Medit
4490 Von Karman Ave
Newport Beach, CA 92660
MeditOrtho.com

Patient Informed Consent and Agreement for Medit Aligners

Your doctor has recommended Medit Aligners for your orthodontic treatment. Although orthodontic treatment can lead to a healthier and more attractive smile, you should also be aware that any orthodontic treatment has limitations and potential risks that you should consider before undergoing treatment.

Device Description

Medit Aligners consist of a series of clear plastic, removable appliances that move your teeth in small increments. Medit Aligners products combine your doctor's diagnosis and prescription with sophisticated computer graphics technology to develop a treatment plan which specifies the desired movements of your teeth during the course of your treatment. Upon approval of a treatment plan developed by your doctor, a series of customized aligners is produced specifically for your treatment.

Procedure

You may undergo a routine orthodontic pre-treatment examination including radiographs (x-rays) and photographs. Your doctor will take impressions or intraoral scans of your teeth and send them along with a prescription to Medit Aligners. Medit Aligners technicians will follow your doctor's prescription to create a Medit Aligners Doctor Portal software model of your prescribed treatment.

Upon approval of the Medit Aligners Doctor Portal treatment plan by your doctor, Medit Aligners will produce and ship a series of customized aligners to your doctor. The total number of aligners will vary depending on the complexity of your mal-occlusion and the doctor's treatment plan. The aligners will be individually numbered and will be dispensed to you by your doctor with specific instructions for use.

Unless otherwise instructed by your doctor, you should wear your aligners for approximately 20 to 22 hours per day, removing them only to eat, brush and floss. As directed by your doctor, you will switch to the next aligner in the series every two to three weeks. Treatment duration varies depending on the complexity of your doctor's prescription. Unless instructed otherwise, you should follow up with your doctor at a minimum of every 6 to 8 weeks. Some patients may require bonded attachments and/or the use of elastics during treatment to facilitate specific orthodontic movements. Patients may require additional impressions, or intra-oral scans, and/or refinement aligners after the initial series of aligners.

Benefits

- Medit Aligners offer an esthetic alternative to conventional braces.
- Aligners are nearly invisible so many people won't realize you are in treatment.
- Treatment plans can be visualized through the Medit Aligners Doctor Portal software.
- Aligners allow for normal brushing and flossing tasks that are generally impaired by conventional braces.
- Aligners do not have the metal wires or brackets associated with conventional braces.
- The wearing of aligners may improve oral hygiene habits during treatment.

Risks and Inconveniences

Like other orthodontic treatments, the use of Medit Aligners product(s) may involve some of the risks outlined below:

- Failure to wear the appliances for the required number of hours per day, not using the product as directed by your doctor, missing appointments, and erupting or atypically shaped teeth can lengthen the treatment time and affect the ability to achieve the desired results.

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- Dental tenderness may be experienced after switching to the next aligner in the series.
- Gums, cheeks and lips may be scratched or irritated.
- Teeth may shift position after treatment. Consistent wearing of retainers at the end of treatment should reduce this tendency.
- Tooth decay, periodontal disease, inflammation of the gums or permanent markings (e.g., decalcification) may occur if patients consume foods or beverages containing sugar, do not brush and floss their teeth properly before wearing the Medit Aligners products, or do not use proper oral hygiene and preventative maintenance.
- The aligners may temporarily affect speech and may result in a lisp, although any speech impediment caused by Medit Aligners products should disappear within one or two weeks.
- Aligners may cause a temporary increase in salivation or mouth dryness and certain medications can heighten this effect.
- Attachments may be bonded to one or more teeth during the course of treatment to facilitate tooth movement and/or appliance retention. These will be removed after treatment is completed, in addition attachments may fall off and require replacement.
- Teeth may require interproximal recontouring or slenderizing in order to create space needed for dental alignment to occur.
- The bite may change throughout the course of treatment and may result in temporary patient discomfort.
- In rare instances, slight superficial wear of the aligner may occur where patients may be grinding their teeth or where the teeth may be rubbing and is generally not a problem as overall aligner integrity and strength remain intact.
- At the end of orthodontic treatment, the bite may require adjustment ("occlusal adjustment").
- Atypically shaped, erupting, and/or missing teeth may affect aligner adaptation and may affect the ability to achieve the desired results.
- Treatment of severe open bite, severe overjet, mixed dentition, and/or skeletally narrow jaw may require supplemental treatment in addition to aligner treatment.
- Supplemental orthodontic treatment, including the use of buttons, orthodontic elastics, auxiliary appliances/ dental devices (e.g., temporary anchorage devices, sectional fixed appliances), and/or restorative dental procedures may be needed for more complicated treatment plans where aligners alone may not be adequate to achieve the desired outcome.
- Teeth which have been overlapped for long periods of time may be missing the gingival tissue below the interproximal contact once the teeth are aligned, leading to the appearance of a "black triangle" space.
- Aligners are not effective in the movement of dental implants.
- General medical conditions and use of medications can affect orthodontic treatment.
- Health of the bone and gums which support the teeth may be impaired or aggravated.
- Oral surgery may be necessary to correct crowding or severe jaw imbalances that are present prior to wearing the Medit Aligner product. If oral surgery is required, risks associated with anesthesia and proper healing must be taken into account prior to treatment.
- A tooth that has been previously traumatized, or significantly restored may be aggravated. In rare instances the useful life of the tooth may be reduced, the tooth may require additional dental treatment such as endodontic and/or additional restorative work and the tooth may be lost.
- Existing dental restorations (e.g., crowns) may become dislodged and require re-cementation or in some instances, replacement.
- Short clinical crowns can pose appliance retention issues and inhibit tooth movement.
- The length of the roots of the teeth may be shortened during orthodontic treatment and may become a threat to the useful life of teeth.
- Product breakage is more likely in patients with severe crowding and/or multiple missing teeth.
- Orthodontic appliances or parts thereof may be accidentally swallowed or aspirated.
- In rare instances, problems may also occur in the jaw joint, causing joint pain, headaches or ear problems.
- Allergic reactions may occur.
- Teeth that are not at least partially covered by the aligner may undergo super-eruption.
- In rare instances patients with hereditary angioedema (HAE), a genetic disorder, may experience rapid local swelling of subcutaneous tissues including the larynx. HAE may be triggered by mild stimuli including dental procedures.

