

Invisalign® - contract and informed consent document

Informed consent and patient agreement document for Invisalign® orthodontic treatment.

Your dentist recommends orthodontic treatment for you using the Invisalign system. Although orthodontic treatment can result in a more healthy and attractive smile, it is also important to remember that any orthodontic treatment (and that includes orthodontic treatment with Invisalign trays) has limitations and carries potential risks that should be considered before treatment begins.

Product description

Invisalign overlays, developed by Align Technology, Inc. (henceforth "Align Company") is a set of clear, removable braces that gradually move the patient's teeth. The Invisalign product combines the doctor's diagnosis and recommendations with advanced computer graphics technology to create a treatment plan that determines the desired tooth displacement during treatment. Once the treatment plan is approved developed by the doctor, a set of unique Invisalign overlays is produced for the treatment of a particular patient.

Procedure

As part of the procedure, a routine pre-treatment examination may be performed on the patient, including X-rays and plain radiographs. The doctor also takes impressions or intraoral scans of the patient's teeth, which are then sent, along with recommendations, to Align's lab. Based on the doctor's recommendations, Align's technicians create a computer model of the ClinCheck® treatment plan. Once the ClinCheck treatment plan is approved by the doctor, Align manufactures and delivers a set of patient-specific overlays. The total number of overlays can vary and depends on the complexity of the patient's malocclusion and the treatment plan proposed by the doctor. The overlays are numbered consecutively and are issued to the patient with special instructions from the doctor. Unless otherwise instructed by the doctor, the overlays should be worn 20 to 22 hours a day and only taken out before meals and brushing and flossing. The overlays are replaced with another pair every two weeks, or every other period if the decides doctor.

The treatment lasts for a period that depends on the complexity of the doctor's recommendations. In addition, the doctor determines the frequency of visits to the dental office, usually no less frequently than every 6–8 weeks.

When treating some patients, it may be necessary to use abutments embedded in the teeth and/or flexible extractions to assist with some orthodontic movements. After treatment with the first set of overlays may be required to take additional impressions or intraoral scans and/or the use of overlays for final correction.

Benefits

- Invisalign overlays are an aesthetic alternative to traditional braces.
- The overlays are almost invisible, so that few people note the fact of the patient's treatment.
- The treatment plan can be visualized using ClinCheck software.
- The overlays allow normal brushing and flossing, activities usually difficult during treatment with traditional braces.
- Overlays do not have the metal wires or brackets used in traditional braces.
- Wearing overlays can lead to improved oral hygiene habits.
- During treatment, Invisalign patients may observe an improvement in periodontal health (gums).

Risks and inconveniences

Similar to other types of orthodontic treatment, Invisalign products may cause some of the risks described below:

- (i) Neglecting to wear the trays for the required number of hours per day, using the product contrary to medical recommendations, failing to attend medical appointments, and erupting teeth or abnormally shaped teeth can prolong the treatment period and adversely affect the ability to achieve the desired results.
- (ii) There may be tooth soreness after replacing the cap with the next one in the kit.
- (iii) Scratching or irritation of the gums, inner cheeks and lips may occur.

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- (iv) Teeth may change alignment after treatment. This phenomenon can be reduced by regularly wearing retention braces after treatment.
- (v) Patients who consume sugary foods or beverages, neglect to thoroughly brush and floss their teeth prior to the placement of Invisalign trays, or fail to maintain proper oral hygiene and take proper prophylaxis may develop tooth decay, periodontal disease, gingivitis, or permanent marks (e.g., due to decalcification).
- (vi) Overlays may cause short-term speech problems and seplenia, but any speech defects caused by Invisalign® products should reverse within no more than two weeks.
- (vii) Overlays can cause a temporary increase in salivation or dry mouth, and some medications can amplify these effects.
- (viii) Abutments are tooth-colored "buttons" that can be attached to one or more teeth during treatment. Their function is to assist tooth displacement and/or to better hold the trays on the teeth. The attachments can make it easier to see that the patient is undergoing orthodontic treatment. They are removed after treatment is completed.
- (ix) The attachments may fall off and require replacement.
- (x) Correction of the tangent surfaces of the teeth may be required to create the space necessary to achieve tooth alignment.
- (xi) The patient's bite may change during treatment, which may lead to temporary discomfort.
- (xii) In rare cases, minor superficial wear of the overlays may occur if the patient gnashes his or her teeth or if the teeth rub against each other, but this usually does not cause any problems because the overall integrity and strength of the overlays does not change.
- (xiii) After orthodontic treatment is completed, a bite correction ("occlusion correction") may be required.
- (xiv) Unusually shaped, erupting teeth and/or cavities may affect overlay adjustment and the ability to achieve desired results.
- (xv) Treatment of severe cases of occlusion Open, horizontal bite, mixed dentition and/or skeletal jaw stenosis may require adjunctive treatment supplemented by overlay treatment.
- (xvi) Complementary orthodontic treatment, such as with bonded cusps, flexible orthodontic extractions, auxiliary appliances/dental devices (e.g., temporary anchorage devices, segmental fixed appliances), and/or restorative dental procedures may be necessary for more complex treatment plans when overlays alone may be insufficient to achieve the desired outcome.
- (xvii) Teeth that have been overlapping for a long time may lack gingival tissue below the proximal surface when aligned, resulting in a hollow "black triangle."
- (xviii) Overlays are not effective in moving dental implants.
- (xix) Orthodontic treatment may be affected by the patient's general health and the medications he or she is taking.
- (xx) The health of the bone tissue and gums supporting the teeth may deteriorate.
- (xxi) Prior to treatment with Invisalign, surgery may be required to correct crowding of the teeth or severe defects in the jaw. If dental surgery is required, the risks associated with anesthesia and proper healing should be considered before starting treatment.
- (xxii) A previously damaged or substantially restored tooth may deteriorate. In rare cases, the longevity of the tooth may deteriorate, the tooth may require additional dental treatments such as root canal and/or additional conservative management, and the tooth may be lost.
- (xxiii) Existing dental restorations (e.g., crowns) may be compromised and require re-cementing or, in some cases, replacement.
- (xxiv) Short clinical crowns can cause problems with brace placement and make it difficult to move teeth.
- (xxv) During orthodontic treatment, the length of the roots of the teeth may shorten, which can impair the longevity of the teeth.
- (xxvi) Product rupture is more likely in patients with severe crowding and/or several cavities.

