

Instructions for use: the ClearCorrect system

Device Description

The ClearCorrect devices are sequential aligners fabricated of clear thin thermo-formed thermoplastic to progressively reposition the teeth. Corrective force is delivered to straighten the teeth via minor changes in tooth position in each subsequent aligner. Retainers may be used to maintain tooth position following completion of the approved treatment plan or at any time during the treatment plan if there is a need to interrupt treatment. Retainers are an optional part of treatment at the discretion of the clinician. Aligners and Retainers are referred to collectively as Appliances.

Indications for Use

The ClearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.

Warnings

In rare instances, some patients may be allergic to the plastic Appliance material. Patients should be advised, if an allergic reaction is experienced, to discontinue use and consult a health care professional immediately. ClearCorrect must also be notified.

Patients with hereditary angioedema (HAE), a rare genetic disorder, may experience a rapid local swelling to subcutaneous tissues including the throat. HAE may be triggered by minor trauma to soft tissue resulting from dental procedures. Patients with HAE should be advised that an HAE attack affecting the throat is potentially life-threatening, because it can interfere with breathing, and they should seek emergency care as soon as possible.

Orthodontic Appliances, in whole or in parts, may be accidentally swallowed or aspirated and may be harmful.

ClearCorrect IFU Precautions

- Treatment time may exceed estimates. Poor compliance with doctor's instructions, wearing aligners less than 22 hours per day, wearing retainers less than doctor recommendation, missing appointments, poor oral hygiene and broken Appliances can lengthen treatment time, increase the cost, and affect the quality of the end results.
- To avoid accidentally damaging Appliances, patients should be instructed to follow the guidance within the Wear & Care Instructions when inserting and removing Appliances to avoid bending or cracking them.

- Do not subject aligners or retainers to hot water or harsh chemicals or cleaning agents.
- Aligners and retainers should be kept out of the reach of children and pets at all times.
- When not in patient's mouth, aligners and retainers should be stored in a cool dry place.
- Treatment of severe malocclusions (e.g. severe open bite, severe overjet, skeletally narrow jaw, etc.) may require supplemental treatment beyond aligner treatment alone.
- For more complicated treatments, where aligners alone may not be sufficient to achieve the desired orthodontic outcome, the use of auxiliary devices (e.g. skeletal expanders, elastics, bonded and/or removable orthodontic devices, etc.) may be needed.
- Oral surgery may be required to correct excessive crowding or severe, pre-existing jaw imbalances. All risks of oral surgery, such as those associated with anesthesia and proper healing, must be considered before treatment.
- Unusually shaped teeth can also extend treatment time and affect results. For instance, short clinical crowns can cause problems with aligner retention and slow or prevent teeth movement.
- Existing dental restorations, such as crowns and bridges, may be affected by wearing aligners. The restorations may become dislodged and require re-cementation or, in some instances, replacement. Patients should be instructed to consult with their treating doctor before any dental restorations are replaced or added, as they can affect the way the Appliances fit.
- Clear aligners cannot move dental implants.
- Patients should be advised that any medications they may be taking, as well as their overall medical condition, can affect their orthodontic treatment.
- Tooth sensitivity and tenderness of the mouth may occur during treatment—especially when advancing from one aligner to the next.
- Initially, the Appliances may temporarily affect your patient's speech, and may cause them to speak with a slight lisp, which usually improves within a few days.
- Sores and irritation of the soft tissue of the mouth (gums, cheeks, tongue and lips) can rarely occur due to wearing Appliances.

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- It may be necessary to temporarily affix engagers (small bumps of composite material) to your patient's teeth to assist with difficult tooth movements. When your patient is not wearing their aligners, these engagers can feel awkward in the mouth.
- Engagers may fall off or lose their shape, requiring them to be evaluated by the doctor.
- Engagers should be removed upon completion of the patient's clear aligner treatment.
- In cases of crowding, IPR, also known as interproximal reduction (reducing the thickness of a tooth's enamel), may be required to create enough space to allow teeth movement.
- Tooth decay, periodontal disease, decalcification (permanent markings on the teeth), or inflammation of the gums may occur if proper oral hygiene and preventative maintenance are not maintained, whether wearing aligners or otherwise.
- The patient's bite may change throughout the course of treatment and may result in temporary patient discomfort.
- At the end of clear aligner treatment, the patients' occlusal contacts, dental morphology, and gingival tissue may require additional adjustments by the doctor.
- Results may relapse if retainers are not worn as directed by doctor.
- Teeth may supra-erupt (come out of the gums more than other teeth) if not at least partially covered by the Appliance.
- While wearing Appliances, patients may experience a temporary increase in salivation or dryness of the mouth. Certain medications can increase this.
- Wearing Appliances may aggravate teeth—previously traumatized or not. Though a rare occurrence, such teeth may require additional dental treatment such as endodontic treatment or other restorative treatment, the useful life of the teeth may be shortened, or the teeth may be lost completely.
- Bone and gums, both of which support the teeth, can be affected by wearing Appliances. In some cases, their health may be impaired or aggravated.
- Root resorption (shortening) can occur during any type of orthodontic treatment, including clear aligners. Shortened roots are of no disadvantage under healthy

conditions. In rare cases, root resorption can result in loss of teeth.

