

("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.

Furthermore, I am choosing to decline consistent and routine check-ups with Gladwell Orthodontics through their "GO Simple" program. I understand that this may result in less effective results than the standard procedure and/or unforeseen complications. I am fully aware of the risks of monitoring orthodontic treatment on my own and the staff at Gladwell Orthodontics has advised me of all the possible risks and benefits to receiving treatment through this program. I am also aware of the opportunity to make an office appointment and be seen by a member of the Gladwell Orthodontics team should a problem or question arise during the course of my treatment. I am as well aware of the option to switch treatment programs to a more traditionally monitored treatment approach at any time during treatment. The process and protocols for this are well written and were explained to me before the start of my treatment.

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 Addendum as indicated by my signature below.

Signature

Print Name

Address

City, State, Zip

Date

Witness

Print Name

Signature of Parent/Guardian

ACKNOWLEDGMENT

The following documents are included in your GO Simple introductory box. Before signing this document, please contact us by phone or email if you have ANY questions. Please check each box to confirm that you have thoroughly read and understand the corresponding document.

- ☐ Welcome Letter
- ☐ Simple Next Steps
- ☐ Additional Services
- ☐ GO Simple vs. GO Traditional
- ☐ Plan For Success
- ☐ Informed Consent And Agreement

Please sign this form acknowledging that you have thoroughly read and completely understand each document included in the GO Simple introductory box.

Signature

Print name

Date



INFORMED CONSENT AND AGREEMENT

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 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. 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 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, or intra-oral scans, and/or refinement aligners after the initial series of aligners.

BENEFITS

- Invisalign® aligners offer an esthetic alternative to conventional braces.
- Aligners are nearly invisible so many people won’t realize you are in treatment.
- 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.

- (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 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 of the 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 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 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;
- (xxiii) Existing dental restorations (e.g. crowns) may become dislodged and require re-cementation or in some instances, replacement;
- (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 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, causing joint pain, headaches or ear problems;
- (xxix) Allergic reactions may occur; and
- (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 generic disorder, may experience rapid local swelling of subcutaneous tissues including the larynx. HAE may be triggered by mild stimuli including dental procedures.

INFORMED CONSENT – “GO SIMPLE”

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 Gladwell Orthodontics 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 (Gladwell Orthodontics), and I hereby consent to orthodontic treatment with Invisalign® products that have been prescribed by Gladwell Orthodontics.

Due to the fact that orthodontics is not an exact science, I acknowledge that Gladwell Orthodontics and Align Technology, Inc.

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