

# INVISALIGN CONSENT FORM



76 Madison Avenue NY, NY 10016  
hello@smilepop.com | 646.770.2091  
www.smilepop.com

## **PATIENT'S INFORMED CONSENT & AGREEMENT REGARDING INVISALIGN ORTHODONTIC TREATMENT AT SMILE POP**

Your doctor has recommended the Invisalign<sup>®</sup> 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<sup>®</sup> 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 digital impressions 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<sup>®</sup> 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 directly 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 week. Treatment duration varies depending on the complexity of your doctor's prescription. Some patients may require bonded aesthetic attachments and/ or the use of elastics during treatment to facilitate specific orthodontic movements. Many patients may require additional digital impressions and/or refinement aligners after the initial series of aligners.

### **BENEFITS**

- Invisalign<sup>®</sup> 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<sup>®</sup> 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 & INCONVENIENCES

As with all forms of medical and dental treatment, orthodontics has some risks and limitations. Fortunately, complications in orthodontics are infrequent, and, when they do occur, they are usually of minor consequence. Nevertheless, they should be considered when making the decision to undergo orthodontic treatment.

Like other orthodontic treatments, the use of Invisalign<sup>®</sup> 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.

(iii) Dental instruments may inadvertently scratch, poke or hit a tooth, causing potential damage to or soreness of affected oral structures. On rare occasions, parts of orthodontic appliances may be accidentally swallowed or aspirated, and the gums, cheeks and lips may be scratched or irritated by loose or broken appliances or by blows/ bumps to the mouth. We will use extreme care to avoid minor injuries..

(iv) Teeth have a tendency to change their positions after orthodontic treatment. There is usually only a minor change, and faithful wearing of retainers at night for an indefinite period should help reduce this tendency. Throughout life the bite can change from various causes (eruption of wisdom teeth, growth and/ or aging, mouth breathing, clenching and other oral habits), all of which are outside the control of the orthodontist.

(v) Tooth discoloration, tooth decay, periodontal disease, inflammation of the gums or permanent markings (e.g. decalcifications) can occur on the teeth if any orthodontic patient eats food containing excessive sugar or acid and does not brush the teeth properly. These same problems occur without

orthodontic treatment, but the risk is greater to an individual wearing traditional braces or aligners. Good oral hygiene and proper preventative maintenance is a must during orthodontic treatment to prevent problems, especially brushing and flossing of teeth properly before wearing the Invisalign products.

(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) 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 ( called an "occlusal adjustment/equilibration").

(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 after alignment.

(xiv) Aligners are not effective in the movement of dental implants.

(xv) General medical conditions and use of medications can affect orthodontic treatment. You should keep your orthodontist informed of any changes in your medical health.

(xvi) The health of the bone and gums which support the teeth may be affected, impaired, and/or aggravated by orthodontic tooth movement if a condition already exists and in some rare cases where a condition doesn't appear to exist. Proper brushing and flossing can usually prevent swollen, inflamed and bleeding gums. Periodontal disease is usually caused by the accumulation of plaque and debris around the teeth and gums, but there are some unknown causes that can also lead to progressive loss of the supporting bones and gums. It is important that the patient have regular cleanings and dental check-ups during orthodontic treatment. If gum disease should become uncontrollable, orthodontic treatment would have to be discontinued prior to completion.

(xvii) Sometimes oral surgery (tooth removal or jaw surgery to correct imbalances) is necessary in conjunction with orthodontic treatment, especially to correct crowding or severe jaw imbalances. Risk involved with anesthesia or any surgical treatment should be discussed with your general dentist or oral surgeon before making your decision to proceed with surgery. If oral surgery is required, risks associated with anesthesia and proper healing must be taken into account prior to treatment.

