

## Device Description:

4D Aligner™ System consists of a series of doctor prescribed, custom-made, thin, clear plastic removable orthodontic appliances (aligners). They are made from light-cured polyurethane resin. They gently move the patient's teeth in small increments from their original state to a more optimal, treated state.

## Wear and Care Guide:

### 1. Preparation

- 1) Wash your hands thoroughly with soap and water before handling your 4D Aligner™.
- 2) Remove your 4D Aligner™ from their packaging for the corresponding step of your treatment.



### 2. Inserting Your 4D Aligner™

- 1) Check if there is any damage (like deep scratches, roughness or cracks) to your 4D Aligner™. If you find damage, stop using it and call your orthodontist/dentist immediately.
- 2) Check the packaging of your 4D Aligner™ for which teeth to put it on. The upper 4D Aligner™ (labeled with a U) is for your top teeth and the lower 4D Aligner™ (labeled with an L) is for your bottom teeth.
- 3) Gently press the 4D Aligner™ first onto your front (anterior) teeth and then back (posterior) teeth (Some parts need to be pushed sideways to help match). Hearing a "click" means it is a good fit.
- 4) Apply equal pressure, using your fingertips, from the front (anterior) teeth to the back (posterior) teeth, pressing the 4D Aligner™ gently and vertically until the it snaps into place.



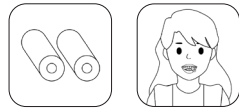
### 3. Using Chewies (if made available by your dental professional)

Chewies (cylindrical, natural silica gel) help set aligners in place, and can help with your orthodontic experience.

- 1) After inserting the 4D Aligner™, take the chewies from their cases.
- 2) Hold one side of the chewies and start with the back (posterior) teeth to bite the other side of the chewies.
- 3) To set every tooth, move the chewies from left to right/right to left. It's recommended that each pair of teeth bite the chewies 5 to 10 times.

#### Note:

- Do NOT use multiple teeth to bite.
- If you have missing teeth, please skip those positions.
- You should use chewies for at least 5 minutes, 3 times a day or follow the instructions from your doctor.



### 4. During Treatment

- Wear your 4D Aligner™ for at least 20 hours every day (except when eating and brushing teeth).
- Follow your doctor's instructions for when you should change to the next 4D Aligner™ in your treatment plan.

#### Note:

- You may have a slight lisp when you first start wearing your 4D Aligner™. This should go away within a few days.
- If there is serious discomfort, call your doctor immediately.
- If you lose your 4D Aligner™, contact your doctor as soon as possible and wear either your previous 4D Aligner™ or your next 4D Aligner™. Make sure you are using a 4D Aligner™ everyday. Do NOT discard your old 4D Aligner™.

### 5. 4D Aligner™ Cleaning and Restoration

Clean and restore your 4D Aligner™ daily using boiling water and cleaning tablets to ensure best possible performance and aesthetics.

*Treating a 4D Aligner™ with boiling water is a unique feature of 4D Aligner™ System solution that results in shape-restoration of the 4D Aligner™ to its original shape.*

### 5.1 You Need to Prepare:



No more than two (2) 4D Aligners™ per cleaning and restoration



Flat, wide-mouth, microwave-safe container. Large enough so two (2) can lie flat at the bottom of the container without touching.

Recommended size:

≥3.6 inches (length) ≥2.8 inches (width)



Boiling water



Cleaning tablets:

- For daily cleaning, one (1) Polident or one (1) Retainer Brite tablet.
- If you have heavy staining, use two (2) Polident or two (2) Retainer Brite tablets.

### 5.2 Cleaning and Maintenance Guide



#### Step 1:

Place 4D Aligners™ side by side, teeth cavities face-up, into the microwave-safe container.



#### Step 2:

- Heat the water until boiling.
- Carefully pour the boiling water into the microwave-safe container until your 4D Aligners™ are fully submerged.



#### Step 3:

Carefully add Polident or Retainer Brite tablet(s) to the microwave-safe container.



#### Step 4:

- The tablet(s) will start foaming in the hot water.
- Allow the tablet(s) to clean the 4D Aligners™ for at least ten (10) minutes.

#### Step 5:

- Pour cold tap water into the microwave-safe container until it starts to overflow.
- Keep adding cold tap water to the microwave-safe container for at least one (1) minute to cool down the 4D Aligners™.



**TIP: Place the microwave-safe container in a sink then add cool water to avoid a mess.**

#### Step 6:

- Drain water from the microwave-safe container into a sink.
- Rinse 4D Aligners™ with running tap water.
- Start wearing your freshly cleaned and restored 4D Aligners™.



**It is normal for the 4D Aligners™ to feel tighter immediately after cleaning and restoration.**

**⚠ Caution:** Use caution and heat-resistant gloves when handling boiling water. If you are under the age of 18, or have difficulty safely completing these tasks, please seek the assistance of a parent or guardian.

#### Additional Guidance:

- Make sure that your 4D Aligners™ aren't touching each other or touch the container wall.
- If your 4D Aligner™ is heavily stained, we recommend using two (2) tablets of Retainer Brite or Polident. You can do the cleaning and restoration treatment multiple times in a row or use more cleaning tablets without any adverse effects.
- If traveling, or unable to access boiling water, you can use room temperature water with the tablet(s) for stain prevention. Daily cleaning is recommended.
- 4D Aligners™ should NOT be cleaned with a toothbrush and toothpaste. This can cause abrasions on the surface that may affect clarity and promote discoloration.
- Despite the cleaning tablet manufacturer's recommendation, please use boiling water as instructed herein for optimal results. Due to the unique feature of the 4D Aligner™ System, not only will boiling water not cause any distortion to the appliance, but it will restore its shape and, hence, improve its performance.

