

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

Device Family: Orthodontic Retainer

GMDN: 35310

Product Code(s): RTRNLNGF, RTRNZEND, TRTRNHLWY, HERMOER,

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)

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

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.

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

.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 (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

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.