

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

Device Family: Bite Registration Rim Wax

GMDN: 38602

Product Code(s): WAXRIM, SWAXPH

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:** Single-use

### 1) Intended Purpose (Intended Use)

Dandy's Wax Rim is a dental appliance that creates an accurate and comfortable fit for restorations. It serves as a temporary framework to guide the bite registration process and establish a VDO. Dandy's Wax Bite Rim is a digitally designed and manufactured dental appliance. It is made from high-quality materials and crafted to provide a precise fit for optimal patient comfort.

### 2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Acrylic base with wax blocks.
- Material: )

[Full Dentures Material Safety Data Sheets](#)

[Partial Dentures Material Safety Data Sheets](#)

### 3) Contraindications

The Wax Bite Rim should not be used in the following situations:

- Severe gum disease or oral infections
- Uncontrolled bleeding disorders

- Allergy or hypersensitivity to the materials used in the device
- Patients who are unable to follow instructions or communicate effectively

#### **4) Warnings / Precautions / Potential Risks**

- Using the Wax Bite Rim carries certain risks, including
  - potential allergic reactions and temporary discomfort.
- To ensure safe and effective use of the Wax Bite Rim, please be aware of the following:
  - This device is intended for use by dental professionals only.
  - Follow the case-specific instructions provided by Dandy carefully.
  - Do not modify or adjust the device without professional guidance.
  - Discontinue use if any discomfort or adverse reactions occur.

#### **5) Cleaning and Care (Patient Care Instructions — as directed by the dental professional)**

##### Directions for Use

- The Wax Bite Rim aims to provide a precise fit, resulting in improved functionality and aesthetics.
- The associated procedure involves taking a bite registration to record the patient's occlusal relationship.

##### Setup instructions:

- Before using the device, thoroughly wash your hands with soap and water.
- Position the Denture Wax Bite Rim in the patient's mouth, evaluate the fit and dimensions of the wax rim intra-orally, and adjust accordingly.
- Border mold the periphery of the wax rim using compound, wax, or heavy body PVS material, having patients perform functional movements. (It is recommended to use PVS tray adhesive.)
- Apply a light body wash and have patients repeat functional movements.
- Trim any excess impression material that may be covering the occlusal or facial portion of the wax rim.
- Adjust the wax rim for proper VDO, bite, and lip support.
- Evaluate the "F, V," and "S" sounds to verify the dimensions of the wax rim.
- Clearly mark the wax bite rim with the patient's smile lines, canine lines, and midlines.
- Also, cut notches in the occlusal and mark up the rest of the unmarked wax rim to break up the monotony of the flat wax. This will greatly assist in capturing the 360-degree scan.
- Capture bite registration and trim excess material away from the buccal and facial sides of the wax rim.
- Perform a 360-degree extraoral scan of the wax bite rim(s).
- Follow any additional instructions provided regarding specific adjustments or tasks.

#### **6) Storage**

To store dental Wax Rims, keep them clean, cool, and away from direct sun/heat to prevent distortion; for short-term, a sealed container works, but for longer storage, especially if they're

part of a denture base, keep them moist (in water/solution) in a secure, covered case to maintain shape and prevent drying, but avoid hot water which can warp them

### **7) Expected Life / Service**

The Wax Bite Rim is designed to withstand normal usage. However, like any dental appliance, it may eventually require replacement due to wear and tear.

The expected lifespan of the device can vary depending on individual factors

### **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**

- Wax rim disposal typically involves handling it as either regulated biohazardous waste or general waste, often through specialized handlers for incineration or secure landfill disposal.
- Always avoid putting them in regular trash without checking local rules.
- Biohazard/Infectious Waste: Treat used or unclaimed wax rims as biohazardous due to saliva/blood; use red bags and authorized carriers.
- Incineration: A common method for final destruction.
- Confidentiality: Redact or destroy patient info on lab boxes before disposal.