

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

Device Family: Aligner

GMDN: 44738

Product Code(s): ALGNCLEAR, RTRNZEND

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)

The Dandy Clear Aligners System contains a sequence of doctor-approved, custom-processed, clear plastic removable aligners that gradually move the patient's permanent teeth in small increments from their original misalignment to a more optimal, aligned, and treated state. This personalized medical device is intended only for use by the individual specified on the packaging.

### 2) Device Description / Key Specifications

- The Dandy Clear Aligners System is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.

- Configuration: sequential trays

- Material: Zendura A (Aligner), Zendura FLX (Retainer)

[Aligner and Retainer Material Safety Data Sheets](#)

### 3) Contraindications

Not to be used if the patient is allergic to plastics. It is not advised for patients with active periodontal disease.

### 4) Warnings / Precautions / Potential Risks

#### Warnings:

- In rare occurrences, patients may be allergic to the thermoplastic polyurethane material of the aligners. Advise patients that if swelling or extreme redness occurs, discontinue use immediately and consult you or other health care professionals.
- In rare occurrences, HAE (hereditary angioedema) patients may experience local swelling, which dental procedures or appliances can trigger. If extreme swelling occurs, advise patients to discontinue use immediately and consult you or other health care professionals.
- Because the aligners are worn in the mouth, accidental swallowing or aspiration of the appliance may occur and may be harmful if not immediately addressed.

#### Potential Risks:

- Keep aligners away from hot water and harsh chemical solutions.
- Keep aligners out of reach for both young children and pets. When not in use, store aligners in the provided case.
- Aligners worn out of sequence can delay treatment and result in complications, including patient discomfort. Always follow the prescribed order and wear aligners.
- Uncharacteristically shaped teeth and missing teeth can potentially extend treatment time and may affect the potential to achieve desired results.
- Existing fixed dental restorations (crowns, bridges) may become dislodged during aligner wear and may require re-cementing or replacement. Any new fixed dental restorations placed during aligner treatment may require a revised treatment plan and new aligner(s).
- Aligner appliances are not effective for the movement of dental implants.
- Certain medications and medical conditions can affect orthodontic treatment. Patients should consult their prescribing physician before beginning treatment.
- Sensitivity and tenderness to teeth may occur during treatment, especially when moving from one aligner step to the next.
- Aligner wear may temporarily affect speech, resulting in a slight lisp. Patients typically adapt quickly to the aligners within a week or two.
- Patients may experience an increase in salivation or dryness of the mouth. Some medications can increase this.
- Extended treatment time may occur due to poor compliance with the doctor's instructions, wearing aligners less than the prescribed hours, missing appointments, poor oral hygiene, excessive bone growth, or broken appliances. Increased cost and/or the ability to achieve the desired results may occur.
- Irritation of the soft tissue in the mouth (gums, cheeks, tongue, and lips) may occur. Patients should consult with you if this persists.
- Some treatment plans may require "attachments" (small bumps of tooth-colored composite material) to be temporarily bonded to one or more teeth to assist with tooth movement. These are critical to proper movement and should be replaced if they fall off.
- All "attachments" should be removed upon treatment completion.
- Tooth decay, permanent stains or decalcification, and periodontal disease (inflammation of the gums) may occur if proper oral hygiene is not followed and preventive maintenance is not followed.

- In the presence of severe crowding, interproximal reduction (IPR—reducing the thickness of enamel on the tooth) may be required to produce enough space for proper tooth movement and alignment. The risks associated with IPR as part of treatment should be considered.
- The health of the gums and bone, both of which support the patient's teeth, can be affected by wearing aligners.
- Throughout the course of treatment, the bite will change and may result in temporary patient discomfort in the jaw joint. Although rare, patients may experience joint pain, headaches, or ear problems. Patients should inform their doctor if any of these symptoms occur.
- At the end of the treatment, it may be necessary to adjust the bite.
- All teeth should be at least partially covered by aligners to avoid supra-eruption of the teeth.
- Aligner wear can aggravate teeth, including previously traumatized or significantly restored teeth. In rare occurrences, additional dental treatment might be required, such as, but not limited to, endodontic treatment, additional restorative treatment, or the tooth may be lost.
- Root resorption (shortening of the root of the tooth) can occur during any orthodontic treatment, including aligner appliances, and could threaten the longevity of the teeth.
- Supplemental treatment, in addition to aligner appliances, may be required for severe open bite, overjet, excessive crowding, or skeletal jaw disproportions. All surgery and anesthesia risks must be considered before treatment if oral surgery is required.
- Other fixed and/or removable orthodontic appliances may be required for more complicated treatment plans where aligners alone will not be adequate to achieve the desired outcome.
- Once treatment has been completed, teeth may shift positions if the proper and consistent wearing of retainers is not followed.
- Upon completion of aligner treatment, some cases may require enhancement with additional aligners, traditional orthodontic treatment, and/or cosmetic restorations such as veneers or crowns to achieve ideal results. Successful treatment outcomes are not guaranteed.

