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CLEARCORRECT INFORMED CONSENT

PATIENT'S INFORMED CONSENT AND AGREEMENT REGARDING CLEARCORRECT ORTHODONTIC TREATMENT

Your doctor has recommended the Clearcorrect 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 Clearcorrect aligners) has limitations and potential risks that you should consider before undergoing treatment.

Successful orthodontic treatment is a partnership between the doctor and the patient. As a general rule, informed and cooperative patients can achieve positive orthodontic results. While recognizing the benefits of a beautiful healthy smile, you should also be aware that, as with all healing arts, orthodontic treatment has limitations and potential risks. These are seldom serious enough to indicate that you should not have treatment: however, all patients should consider the option of no treatment at all by accepting their present oral conditions. You should also ensure that you have discussed all orthodontic alternatives available to you with your doctor prior to beginning treatment.

Please read this information carefully and ask the doctor to explain anything you do not fully understand. Ensure you know what is expected of you as the patient (or as the parent/guardian of a young patient) during treatment.

About Clear Aligners

Clear aligner therapy is an orthodontic treatment in which the patient wears a series of clear, removable aligners that gradually move the teeth to improve bite function and/or esthetic appearance. This treatment is intended to provide the end benefits of traditional "wire" orthodontic treatment, such as straight teeth and improved bite function, as well as the following benefits that are only available when going wireless:

-The aligners are clear, so people may not even notice you wearing them.
-There are no cuts or abrasions from wires or brackets, so clear aligners are more comfortable than traditional braces.
-The aligners area removable, allowing you to eat, drink and flow with freedom.

Although the benefits generally outweigh the potential risks, all factors should be considered before making the decision to wear aligners. If you choose to undergo clear aligner therapy, ClearCorrect Operating, LLC ("ClearCorrect"), a Texas-based dental laboratory, will manufacture aligners customized for your teeth based on your doctor's prescription. your doctor (not ClearCorrect) is responsible for delivering and managing your care.

Potential Risks of Clear Aligners

As with other orthodontic treatments, clear aligners may carry some risk, including (but not limited to) some of the potential risks described below:

*Treatment time may exceed estimates. Poor compliance with your doctor's instructions, wearing aligners less than 22 hours per day, missing appointments, excessive bone growth, poor oral hygiene and broken appliances can lengthen treatment time, increase the cos, and affect the quality of the end results.
*Unusually shaped teeth can also extend treatment time and affect results. For instance, short clinical crowns can cause problems with aligner retention and slow or prevent movement.
* Tooth decay, periodontal disease, decalcification (permanent markings on the teeth), or inflammation of the gums may occur if proper oral hygiene and preventative maintenance are not maintained, whether wearing aligners or otherwise.
*Sores and irritation of the soft tissue of the mouth (gums, cheeks, tongue and lips) are possible but rarely occur due to wearing aligners.
*Initially, the aligners may temporarily affect your speech. Patients generally adapt quickly to wearing aligners and it is rare that speech is impaired for an extended period of time.
*While wearing aligners, you may experience a temporary increase in salivation or dryness of the mouth. Certain medications can increase this.
*It may be necessary to temporarily affix engagers (small bumps of composite material) to your teeth to assist with difficult tooth movements. When you are not wearing your aligners, these engagers can feel awkward in the mouth. Because the tooth surface is roughened to assure engagers have a reliable bond, the tooth may appear dull or discolored when the engagers are removed; your doctor can correct this.
*In cases of crowding, IPR, also known as interproximal reduction (reducing the thickness of a tooth's enamel), may be required to create enough space to allow teeth movement.

*Your aligners may include features that placed on the inner surface toward your tongue. These features may temporarily irritate your tongue until you get used to their presence.
*Any medications you may be taking, and your overall medical condition can affect your orthodontic treatment.
*Though uncommon, allergic reactions to the material used during treatment may occur. If you believe you are experiencing and adverse reaction, inform your doctor immediately.

*Tooth sensitivity and tenderness of the mouth may occur during treatment- especially when advancing from one aligner to the next.
*Bone and gums, both of which support the teeth, can be affected by wearing aligners. In some cases, their health may be impaired or aggravated.
*Oral surgery may be required to correct excessive crowding or severe, pre-existing jaw imbalances. All risks of oral surgery, such as those associated with anesthesia and proper healing, must be considered before treatment.
*Wearing aligners may aggravate teeth- previously traumatized or not. Through a rare occurrence, such teeth may require additional dental treatment such as endodontic treatment or other restorative treatment, the useful life of the teeth may be shortened, or the teeth may be lost completely.
*Existing dental restorations. such as crowns and bridges, may be affected by wearing aligners. They may become dislodged and require re-cementation or in some instances, replacement. Before any dental restorations are replaced or added, consult your doctor, as they can affect the way your aligners fit.
*Teeth may supra-erupt (come out of the gums more than other teeth) if not at least partially covered by the aligner.
*Root resorption (shortening) can occur during any type of orthodontic treament, including clear aligners. Shortened roots are of no disadvantage under healthy conditions. In rare cases, root resorption can result in loss of teeth.

