

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

Device Family: Sleep-Disordered Breathing Orthosis

GMDN: 47526

Product Code(s): SLEEPAPD, SLEEPAPH

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)

A Dandy sleep apnea device is a type of dental device used to treat snoring and mild to moderate obstructive sleep apnea. It is also known as a mandibular advancement device or mandibular repositioning device.

### 2) Device Description / Key Specifications

- Custom-made, patient-specific device manufactured per dental professional prescription and digital input data.
- Configuration: Dandy devices are custom-made to fit your patient's mouth and are designed to be as comfortable and unobtrusive as possible.
- Material: PMMA Block

[PMMA Block](#)

### 3) Contraindications

Sleep apnea devices may not be appropriate for individuals with severe respiratory conditions, such as severe chronic obstructive pulmonary disease (COPD), severe asthma, or other conditions that the use of positive airway pressure could exacerbate.

Oral devices, which are used to treat sleep apnea by repositioning the jaw and tongue, may not be suitable for individuals with severe dental issues, such as untreated gum disease or

extensive tooth decay. Similarly, individuals with severe jaw problems or temporomandibular joint (TMJ) disorders may require careful evaluation to determine if an oral appliance is appropriate.

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

It is common for patients to experience some initial discomfort or soreness when the appliance is first placed or adjusted. This discomfort usually subsides as the patient adapts to the device.

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

Directions for Use

- To ensure proper use of the devices, follow these steps:
  - Before inserting the sleep apnea device, brush and floss the teeth and rinse the mouth with water to ensure good oral hygiene and prevent any food particles from getting trapped under the device.
  - The appliance is crafted to cover the upper and lower teeth and stays secure through adaptable metallic connectors. You may engage the device by means of adjustable lugs or by the Herbst® mechanism, which is a rod and tube assembly that orients the jaws in a predetermined relationship. Place the upper piece of the appliance in the patient's mouth and have the patient bite down gently to position it properly.
  - The Herbst® is a one-piece construction held together by two adjustment mechanisms on the buccal or outer area of the upper and lower appliances. The adjustment mechanisms are designed for the doctor to advance the mandible to the desired position incrementally. Dorsal is a two-piece design with separate upper and lower acrylic portions that, when engaged, propel the mandible into a protrusive position via acrylic fins built in the lower acrylic portion.
  - The Dorsal is an adjustable design utilizing advancement; once the upper piece is in place, insert the lower piece of the device, and then adjust the metal connectors to hold the lower jaw in a slightly advanced position. Finding the most comfortable and effective position may require some trial and error.
  - The patient should breathe through their nose and ensure that the appliance is properly seated and comfortable. It may take some time to adjust to the feeling of the appliance in the mouth, but most patients find that they can sleep comfortably with it in place.
  - The patient is advised to use the device according to the guidelines provided by your practice, which may encompass detailed instructions regarding the daily duration of wear and the appropriate times for removal.

Cleaning instructions

- Dandy recommends cleaning your sleep apnea device daily before and after every use. Immediately after removal, use warm water (not to exceed 45°C/113°F) and soap to remove remaining saliva and debris from the device. The manufacturer advises against immersing the device in solutions, which could lead to delamination.

#### **6) Storage**

Use a case specifically designed for dental devices to protect them from contamination and damage. The case should have good airflow to prevent moisture buildup.

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

Sleep apnea mouth appliances (oral appliances) typically last 2 to 5 years, but this duration can vary depending on the design and care. Signs indicating the need for replacement include a poor fit, wear, or reduced effectiveness. Therefore, regular dental check-ups are crucial to monitor their condition and ensure they remain functional.

### **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**

To dispose of a sleep apnea oral appliance, you should primarily consult with your dental specialist or use local e-waste/recycling facilities. Do not dispose of it with regular household trash unless directed by local regulations.