

## CLEAR ALIGNER (INVISALIGN®) ORTHODONTIC TREATMENT PATIENT'S INFORMED CONSENT AND AGREEMENT

Your doctor has recommended the Clear Aligner (Invisalign®) 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® clear aligners consist of a series of clear plastic, removable appliances that move your teeth in small increments. Clear Aligner (Invisalign®) orthodontic treatment combines 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 the course of 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

You may undergo a routine orthodontic pre-treatment examination including radiographs (x-rays) and photographs. Your doctor will take impressions or intra-oral scans of your teeth and send them along with a prescription to the Align laboratory, who will create a ClinCheck® software model of the 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 malocclusion and the doctor's treatment plan.

Interproximal reduction (IPR) is often performed. IPR is the reduction of tooth structure in between teeth to create space. In cases of tooth crowding, IPR can provide space for repositioning teeth in optimal location and tooth alignment. IPR may be performed by diamond-coated discs on a rotary handpiece or by hand using diamond-coated strips that are worked back and forth between teeth like a nail file. A small part of the thickness of a tooth's enamel is trimmed where space is needed for orthodontic realignment.

*Will interproximal reduction hurt?* Although enamel is removed from living teeth, the amount of enamel being removed is small. Since there are no nerve endings in enamel of teeth, stripping enamel usually has no sensation. However, the vibration on teeth may be perceived as uncomfortable by some patients, but certainly tolerable by most.

*Will I notice gaps between my teeth?* After interproximal reduction you will notice small gaps between your teeth. As your treatment progresses your gaps will become smaller and eventually fully close.

*Will IPR change, damage or hurt my teeth?* Because only a very minor amount of enamel is removed, IPR does not result in the tooth appearing any thinner, nor should it result in an increased risk of tooth decay or sensitivity.

Attachments, which are small tooth-colored bumps, may be bonded on your teeth, using dental composites. Attachments are bonded at precise locations to allow the aligners to grip the teeth as they are guiding them to their new locations. These attachments will be removed at the end of treatment.

Metal or tooth-colored ceramic buttons may be bonded to some of your teeth. These are auxiliaries that are used to attach or anchor rubber bands.

Micro screws may be installed into your bone to serve as anchorage for elastics during treatment to facilitate specific orthodontic movements.

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. Careful monitoring is essential to the success of treatment. By the same token, failure to

present for monitoring visits can pose the risk of not detecting problems and managing such problems.

**Refinement.** Teeth may not move as anticipated. There are many potential reasons for teeth not moving according to plan. This may be due to incomplete compliance, where the aligners are not worn as directed. Some teeth may be too short and insufficient tooth may be available for aligners to engage. Some teeth may be ankylosed, which is fused to the jawbone and unable to move.

Patients may require additional impressions, or intra-oral scans, and/or refinement aligners after the initial series of aligners. This may be necessary to optimize the outcome. There may be additional expenses associated with refinement aligners.

**Retainers:** at the conclusion of active orthodontic treatment, it will be necessary to maintain the teeth and prevent them from shifting. Various options for retention are discussed by your doctor, which include removable retainers or fixed retainers. x

## **BENEFITS**

- Invisalign® aligners offer an esthetic alternative to conventional braces.
- Aligners are less visible than braces.
- Treatment plans can be visualized through the ClinCheck® 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.
- The wearing of aligners may improve oral hygiene habits during treatment.
- Invisalign patients may notice improved periodontal (gum) health during treatment.

## **RISKS AND INCONVENIENCES**

Like other orthodontic treatments, Invisalign® therapy 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. At the end of treatment, the options for retainers will be discussed. Consistent wearing of retainers at the end of treatment will be necessary to reduce this tendency for relapse. Retainers have to be worn indefinitely in order to maintain stable position of the teeth
- (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 any speech impediment caused by the Invisalign products 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) Attachments may fall off and require replacement.
- (x) Teeth may require interproximal recontouring or slenderizing 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 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.
- (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, such as surgery, 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 such as screws, 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 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 (root canal) and/or additional restorative work and the tooth may be lost;
- (xxiii) Existing dental restorations (e.g. crowns or veneers) may become dislodged or damaged and require re-cementation or in some instances, replacement;
- (xxiv) Short clinical crowns can pose appliance retention issues and inhibit tooth movement;
- (xxv) Root resorption (shortening the length of the roots) may occur during orthodontic treatment and may become a threat to the useful life of teeth;
- (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, such as degeneration of the jaw joint, causing joint pain and/or headaches
- (xxix) Allergic reactions may occur;
- (xxx) Teeth that are not at least partially covered by the aligner may undergo supraeruption;
- (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) Regular professional cleanings are necessary at more frequent intervals (usually every 3 months or more often), during orthodontic tooth movement. Failure to present for regular professional cleanings may lead to increased inflammation of gums, loss of supporting bone around teeth and/or gum recession.
- (xxxiii) Some degree of gum recession may occur after treatment. This may be noticeable as exposure of root surfaces on the outer portions of your teeth and/or spaces in between teeth.
- (xxxiv) Shape of natural teeth or crowns may change as a result of adjustment made to teeth during various stages of therapy
- (xxxv) Failure to comply with regular monitoring visits during active treatment can increase the risk of adverse events. Your dentist needs to carefully monitor your progress to detect any problems that may have occurred at an early phase to provide appropriate management. This may lead to undetected problems that can become worse.

### 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 my doctor from whom I intend to receive treatment. I understand that I should only use the Invisalign products after consultation and prescription from my doctor, and I hereby consent to orthodontic treatment with Invisalign products that have been prescribed by my doctor.

Due to the fact that orthodontics is not an exact science, I acknowledge that my doctor has not and cannot make any guarantees or assurances concerning the outcome of my treatment. No assurances or guarantees of any kind have been made to me by my doctor, his/her representatives, 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, 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.

I consent to my photographs, as well as audio and video recordings, including facial images or videos to be used by my doctor or affiliates for the purpose of education and/or in promotional material.

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.

It is essential to wear appropriate retainers at the end of active treatment to avoid relapse.

**Initials:** \_\_\_\_\_ Several options are available for retainers. Retainers and associated fees are not included in this treatment plan. The options for retainers and the fees for retainers will be presented at the conclusion of active Invisalign treatment.

<p>_____ <b>Signature</b></p> <p>_____ <b>Print Name</b></p> <p>_____ Address</p> <p>_____ City, State, Zip Date</p>	<p>_____ Witness</p> <p>_____ Print Name</p> <p>_____ Signature of Parent/Guardian:</p> <p>If signatory is under 21, the parent or legal Guardian must also sign to signify agreement.</p>
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**Patient initial** \_\_\_\_\_