*In cases of severe crowding or multiple missing teeth, it is more likely that the aligner may break. Contact your doctor as soon as possible if this occurs.
*Because orthodontic appliances are worn in the mouth, accidentally swallowing or aspirating the aligner- in whole or in part- may occur.
*Through rare, problems may occur in the jaw joint, causing joint pain, discomfort, headaches or ear problems. Inform your doctor of any such problems immediately.
*Aligners worn out of their intended sequence can delay treatment results and result in complications including (but not limited to) patient discomfort. Always wear aligners in the order specified by your doctor.
*In some cases, a "black triangle" of missing gingival tissue may be visible below the interproximal contact when teeth are aligned after being overlapped for an extended period of time.
*Results may relapse if retainers are not worn as directed by your doctor.
*A successful treatment outcome cannot be guaranteed. After the final planned aligners have been shipped, some cases may require refinement with additional clear aligners. traditional orthodontic techniques, and/or cosmetic procedures like crowns or veneers to achieve ideal results. There may be additional costs to you if you require such procedures. Always follow the directions for use (included with each aligner package) for best results.

INFORMED CONSENT & AGREEMENT

I have read and understand the content of this document describing considerations and risks of clear aligners. I have been sufficiently informed and have been given the opportunity to discuss this form and its contents with the undersigned doctor, and to have my questions adequately answered. I have been asked to make a choice about my treatment, and I hereby consent to receive treatment with clear aligners manufactured by ClearCorrect as planned, prescribed and provided by the undersigned doctor. I agree to follow my doctor's treatment exactly as s/he plans, 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.

I acknowledge that neither my doctor nor ClearCorrect, its employees, representatives, successors, assigns, or agents, have, can, or will make any promises or guarantees as to the success of my treatment or give any assurances of any kind concerning any particular result of my treatment. I understand that ClearCorrect does not practice dentistry or give medical advice. I understand that I should always contact my doctor in the first instance (not ClearCorrect) regarding my expectations, difficulties, results, or any other aspects of my treatment.

I understand that it may be necessary to take impressions, intraoral scans, digital model scans, radiographs (x-rays), and/or photo-graphs for diagnosis, professional review by my doctor or other consulting dentists, orthodontists, and submission to ClearCorrect. I recognize that these will be included in my medical records, which records encompass "individually identifiable health information" as that term is defined and protected by the HIPAA Privacy Rule. I understand that my doctor, as covered entity under HIPAA, is not required to obtain my consent to use and disclose my individually identifiable health information for treatment, payment, and health care operations activities, but has chosen to do so voluntarily through this document.

I further agree that my doctor, ClearCorrect or a ClearCorrect affiliate may use my medical records and health information including but not limited to the following:
*Age group
*Type of malocclusion
*Medical history (related to treatment)
*Treatment of procedure, number of aligners and revisions
*Duration of the treatment
*Attachments used (# and price)
*Description of the Malocclusion, Indication
*Teeth movements
*Material used
*Pictures of the teeth
*Dental arches
*right and left buccal view in occlusion
*facial view in occlusion
*other views if appropriate (no full face, or half face)

for research, for submission to regulatory authorities worldwide, post market surveillance including post market clinical follow up studies and educational purposes, but only to the extent that no individual identifiers, including but not limited to my name or address, are disclosed. The doctor receiving my medical records and health information under this authorization will not receive direct or indirect remuneration in exchange for disclosing the health information or medical records. I understand that health information or medical records used or disclosed pursuant to this authorization may be redisclosed by the recipient and its confidentiality may no longer be protected by federal or state law.

I hereby consent to such uses and disclosure(s) as described herein. I acknowledge I have the right to revoke this consent at any time except to the extent the recipient has already acted in reliance upon it. This consent is valid until I revoke it in writing and present it to my doctor.

Unless otherwise permitted or required by law; other uses and disclosures of my medical records, including advertising or marketing by either my doctor or ClearCorrect, shall be made only with my prior written authorization (for which I acknowledge my doctor or ClearCorrect may use my contact information to seek to obtain).

I acknowledge I will not, nor shall anyone on my behalf, seek or obtain damages or remedies - legal, equitable, monetary, or otherwise - arising from any use of my medical records that complies with the terms of this informed Consent and Agreement.

I acknowledge I have read, understand and voluntarily consent to the use of clear aligners and use of my health information in accordance with terms of this Informed Consent and Agreement.

☐ * **By checking this box, I acknowledge I have read, understand and voluntarily consent to the use of clear aligners and use of my health information in accordance with terms of this Informed Consent and Agreement.**

Signature of patient, parent or guardian (responsible party):

Signature _____ **Date** _____

Signature of Witness:

Signature _____ **Date** _____

Name of Witness:

_____

_____

Signature of Parent/Guardian:
*If signatory is under 18, the parent or legal guardian must also sign to signify agreement;

Signature _____ **Date** _____

Relationship to Patient:

☐ SELF ☐ PARENT ☐ STEP PARENT ☐ GRANDPARENT ☐ GUARDIAN ☐ ESCORT ☐ OTHER

Date: * _____

Response Date: _____