

## **Informed Consent and Agreement**

### **Regarding Invisalign® Orthodontic Treatment**

Our doctors have 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’s product combines our 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 our doctors, a series of customised Invisalign aligners is produced specifically for your treatment.

#### **PROCEDURE**

You may undergo a routine orthodontic pre-treatment examination including radiographs (x-rays) and photographs. Our Orthodontic Therapist or Assistant will take intra-oral scans of your teeth and send them along with a prescription to the Align laboratory. Align technicians will follow our doctors prescription to create a ClinCheck® software model of your prescribed treatment. Upon approval of the ClinCheck treatment plan by our doctors, Align will produce and ship a series of customised aligners to our office. The total number of aligners will vary depending on the complexity of your malocclusion and our doctors’ treatment plan. The aligners will be individually numbered and will be dispensed to you with specific instructions for use. Unless otherwise instructed, you should wear your aligners for approximately 20 to 22 hours per day, removing them only to eat, brush and floss. As directed, you will switch to the next aligner in the series every week or as directed. Treatment duration varies depending on the complexity of your prescription. You will be instructed on when to schedule your follow up appointments.

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

#### **BENEFITS**

- Invisalign 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 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, the use of Invisalign product(s) may involve some of the risks outlined below:

Perfection is our goal; however, in dealing with the human body and problems of growth and development and patient cooperation, achieving perfection is not always possible. Often a functionally and aesthetically adequate result must be accepted.

Failure to wear the appliances for the required number of hours per day, not using the product as directed, missing appointments, and erupting or atypically shaped teeth can lengthen the treatment time and affect the ability to achieve the desired results;

Dental tenderness may be experienced after switching to the next aligner in the series. Gums, cheeks and lips may be scratched or irritated;

Teeth may shift position after treatment. The consistent wearing of retainers at the end of treatment should reduce this tendency;

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;

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;

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;

Attachments may fall off and require replacement;

Teeth may require interproximal recontouring or slenderising 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;

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;

At the end of orthodontic treatment, the bite may require adjustment (“occlusal adjustment”);

Atypically shaped, erupting and/or missing teeth may affect aligner adaptation and may affect the ability to achieve the desired results;

Treatment of severe open bite, severe overjet, mixed dentition, and/or skeletally narrow jaw may require supplemental treatment in addition to aligner treatment;

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;

Teeth that have been overlapped for long periods may be missing the gingival tissue below the inter-proximal contact once the teeth are aligned, leading to the appearance of a “black triangle” space;

Aligners are not effective in the movement of dental implants;

General medical conditions and use of medications can affect orthodontic treatment;

The health of the bone and gums which support the teeth may be impaired or aggravated;

Oral surgery may be necessary to correct crowding or severe jaw imbalances that are present before wearing the Invisalign product. If oral surgery is required, risks associated with anaesthesia and proper healing must be taken into account before treatment;

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;

Existing dental restorations (e.g. crowns) may become dislodged and require re-cementation or in some instances, replacement;

Short clinical crowns can pose appliance retention issues and inhibit tooth movement;

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;

Product breakage is more likely in patients with severe crowding and/or multiple missing teeth;

Orthodontic appliances or parts thereof may be accidentally swallowed or aspirated;

In rare instances, problems may also occur in the jaw joint, causing joint pain, headaches or ear problems;

Allergic reactions may occur;

Teeth that are not at least partially covered by the aligner may undergo supra-eruption;

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.

#### **ADDITIONAL FEES THAT MAY BE PAYABLE**

1. Procedures associated with the treatment done in other offices. (E.g. x-rays, extractions, fillings, dental checkups, cleanings, jaw surgery, TMJ therapy or cosmetic dental work) - Cost is at the dentists'/specialists' discretion
2. Extended treatment due to lack of patient co-operation
3. Replacement of lost or broken aligners
4. If aligners no longer fit due to compliance.
5. If your aligners no longer fit due to dental treatment such as fillings, crowns, veneers etc
6. If you wish to alter your treatment plan mid-treatment.
7. If a patient is non-compliant and changes over to metal braces, a fee of \$500 will be payable.
8. If consent to treatment is withdrawn before starting the proposed treatment, any expenses incurred for laboratory fees, administration services, appliance fees or any other expenses will still be payable.

#### **INFORMED CONSENT**

##### **CONSENT TO UNDERGO ORTHODONTIC TREATMENT**

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's product with our doctors from whom I intend to receive treatment.

I hereby consent to the treatment proposed and authorise our doctors and, where appropriate his staff providing orthodontic treatment prescribed by him/her for me.

##### **FINANCIAL COMMITMENT:**

Informed Consent Invisalign

Feb 21, Apr 21, Aug 20, Oct 21



I have been provided with a copy of the "Treatment Fee Schedule" outlining my financial commitment.

**AUTHORISATION FOR RELEASE OF PATIENT INFORMATION:**

I hereby authorise our doctor's to provide other health care providers with information regarding my orthodontic care as deemed appropriate.

Patient's Name.....

Signature of patient/parent guardian: .....

Relationship to patient.....

Date.....