



## PATIENT INFORMED ACKNOWLEDGMENT AND CONSENT – Clear Aligners

Your Dental Professional will only provide you with Clear Aligners subject to your execution of this Patient Informed Acknowledgment and Consent (“Informed Consent”). Please read this document carefully.

Your Dental Professional and its suppliers, designers, manufacturers, and resellers (collectively, the “Suppliers”) design, manufacture, and sell custom clear oral tray aligners (“Clear Aligners”) that are designed to move teeth in small increments based on a treatment plan approved by your qualified medical dental professional (“Dental Professional”).

### Process From Dental Digital Scans to Clear Aligners

An independent design bureau will use your digital scans to provide a custom dental design for your Dental Professional’s approval.

Once the design is approved by your Dental Professional, and your Dental Professional gives you a prescription for orthodontic treatment for your orthodontic condition using Clear Aligners your Dental Professional’s manufacturer will translate the design into Clear Aligners for you to use.

### Conditions to Manufacture of Clear Aligners

You represent, warrant, and certify that:

- you are 18 years of age or older and not subject to any conservatorship;
- you are otherwise eligible under Federal and applicable state law to provide the consents required pursuant to this Informed Consent;
- you desire to obtain Clear Aligners based on the treatment plan to be developed by your Dental Professional; and
- all statements made by you in this Informed Consent are true and correct and you understand that your Dental Professional and the Suppliers will rely on them in creating your Clear Aligners.

You understand that Your Dental Professional and the Suppliers will only create your Clear Aligners subject to your agreement and you acknowledge that you hereby agree to:

- comply with all terms and conditions of this Informed Consent;

- meet with your Dental Professional who will examine your teeth and the digital scans, and who will give you information about your orthodontic condition and give you your Prescription; and
- discuss with your Dental Professional available alternatives for treatment for your orthodontic condition, including using conventional braces, the potential benefits and risks of using Clear Aligners to treat your orthodontic condition, the likely result without such treatment, and any questions you may have about any of the foregoing.

### Potential Benefits and Risks

#### Potential Benefits of Using Clear Aligners

Using Clear Aligners to make adjustments to correct your orthodontic condition may offer some benefits over using conventional braces. Clear Aligners are clear and more discreet giving you privacy and drawing less attention to the fact that you are undergoing treatment for your orthodontic condition. Additionally, Clear Aligners do not have metal wires or brackets as do conventional braces, making them easier to wear and less likely to cause pain or gum injuries. Since Clear Aligners are removable, it will be easier to clean your teeth and gums than if you were to wear conventional braces.

#### Potential Risks of Using Clear Aligners

In addition to certain benefits of using Clear Aligners to make adjustments to correct your orthodontic condition, using Clear Aligners may also involve some risks, including, but not limited to:

- possible allergic reaction to Clear Aligners;
- gum injury or inflammation;
- dental tenderness when progressing to the next Clear Aligners in the Prescription;
- increased salivation;
- mouth dryness;
- difficulty in speaking (when using Clear Aligners as required);
- unlikely aggravated dental health, possibly requiring dental surgery and other medical treatment;

- unsuccessful results, unlikely complications, injury, or even death from unforeseen causes; and
- not achieving the desired outcome for your orthodontic condition, especially if you do not strictly follow the Prescription, fail to wear Clear Aligners as required, or otherwise use Clear Aligners incorrectly.

In the practice of orthodontic adjustments, other unexpected risks or complications may occur. All such possible risks and complications should be discussed with your Dental Professional. In addition, during the course of using Clear Aligners in accordance with your Prescription, unforeseen conditions may be revealed requiring the performance of additional medical procedures. Any and all such conditions or complications should be immediately discussed with your Dental Professional.

Unexpected Risks or Unforeseen Conditions

**Patient Informed Consent and Agreement**

Based on the foregoing, I hereby consent:

1. for the use of my digital scans to make Clear Aligners for me;
2. and authorize my Dental Professional and other health care personnel involved in the treatment of my orthodontic condition to share with your Dental Professional and the Suppliers my medical records, including without limitation my Prescription, for the purpose of making and providing me Clear Aligners; and
3. to all disclosures and uses of my “individually identifiable health information” as defined by the Health Insurance Portability and Accountability Act (“HIPAA”) in connection with the digital scans, Prescription, and Clear Aligners.

By signing this Informed Consent:

I HEREBY UNDERSTAND AND AGREE THAT: (A) I WILL NOT GO FORWARD AND OBTAIN AND USE CLEAR ALIGNERS UNTIL AND UNLESS I CONSULT WITH MY DENTAL PROFESSIONAL AND RECEIVE SATISFACTORY ANSWERS TO ALL MY QUESTIONS AND CONCERNS AND UNDERSTAND ALL THE BENEFITS AND RISKS OF USING CLEAR ALIGNERS TO TREAT MY ORTHODONTIC CONDITION; (B) I WILL ONLY USE CLEAR ALIGNERS AFTER CONSULTING WITH MY DENTAL PROFESSIONAL, AND THAT MY USE OF CLEAR ALIGNERS INDICATES AND CONSTITUTES MY INFORMED CONSENT TO ORTHODONTIC TREATMENT USING CLEAR ALIGNERS IN ACCORDANCE WITH THE PRESCRIPTION PRESCRIBED BY MY DENTAL PROFESSIONAL; (C) CLEAR ALIGNERS ARE ONLY FOR USE BY ME AND I HEREBY ASSUME ALL RISKS ASSOCIATED WITH USING SUCH CLEAR ALIGNERS; (D) ONLY MY DENTAL PROFESSIONAL IS PROVIDING ME ANY DENTAL CARE SERVICES. SUPPLIERS DO NOT AND CANNOT PRACTICE DENTISTRY AND ANY QUESTIONS I HAVE ARE TO BE DISCUSSED WITH MY DENTAL PROFESSIONAL; AND (E) CLEAR ALIGNERS ARE BEING SUPPLIED TO ME ONLY ON AN AS-IS BASIS WITH NO ASSURANCES OR GUARANTEES UNDER FEDERAL OR APPLICABLE STATE LAW OF ANY KIND CONCERNING THE RESULTS OF USING CLEAR ALIGNERS TO TREAT MY ORTHODONTIC CONDITION.

In the event any portion of this Informed Consent is held invalid under Federal or applicable state law, the remaining portions shall remain in full force and effect.

I HAVE READ THE FOREGOING AND INTENTIONALLY AND VOLUNTARILY SIGN THIS PATIENT INFORMED ACKNOWLEDGMENT AND CONSENT. MY SIGNATURE ON THIS INFORMED CONSENT INDICATES THAT (A) I HAVE READ AND FULLY UNDERSTAND ITS CONTENT, (B) I HAVE HAD THE OPPORTUNITY TO ASK QUESTIONS REGARDING ITS CONTENT, (C) I AM AWARE THAT THIS IS A RELEASE OF LIABILITY AND A CONTRACT, AND (D) I SIGN IT OF MY OWN FREE WILL.

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Signature of Patient

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Date