(xviii) Sometimes a tooth may have been traumatized by a previous accident or a tooth may have a large filling, which can cause damage to the nerve of the tooth. Orthodontic tooth movement may aggravate this condition and, in rare instances, may lead to root canal treatment. It may also reduce the useful life of the tooth or may require additional dental treatment such as additional restorative work. Existing dental restorations (e.g. crowns) may become dislodged and require re-cementation or in some instances, replacement. This type of treatment is not covered in your orthodontics and is done by another specialist if needed.

(xx) Short clinical crowns can pose appliance retention issues and inhibit tooth movement.

(xxi) Some patients are prone to the roots of their teeth being shortened during orthodontic treatment, some are not. This usually does not have significant consequences, but in the presence of gum problems and bone loss, it may become a threat to the long-term health of the teeth involved. 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) Product breakage is more likely in patients with severe crowding and/or multiple missing teeth.

(xxiii) Orthodontic appliances or parts thereof may be accidentally swallowed or aspirated.

(xxiv) Patients with bad bites have a high potential for TMJ or jaw joint problems. These problems may be present before orthodontic treatment, and symptoms may develop during or after orthodontic treatment. TMJ problems will occur with or without orthodontic treatment. TMJ symptoms include joint stiffness, limited jaw motion, facial pain, ear pain, dizziness, headaches and neck aches. There is no guarantee that orthodontic treatment will correct or prevent TMJ symptoms. Any of the above noted symptoms should be promptly reported to the orthodontist.

(xxv) Allergic reactions may occur.

(xxvi) Teeth that are not at least partially covered by the aligner may undergo supereruption.

(xxvii) Due to the wide variation in the size and shape of teeth, achievement of the most ideal result (for example, complete closure of excessive space) may require restorative dental treatment. The most common types of treatment are cosmetic bonding, crown and bridge restorative dental care and/or periodontal therapy. You are encouraged to ask questions regarding dental and medical care adjunctive to orthodontic treatment of the doctors who provide these services.

## **SPECIAL CONSIDERATIONS FROM SMILE POP**

Positive orthodontic results can be achieved by an informed and cooperative patient; therefore, the following information is routinely supplied to all who consider orthodontic treatment. While recognizing the benefits of healthy teeth and a pleasing smile, you should also be aware that orthodontic treatment has limitations and potential risks. These are seldom enough to avoid treatment but should be considered in making the decision to undergo orthodontic treatment. Orthodontic treatment usually proceeds as planned; however, like all areas of the healing arts, results cannot be guaranteed.

For the vast majority of patients, orthodontic treatment is an elective procedure. One possible alternative to orthodontic treatment is no treatment at all. You could choose to accept your present oral condition.

Every patient is unique, with different facial features, facial contours, soft tissue proportions, bone structure, tooth size, tooth shape, gum height, gum thickness, gum positioning, lip size and lip positioning, etc. We optimize treatment taking into account those variables, but there are physical limits to what orthodontics alone can do.

During orthodontic treatment, your teeth and their roots will move in a limited capacity due to the structural shape, size, and position of your pre-existing bone; this movement is typically measured in millimeters and doesn't dramatically change your face. Further, variable results are compounded by the fact that we are all human and our bodies change over time. As people age, the bone continually remodels and the soft tissue thins and drops. Regardless of the treatment plan, your smile and face will not look the same at the beginning and end of the treatment due to a variety of factors including aging, weight loss/gain, sun exposure, adjunctive facial and cosmetic procedures, variable medical conditions, and life in general.

Prior to any orthodontic treatment, you will be required to undergo any necessary periodontal and/or restorative care to eliminate any active disease.

It is very important and necessary to maintain regular dental hygiene and check-up appointments with your

dentist while undergoing orthodontic treatment. You should continue to see your general dentist at least every six (6) months for a check-up and cleaning.

Ideal oral hygiene will be necessary to aid in affecting optimal tooth movement and to prevent decalcifications around the fixed appliances.

