

Description of Device

Custom Clear Aligner 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 device is a personalized medical device intended only for use by the individual noted on the packaging.

Indications for Use

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

Contraindication

Not to be used if you are allergic to plastics.

It is not advised for patients with active periodontal disease.

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 professional.
- In rare occurrences patients with HAE (hereditary angioedema) may experience local swelling and can be triggered by dental procedures or appliances. If extreme swelling occurs, advise patients to discontinue use immediately and consult a health care professional.
- Because the aligners are worn in the mouth, accidental swallowing or aspiration of the appliance may occur and may be harmful.

Precautions / Potential risks of Aligner system: Advise patients of the following:

- Keep appliances away from hot water and harsh chemical solutions.
- Keep appliances out of reach of young children and pets. When not in use, store appliances in provided container.
- Aligners worn out of sequence can result in delayed treatment and complications including patient discomfort. Always follow the order and wear of aligners prescribed.
- 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 result in the need for a revised treatment plan and new aligner(s).
- Aligner appliances are not effective in the movement of dental implants.
- Certain medications and medical conditions can affect orthodontic treatment. Consult your physician before beginning treatment.
- Sensitivity and tenderness to teeth may occur during treatment, especially when moving forward 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 as a result of poor compliance to 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 doctor 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" will be removed upon treatment completion.
- Tooth decay, permanent stains/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. Risk associated with IPR as part of treatment should be taken into account.
- The health of gums and bone, both of which support your 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, patient may experience joint pain, headaches or ear problems. Patients should inform doctor if any of these symptoms occur.
- At the end of the treatment, it may be necessary to make adjustments to the bite.
- All teeth should be at least partially covered by aligners to avoid supra-eruption of teeth.
- Aligner wear can aggravate teeth; previously traumatized, significantly restored or not. In rare occurrence, 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 result in a threat to the longevity of the teeth.

- Supplemental treatment in addition to aligner appliances may be required for severe open bite, over jet, excessive crowding or skeletal jaw disproportions. If Oral Surgery is required, all risks of surgery and anesthesia must be taken into consideration before treatment.
- 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 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 complete ideal results. Successful treatment outcome cannot be guaranteed.

Directions for Use

1. Rinse new aligners with cold water prior to wear.
2. If any extractions have been performed prior to aligner treatment beginning, space should be maintained while healing occurs. Attachments should only be applied after healing is completed in the extraction site.
3. Review the Use and Care Instructions with patient.
4. Complete attachment placement and perform any required IPR (interproximal reduction) as required by treatment plan.
5. Seat Step #1 aligner on patient's teeth and check for tissue impingement/blanching. If necessary, trim aligner and polish trimmed area.
6. Each set of aligners are designed to be exchanged with the next step aligner in sequence, in approximately 2 weeks of wearing the aligner(s) 20-22 hours per day.
7. Provide the patient with the first 2 sets of aligners and Clear Aligner Accessory Kit which includes aligner case and aligner Chewies™.
8. At follow up appointments, check teeth for proper interproximal contacts and perform IPR as required by treatment plans. Check for appropriate aligner stage, fit and treatment progress.
9. Provided treatment is on track, provide the next set(s) of aligners. Treatment and progress should be monitored on a monthly appointment schedule, unless otherwise required in treatment plan.
10. New impressions and aligners may be required if treatment requires modifications.
11. At the completion of aligner treatment, retainer wear is highly advised to maintain corrected alignment.

Daily Care and Maintenance of Clear Aligners

- Aligners should be cleaned prior to insertion. Use a soft bristled toothbrush and a small amount of toothpaste. 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 an over-the counter product designed for removable braces/aligners. Retainer Brite or similar product is recommended.
- Do not use Denture Cleaner, abrasive toothpaste or soak aligners in mouthwash. These products can deteriorate the surface of the aligner and cause them to become dull or cloudy.

Smile Shapers recognizes and operates according to the requirement that all dental laboratories are subject to compliance with the Food and Drug Administration's (FDA) current Good Manufacturing Practice outline in Title 21, Subchapter H, Part 820 of the Code of Federal Regulations. Items manufacturing in the USA by Smile Shapers, and the materials used in the manufacture of patient specific devices meet FDA and other international recognized requirements. Information that is requested by FDA regarding the materials and processes used in the manufacture of any and all devices manufactured by Smile Shapers will be provided accordingly.