

CLEAR ALIGNER INFORMATION (1)



Patient informed consent & agreement

Successful orthodontic treatment is a partnership between the dentist and the patient. Your dentist has recommended the clear aligners for your orthodontic treatment. Although informed and cooperative patients can achieve a healthier and more attractive smile, you should also be aware that any orthodontic treatment (including orthodontic treatment with clear aligners) has limitations and potential risks that you should consider before undergoing treatment. You should also ensure that you have discussed all orthodontic alternatives available to you with your dentist prior to beginning treatment.

Please read this information carefully, and ask the dentist to explain anything you do not fully understand. Ensure you know what is expected of you as the patient during treatment.

CHOICE OF CLEAR ALIGNER SYSTEM

ABOUT CLEAR ALIGNERS

A series of clear, removable appliances that move your teeth in small increments to improve bite function and/or aesthetic appearance. It combines your dentist's diagnosis and prescription with sophisticated computer graphics technology to develop a treatment plan which specifies the desired movements of your teeth during the course of your treatment. Upon approval of a treatment plan developed by your dentist, a series of customised aligners is produced specifically for your treatment.

PROCEDURE

You may undergo a routine orthodontic pre-treatment examination including radiographs (x-rays) and photographs. Your dentist will take impressions or intra-oral scans of your teeth and send them along with a prescription to the technician. Aligner technicians will follow your dentist's prescription to create a software model of your prescribed treatment. Upon approval of the treatment plan by your dentist, a series of customised aligners will be produced and shipped to your dentist. The total number of aligners will vary depending on the complexity of your malocclusion and the dentist's treatment plan. The aligners will be individually numbered and will be dispensed to you by your dentist with specific instructions for use. Unless otherwise instructed by your dentist, you should wear your aligners for approximately 20 to 22 hours per day, removing them only to eat, brush and floss. As directed by your dentist, you will switch to the next aligner in the series every two weeks or as directed by your dentist. Treatment duration varies depending on the complexity of your dentist's prescription. Unless instructed otherwise, you should follow up with your dentist at a minimum of every 6 to 8 weeks.

Some patients may require bonded aesthetic attachments and/ or the use of elastics during treatment to facilitate specific orthodontic movements. Patients may require additional impressions or intra-oral scans and/or refinement aligners after the initial series of aligners.

BENEFITS

- **Clear aligners offer an aesthetic alternative to conventional braces.**
- **Aligners are nearly invisible so many people won't realise you are in treatment.**
- **Treatment plans can be visualised through the planning software.**
- **Aligners allow for normal brushing and flossing tasks that are generally impaired by conventional braces.**
- **Aligners do not have the metal wires or brackets associated with conventional braces, which is more comfortable.**
- **The wearing of aligners may improve oral hygiene habits during treatment.**
- **Clear aligner patients may notice improved periodontal (gum) health during treatment.**
- **The aligners are removable, allowing you to eat, drink, brush and floss with freedom.**

CLEAR ALIGNER INFORMATION (2)



RISKS AND INCONVENIENCES

Although the benefits generally outweigh the potential risks, all factors should be considered before making the decision to wear aligners. Like any other orthodontic treatments, the use of clear aligners may include (but not limited to) some of the risks outlined below:

