

## Patient's Bill of Rights for Clear Aligner Therapy

Clear aligner therapy is an orthodontic treatment that utilizes class IIa medical devices<sup>1</sup> designed specifically for the individual treatment needs of each patient.

Whether a patient's goal is cosmetic improvement or correction of a malocclusion, ***all clear aligner treatment impacts an individual's skeletal structure.*** Moving teeth through the bone of the jaw is always a medical procedure that requires expert knowledge of trained, accredited dentists or specialist orthodontists.

Clear aligner treatment requires a comprehensive diagnosis by a qualified dentist and/or orthodontist. Patients should expect direct involvement and continuing oversight by an accredited orthodontist or dentist with whom he or she has a trusted doctor-patient relationship.

### **Patients undergoing clear aligner treatment have the right to:**

- Undergo a thorough in-office dental exam by a licensed dentist or orthodontist before treatment begins that adheres to the medical standards set by professional societies.
- Expect the dental exam to include a review of their medical and dental health history.
- Expect the dentist or orthodontist to review recent diagnostic radiographs or equivalent bone imaging studies and photographs to assure that the dentist has been able to clearly visualize the patient's teeth in the bone of the jaw below the gumline, and evaluate the health of periodontal tissues and the position of the teeth and temporomandibular joints and the way they function together.
- Receive unbiased advice and counsel from an independent, experienced healthcare professional who is licensed to practice dentistry, is bound by oath to the ethical conduct, patient confidentiality and treatment standards issued by his or her professional society, and who carries professional insurance.
- Receive advice on treatment based solely on the dentist's personal examination and his or her independent professional judgment and experience about:
  - all options to achieve the patient's treatment goals, including the risks and benefits of care associated with each.
  - the patient's personal eligibility and suitability for any orthodontic treatment option.
- Receive confirmation from the dentist or orthodontist who performed their examination that:
  - the patient does not have any clinical issues, such as cavities, periodontal disease, bone conditions, hereditary angioedema or other contra-indications that would otherwise delay or preclude the beginning of clear aligner orthodontic treatment,
  - the dentist has reviewed and signed off on the digital treatment plan that specifies the correction (tooth and/or jaw movement) achieved with each sequential set of clear aligners,
  - the dentist will monitor the patient's treatment and make all adjustments necessary to the treatment plan to achieve a successful treatment outcome.

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<sup>1</sup> For further reference: Under Regulation (EU) 2017/745 on medical devices (as amended), Annex VIII, Rule 5, Invisalign aligners are classified as Class IIa medical devices in the EU [<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20200424>]

- Expect to make a clear, informed decision about treatment and confirm their consent only after having received professional advice and adequate responses to all their questions.
- Receive protocols for emergency and routine follow-up care including the name, telephone number, emergency contact telephone number, license number, and practice contact address of the orthodontist or dentist managing their care.
- Expect ongoing monitoring through both telehealth and in-person visits of their treatment progress from the dentist or orthodontist who examined them to identify and address any issues that may occur during treatment.
- Know who they are contracting with for their treatment and ensure that a healthcare professional is responsible for the delivery of care.
- Expect to receive a contract for review that contains clear contractual terms, including information identifying who (which dentist, clinic or entity) the patient contracting with and who will be providing care, and clarity on binding financial, non-disclosure or other legal obligations.
- Expect clarity about the date on which they are contractually bound to undergo treatment, and the ways and timelines they have to withdraw their consent prior to undergoing treatment.
- Not be required to sign an agreement that limits or excludes his or her ability to file a complaint or lawsuit regarding their treatment or agree to contract clauses that would prevent them from making public disclosure about a complaint or resolution of their complaint.