



PATIENT INFORMED CONSENT FORM FOR B-SMART ALIGNERS

Successful orthodontic treatment is a partnership between the doctor and the patient. The doctor and staff are dedicated to achieving the best possible result for each patient. As a 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 condition. You should also ensure that you have discussed all orthodontic alternatives available to you with the 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 B-SMART CLEAR ALIGNERS

The purpose of this document is to explain B-Smart clear aligners and to inform you of potential risks associated with their use. B-Smart clear aligners are 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 “wired” 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 B-Smart aligners are more comfortable than traditional braces.
- The aligners are removable, allowing you to eat, drink, brush and floss with freedom.

Although the benefits generally outweigh the potential risks, all factors should be considered before making the decision to wear aligner.

POTENTIAL RISKS OF CLEAR ALIGNER

As with other orthodontic treatments, clear aligners may carry some of the potential risks described below:

- Treatment time may exceed your doctor’s estimates. Poor compliance to 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 the cost, and affect the quality of the end results.
- Unusually shaped teeth can also extend treatment time. For instance, short clinical crowns can cause problems with aligner retention and slow or prevent teeth 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.
- Specially fabricated engagers may be necessary to successfully complete your orthodontic treatment. When you are not wearing your aligners, these engagers can feel awkward in the mouth.
- In cases of crowding, interproximal reduction (trimming the thickness of a tooth's enamel) may be required to create enough space to allow teeth movement.
- 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.
- 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. Though 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 treatment, including clear aligners. Shortened roots are of no disadvantage under healthy conditions. In rare cases, 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. Contact your doctor as soon as possible to replace it.
- Because orthodontic appliances are worn in the mouth, accidentally swallowing, or aspirating the aligner—in whole or in part—may occur.
- Though rare, problems may occur in the jaw joint, causing joint pain, discomfort, headaches, or ear problems. Inform your doctor of any such problems immediately.
- Results may relapse if proper retainer wear is not followed as directed by your doctor. Difficulty removing aligners may occur if you have multiple engagers in place during treatment, and/or excessive crowding, and/or some particular bite patterns. The doctor will give instructions to assist you if this is the case.
- In some cases, due to the anatomy of the teeth, traditional orthodontic treatment, or additional cosmetic dental procedures (e.g., crowns, veneers) may be necessary to complete treatment. There may be an additional cost to you if you require such procedure

INFORMED CONSENT & AGREEMENT

I have read and understand the content of this document describing considerations and risks of B-Smart 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 B-Smart clear aligners 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 a lack of compliancy, poor oral hygiene, and missed appointments lengthen treatment time. Regular checkups are required, and instructions need to be followed perfectly. If appointments are not attended, completion may be delayed, and successful treatment is not guaranteed. I also understand that not properly following the treatment or not using my aligners according to the indications of my doctor, not only cause the treatment to be delayed, but also that more aligners will have to be manufactured than those established, these will be entirely my responsibility regarding payment, and I will absorb any expenses that are required to continue with my treatment.

I acknowledge that neither my doctor nor B-Smart, 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 B-Smart 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 dentists and orthodontists, and case submission to B-Smart. 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 B-Smart may use my medical records for research and educational purposes, but only to the extent that no individual identifiers, including but not limited to my name or address, are disclosed. I hereby consent to such uses and disclosure(s) as described herein.

I acknowledge I have read, understand, and voluntarily consent to the terms of this Informed Consent and Agreement.

Patient Name

Date

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

Signature of Orthodontist



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