

EU Patient informed consent form

Successful orthodontic treatment is a partnership between the doctor and the patient. As a general 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 your 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 clear aligners

Clear aligner therapy is 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 aesthetic 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 clear 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 aligners. If you choose to undergo clear aligner therapy, ClearCorrect Operating, LLC (“ClearCorrect”), a Texas-based dental laboratory, will manufacture aligners customized for your teeth based on your doctor’s prescription. Your doctor (not ClearCorrect) is responsible for delivering and managing your care.

Potential risks of clear aligners

As with other orthodontic treatments, clear aligners may carry some risk, including (but not limited to) some of the potential risks described below:

- Treatment time may exceed estimates. Poor compliance with your doctor’s instructions, wearing aligners less than 22 hours per day, missing 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 and affect results. 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.
- It may be necessary to temporarily affix engagers (small bumps of composite material) to your teeth to assist with difficult tooth movements. When you are not wearing your aligners, these engagers can feel awkward in the mouth.
- In cases of crowding, IPR, also known as interproximal reduction (reducing 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. If you believe you are experiencing an adverse reaction, inform your doctor immediately.
- Tooth sensitivity and tenderness of the mouth may occur during treatment—especially when advancing from one aligner to the next.

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- 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 anaesthesia 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.
- In cases of severe crowding or multiple missing teeth, it is more likely that the aligner may break. Contact your doctor as soon as possible if this occurs.
- 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.
- Aligners worn out of their intended sequence can delay treatment results and result in complications including (but not limited to) patient discomfort. Always wear aligners in the order specified by your doctor.
- In some cases, a “black triangle” of missing gingival tissue may be visible below the interproximal contact when teeth are aligned after being overlapped for an extended period of time.
- Results may relapse if retainers are not worn as directed by your doctor.
- A successful treatment outcome cannot be guaranteed. After the final planned aligners have shipped, some cases may require refinement with additional clear aligners, traditional orthodontic techniques, and/or cosmetic procedures like crowns or veneers to achieve ideal results. There may be additional costs to you if you require such procedures. Always follow the directions for use (included with each aligner package) for best results.

Informed consent & agreement

I have read and understand the content of this document describing considerations and risks of 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 adequately answered. I have been asked to make a choice about my treatment, and I hereby consent to receive treatment with clear aligners manufactured by ClearCorrect 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 neither my doctor nor ClearCorrect, 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 that ClearCorrect does not practice dentistry or give medical advice. I understand that ClearCorrect manufactures medical devices based on instructions from the prescribing doctor. I understand that I should always contact my doctor (and not ClearCorrect) regarding my expectations, difficulties, results, or any other aspects of my treatment.

I understand that in addition to the collection of personal information such as my age or contact details, it may be necessary to take impressions, intraoral scans, digital model scans, radiographs (x-rays), and/or photographs for diagnosis, professional review, and submit these to ClearCorrect, in order to create customized aligners for my orthodontic treatment. ClearCorrect will be the controller for such data processes that are strictly limited to the manufacturing of aligners according to my doctor's prescription. For other data processes relating to my health and treatment I understand that my doctor is the controller for such purposes and that I should contact him for any questions related to my personal data.

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I recognize that these will be included in my medical records, which may include “personal data” as that term is defined and protected by applicable data protection laws and regulations. This personal data may be disclosed to my doctor, other consulting dentists and orthodontists, and ClearCorrect’s Affiliates inside of the StraumannGroup, some or all of whom may be located outside of the European Union and/or the United States of America, for the purpose of treatment, payment, and health care operations. I acknowledge that data protection standards and legislation in such countries may differ from those in the European Union. For such transfers, ClearCorrect will protect the personal data in compliance with what is required under applicable data protection laws and ensure that an adequate level of protection is satisfied under such laws. I understand that there may also be situations where ClearCorrect is under a duty to share my information, due to a legal requirement or court order. ClearCorrect takes technical and organizational security measures to protect my personal data against accidental or intentional manipulation, loss, destruction or access by unauthorized persons. The measures are designed to ensure the confidentiality and integrity of the data and to ensure the continued availability and resilience of the systems and services processing them. ClearCorrect’s security measures include encryption of personal data, firewalls and password protection. The personal data will be retained for as long as is necessary to fulfil the purpose for which it was collected, or to comply with legal or regulatory requirements and defend legal claims. I acknowledge that ClearCorrect may for its legitimate interest use my personal data for research and the development and improvement of new products and services, without directly identifiable personal identifiers such as name or address. Unless otherwise permitted or required by law, other uses and disclosures of my medical records, including advertising or marketing by either my doctor or ClearCorrect, shall be made only with my prior written authorization (for which I acknowledge my doctor or ClearCorrect may use my contact information to seek to obtain). I am aware that under applicable data protection laws and regulations, I may have the right to access, rectify, delete, restrict, or oppose to the processing of my personal data, and in some instances ask for the portability of such data. Where I have given my consent, I can withdraw it at any time, however in such case ClearCorrect may not be able to continue providing the healthcare related operations my Doctor has prescribed to me. The aforementioned rights’ scope may be limited by applicable laws and regulations. I am informed that I can forward any concerns, inquiries or information requests to privacy.uk@straumann.com, or at the following postal address: Straumann Ltd, Privacy, 3 Pegasus Place, Gatwick Road, RH10 9AY Crawley, United Kingdom. I am aware that should I be dissatisfied with how ClearCorrect handled a complaint or a request relating to data protection, I may contact my local Data Protection Authority to file a complaint. 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 and personal information that complies with the terms of this Informed Consent and Agreement.

- I consent to the use of my personal data for the provision of health care services as detailed above.
- I acknowledge I have read, understand, and voluntarily consent to the use of clear aligners in accordance with terms of this Informed Consent and Agreement.

PATIENT NAME

SIGNATURE OF PATIENT OR PARENT/GUARDIAN (IF PATIENT IS MINOR)

DATE | TIME

SIGNATURE OF DENTIST/ORTHODONTIST

DATE | TIME