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

- Rinse the new aligners with cold water before wearing them.
- If any extractions have been performed before aligner treatment begins, space should be maintained while healing occurs. Attachments should only be applied after healing is completed at the extraction site.
- Review the use and care instructions with the patient.
- Finish placing the attachments and carry out any necessary interproximal reduction (IPR) as the treatment plan dictates.
- Seat the Step #1 aligner on the patient's teeth and check for tissue impingement or bleaching. If necessary, trim the aligner and polish the trimmed area.
- Each set of aligners is designed to be exchanged with the next step aligner in sequence after approximately two weeks of wearing the aligner(s) for 20–22 hours daily.

- Provide the patient with the first two sets of aligners and Dandy's Clear Aligner Accessory Kit, which includes an aligner case, aligner OrthoChews™, Clear Aligner cleaning spray, a zippered pouch, a patient education pamphlet, and a tote.
- At follow-up appointments, check teeth for proper interproximal contacts and perform IPR as the treatment plan requires. Check for appropriate aligner stage, fit, and treatment progress.
- If the treatment proceeds as planned, supply the subsequent set of aligners. Monitor the treatment and its progression through monthly appointments unless the treatment plan specifies a different schedule.
- New scans and aligners may be required if treatment requires modifications or refinements.
- At the completion of aligner treatment, retainer wear is highly advised to maintain corrected alignment. Retainer wear should follow the same instructions for aligner wear as described above unless advised otherwise by a dental professional.
- Daily Care and Maintenance of Clear Aligners by Patients
- Clean aligners before insertion. Use Dandy's Aligner Cleaner or a soft-bristled toothbrush and water. Do not expose aligners to hot water.
- Take care to rinse each aligner thoroughly with cool water after cleaning and before wearing.
- It is recommended to clean aligners once a week or as needed using the Dandy Clear Aligner cleaning spray.
- Do not use denture cleaner, whitening toothpaste, or soak aligners in mouthwash. These products can deteriorate the surface of the aligner and cause it to become dull or cloudy.

Do not use:

Avoid cleaning/immersing the device in sodium hypochlorite (chlorine bleach), hydrogen peroxide, mouthwash, or alcohol products, as these may damage or discolour the material.

Dandy Aligner Cleaner Information

- Ingredients: water, hydrogen peroxide, glycerin, PVP, PEG-180, sodium lauryl sulfate, sucralose, sodium citrate, sodium benzoate, and mentha arvensis (mint) oil.
- Manufactured by EverBrands, Inc., 11791 Monarch St, Garden Grove, CA 92841
- KILLS 99.99% OF BACTERIA (Study results available at [eversmilewhite.com/studies](http://eversmilewhite.com/studies))

Dandy Aligner Cleaner Instructions

- Remove your trays and dispense up to a full foam pump inside each tray. Spread the foam evenly using the nozzle tip. Place your foam-filled trays back in your mouth, spit out any excess, and let the foam naturally dissipate.

## **6) Storage**

Proper aligner storage involves keeping them dry, clean, and protected in a dedicated, ventilated case when not in your mouth, ensuring they're fully dry before placing them inside to prevent mold, and always carrying the case to avoid damage or loss, adhering to the 20-22 hour daily wear rule for best results.

- Use the Case: Always use the hard, protective case provided or a similar one to shield aligners from dirt, bacteria, and crushing.
- Keep it Dry & Cool: Before storing, rinse and gently dry your aligners; keep the case in a cool, dry place, away from moisture or extreme heat.
- Ventilation is Key: Ensure the case is slightly open or has vents to prevent moisture buildup, which can lead to odors or mold.
- Clean the Case: Wash the case daily with soap and water to maintain hygiene,
- Carry It Everywhere: Always have your case with you (in a dedicated bag or pouch) when you remove aligners to eat or drink anything other than water,

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

An aligner's "life" depends on treatment duration or how long each tray lasts (1-2 weeks) before switching, with the overall treatment lasting 6 months to 2 years, depending on complexity, while retainers (post-treatment) last 1-2 years.

## **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**

- Aligner disposal involves special recycling programs or returning them to your orthodontist for proper handling
  - Standard curbside recycling often rejects them due to their complex plastic.
- If recycling isn't available
  - Clean and seal them in a bag before trashing to prevent environmental contamination and keep these medical-grade plastics out of landfills.