

## INSTRUCTIONS FOR USE (IFU) - UK CUSTOM-MADE DEVICE (CMD - Custom Made Device)

Device Family: Dental Occlusal Splint  
GMDN: 43025  
Product Code(s): TMJNTI, TMJAD, TMJDBS, TMJGA

Manufacturer:  
Zima International, Inc. Also DBA Dandy  
1320 N. 300 W.  
Lehi, UT 84043  
United States

### Contact:

UK Responsible Person (UKRP):  
Name = DANDY LABS GB, LTD  
Company Number = 16873608  
Registered Address = 5 New Street Square, London EC4A 3TW.

**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)

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

#### WARNINGS

- Tooth movement or changes in dental occlusion

- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Obstruction of oral breathing
- Excessive salivation

#### PRECAUTIONS

- 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 (Patient Care Instructions — as directed by the dental professional)**

##### 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 (UK)**

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) in accordance with local requirements.

### **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.