- In rare instances, clear aligners can aggravate pre-existing problems in the temporo-mandibular joint (TMJ), and may result in joint discomfort, headaches, or other problems.
- In cases of severe crowding or multiple missing teeth, it is more likely that the Appliance may break or not fit completely over teeth. Patients should be instructed to contact their treating doctor as soon as possible if this occurs.
- Appliances worn out of their intended sequence can delay treatment results and result in complications including (but not limited to) patient discomfort. Patients should be instructed to always wear the Appliances in the order specified by their treating doctor.
- In some cases, a "black triangle" of missing gingival tissue may be visible below the interproximal contact when teeth are aligned after being overlapped for an extended period of time.
- A successful treatment outcome cannot be guaranteed. After the final planned aligners have shipped, some cases may require refinement with additional clear aligners, traditional orthodontic techniques, and/or cosmetic procedures like crowns or veneers to achieve ideal results. Such procedures can result in additional costs to the patient and/or treating clinician.

Directions for Use

- Rinse Appliances when you first remove them from the packaging.
- Insert Appliances by placing them over your front teeth first, then work backwards, applying gentle, even pressure over your molars until the Appliance clicks into place. Do not bite Appliances into place.
- It is normal for aligners to fit tightly and apply pressure to your teeth; this is less likely with retainers. This pressure should lessen over time as you wear them.
- To remove Appliances, start by using your fingertip on your rear molar on one side. Carefully pull the Appliance away from the tooth. Repeat this motion on the opposite side before trying to remove the Appliance completely. Once both sides are free, you should be able to begin working your way forward to gently pry the Appliance away from your front teeth.
- Do not use excessive bending or twisting force to re-

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move an Appliance.

- Do not use a sharp object to remove Appliances.
- Inform your doctor if you find that your Appliances are extremely difficult to remove.
- Wear your aligners for at least 22 hours every day; wear retainers as instructed by treating clinician.
- Each time you insert your Appliances, inspect for cracks or deformities. If discovered, report them to your doctor immediately.
- Make sure to wear the Appliances that your doctor directed you to use! They're marked with the step number, as well as a "U" for your upper teeth, and an "L" for your lower teeth.
- You may speak with a slight lisp while your tongue adjusts to the Appliances—this usually goes away within a few days.
- You may experience dry mouth, so drink plenty of water.

Daily Care and Maintenance

- Always remove Appliances to eat.
- Rinse Appliances with cool water and store them in a safe place.
- Take extra care to keep Appliances away from alcohol and hot, sweet, or colored liquids.
- Brush and floss after every meal to prevent food and drink from getting trapped under the Appliances.
- Clean Appliances with a toothbrush and cool water. For more thorough cleaning, you can use nonabrasive toothpaste, but do not use denture cleaners or mouthwashes.
- Keep Appliances away from pets and children.

Proper Oral Hygiene

- Appliances should always be removed for eating and drinking, except when drinking cool water.
- Patients should brush or floss their teeth after each meal and snack prior to re-inserting their Appliances. If a toothbrush is not available, patients can simply rinse their mouth and clean the Appliances by running cool water over them. Appliances should then be thoroughly cleaned at the patient's next earliest convenience.
- If patients have questions about hygiene techniques,

they should be instructed to consult with their treating clinician.

- Regular dental checkups and cleanings are recommended for the continued health of patients' teeth and gums.

How Supplied

- Each Appliance is cleaned and packaged prior to delivery.
- Each Appliance is etched with the ClearCorrect logo, the patient case number, along with a number representing the stage of treatment and a letter to designate the upper "U" or lower "L" jaw.
- For professional dental use - Rx only, custom made device.

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	ClearCorrect EN ISO 15223-1; 5.1.1
Indicates the medical device manufacturer, as defined in EU directive 93/42/EEC.	
	Emergo Europe EN ISO 15223-1; 5.1.2
Indicates the Authorized Representative in the European Community.	
	Caution EN ISO 15223-1; 5.4.4
Indicates the need for the user to consult the instructions for use important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	
	Consult instructions for use EN ISO 15223-11; 5.4.3
Indicates the need for the user to consult the instructions for use.	
	Non-sterile EN ISO 15223-1; 5.2.7
Indicates a medical device that has not been subjected to a sterilization process.	
	Rx Only US Code of Federal Regulations, Title 21, Part 801.15(c)(1)(i)(F)
Caution: Federal law restricts this device to sale by or on the order of a licensed dental professional.	
	Use-by-date EN ISO 15223-1; 5.1.4
Indicates the date after which the medical device is not to be used.	