

Successful aligner treatment can be achieved when the patient is cooperative and there is a trusting relationship between the patient and doctor. Aligner therapy can lead to a beautiful and healthier smile, but you should be aware that like all orthodontic treatment, there are potential risks and limitations. Before starting treatment, the patient should make sure they have discussed all possible alternative treatments options with their doctor. This includes discussing the option of no treatment at all. Please review the following information carefully. Ask your doctor for explanation of any items you do not understand. Patients and/or the patient's parent/guardian should know what is expected of them during treatment.

» About Clear Aligners

Aligner treatment consists of removable, clear plastic aligners that incrementally move teeth in small amounts to improve function and esthetic appearance. Clear aligner treatment is designed to provide the same result as other orthodontic treatment. Choosing aligners over brackets can result in, but is not limited to, benefits like:

- Aligners are clear, and often people don't notice you're wearing them.
- Aligners don't cause cuts or abrasions from wires or brackets like traditional braces, making them more comfortable.
- Aligners are removable, allowing you to eat, drink, brush and floss without restrictions created by traditional braces.

Although the benefits generally outweigh the potential risks, all factors should be considered before making the decision to wear aligners. If you choose to undergo clear aligner therapy, Great Lakes Dental Technologies, a New York-based dental laboratory, will manufacture aligners customized for your teeth based on your doctor's prescription. Your doctor (not Great Lakes Dental Technologies) is responsible for delivering and managing your care.

» Potential Risks of Clear Aligners

As with other orthodontic treatments, clear aligners may involve some of the risks outlined below:

- Treatment time may exceed initial estimates. Missing appointments, poor compliance, wearing aligners less than then 22 hours per day, broken appliances, poor oral hygiene, and excessive bone growth can impact the result, increase costs of treatment, and lengthen treatment time.
- Treatment can be extended by unusually shaped teeth, such as short clinical crowns, which can cause issues with retainer retention and may result in slow progress. In some cases, this may prevent teeth from moving.
- Not maintaining proper oral hygiene and preventative maintenance may result in tooth decay, periodontal disease, decalcification, or inflammation of the gums and teeth.
- Soreness and irritation of the gums, cheeks, tongue, and lips is possible but seldom occurs due to wearing aligners.
- At first, aligners may temporarily affect your speech. Patients typically acclimate quickly to wearing aligners and it's uncommon their speech is impaired for an extended time.

- You may experience a temporary increase in salivation or dryness of the mouth while wearing the aligners. Certain medications can exacerbate both conditions.
- Attachments may be temporarily fastened to your teeth to aid the aligners with difficult movements. The attachments may feel foreign in the mouth when not wearing aligners.
- In certain cases, IPR, also known as interproximal reduction, may be necessary to create appropriate space between teeth to allow for correct movement.
- Any medications you may be taking, as well as your overall medical condition, can affect your orthodontic treatment.
- Allergic reactions to material used during treatment may occur, but this is uncommon. If you feel as if you are having a reaction, inform your doctor immediately.
- You may experience sensitivity of the teeth and mouth during treatment. This may be more pronounced when progressing to a new aligner in the series.
- Bone and gums, both of which support the teeth, can be affected by wearing aligners. In some cases, their health may be impaired or aggravated.
- Oral surgery may be required during aligner treatment to correct excessive crowding or severe, pre-existing jaw imbalances. Any and all risks associated with oral surgery must be considered before treatment.
- Wearing aligners 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.
- Existing dental restorations, such as crowns and bridges, may be affected by wearing aligners. They may become dislodged and require re-cementation or in some instances, replacement. Before any dental restorations are replaced or added, consult your doctor, as aligner fit may be affected.
- Teeth may supraerupt (come out of the gums more than other teeth) if not at least partially covered by the aligner.
- Root resorption (shortening) is a risk with all types of orthodontic treatment including aligners. Shortened roots are not concerning under healthy conditions. In rare cases root shortening can result in loss of teeth.
- Your aligner is more likely to break when there is severe crowding or if multiple teeth are missing. If your aligner breaks, contact your doctor as soon as possible.
- Because orthodontic appliances are worn in the mouth, accidentally swallowing or aspirating the aligner, in whole, or in part, may occur.
- Issues may occur in the jaw joint, causing joint pain, discomfort, headaches or ear problems although uncommon, contact your doctor if any issues arise.
- Wearing aligners out of their specific order can delay progress and affect treatment results. Follow your doctor's instructions while wearing aligners.



- 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.
- 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. There may be additional costs to you if you require such procedures.

» **Informed Consent & Agreement**

I have read and understand the content of this document describing considerations and risks of clear aligners. I have been sufficiently informed and have been given the opportunity to discuss this form and its contents with the undersigned doctor, and to have my questions adequately answered. I have been asked to make a choice about my treatment, and I hereby consent to receive treatment with clear aligners manufactured by Great Lakes Dental Technologies as planned, prescribed and provided by the undersigned doctor. I agree to follow my doctor’s treatment exactly as s/he plans, prescribes and provides it for me, and I understand that any questions, concerns or complaints I have regarding my treatment must be communicated to my doctor as soon as they arise.

I acknowledge that neither my doctor nor Great Lakes Dental Technologies, its employees, representatives, successors, assigns, or agents, have, can, or will make any promises or guarantees as to the success of my treatment or give any assurances of any kind concerning any particular result of my treatment. I understand that if retainers are not properly worn as directed by my doctor my results may relapse. I understand that Great Lakes Dental Technologies does not practice dentistry or give medical advice. I understand that Great Lakes Dental Technologies manufactures medical devices based on instructions from the prescribing doctor. I understand that I should always contact my doctor in the first instance (not Great Lakes Dental Technologies) regarding my expectations, difficulties, results, or any other aspects of my treatment.

I understand that it may be necessary to take impressions, intraoral scans, digital model scans, radiographs (x-rays), and/or photographs for diagnosis, professional review by my doctor or other consulting dentists and orthodontists, and submission to Great Lakes Dental Technologies. I recognize that these will be included in my medical records, which records encompass “individually identifiable health information” as that term is defined and protected by the HIPAA Privacy Rule.

I understand that my doctor, as a covered entity under HIPAA, is not required to obtain my consent to use and disclose my individually identifiable health information for treatment, payment, and health care operations activities, but has chosen to do so voluntarily through this document. I further agree that my doctor or Great Lakes Dental Technologies may use my medical records for research and educational purposes, but only to the extent that no individual identifiers, including but not limited to my name or address, are disclosed. I hereby consent to such uses and disclosure(s) as described herein.

Unless otherwise permitted or required by law, other uses and disclosures of my medical records, including advertising or marketing by either my doctor or Great Lakes Dental Technologies, shall be made only with my prior written authorization (for which I acknowledge my doctor or Great Lakes Dental Technologies may use my contact information to seek to obtain).

I acknowledge I will not, nor shall anyone on my behalf, seek or obtain damages or remedies, legal, equitable, monetary, or otherwise, arising from any use of my medical records that complies with the terms of this Informed Consent and Agreement.

I acknowledge I have read, understand, and voluntarily consent to the use of clear aligners in accordance with terms of this Informed Consent and Agreement.



the smarter way to a beautiful smile™

Lab FM142Rev12220

Patient Name	Date
Signature of Patient or Parent/Guardian	Date
Signature of Dentist/Orthodontist	Date