

# INSTRUCTIONS FOR USE FIRSTCLASS ALIGNERS

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## FOR DOCTORS



## Product description

Firstclass 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.

## Material Composition

Firstclass 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

Firstclass 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. In such case patient should consult with his orthodontist. After treatment, teeth may tend to return to their previous position which is prevented by the patient wearing the retainers included with their aligners and as directed by their doctor.

## MRI Safety Information

Firstclass aligners are MR Safe. Firstclass 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 persists or is significant patient should consult with doctor.

Firstclass 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 eating.

Inadequate oral hygiene and/or consumption of sugary or acidic foods/drinks during treatment may lead to tooth staining, decalcifications, and/or tooth decay.

## Instructions

- » Firstclass Aligners should be worn 20-22 hours per day.
- » Individual aligner stages should be worn for two (2) weeks unless otherwise instructed by a doctor.
- » Aligners must be removed when eating all snacks and meals, and when drinking any liquids other than water.
- » Patients should not chew gum while wearing aligners.
- » Hands should be washed 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, patients should discontinue use and consult their doctor immediately.
- » If an aligner or an attachment is lost or broken, it must not be used. Patients should always keep the last pair of aligners for this kind of emergency and of course consult with doctor for assistance/replacement.

## 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 case

## Inserting the aligners

- » Patient should wash their 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.
- » To ensure that the patient has the correct aligner at each scheduled aligner change they should refer to the “U” or “L” (for upper and lower) marking and the sequence number that is on both the aligner and on the bag the aligner came in.
- » Only one aligner should be inserted at a time.
- » To insert, patients should place an aligner over the teeth and apply slight pressure with fingers until it is seated firmly over the teeth. Patients should 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, patient should remove the aligner and contact the prescribing dentist for further guidance.



## **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 for patients 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, the patient must:

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

## **Removing the aligners**

- » The patient should use their 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.
- » The patient should 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.
- » The patient should consult their doctor if aligners are difficult to remove.

## **Reporting of Adverse events**

A space has been provided in the patient Instructions for Use document for the practitioner to provide contact information in case of an adverse event with the patient's aligners. Any serious incident or potential serious incident involving the aligners must be reported to K Line Europe GmbH.

## Symbols



### **K Line Europe**

Indicates the medical device manufacturer, as defined in EU MDR 2017/745.



### **Usable until**

After this date the medical Device/Product should not be used.



### **Follow the instructions**

The user needs to follow the instructions for use.



### **Danger**

The user needs to review the instructions for use for important safety-related information, such as warnings and precautionary measures, which for a variety of reasons cannot be affixed to the medical device itself.



### **Non-Sterile**

The medical device has not been subjected to a sterilization process.



### **Protect from sunlight**

The medical product needs protection from sunlight



### **Temperature limit**

The device/Product should be kept within the temperature limit.



### **Magnetic resonance safety**

These aligners are fabricated from thermoplastic materials which do not contain any metal, and are electrically nonconductive, nonmetallic, and nonmagnetic.



### **Prescription Product**

Theses aligners can be prescribed by a registered physician/dentist only.



### **Medical device**

Indicates that the item is a medical device.

## HOW TO SUBMIT A CASE

### Registration

Register at [portal.firstclassaligners.com](https://portal.firstclassaligners.com)

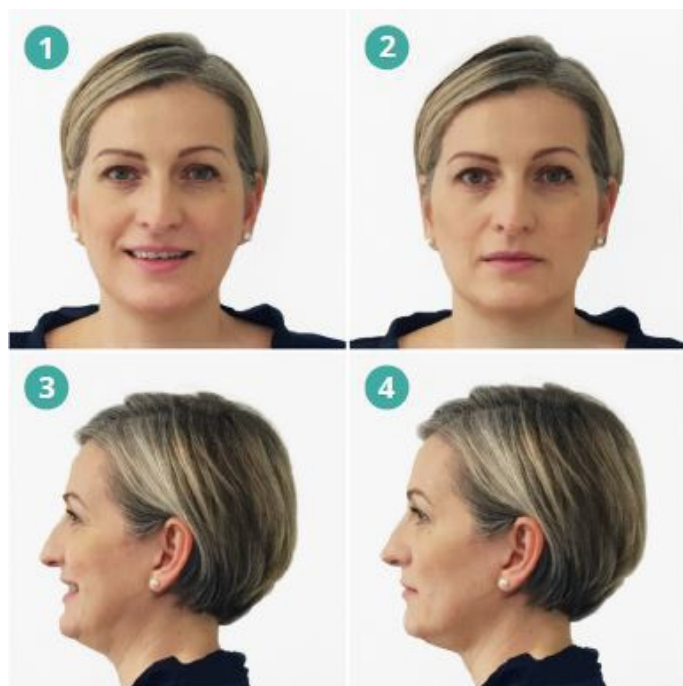
If you have successfully registered, your account will be activated soon. After that, you can already submit your first case.

### Submit patient information

Please submit your patient information, clinical photos and X-rays via the upload section of our portal.

### Extraoral pictures

Please upload all pictures in the upload section of the portal.



1 Frontal with smile

2 Frontal without smile

3 Lateral view

4 Profile view

### Intraoral pictures



1 Upper jaw occlusal view

2 Frontal in occlusion

3 Lower jaw occlusal view

4 Slight open bite

5 Lateral view on the right

6 Lateral view on the left

### Treatment plan

Once we have received all necessary information, it takes three to five business days until you will receive the estimate by e-mail. You will find the treatment plan including 3D simulation in our portal.

### Confirming the case

After discussing the case with your patient, please confirm it on our portal. Any questions and comments can be added via the comment box.

After confirming the case it takes about 10-12 working days plus shipping until the aligners arrive in your practice.