## 6. Oral Hygiene

- Poor oral hygiene may increase the likelihood of discoloration in 4D Aligner™, but it can be relieved by maintaining good oral hygiene and following the cleaning protocol in Section 5.
- Brush your teeth every morning and evening, and use floss, water pick, or mouthwash to increase oral hygiene. After thoroughly cleaning your teeth, wear the 4D Aligner™. If your teeth are not cleaned properly, you will have a higher risk of tooth decay.
- 4D Aligners™ should be taken out when eating or drinking anything but water. If drinking strongly acidic beverages (e.g. soft drinks, coffee, tea, and wine), we recommend rinsing your mouth with water or mouthwash prior to re-insertion of your 4D Aligners™.
- Observe good oral hygiene practices like brushing and flossing after every meal, unless directed otherwise by your dentist or doctor.

## 7. Removing 4D Aligner™

- 1) Use your fingertips or aligner remover to slowly dislocate the 4D Aligner™.
- 2) Start with the last back tooth (terminal molar) on one side and repeat this process on the other side.
- 3) After removing from the back (posterior) teeth, remove the 4D Aligner™ on the front (anterior) teeth until the 4D Aligner™ is completely removed.
- 4) Put the 4D Aligners™ in the storage case to protect them and avoid losing them.

### Tip:

Do NOT use paper products to wrap your 4D Aligner™ for storage, as it can't easily be seen and makes it more likely to be thrown away accidentally.



### Cautions:

- Remove the 4D Aligners™ each time you eat unless directed otherwise by your doctor.

- Do NOT wear your 4D Aligners™ when drinking alcohol, sugary/acidic beverages, or colored beverages.
- Brush your teeth after meals for good oral hygiene.
- Rinse your mouth or brush your teeth after eating food with strong colors (like curry and blueberry pie) to avoid discoloring 4D Aligner™.
- Rinse your mouth with water or mouthwash after drinking or smoking.
- Clean and store your 4D Aligners™ in a safe place until you are ready to use them again.
- Keep your 4D Aligners™ away from pets and young children.

### Your Doctor:

- For questions regarding best oral hygiene practices and 4D Aligner™ maintenance, please contact your dentist/orthodontist. Attend dental checkups and cleanings regularly and bring all previously worn 4D Aligners™. Do NOT discard any 4D Aligners™ until your dentist/orthodontist confirms that you will not be needing them again. Your dentist/orthodontist will advise you when to progress to the next step of your 4D Aligner™ treatment plan.
- If you suspect you are having adverse reactions to your 4D Aligner™, discontinue use and consult your dentist/orthodontist. Your dentist/orthodontist is responsible for managing your treatment, not the 4D Aligner™ brand.

### Frequently Asked Questions:

**Q:** What should I do if my 4D Aligners™ is stained?

**A:** Clean the 4D Aligner™ with Polident or Retainer Brite and boiling water (see Section 5 for more information). Two cleaning tablets are recommended to remove heavy staining.

**Q:** What should I do if I am traveling and cannot boil water?

**A:** For cleaning only, you can use Polident or Retainer Brite with warm tap water until you get home. You should do this daily..

**Q:** What should I do if I lose or break a 4D Aligner™?

**A:** Contact your orthodontist's office as soon as possible and wear either your previous 4D Aligner™ or your next 4D Aligner™ until directed by doctors.

**Q:** Will treatment be painful?

**A:** Wearing aligners can be mildly uncomfortable, especially during the first few days of a new treatment step, but this should go away after a few days.

**Q:** Will wearing 4D Aligners™ affect my speech?

**A:** You may speak with a lisp when you first start wearing 4D Aligners™, but this should go away after a few days.

**Q:** What should I do if one of my 4D Aligners™ doesn't fit?

**A:** Talk to your dentist/orthodontist as soon as possible.

**Q:** Can I brush my 4D Aligners™ for cleaning?

**A:** We recommend the cleaning procedure in section 5. If you use a brush to clean your aligner, only use a soft bristle toothbrush and brush with liquid soap and water. Do NOT use a toothbrush and toothpaste.

**Q:** Are there any foods I cannot eat during treatment?

**A:** After taking out your 4D Aligner™, unless directed by your doctor, there is no limitation for food. When you are wearing your 4D Aligner™, avoid eating food, especially hard, sticky food, and candies and avoid dark, sugary drinks like coffee, tea, carbonated drink, and wine.

**Q:** Is it OK to drink hot or cold beverages while wearing 4D Aligners™?

**A:** Do NOT drink anything besides water when wearing your 4D Aligners™.

**Q:** Can I chew gum while wearing 4D Aligners™?

**A:** Do NOT chew gum when wearing your 4D Aligners™.

**Q:** Can I smoke with the 4D Aligners™?

**A:** It is NOT recommended to smoke when wearing your 4D Aligners™, as it can stain them.



Learn More



# 4D Aligner™ System

## Patient Wear and Care Guide

Please read through all of this guide prior to proceeding.

**Caution:** LuxCreo shall not be held responsible for any adverse effects, safety concerns, or performance issues arising from the use of non-LuxCreo validated compatible equipment or failure to adhere to LuxCreo validated printing/post-processing settings.