



Tru-Smile Clear Aligners - Informed Consent & Agreement

Tru-Smile is committed to making orthodontic treatment a collaborative process between the clinician and patient. Orthodontic treatment requires the input and expertise of doctors, as well as a full understanding from the patients to ensure the best results. While starting your orthodontic treatment is an exciting time, it is crucial that you are mindful of the inherent limitations and potential risks that are associated with clear aligner treatment. The related risks are rarely severe enough to suggest forgoing treatment altogether, however choosing to cancel treatment and instead embrace the current condition of your smile is an available and valid option. It is also essential that you have gone over all possible alignment solutions with your doctor before starting on your Tru-Smile journey.

We advise you to read the following information carefully and share any questions or concerns you have with your doctor, who is available as a resource to ensure you fully understand the treatment and all expectations placed on you as a patient or parent/guardian.

About Tru-Smile Clear Aligners

The Tru-Smile team created this document to fully explain Tru-Smile and lay out the potential risks related to the treatment. Tru-Smile Clear Aligners are an orthodontic treatment that utilizes patient-specific, sequential aligners to shift dentition into a patient's desired smile and alleviate any functional difficulties. Clear aligners are used to achieve the same results as traditional metal braces, without the adverse side effects of metal brackets in the sensitive oral environment.

Benefit of Tru-Smile:

- Reduced appointment time
- Removable for easy cleaning and eating
- Smooth surfaces to eliminate cuts inside the mouth
- Invisible appearance for an unnoticeable solution

The benefits of clear aligners generally outweigh the potential risks; however, we want you to be fully aware of the treatment so you can make a confident and informed decision when choosing Tru-Smile.

Potential Risks of Clear Aligners

Like all other orthodontic treatment, Tru-Smile may carry some of the potential risks as listed below:

- While our plans are optimized to be as precise to your situation as possible, treatment time may exceed expectations. This can be the result of not wearing aligners for the recommended number of hours a day, missing appointments, excessive bone growth, poor oral hygiene, and broken appliances. In addition to increased treatment time, these situations may also increase cost and impact overall results.
- Unusually shaped teeth may impact treatment time. Shorter than average teeth can present issues with aligner retention and slow/halt the shifting of teeth.
- Good oral hygiene is always important, but it is especially vital during your treatment. Tooth decay, periodontal disease, decalcification,

- or inflammation of the gums may occur if proper hygiene habits are not in place or aligners are not thoroughly cleaned during treatment.
- Sores and swelling of the soft oral tissue, such as gums, cheeks, tongue, and lips, may occur, although this is rare due to the smooth surfaces of clear aligners.
 - Speech may temporarily be affected when first wearing aligners, or when switching to a new set of aligners throughout the treatment plan. This issue generally solves itself as you grow accustomed to the aligners and typically only lasts for a few days.
 - A temporary increase or decrease in salivation may occur. Certain medications can exacerbate this.
 - Specially designed fabricators may be necessary to complete treatment. When you are not wearing the aligners, these engagers can feel awkward in the mouth.
 - In situations of crowding, interproximal reduction may be required to create enough area for teeth movement.
 - Prescription medication and overall medical health can impact the treatment.
 - Allergic reactions to the aligner material may occur in rare instances.
 - Tooth and soft tissue sensitivity may occur during treatment, especially when moving to the next aligner in the plan.
 - Bone and gums may be affected by wearing aligners, and their health may be impacted.
 - Oral surgery may be necessary 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 taken into account before treatment.
 - Wearing aligners may exacerbate teeth. Rarely, impacted teeth may need additional dental treatment, including endodontic or restorative treatment. The vitality of the teeth may be compromised, and tooth loss may occur.
 - Existing dental restorations, such as crowns and bridges, may be affected by aligners. These restorations may become dislodged and require re-cementation or replacement. The replacement or addition of a dental restoration will potentially require reformatting of the plan and extended treatment time.
 - Teeth may supra-erupt if not at least partially covered by the aligner.
 - Root shortening may occur during any orthodontic treatment. Root resorption does not pose any disadvantage in health conditions; however, in a poor oral environment, they may cause tooth loss.
 - An aligner is more likely to break when treating a case with multiple missing teeth. If breakage occurs, contact your doctor immediately.
 - Due to its placement in the mouth, there is a chance the aligner may be partially or fully swallowed or aspirated on accident.
 - Temporomandibular joint issues may occur, such as joint pain, discomfort, headaches, or ear problems. This is a rare issue and requires immediate notification of your doctor.
 - Results are not permanent and may relapse if proper retainer wear is not followed. Difficulty removing aligners may occur if you required multiple engagers in place during treatment or excessive crowding, or particular bite patterns. Contact your doctor for assistance if this happens.
 - Traditional orthodontic treatment or additional cosmetic dental procedures, such as crowns or veneers, may be required to achieve desired results. This may incur an additional cost.

Informed Consent & Agreement

I have read and understood the contents of this document, which describes the considerations and risks of Tru-Smile 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 sufficiently answered. I have been asked to make a choice about my treatment, and I hereby consent to receive treatment with Tru-Smile Clear Aligners as planned, prescribed, and provided by the undersigned doctor. I agree to follow my doctor's treatment precisely as they plan, prescribe, and provide 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 Tru-Smile, 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 Tru-Smile is not a provider of dental, medical, or health care services and cannot and does not practice dentistry, medicine, or give medical advice.

I understand before beginning, and in some cases during, treatment it will be necessary to take impressions, radiographs (x-rays) and photographs for diagnosis, professional review by my doctor or other consulting dentist and orthodontists, and case submission to Tru-Smile. 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 a 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 or Tru-Smile may use my medical records for research and educational purposes, but only to the extent that not individual identifies, including but not limited to my name or address, are disclosed. I hereby consent to such uses and disclosure(s) as described herein.

Unless otherwise permitted or required by law, other uses and disclosures of my medical records, including advertising or marketing by either my doctor or Tru-Smile, shall be made only with my prior written authorization (for which I acknowledge my doctor or Tru-Smile 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 terms of this Informed Consent and Agreement.

Patient Name

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

Date

Time

Signature of Dentist/Orthodontist

Witness Name