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INFORMED CONSENT TEMPLATE FOR USE IN CONNECTION WITH PATIENTS UNDERGOING CLEAR ALIGNER ORTHODONTIC TREATMENT

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INFORMED CONSENT FORM FOR PATIENTS UNDERGOING CLEAR ALIGNER ORTHODONTIC TREATMENT

The effectiveness of your orthodontic treatment depends on your cooperation with your doctor. An informed and cooperative patient who carefully follows his or her doctor's prescribed orthodontic treatment plan will have the best chance to achieve positive results.

Your doctor has recommended that you use a clear aligner orthodontic treatment system. Although you may already understand the obvious potential benefits of using clear aligner treatment, i.e., a beautiful, healthy smile, it is important that you consider that, as is the case with all medical treatments and procedures, orthodontic treatment has limitations, risks, and inconveniences, and, occasionally, such risks may warrant foregoing treatment altogether. Prior to treatment, speak with your doctor about the potential risks of using a clear aligner orthodontic treatment system and available orthodontic alternatives, including the option of having no treatment at all.

Please read this information carefully. Be sure to ask your doctor about anything that you do not completely understand, and make sure that you know exactly what is required of you as the patient (or as the parent/guardian of a patient) during treatment.

About Clear Aligner Treatment

Clear aligner orthodontic treatment consists of a series of clear plastic, removable appliances worn by the patient. The liners are designed to move your teeth in small increments to improve bite function and/or esthetic appearance.

Clear aligner orthodontic treatment combines your doctor's diagnosis and prescription with specialized technology to formulate a treatment plan that specifies the desired movements of your teeth. Once your doctor has developed your treatment plan, a series of customized aligners will be fabricated specifically for you.

Procedure

Your doctor may first conduct a regular exam and take x-rays and photographs of your teeth. Impressions/Scans of your teeth will be taken by your doctor and sent with a prescription to the laboratory of your clear aligner treatment system's manufacturer (the "Manufacturer"), where technicians will develop your treatment plan in accordance with your doctor's prescription. Based on the treatment plan, a series of custom-made aligners, designed specifically for you, will be created and sent to your doctor. The total number of aligners will vary depending on the complexity of your malocclusion (misaligned bite) and treatment plan prescribed by your doctor.

Your doctor will provide you with the aligners in accordance with the treatment plan and give you specific instructions for their use. Unless your doctor instructs otherwise, **you MUST wear your aligners at least 22 hours per day, removing them only to eat, brush, and floss.**

Your doctor will inform you when it is time to switch aligners. Generally speaking, you will wear a given set of aligners for about two to three weeks before switching to the next set in the series. The duration of your treatment plan depends on the complexity of your doctor's prescription.

Unless your doctor instructs otherwise, you should follow up with your doctor at least every four to six weeks. **Missing and cancelling appointments will negatively impact your treatment and may result in unwanted teeth shifting. If you miss a scheduled appointment, your doctor will have no responsibility for unwanted teeth shifting and/or incomplete treatment.**

Unwanted teeth shifting and/or incomplete treatment is a risk you assume if you miss a scheduled appointment.

Benefits of Clear Aligner Treatment

The clear aligner treatment system is intended to provide the end benefits of traditional "wired" orthodontic treatment, such as straight teeth and

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improved bite function, as well as the following benefits that are only available when going wireless:

- Clear aligners offer an esthetic alternative to conventional braces.
- The aligners are practically invisible.
- Aligners are removable, allowing you to eat, drink, brush, and floss without difficulty.
- There are no cuts or abrasions from metal wires or brackets, so clear aligners are generally more comfortable than traditional braces.

In addition, the wearing of clear aligners may improve oral hygiene habits during treatment, and you may notice improved overall gum health.

Possible Risks and Inconveniences

As with other orthodontic treatments, clear aligner treatment product(s) may carry some of the following risks and inconveniences:

- Treatment time may exceed your doctor's estimates. Poor compliance with your doctor's instructions, not wearing aligners the required number of hours per day, missed appointments, excessive bone growth, poor oral hygiene, and broken appliances can lengthen treatment time, increase your costs, and affect the quality of your results.
- 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 aligners.
- Sores and irritation of the soft tissue of the mouth (i.e., gums, cheeks, tongue, and lips) are possible but rarely occur due to wearing aligners.
- Teeth may shift position after treatment. Following your doctor's post-treatment retention plan, which will include consistent wearing of retainers at the end of treatment, should reduce this tendency.
- The aligners may temporarily affect speech, although any speech impediment caused by the clear aligner treatment products should disappear within one or two weeks.
- You may experience 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).
- Tooth decay, periodontal disease, inflammation of the gums, or permanent markings may occur if patients consume food or beverages containing sugar, do not brush and floss their teeth properly before wearing the clear aligner treatment products, or do not use proper oral hygiene and preventative maintenance.
- Teeth may require interproximal recontouring or slenderizing in order to create space needed for dental alignment to occur.
- Your bite may change throughout treatment, which may cause you to experience temporary discomfort.
- Additional orthodontic treatment, including the use of bonded buttons, orthodontic elastics, auxiliary appliances/dental devices (e.g., temporary anchorage devices or 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 (there may be an additional cost to you if you require such procedures).
- You may require additional impressions and/or refinement aligners after the initial series of aligners.
- 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.
- Aligners are not effective in the movement of dental implants.
- At the end of orthodontic treatment, the bite may require adjustment ("occlusal adjustment").

