

INFORMED CONSENT AND AGREEMENT *FOR THE INVISALIGN PATIENT*

PATIENT'S INFORMED CONSENT AND AGREEMENT REGARDING INVISALIGN[®] ORTHODONTIC TREATMENT

Your doctor has recommended the Invisalign[®] system for your orthodontic treatment. Although orthodontic treatment can lead to a healthier and more attractive smile, you should also be aware that any orthodontic treatment (including orthodontic treatment with Invisalign aligners) has limitations and potential risks that you should consider before undergoing treatment.

DEVICE DESCRIPTION

Invisalign[®] aligners, developed by Align Technology, Inc. ("Align") consist of a series of clear plastic, removable appliances that move your teeth in small increments. Invisalign products combine your doctor's diagnosis and prescription with sophisticated computer graphics technology to develop a treatment plan which specifies the desired movements of your teeth during your treatment. Upon approval of a treatment plan developed by your doctor, a series of customized Invisalign aligners is produced specifically for your treatment.

PROCEDURE

After your initial examination including radiographs and photographs an intra-oral scan of your teeth will be done and sent with a prescription to the Align laboratory. Align technicians will follow your doctor's prescription to create a ClinCheck[®] software model of your prescribed treatment. Upon approval of the ClinCheck treatment plan by your doctor, Align 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 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. Treatment duration varies depending on the complexity of your doctor's prescription.

RISKS AND INCONVENIENCES

Like other orthodontic treatments, the use of Invisalign[®] product(s) 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; Gums, cheeks and lips may be scratched or irritated;
- (iii) Teeth may shift position after treatment. Consistent wearing of retainers at the end of treatment should reduce this tendency;
- (iv) 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;
- (v) The aligners may temporarily affect speech and may result in a lisp, although any speech impediment caused by the Invisalign products should disappear within one or two weeks; Aligners may cause a temporary increase in salivation or mouth dryness and certain medications can heighten this effect;
- (vi) Attachments may be bonded to one or more teeth during treatment to facilitate tooth movement and/or appliance retention. Attachments may fall off and require replacement and they will all be removed when treatment is complete;
- (vii) Teeth may require interproximal re-contouring or slenderizing to create space needed for dental alignment to occur; The bite may change throughout the course of treatment and may result in temporary patient discomfort.
- (viii) In rare instances, slight superficial 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 remain intact.

- (ix) Atypically-shaped, erupting, and/or missing teeth may affect aligner adaptation and may affect the ability to achieve the desired results.
- (x) Treatment of severe open bite, severe overjet, mixed dentition, and/or skeletally narrow jaw may require supplemental treatment in addition to aligner treatment.
- (xi) 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.
- (xii) 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.
- (xiii) Aligners are not effective in the movement of dental implants.
- (xiv) General medical conditions and use of medications can affect orthodontic treatment;
- (xv) Health of the bone and gums which support the teeth may be impaired or aggravated;
- (xvi) 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;
- (xvii) Existing dental restorations (e.g. crowns) may become dislodged and require re-cementation or in some instances, replacement;
- (xviii) 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;
- (xix) Product breakage is more likely in patients with severe crowding and/or multiple missing teeth;
- (xx) Orthodontic appliances or parts thereof may be accidentally swallowed or aspirated;
- (xxi) In rare instances, problems may also occur in the jaw joint, causing joint pain, headaches or ear problems;
- (xxii) Allergic reactions may occur; and teeth that are not at least partially covered by the aligner may undergo supraeruption;
- (xxiii) In rare instances patients with Hereditary Angio Edema (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.

INFORMED CONSENT:

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

Because orthodontics is not an exact science, I acknowledge that Dr. Datwyler and Align Technology, Inc. (“Align”) have not and cannot make any guarantees or assurances concerning the outcome of my treatment. I understand that Align 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 Align, its representatives, successors, assigns, and agents concerning any specific outcome of my treatment.

I authorize Dr. Datwyler to release my medical records, including, but not be limited to, radiographs (x-rays), reports, charts, medical history, photographs, findings, plaster models, impressions of teeth, or intra-oral scans, 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 Align, 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 Align 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 digital 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.

ACKNOWLEDGEMENT:

I hereby acknowledge that I have read and fully understand the treatment considerations and risks presented in this form. I also understand that there may be other problems that occur less frequently than those presented, and that actual results may differ from the anticipated results. I always can discuss and ask Dr. Datwyler any questions regarding this form. I hereby consent to the treatment proposed and authorize Dr. Datwyler to provide the treatment. I understand that my treatment fee covers only treatment provided by Dr. Datwyler and that treatment provided by other dental or medical professionals is not included in the fee for my orthodontic treatment.