

CLEAR X

INSTRUCTIONS FOR USE

CLEARX

FOR PATIENTS





Caution: Federal law restricts this device to sale by or on the order of a dentist.

Product Description

CLEARX aligners are made from thermoformable polymer sheet that is used to incrementally move teeth using gentle force from a sequence of aligners to be worn by the patient over a designated period. The aligners are held in place by pressure and can be removed by the patient at any time.

CLEARX is unique with a shape memory feature which enables to reduce the number of aligners needed for aligning the teeth. A boosting step for each aligner is necessary to activate this unique feature of CLEARX .

Material Composition

CLEARX Aligner is composed of a 3 layered thermoformable Orthodontic material. The top and bottom layer is of cycloaliphatic polyester with a polyether polyurethane layer in between.

Indications for Use/Intended Use

CLEARX aligners are indicated for the alignment of teeth during orthodontic treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars).

Contraindications for Use

Aligners are contraindicated for use in patients with active periodontal disease, active caries, and temporomandibular disorder.

Warnings

In rare circumstances patients may be allergic to plastic. Patients with a history of plastic allergies should not use this product. Damaged or broken aligners should not be used as small pieces of plastic can be swallowed or aspirated. Patients should inform their dentist immediately if an aligner is lost or damaged.

Adverse Reactions

In rare circumstances, an individual may be allergic to plastics. In the case of a reaction, remove aligners, discontinue treatment and consult with your prescribing dentist immediately.

At the end of the treatment, the bite shifting may go wrong or teeth may tend to return to their previous position. In such cases patient should consult with his orthodontist.

MRI Safety Information

CLEARX aligners are MR Safe. CLEARX aligners are fabricated from thermoplastic materials which do not contain any metal and are electrically non-conductive, nonmetallic, and nonmagnetic.

Precautions

Patients may experience tenderness or temporary discomfort/pain with the initial clear aligner and after switching to each new clear aligner set as prescribed. If pain persist or is significant patient should consult with doctor.

CLEARX aligners may adversely affect speech resulting in a lisp or slur. This normally dissipates/disappears in a week or two.

Patients may experience an increase in saliva production or dry mouth. In this situation patient should get accustomed to wearing the aligners, drink more water and have patience.

Aligners may irritate or scratch the insides of the lips, cheeks, or gums. If this condition persists the patient should contact their dentist.

Patients should not wear aligners when drinking liquids that contain sugars, pigments, or acids. Patients should remove aligners before drinking hot tea or coffee and eating.

Failure to wear the aligners for the prescribed number of hours per day or not using the aligners as directed can result in increased treatment times or could affect the desired outcome.

Instructions

- Wear your aligners per doctor's instructions – generally 20-22 hours per day.
- Each aligner is powered with a shape memory which will be activated only after boosting as shown in the below picture.
- Each aligner in your CLEARX pouch is to be worn for 2 weeks starting from the aligner number one, unless otherwise instructed by your doctor. In the first weeks for each aligner, you wear it directly from the pouch (**without boosting**).



Step 1

Preparing your aligner

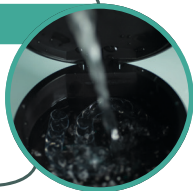
Carefully place your CLEARX aligners into the booster (open side up) with a spoon.



Add some heat!

Step 2

Boil a kettle of water. Once boiled, immediately pour hot water into the booster up to the max fill line. Ensure that your CLEARX aligners are fully submerged.



Step 3

Give it some time

Close the lid of your CLEARX booster to maintain the optimal temperature and wait 10 minutes.



Open booster

Step 4

Open the lid of your booster carefully and gently remove your CLEARX aligners with the help of a spoon.



Step 5

Cool down

Rest your CLEARX aligners for a few minutes at room temperature to cool down. Once cooled, your aligners are ready to use.



How to boost

- After wearing for 1 week, you need to boost the aligner as described in the “How To Boost” section.
- After wearing your boosted aligner for next 1 week , you need to discard the aligner.
- Now its time to start with the next aligner from your CLEARX pouch.
- Wear this new aligner for next 2 weeks by following the same procedure (1 week without boosting followed by 1 week with boosting) and repeat until you finish your treatment with CLEARX.
- Aligners must be removed when eating all snacks and meals, and when drinking any liquids other than water.
- Do not chew gum while wearing aligners.
- Wash your hands with soap and water before removing or inserting aligners.
- Only one aligner at a time should be handled when inserting, removing, or cleaning.
- If a reaction occurs while wearing aligners, discontinue use and consult your doctor immediately.
- If an aligner or an attachment is lost or broken, it must not be used. You should always keep the last pair of aligners for this kind of emergency and of course consult with doctor for assistance/replacement.