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- General medical conditions and use of medications can affect orthodontic treatment.
- Allergic reactions may occur.
- 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 prior to wearing the clear aligner product(s) (if oral surgery is required, risks associated with anesthesia and proper healing must be taken into account prior to treatment).
- Previously traumatized or significantly restored teeth 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/or the tooth may be lost.
- Existing dental restorations, such as crowns and bridges, may become dislodged and require re-cementation or, in some instances, replacement.
- Short clinical crowns can pose appliance retention issues and inhibit tooth movement.
- Root resorption (shortening) can occur during treatment. Shortened roots are not a problem under healthy conditions. In rare cases, however, root resorption can result in loss of teeth (there is no way to foresee if this will occur during your treatment and nothing can be done to prevent it).
- In cases of multiple missing teeth, it is more likely that the aligner may break (if this happens, contact your doctor immediately to replace it).
- Because orthodontic appliances are worn in the mouth, accidentally swallowing or aspirating the aligner may occur.
- In rare instances, problems may occur in the jaw joint, causing joint pain, discomfort, headaches, or ear problems (if you experience any of these symptoms, contact your doctor immediately).
- Teeth that are not at least partially covered by the aligner may undergo supra-eruption (i.e., come out of the gums more than other teeth).

Patient Commitment

Your commitment is critical to achieving the best possible results with the clear aligner treatment system. **It is absolutely crucial that you wear your aligners at least 22 hours per day, every day, except when eating, brushing, and flossing. Failure to do so will negatively impact treatment and prevent you from achieving the desired results.**

Smile Retention

Due to the tendency of teeth to shift in the human dentition, you can expect that your teeth will naturally begin to shift back to their original position once your prescribed course of aligners is complete. **For this reason, you MUST wear the retainer(s) provided by your doctor for life. This is the most critical part of your treatment and is essential to maintaining your results.**

Upon completion of your clear aligner treatment, lingual bars may be installed. These are rigid metal reinforcements placed behind your teeth to prevent them from moving.

In addition, all patients will need to wear retainers indefinitely. Retainers are to be worn full time over your lingual bar, at least 22 hours a day, for the first two weeks of use. After a few months of gradually wearing the retainers less frequently throughout the day, you may, with permission from your doctor, begin wearing your retainers at night only.

Retainers should be cleaned with a toothbrush and water every time you brush your teeth, and should be replaced every nine to 12 months due to cleanliness and firmness issues. You must clean around your lingual bar carefully and diligently every night to prevent plaque and gum disease.

If either your lingual bar or retainer is lost or broken it should be replaced immediately. If your lingual bar breaks, you **MUST** immediately begin wearing your last set of aligners until it is replaced to prevent your teeth from shifting.

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Fees

Payment of your bills is considered part of your treatment, and all charges incurred are your responsibility. Please note that our relationship is with you, the patient, not your insurance company. Depending on your insurance company, we may, as a courtesy, bill your insurer directly; however, you are responsible for any co-payment and the portion that your insurance does not cover.

Please keep in mind that insurance is strictly an estimate not a guarantee of payment. Our practice is committed to providing the best treatment for our patients and we charge what is usual and customary. Understand that clear aligner treatment involves significantly more steps and higher laboratory fees than traditional braces, and you are responsible for payment regardless of any insurance company's arbitrary determination of usual and customary rates based on traditional braces. Our office will cooperate fully with the regulations and requests of those specific insurance companies for which we are providers. However, we will not enter into a dispute with your insurance company over any claim.

If your treatment time is extended and/or the treatment plan changes beyond the estimated time due to your choice, or **specifically because of missed appointments, and/or failure to comply with your doctor's instructions, there may be additional fees** until completion of your treatment.

Any patient who cancels or breaks a scheduled appointment on less than 24 hours notice may incur a cancellation fee.

If you do not comply with your doctor's instructions and, as a result, your aligners do not conform to your teeth, there will be an additional charge to get more aligners fabricated for correction.

Old aligners will be discarded after one year from your last appointment if you fail to continue your treatment and new impressions will be required to restart.

If supplemental orthodontic treatment or additional cosmetic procedures (e.g., crowns or veneers) are necessary to complete treatment, there may be an additional cost to you if you require such procedures.

If for any reason you fail to pay while in treatment, and, after receiving adequate notice of your failure to pay, your account remains in arrears, treatment may be discontinued until your balance is paid, at which time treatment will resume. Unless otherwise agreed, acceptance of late payment, partial payment, or nonpayment shall not constitute a waiver of our entitlement to have all bills paid in full and on time; nor shall such acceptance constitute a waiver of any legal rights and remedies available to us.

Informed Consent and Agreement

I have been given adequate time to read and have read the preceding information describing clear aligner orthodontic treatment. **I have discussed with my doctor and understand the benefits, risks, alternatives and inconveniences, required patient commitment and smile retention practices, and fees 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 clear aligner orthodontic treatment products with my doctor from whom I intend to receive treatment. I understand that I should only use clear aligner orthodontic treatment products after consultation and prescription from a trained doctor, and I hereby consent to orthodontic treatment with clear aligner treatment products that have been prescribed by my doctor.**

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I agree to follow my doctor's treatment exactly as my doctor prescribes and provides it for me, and I understand that any questions, concerns, or complaints I have regarding my treatment must be communicated to my doctor as soon as they arise.

Due to the fact that orthodontics is not an exact science, **I acknowledge that my doctor and the Manufacturer have not and cannot make any guarantees or assurances concerning the outcome of my treatment.** I understand that the Manufacturer 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 the Manufacturer, 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 the Manufacturer, its representatives, employees, successors, assigns, and agents for the purposes of investigating and reviewing my medical history as it pertains to orthodontic treatment with the Manufacturer's product(s) 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 Informed Consent and Agreement as indicated by my signature below.

Patient Name

Signature of Patient or Parent/Guardian (if patient is a minor)

Date

Time

Signature of Dentist/Orthodontist

Witness Name

Witness Signature

Date

Time