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- (xxvii) There is a risk of accidentally swallowing orthodontic appliances or parts of them or pulling them into the airways with air.
- (xxviii) In rare cases, problems in the temporomandibular joint may also occur, causing joint pain, headaches or ear problems.
- (xxix) Allergic reactions may occur.
- (xxx) Supereruption of teeth that are not at least partially covered by the overlay may occur.
- (xxxi) In rare cases, patients with hereditary angioedema (a condition genetically determined) may experience rapid local swelling of subcutaneous tissues, including the larynx. Hereditary angioedema can be triggered by weak stimuli, such as dental procedures.

Informed consent

I have been given sufficient time to reading and I was given the opportunity to read the above information describing treatment orthodontic treatment with Invisalign trays. I understand the benefits, risks, alternatives and inconveniences of treatment and that I have the option of opting out of all forms of treatment. I have been sufficiently informed and given the opportunity to ask questions and discuss concerns about orthodontic treatment with Invisalign® products with my treating physician. I understand that Invisalign products should be used only after seeking the advice of and in accordance with the recommendations of a trained Invisalign practitioner, and I hereby consent to orthodontic treatment with Invisalign products as recommended by my practitioner. Because orthodontics is not an exact science, I acknowledge that my practitioner and Align Technology, Inc. of San Jose, California (henceforth "Align") do not and cannot make any warranty or guarantee with respect to the outcome of treatment. I understand that Align is not a medical, dental or health care provider and does not and cannot provide medical, dental or health care advice. No assurances or guarantees regarding the specific outcome of my treatment have been made to me by my physician or Align, its representatives, successors in interest, assignees and agents.

I understand the policy and consent to the doctor's collection and use of my medical records, including, but not limited to, x-rays, reports, charts, medical history, photographs, findings, plaster models of my teeth, impressions of my teeth or intraoral scans, recommendations, diagnoses, medical examinations, test results, ethnic group information and billing data, and other treatment records in my doctor's possession (henceforth "medical records") as necessary for treatment, customer service and billing. If I do not consent to the use of my medical records as indicated above, it may not be possible to provide Invisalign treatment of my teeth.

I agree not to assert or authorize anyone to assert on my behalf any damages, compensation, indemnification or right to seek other remedies regarding such disclosure. I understand that I am not entitled to remuneration for the use of my medical records and that neither I nor any person acting on my behalf shall have the right to authorize, make any other claim for remuneration, the right to seek or receive damages, indemnification or compensation, or the right to exercise any other protections arising from use consistent with the terms of this Consent.

A copy of this Consent will be considered as effective and binding as the original. By my signature below, I acknowledge that I have read and understand the terms and conditions set forth herein and that I agree to those terms and conditions.

Privacy notice privacy

The doctor is the controller of the personal information contained in the patient's medical records. Align and other members of its group of companies (henceforth the "Align Group") will receive the patient's medical records and they may be stored on Align Group servers outside the patient's country of residence. However, Align Group will continue to protect patient data in accordance with Align Group's binding corporate rules, which can be learned from www.aligntech.com.

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The patient's medical records will be shared to third parties only in cases permitted by applicable regulations, such as when it will be necessary to protect the vital interests of the patient or another person or to establish, enforce or protect legal claims. Physician and Align Group will process the patient's medical records as part of the patient's treatment. Align Group can also anonymize a patient's medical records of the patient and use it for internal analytics and research. The doctor and the Align Group will keep the patient's medical records only for as long as there is a justifiable need, such as further treatment of the patient or fulfillment of regulatory obligations. At the end of this period, the medical records will be deleted or anonymized or, if this is not possible (for example, as a result of archived patient's medical records in a backup copy), it will be securely stored until the opportunity for its disposal. Any questions about how to use medical records should be directed by the patient To their doctor. The doctor will provide information Regarding the patient's right to:

- receive access to your medical records and to request corrections, updates or deletion of these records;
- restrictions on the processing of its medical records medical records;
- requests that a doctor transfer medical records to To another doctor;
- withdraw consent at any time to process your medical records.

In addition, the patient also has the right to file with the local data protection authority with complaints regarding the collection and processing of his medical records.

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Signature _____

Name in capital letters _____

Address _____

City _____

Date _____

Witness _____

Name in capital letters _____

Signature of the parent / guardian

If the patient does not have the legal capacity to give consent,
the consent document must also be signed by a parent or guardian.

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