

SureSmile® Aligners

SureSmile® Informed Consent Form

Congratulations on your decision to pursue orthodontic treatment. SureSmile® Aligners is an excellent choice made by your doctor to improve your long-term oral health and create a beautiful, new smile. Please read the following information and make sure that you ask any questions or raise any concerns you may have before signing this **Informed Consent Agreement**.

ORTHODONTIC DEVICE DESCRIPTION:

SureSmile aligners, developed by Dentsply Sirona consist of a series of transparent plastic, removable orthodontic splints that move your teeth in small increments. SureSmile links your doctor's diagnosis and prescription with the latest digital software technology to develop a treatment plan which define the desired movements of your teeth during treatment. Once your doctor has approved the treatment plan, a series of customized SureSmile aligners is produced explicitly for your treatment.

SURESMILE ALIGNER PROCEDURE:

It is important that you have good oral health before you start aligner treatment. You may undergo a small dental examination and a routine orthodontic pre-treatment examination including radiographs (x-rays) and photographs. Your doctor will take intra-oral scans of your teeth and send them together with a prescription to the Digital Laboratory (DL). SureSmile Digital Lab Specialists will follow your doctor's prescription to create a software model of your prescribed orthodontic treatment. Once your doctor has approved the treatment, the DL will produce and ship a series of customized aligners to your doctor. The total number of aligners will vary depending on the doctor's treatment plan and the complexity of your malocclusion. The aligners will be individually numbered and will be handed out to you by your doctor with specific instructions for use. You will switch to the next aligner in the series every two weeks or as directed by your doctor.

Unless otherwise instructed by your doctor, you should wear your aligners for 22 hours/day, removing them only to eat and drink and to brush and floss your teeth.

Treatment duration differs depending on the complexity of your malocclusion and your doctor's prescription. Unless otherwise instructed, you will be followed up by your doctor at a minimum of every 6 to 8 weeks. Most patients may require bonded aesthetic attachments and some also the use of elastics during treatment to enable specific orthodontic movements. Patients may need additional intraoral scans and/or refinement aligners after the initial series of aligners.

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BENEFITS OF ORTHODONTIC ALIGNER TREATMENT:

- 1) SureSmile aligners offer an aesthetic almost invisible and comfortable alternative to conventional braces.
- 2) Aligners do not need metal wires or metal brackets, that are associated with conventional braces.
- 3) Treatment plans can be visualized through digital software.
- 4) Aligners allow for normal tooth brushing and flossing measures compared to conventional braces where these measures are generally obstructed.
- 5) The wearing of aligners may improve oral hygiene habits and patients may observe improved periodontal (gum) health during treatment.

INFORMATION AND RISKS OF ORTHODONTIC ALIGNER TREATMENT:

Although orthodontic treatment can lead to a healthier, straighter, and better smile, you should also be aware that any orthodontic treatment (including orthodontic treatment with aligners) has limitations and potential risks, that you should consider before undergoing treatment.

The use of SureSmile aligners may involve some of the inconveniences and risks outlined below:

- 1) Failing to follow your doctor's instructions may interfere with achieving treatment objectives and may lengthen the treatment time. This includes not wearing your aligners as directed or missed appointments. All treatment times are estimated and may be extended by eruption of teeth or issues related to patient's specific dentition, including uncommon tooth shape and any other anomaly encountered during treatment.
- 2) Poor oral hygiene and lack of preventive measures during treatment or consumption of food or beverages containing sugar when wearing the aligners or, not brushing and flossing your teeth properly before wearing the aligners may result in caries (tooth decay), periodontal disease (gum disease), inflammation of the gums, or permanent discoloration of teeth.
- 3) Not complying with the doctor's oral hygiene instructions, regarding regular tooth brushing and flossing, preventive measures, and regular practice of standard oral hygiene, may result in caries, inflammation of the gum or gum disease.
- 4) Teeth may require interproximal (space between the teeth) reduction or minor shaping to create the space needed for teeth to move for proper dental alignment.

