

INFORMED CONSENT AND AGREEMENT FOR U-ALIGNER PATIENTS

Your doctor has recommended the U-Aligner system as part of your orthodontic treatment. Although orthodontic treatment can lead to a more attractive and healthier smile, you should also be aware that such treatment has limitations and potential risks that you should consider before commencing your treatment.

The U-Aligner system consists of a series of clear thermoformed plastic trays that move your teeth gradually during the duration of the treatment. U-Aligner treatment combines your doctor's diagnosis and prescription to develop a treatment plan that specifies the desired movements of your teeth. Upon approval of a treatment plan by your doctor, a series of customized U-Aligners are produced specifically for you.

PROCEDURE

You may undergo a routine orthodontic pre-treatment examination including radiographs (x-rays) and photographs. Your doctor will take scans of your teeth and send them along with a prescription to the laboratory. Technicians will follow your doctor's prescription to create a digital model of your prescribed treatment. Upon approval of the treatment plan by your doctor, the laboratory will produce and ship a series of customized aligners to your doctor. The total number of aligners will vary depending on the complexity of your malocclusion and the doctor's treatment plan. The aligners will be individually numbered and will be dispensed to you by your doctor with specific instructions for use. Unless otherwise instructed by your doctor, 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 doctor, you will switch to the next aligner in the series every two to three weeks. Treatment duration varies depending on the complexity of your doctor's prescription. Unless instructed otherwise, you should follow up with your doctor 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 and/or refinement aligners after the initial series of aligners.

RISKS AND INCONVENIENCES

Like other orthodontic treatments, the use of U-Aligner may involve some of the risks outlined below:

- (i) Failure to wear the appliances for the required number of hours per day, not using the product as directed by your doctor, missing appointments, and erupting or atypically shaped teeth can lengthen the treatment time 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;
- (iv) Teeth may shift position after treatment. 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 aligners, or do not use proper oral hygiene and preventative maintenance;
- (vi) The aligners may temporarily affect speech and may result in a lisp, although any speech impediment caused by the aligners should disappear within one or two weeks;

- (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. These will be removed after treatment is completed;
- (ix) Teeth may require interproximal recontouring or slenderizing in order to create space needed for dental alignment to occur;
- (x) The bite may change throughout the course of treatment and may result in temporary patient discomfort.
- (xi) At the end of orthodontic treatment, the bite may require adjustment (“occlusal adjustment”);
- (xii) 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;
- (xiii) 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;
- (xiv) Aligners are not effective in the movement of dental implants;
- (xv) General medical conditions and use of medications can affect orthodontic treatment;
- (xvi) Health of the bone and gums which support the teeth may be impaired or aggravated;
- (xvii) Oral surgery may be necessary to correct crowding or severe jaw imbalances that are present prior to wearing the U-Aligner product. If oral surgery is required, risks associated with anesthesia and proper healing must be taken into account prior to treatment;
- (xviii) A tooth that has been previously traumatized, 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;
- (xix) Existing dental restorations (e.g. crowns) may become dislodged and require re-cementation or in some instances, replacement;
- (xx) Short clinical crowns can pose appliance retention issues and inhibit tooth movement;
- (xxi) The length of the roots of the teeth may be shortened during orthodontic treatment and may become a threat to the useful life of teeth;
- (xxii) Orthodontic appliances or parts thereof may be accidentally swallowed or aspirated;
- (xxiii) In rare instances, problems may also occur in the jaw joint, causing joint pain, headaches or ear problems;
- (xxiv) Allergic reactions may occur; and
- (xxv) Teeth that are not at least partially covered by the aligner may undergo supraeruption.

INFORMED CONSENT

I have been given adequate time to read and have read the preceding information describing orthodontic treatment with U-Aligner. 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 U-Aligner products with my doctor from whom I intend to receive treatment. I understand that I should only use the U-Aligner products after consultation and prescription from an U-Aligner trained doctor, and I hereby consent to orthodontic treatment with U-Aligner products that have been prescribed by my doctor.

Due to the fact that orthodontics is not an exact science, I acknowledge that my doctor and U-Aligner have not and cannot make any guarantees or assurances concerning the outcome of my treatment. I understand that U-Aligner 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 doctor or U-Aligner, its representatives, successors, assigns, and agents concerning any specific outcome of my treatment.

I authorize my doctor to release my medical records, including, but not be limited to, radiographs (x-rays), reports, charts, medical history, photographs, findings, plaster models or impressions of teeth, prescriptions, diagnosis, medical testing, test results, billing, and other treatment records in my doctor’s possession (“Medical Records”) (i) to other licensed dentists or orthodontists and organizations employing licensed dentists and orthodontists and to U-Aligner, 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 U-Aligner 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.

Any 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.

Signature

Witness

Print Name

Print Name

Address

Signature of Parent/Guardian

City, State, Zip

If signatory is under 21, the parent of legal Guardian must also sign to signify agreement.