- (i) Treatment time may exceed estimates. Failure to wear the appliances for 22 hours per day, not using the product as directed by your dentist, missing appointments, and erupting or atypically shaped teeth can lengthen the treatment time, increase the cost and affect the ability to achieve the desired results;
- (ii) Dental tenderness may be experienced after switching to the next aligner in the series;
- (iii) Gums, cheeks and lips may be scratched or irritated, especially can cause ulcers in the beginning of the treatment;
- (iv) Teeth may shift position after treatment if retainers are not worn as directed by your dentist. Choice of retainers will be discussed with your dentist. Consistent wearing of retainers at the end of treatment should reduce this tendency;
- (v) Tooth decay, periodontal disease, inflammation of the gums or permanent markings (e.g. decalcification) may occur if patients consume foods or beverages containing sugar, do not brush and floss their teeth properly before wearing the Invisalign products, or do not use proper oral hygiene and preventative maintenance;
- (vi) The aligners may temporarily affect speech and may result in a lisp, although patients generally adapt quickly to wearing aligners and it is rare that speech is impaired for an extended period of time. The aligners may affect playing of music instruments using mouth;
- (vii) Aligners may cause a temporary increase in salivation or mouth dryness and certain medications can heighten this effect;
- (viii) Attachments may be bonded to one or more teeth during the course of treatment to facilitate tooth movement and/or appliance retention. When you are not wearing your aligners, these engagers can feel awkward in the mouth. These will be removed after treatment is completed;
- (ix) Attachments may chip or fall off, which may require replacement;
- (x) In cases of crowding, IPR, known as interproximal recontouring may be required in order to create space needed for dental alignment to occur;
- (xi) The bite may change throughout the course of treatment and may result in temporary patient discomfort;
- (xii) In rare instances, slight superficial surface wear of the aligner may occur where patients may be grinding their teeth or where the teeth may be rubbing and is generally not a problem as overall aligner integrity and strength remains intact;
- (xiii) At the end of orthodontic treatment, the bite may require adjustment ("occlusal adjustment");
- (xiv) Atypically shaped, erupting and/or missing teeth may affect aligner adaptation and may affect the ability to achieve the desired results;
- (xv) Treatment of severe open bite, severe overjet, mixed dentition, and/or skeletally narrow jaw may require supplemental treatment in addition to aligner treatment;
- (xvi) Supplemental orthodontic treatment, including the use of bonded buttons, orthodontic elastics, auxiliary appliances/ dental devices (e.g. temporary anchorage devices, sectional fixed appliances), and/or restorative dental procedures may be needed for more complicated treatment plans where aligners alone may not be adequate to achieve the desired outcome;
- (xvii) Teeth which have been overlapped for long periods of time may be missing the gingival tissue below the interproximal contact once the teeth are aligned, leading to the appearance of a "black triangle" space;
- (xviii) Aligners are not effective in the movement of dental implants;
- (xix) General medical conditions and use of medications can affect orthodontic treatment;
- (xx) Health of the bone and gums which support the teeth may be impaired or aggravated;
- (xxi) Oral surgery may be necessary to correct crowding or severe jaw imbalances that are present prior to wearing the Invisalign product. If oral surgery is required, risks associated with anesthesia and proper healing must be taken into account prior to treatment;
- (xxii) A tooth that has been previously traumatised, or significantly restored may be aggravated. In rare instances the useful life of the tooth may be reduced, the tooth may require additional dental treatment such as endodontic and/or additional restorative work and the tooth may be lost;
- (xxiii) Existing dental restorations (e.g. crowns) may become dislodged and require re-cementation or in some instances, replacement; Before any dental restorations are replaced or added, consult your dentist, as they can affect the way your aligners fit.
- (xxiv) Short clinical crowns can pose appliance retention issues and inhibit tooth movement;
- (xxv) The length of the roots of the teeth may be shortened during any orthodontic treatment including clear aligners and may become a threat to the useful life of teeth; 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
- (xxvi) Product breakage is more likely in patients with severe crowding and/or multiple missing teeth;
- (xxvii) Orthodontic appliances or parts thereof may be accidentally swallowed or aspirated;
- (xxviii) In rare instances, problems may also occur in the jaw joint, causing joint pain, headaches or ear problems;
- (xxix) Though uncommon, allergic reactions to the material used during treatment may occur. If you believe you are experiencing an adverse reaction, inform your doctor immediately.
- (xxx) Teeth that are not at least partially covered by the aligner may undergo supereruption (come out of the gums more than other teeth);
- (xxxi) In rare instances, patients with hereditary angioedema (HAE), a genetic disorder, may experience rapid local swelling of subcutaneous tissues including the larynx, HAE may be triggered by mild stimuli including dental procedures;
- (xxxii) Tooth sensitivity and tenderness of the mouth may occur during treatment—especially when advancing from one aligner to the next;
- (xxxiii) You will be given series of aligners to be worn in the correct sequence. Aligners worn out of their intended sequence can delay treatment results and may result in extended treatment time with extra cost.
- (xxxiv) 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. Always follow the directions for use (included with each aligner package) for best results.



CLEAR ALIGNER CONSENT (3)

INFORMED CONSENT

I have been given adequate time to read and have read the preceding information describing orthodontic treatment with clear aligners. I understand the benefits, risks, alternatives and inconveniences associated with treatment as well as the option of no treatment. I have been sufficiently informed and have had the opportunity to ask questions and discuss concerns about orthodontic treatment with my dentist from whom I intend to receive treatment. I understand that the treating dentist is a trained general dentist using clear aligners and not an orthodontist, and I hereby consent to orthodontic treatment with clear aligners that have been prescribed by my dentist. Due to the fact that orthodontics is not an exact science, I acknowledge that my dentist and the clear aligner company have not and cannot make any guarantees or assurances concerning the outcome of my treatment. I understand that the aligner company is not a provider of medical, dental or health care services and does not and cannot practice medicine, dentistry or give medical advice. No assurances or guarantees of any kind have been made to me by my dentist or clear aligner company, its representatives, successors, assigns, and agents concerning any specific outcome of my treatment.

I authorise my dentist to release my medical records, including, but not be limited to, radiographs (x-rays), reports, charts, medical history, photographs, findings, plaster models or impressions or intra-oral scans of teeth, prescriptions, diagnosis, medical testing, test results, billing, and other treatment records in my dentist's possession ("Medical Records") (i) to other licensed dentists or and organisations employing licensed dentists and orthodontists and to aligner company, its representatives, employees, successors, assigns, and agents for the purposes of investigating and reviewing my medical history as it pertains to orthodontic treatment with product(s) from aligner company and (ii) for educational and research purposes.

I understand that use of my Medical Records may result in disclosure of my "individually identifiable health information" as defined by the Health Insurance Portability and Accountability Act ("HIPAA"). I hereby consent to the disclosure(s) as set forth above. I will not, nor shall anyone on my behalf seek legal, equitable or monetary damages or remedies for such disclosure. I acknowledge that use of my Medical Records is without compensation and that I will not nor shall anyone on my behalf have any right of approval, claim of compensation, or seek or obtain legal, equitable or monetary damages or remedies arising out of any use such that comply with the terms of this Consent.

A photostatic copy of this Consent shall be considered as effective and valid as an original. I have read, understand and agree to the terms set forth in this Consent as indicated by my signature below.

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Patient Signature

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Dentist's signature

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Patient name

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Dentist's name

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Date