When to Boost

Each of your CLEARX aligner that you received in the pouch are to be used for consecutive two weeks unless otherwise instructed by your dentist. First week you will directly wear the provided aligner. Following

week you need to boost it through the boosting process as described in the picture. After boosting it will be ready to use in the second week.

Reuse the Booster

After each boost session, empty and thoroughly rinse the booster with tap water. Allow to dry prior to next use.

Cleaning the Aligners

Aligners must NOT be cleaned with toothpaste or soaked in mouthwash or any other cleaning agent as this may scratch or dull the plastic. Aligners should be cleaned with a soft toothbrush and cool water to prevent wrapping.

Storage and Changing Aligners

To help protect the aligners from loss or damage, they should be stored in a dry and cool place when they are not in use. Aligners are not to be stored near a heat source as this can cause them to distort.

Inserting the aligners

- Wash your hands with soap and water before handling the aligners.
- Aligners must be rinsed before insertion into the mouth. Teeth should be brushed and flossed after every meal prior to inserting the aligners.
- Ensure that you have the correct aligner at each scheduled aligner change by referring to the “U” or “L” (for upper and lower) marking and the sequence number that is both on the aligner and on the bag the aligner came in.
- Only one aligner should be inserted at a time. To insert, place an aligner over the teeth and apply slight pressure with fingers until it is seated firmly over the teeth. NEVER bite the aligners to place them.

- Minor discrepancies between the teeth and a new aligner are normal since the teeth have not moved into their new position. If significant pain or discomfort is experienced, remove the aligner and contact your doctor immediately.

Removing the Aligners

- Use your fingers to grasp the aligner starting at the back (the molars) and gently pulling away. When the aligner gets released from the molars, the aligner can be pulled away from back to front.
- If resistance is felt, it may be necessary for the patient to repeat the previous step in several locations. Excessive force should not be used as it may damage the aligner.
- Care should be taken when removing aligners especially if there are multiple attachments.
- Do not bend, twist, or use excessive force when removing aligners or they may distort or be damaged.
- Sharp objects should never be used to remove aligners.
- Consult your dentist if aligners are difficult to remove.

Tooth Nerves

Excess pressure by the aligner can cause teeth nerve damage. In such case report to your doctor.

Oral Hygiene

During treatment it is important to maintain excellent oral hygiene. Food left on the teeth and trapped inside the aligner trays can lead to tooth decay or Enamel de- calcification. To maintain good dental health during aligner treatment, you must:

- Remove the aligners when eating or drinking anything other than water.
- Brush and floss your teeth after every meal prior to re-inserting the aligners.
- Maintain regular dental check-ups during treatment.

Reporting of Adverse Events

Any serious incident or potential serious incident involving CLEARX aligners must be reported to K Line Europe GmbH. Please contact your Doctor immediately in such an issue.



TROUBLESHOOTING

Check the Pressure:

After the boosting process, you should notice a distinct pressure from the aligner on your teeth.

If the aligner feels the same as it did before the boosting process, it's likely that the boosting process hasn't been successful and needs to be repeated.




Right Temperature:

Ensure you pour the boiled water into the booster immediately after boiling. Waiting too long can reduce the temperature and affect the process.






Right Position:

Make sure your CLEARX aligners are placed into your booster open side up and are fully submerged in the hot water.



SYMBOL EXPLANATION

Symbol graphic	Title	Description	Reference
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
REF	Reference number	Indicates the manufacturer's reference number so that the medical device can be identified.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

SYMBOL EXPLANATION

Symbol graphic	Title	Description	Reference
	Temperature limit	Indicates the temperature range at which the device need to be maintained.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Consult Instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Prescription only	Requires a prescription in the United States of America Caution: In the United States of America, federal law restricts this device to sale or use by, or on the order of, a dentist .	USA Code of Federal Regulations 21CFR Part 801 § 801.109 (b)(1)
	Magnetic resonance	CLEARX aligner is MR Safe.	FDA Guidance document: Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment dated May 20, 2021.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	EN ISO 15223 - 1:2021

SYMBOL EXPLANATION

Symbol graphic	Title	Description	Reference
	Non Sterile	Indicates a medical device that has not been subjected to a sterilization process.	EN ISO 15223 - 1:2021
	Medical device	Indicates the item is a medical device.	EN ISO 15223 - 1: 2021

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Manufacturerd by:

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