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- 5) Attachments are tooth-colored "buttons" that may be bonded to one or several teeth during treatment to facilitate tooth movement and/or appliance retention. The attachments will be removed after treatment completion. Use of attachments may make it more noticeable that you are wearing aligners.
- 6) Attachments may be lost and require replacement.
- 7) In some cases, additional treatments or appliances may be required for more severe malocclusions (e.g. severe open bite, severe overjet and/or skeletally narrow jaw) or complicated treatment plans where aligners alone may not be adequate to achieve the desired outcome. Such additional clinical requirements will be explained by your doctor. These may include:
 - Additional orthodontic treatment, including the use of bonded buttons, orthodontic elastics, auxiliary appliances/dental devices (e.g., temporary anchorage devices, sectional fixed appliances).
 - Restorative dental treatment.
 - Oral surgery to correct jaw position or severe crowding, which must be completed prior to aligner treatment. If oral surgery is required, risks associated with anesthesia and proper healing must be considered prior to treatment.
- 8) Orthodontic treatment involves moving teeth and, in some cases, after treatment completion, teeth may shift. Retainers must be worn as directed by your doctor to control this tendency. In short, consistent wearing of retainers after treatment completion is crucial to maintaining your new smile.
- 9) Minor discomfort, such as dental tenderness, when switching aligners during treatment is expected. However, any concern regarding pain or difficulty with placing a new aligner should be immediately reported to your doctor. In some cases, patients may experience irritation to gums, cheeks, or lips during treatment, which should also be communicated to your doctor.
- 10) Aligners may cause a temporary increase in salivation or mouth dryness and certain medications can intensify this effect.
- 11) The aligners may temporarily affect speech and may result in a lisp, though any speech impairment caused by the aligner should disappear within 1 or 2 weeks.
- 12) Notify your doctor if you have any general medical conditions, allergies or are on any medications as they could affect orthodontic treatment.
- 13) In a small number of cases, allergic reactions may occur. In the case of allergic reactions, please contact your doctor or healthcare provider immediately.
- 14) Dental implants cannot be moved by aligners.

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- 15) Existing dental restorations (e.g. crowns) may require, re-cementation or in some cases, replacement as the result of treatment, which may require additional dental, surgical or endodontic treatment.
- 16) A tooth that has been previously traumatized, or significantly restored may be aggravated. In rare cases long-term tooth survival may be reduced, the tooth may require additional dental treatment such as endodontic and/or additional restorative treatment and in extreme cases the tooth may be lost.
- 17) Teeth that are not at least partially covered by the aligner may undergo supra-eruption
- 18) The bite may change during the course of treatment and may result in temporary patient discomfort.
- 19) In rare cases, problems may occur in the jaw joint, causing joint pain, headaches, or ear problems.
- 20) At the end of orthodontic treatment, the bite may require adjustment ("occlusal adjustment").
- 21) Teeth which have been overlapped for a long period may be missing the gingival tissue below the approximal contact when the teeth are aligned, leading to the appearance of a "black triangle" space.
- 22) The health of the bone and gums which support the teeth may be impaired or aggravated.
- 23) The length of the roots of the teeth may be shortened during orthodontic treatment and may shorten long-term tooth survival.
- 24) Atypically shaped, erupting, and/or missing teeth may affect aligner adaptation and may affect the ability to achieve the desired results.
- 25) Short clinical crowns may pose aligner retention problems and inhibit tooth movement.
- 26) In rare cases, minor superficial wear of the aligner may occur where patients may be grinding or rubbing their teeth. This is usually not a problem as overall aligner integrity and strength remain intact.
- 27) Orthodontic appliances or parts thereof may be accidentally swallowed or aspirated. Any looseness of aligners or any other appliance used during treatment should be immediately reported to your doctor. In cases involving extreme crowding or multiple missing teeth, product breakage is more common.

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SURESMILE TREATMENT INFORMED CONSENT

I have been sufficiently informed and have had the opportunity to ask questions and discuss concerns about orthodontic treatment with SureSmile aligners with my doctor from whom I intend to receive treatment.

I have been given sufficiently time to read and have read the preceding information describing orthodontic treatment with SureSmile aligners.

I understand the benefits, risks and inconveniences associated with aligner treatment and options available for orthodontic treatment as well as the option of no treatment.

I understand that orthodontics is not an exact science, and I acknowledge that my doctor and Dentsply Sirona have not and cannot make any guarantee or provide any other assurances regarding the outcome of my treatment.

I understand that Dentsply Sirona is not a provider of medical, dental or health care services and does not and cannot practice medicine, dentistry or give any medical advice.

I understand that I should only use SureSmile aligners after consultation and prescription from a SureSmile trained doctor, and I hereby consent to orthodontic treatment with SureSmile aligners that have been prescribed by my doctor.

In signing this document, I'm confirming that I have read and understand the information related to my SureSmile aligner treatment and that the goal of the treatment is to reach the result shown in my customized treatment plan, with the reservation that any individual biological conditions may affect the result and that I consent to treatment for myself or a minor under my legal care.

I consent that I have read, understand, and agree to the terms stated in this document as indicated by my signature below.

A copy of this Consent shall be considered as effective and valid as an original.

Patient name:

Patient signature
(Or in case of a minor, parent or legal guardian signature).....

Date: