articolo richiede una rigenerazione, Dandy chiede la restituzione dell'articolo in modo da poter recuperare i componenti metallici.

UNITED KINGDOM (ENGLISH)

INSTRUCTIONS FOR USE (IFU)

United Kingdom — Custom-Made Device (CMD)

GMDN / EMDN	43025
Product Code(s)	TMJNTI, TMJAD, TMJDBS, TMJGA

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	Single-use

1) Intended Purpose (Intended Use)

Dandy TMJ Appliances are intended to reduce pain and discomfort in the TMJ and sometimes help re-train muscles to avoid these movements.

2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: The devices are worn while sleeping to support patients' TMJ in the position prescribed by the dentists. The appliances are removable by the patient.
- Material: Erkodent Disc

Night Guard Material Safety Data Sheets

3) Contraindications

For the select subset of patients who have surgery to treat TMD or any TMJ issues, any further treatment with TMJ appliances or splints should be prescribed by the surgeon.

4) Warnings / Precautions / Potential Risks

⚠ WARNING

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Obstruction of oral breathing
- Excessive salivation

⚠ CAUTION

Dentists should consider the medical history of their patients. Including history of arthritis, surgery, impact trauma, any previous TMJ treatment, respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.

5) Cleaning and Care

Appliance Fit & Adjustments

- The dental staff or dentist should remove the appliance from its packaging and rinse it under water. Then, place the device in the patient's mouth, checking for the proper fit and function of the appliance. The prescribing dentist should always perform the appliance adjustments. Any adjustments in the fit of the device should easily be made chairside to ensure that the patient is pleased with the fit and function of their new appliance.

Operating Instructions

CLEANING

- Brush with a soft-bristle toothbrush before each use.

FIT ADJUSTMENT

- The prescribing dentist or physician should make all adjustments.

REMOVAL INSTRUCTIONS

- To remove the appliance properly, use both index fingers to pull down the front area of the upper appliance.

For Dawson B-splint,

- Do this for the upper first; second, for the lower, pull up in the front area.
- To avoid breakage, do not pull down the back of the appliance.

6) Storage

Dry and store in the provided case when not in use. .

7) Expected Life / Service

Expect a 2-3 year product life with the appliance.

Appliance replacement signs are cracks in the acrylic and failure of the device to maintain retention in the patient's mouth.

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

- Disposing of a TMJ appliance depends on its material and your location, but generally involves treating it as a small electronic/medical item, focusing on local rules for special waste.
- If the item requires refabrication, Dandy requests that the item be returned so the hardware can be retrieved.

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 01:40

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