

## REVEAL CLEAR ALIGNERS INFORMED CONSENT AND AGREEMENT – PATIENT FORM

Your doctor has prescribed the **Reveal Clear Aligners** system for your orthodontic treatment. This document is intended to inform you that any orthodontic treatment (including clear aligners) has limitations and potential risks that you should take into consideration. Please read the following information and discuss with your provider if further clarification is needed before undergoing treatment. Ensure that you know what is expected of you as the patient (or as the parent/guardian of a young patient) during the full course of the treatment.

### ABOUT REVEAL CLEAR ALIGNERS:

*Reveal Clear Aligners, a Henry Schein® Orthodontics™ product, are a series of removable, clear plastic trays that have been custom manufactured for you based on the prescription and records submitted by your provider to create incremental movement of your teeth through gentle force application. Indications for use include, but are not limited to, correction of dental malocclusions in patients with permanent dentition (i.e. presence of fully erupted second molars), improved bite function, and/or aesthetic appearance. In case of known allergies to plastic, you are not a candidate for *Reveal Clear Aligners* treatment. Please ask your provider to discuss other treatment options that may be more suitable for you.*

### PROCEDURE OVERVIEW

You may undergo a routine, in-office, pre-treatment examination followed by X-rays, intra and extra oral photographs and/or impressions of your teeth. These records are attached to a prescription filled out by your provider to generate a custom treatment plan for you. Your provider may review this treatment plan with you to discuss next steps.

Once you and your provider agree with the proposed treatment plan, *Reveal Clear Aligners* are custom manufactured for you. Total number of aligner sets may vary by patient and the complexity of the treatment plan. You will receive your aligners in accordance with the treatment plan; we highly recommend that you comply with the follow-up schedule as determined by your provider so your progress can be monitored during the full course of treatment.

Orthodontic treatment generally proceeds as planned, and we intend to do everything possible to achieve the best results for each patient. We cannot guarantee, however, that you will be completely satisfied with your results, nor can all complications or consequences be anticipated. The success of treatment depends on your cooperation in following the doctor's instructions carefully, including keeping scheduled appointments, maintaining good oral hygiene, and avoiding broken appliances. Failure to follow your provider's instructions may be detrimental to the results of your treatment.

The length of treatment is variable, including the severity of the problem, changes in oral anatomy, and level of compliance. The actual treatment time is often close to the estimated treatment time, but treatment may be lengthened as determined by your doctor.

Mild discomfort is expected in the first few days of wearing a new clear aligner tray. You may expect an adjustment period and mild discomfort due to the use of orthodontic appliances. Discuss with your provider suitable options for pain management.

Post treatment, retainers are required to keep your teeth in their new positions as a result of your orthodontic treatment. You must wear your retainers as instructed or teeth are likely to shift back into their original position. Regular retainer wear is often necessary for several years following orthodontic treatment. However, changes after that time can occur due to natural causes, including habits such as tongue thrusting, mouth breathing, and growth and maturation that continue throughout life. Later in life, most people will see their teeth shift. Minor irregularities, particularly in the lower front teeth, may have to be accepted. Some changes may require additional orthodontic treatment or, in some cases, surgery. Some situations may require non-removable retainers or other dental appliances made by your family dentist.

### As typical for other orthodontic treatments, you may experience some of the potential risks highlighted below:

- Sores and irritation of the intraoral soft tissue (gums, cheeks, tongue and lips) are possible.
- Tooth sensitivity and tenderness in the mouth, which may be more prevalent when switching from one aligner set to the next.
- Temporary increase in salivation or dryness of the mouth which may be increased if you take certain medications.
- Tooth decay, periodontal disease, or decalcification (permanent markings on the teeth).
- As with any orthodontic appliance worn in the mouth, you could accidentally swallow or aspirate the aligner – in whole or in part.
- You may experience problems in your jaw, leading to TMJ pain, discomfort, headaches or ear problems.  
Please contact your provider immediately if such problems occur.
- The aligners may initially affect your speech, although this disappears as you become more comfortable wearing them.

**Use of Tobacco Products:**

Smoking or chewing tobacco has been shown to increase the risk of periodontal disease and may reduce the ability of your mouth to heal any abrasions or other irritation caused by aligners. Tobacco users are also more prone to oral cancer, gum recession, and delayed tooth movement during aligner treatment. If you use tobacco, you must carefully consider the possibility of a compromised result from your aligner treatment.

**INFORMED CONSENT AND AGREEMENT**

I have read and understand the content of the *Reveal* Clear Aligners Informed Consent and Agreement Form. Further, I discussed the potential risks associated with my *Reveal* Clear Aligners treatment with my provider and had all my questions adequately answered. After carefully considering the treatment proposed, as well as the potential risks associated with that treatment, I hereby consent to receive the treatment recommended and prescribed by my provider for use of *Reveal* Clear Aligners manufactured by *Henry Schein Orthodontics* and its affiliates (“HSO”). 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 understand that neither my provider or HSO can make any guarantees regarding the outcome of my treatment, nor have they made any such assurance or guarantees about my treatment.

I authorize my doctor to release my medical records, including but not limited to, impressions, intraoral scans, radiographs (x-rays), and intra and extra oral photographs, 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 HSO, 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 HSO and (ii) for educational and research purposes.

I understand that my Medical Records encompass “individually identifiable health information” as that term is defined and protected by the HIPAA Privacy Rule. I hereby consent to the disclosure of my individually identifiable health information as set forth in the paragraph above. I acknowledge that 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 *Reveal* Clear Aligners Informed Consent and Agreement Form.

My signature below confirms my understanding of the contents of this document and my agreement to be bound by the representations contained herein.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Address

\_\_\_\_\_  
City, State, Zip

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Signature of Parent/Guardian