Insufficient, excessive or abnormal changes in growth of the jaws may limit our ability to achieve the desired result. If growth becomes disproportionate during or after treatment, or if a tooth forms very late, the bite may change, requiring additional treatments or, in some cases, surgery. Growth disharmony and unusual tooth formations are biological processes beyond the orthodontist's control. Growth changes that occur after orthodontic treatment may alter the quality of the treatment results.

## **TREATMENT LENGTH**

The total time required to complete treatment may exceed the original estimate. Excessive or deficient bone growth, poor cooperation in wearing a removable appliance the required hours per day, poor oral hygiene, broken appliances and missed appointments can lengthen the treatment time and affect the quality of the treatment results. We will continue to monitor treatment and take appropriate steps when required. If for any reason we feel that the response is less than adequate, we will review the situation and any treatment alternatives that are available. If treatment time is grossly over the estimated time frame to due patient non-compliance, missed appointments, or not following the prescribed treatment plan or aligner change schedule, the current financial contract and standing in the practice will be reevaluated. The doctor reserves the right to terminate your treatment.

If there comes a point in treatment where the patient becomes overtly non-compliant, we will review the situation and discuss any treatment alternatives that are available, including discontinuation of treatment and referral out of the practice.

Our success in orthodontics is dependent upon your cooperation. You are ultimately responsible for

keeping your regularly scheduled appointments, keeping your teeth clean, wearing the aligners and/or rubber bands as instructed, and taking care not to damage the appliances.

Compliance in the use of all prescribed appliances is essential in order to achieve the desired treatment goals. This includes 20-22 hour per day wear of your aligners and instructed weekly aligners changes.

We are out of network with insurances. Please be aware that any insurance benefits are estimated and are subject to your eligibility and continued participation with the policy. If the policy is terminated at any time, you will be responsible for the financial balance.

Any non-identifiable photographs taken during the course of treatment can be used privately/publicly at the doctor's discretion unless requested otherwise.

#### **IF PATIENT RELOCATES DURING TREATMENT**

In the case where a patient moves during active treatment, in most cases, treatment can continue remotely at Smile Pop provided that the patient has a local doctor to take records (e.g. digital impressions, photos) that can be shared with Smile Pop and to provide adjunctive care. Some offices charge a fee for these records and visits and the patient will be responsible for these charges. The patient will also be responsible for any shipping fees incurred if additional aligners are shipped from Smile Pop.

If at any point the patient moves and desires to transfer services to a new doctor, the patient will need to settle their accounts with Smile Pop prior to transferring the treatment. Our office charges for treatment rendered which includes the cost of your initial treatment records, x-rays, bonding your clear aligners/braces and all adjustments up to the date of your transfer. When transferring active treatment, you will most likely have a new financial plan and contract at the new office that covers the remainder of your treatment at the new office. Your new treatment fee may be more or less than your original contracted amount at Smile Pop.

#### **FINAL STAGE OF TREATMENT**

Retention therapy following orthodontic treatment will be necessary indefinitely to maintain the orthodontic results. One year of retention visits is included with your treatment fee. Retainers have an average lifespan of one to three years, but this timeline may be reduced due to poor care and/or maintenance of retainers and any clenching, grinding, or any other detrimental oral habits.

#### **INFORMED CONSENT**

All orthodontic treatment alternatives and potential risks associated with orthodontic therapy have been covered. The patient and legal guardian have been given ample opportunity to ask questions regarding the treatment options and risks.

I have read this form and hereby acknowledge the major treatment considerations and potential risks that may or may not occur during orthodontic treatment. The doctor and staff have answered all my questions about proposed treatment/risks and presented information to aid in my decision making process. I have received a copy of this Invisalign Consent Form and hereby consent to 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® 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 an Invisalign trained 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 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 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 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 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.

**SIGNATURES**

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Signature of Patient

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Printed Name of Patient

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Date

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Signature of Witness

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Printed Name of Witness

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Signature of Parent/Guardian if Under 21