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Informed Consent for Medit Aligners

I have read the preceding information describing orthodontic treatment with Medit Aligners. I understand the benefits, risks, alternatives, and inconveniences associated with treatment as well as the option of no treatment. I have been sufficiently informed and have had the opportunity to ask questions and discuss concerns about orthodontic treatment with Medit Aligners products with my doctor from whom I intend to receive treatment. I understand that I should only use Medit Aligners products after consultation and prescription from a trained doctor, and I hereby consent to orthodontic treatment with Medit Aligners products that have been prescribed by my doctor.

Due to the fact that orthodontics is not an exact science, I acknowledge that my doctor and Medit Aligners have not and cannot make any guarantees or assurances concerning the outcome of my treatment. I understand that Medit Aligners is not a provider of medical, dental, or health care services and does not and cannot practice medicine, dentistry, or give medical advice. No assurances or guarantees of any kind have been made to me by my doctor or Medit Aligners, its representatives, successors, assigns, and agents concerning any specific outcome of my treatment.

I understand and consent to my doctor collecting, using and disclosing my medical records, including, but not be limited to, radiographs (x-rays), reports, charts, medical history, photographs, findings, plaster models, impressions of teeth, or intra-oral scans, prescriptions diagnosis, medical testing, test results, billing, and other treatment records in my doctor's possession ("Medical Records") (i) to other licensed dentists or orthodontists and organizations employing licensed dentists and orthodontists; or (ii) to Medit and its affiliated companies, subcontractors, manufacturing partners, service providers, and other authorized recipients involved in providing Medit Aligners treatment and related support services, to the extent necessary for treatment planning, clinical review, manufacture, delivery, customer support, billing, regulatory compliance, quality assurance, product development and improvement, internal administration, internal education and training, and, to the extent permitted by applicable law, internal research and analytics related to Medit Aligners products and services. If I do not provide my consent to the collection, use, and disclosure of my Medical Records to the extent necessary to provide Medit Aligners treatment and related services, I may not be able to receive treatment with Medit Aligners.

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Privacy Notice

Your doctor is the controller of your Medical Records and personal data processed in connection with your treatment.

In order to provide Medit Aligners treatment, your doctor may share certain Medical Records with Medit and its authorized service providers. Medit processes such information on behalf of your doctor and in accordance with applicable data protection laws.

Further information regarding the processing of personal data, including applicable privacy rights, is available in Medit's Privacy Policy and, where applicable, the data protection documentation provided by your doctor.

I hereby consent to the disclosure(s) as set forth above. I will not nor shall anyone on my behalf seek legal, equitable or monetary damages or remedies for such disclosure. I acknowledge that use of my Medical Records is without compensation and that I will not nor shall anyone on my behalf have any right of approval, claim of compensation, or seek or obtain legal, equitable or monetary damages or remedies arising out of any use such that comply with the terms of this Consent. A photostatic copy of this Consent shall be considered as effective and valid as an original. I have read, understand, and agree to the terms set forth in this Consent as indicated by my signature below.

Patient Signature	Date	Signature of Guardian (Mandatory if patient is a minor)	Date
Printed Name		Printed Name	
Witness Signature	Date	Street Address	
Printed Name		City	State ZIP Code