



# Invisalign system instructions for use

**Device description**

The Invisalign System consists of a series of doctor-prescribed, thin, clear plastic removable orthodontic appliances (aligners) that gently move the patient's teeth in small increments and may also position the mandible forward from their original state to a more optimal, treated state.

**Indications for use**

The Invisalign System is indicated for the orthodontic treatment of malocclusion.

**Contraindication**

The Invisalign System is contraindicated for use in patients with the following condition:

- Active periodontal disease.

**Warnings**

- In rare instances, some patients may be allergic to the plastic aligner material.
- 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.
- In both cases, discontinue use and consult a health care professional immediately. Align Technology must also be notified.
- Orthodontic appliances, or parts thereof, may be accidentally swallowed or aspirated and may be harmful.

**Precautions**

- Aligners are intended to only be removed for eating, drinking, and for oral care. Unnecessary and excessive removal and insertion of aligners with precision wings may prematurely damage and/or break the aligners.
- To avoid aligner damage, instruct patients to use proper techniques to insert and remove aligners.
- For aligners with precision wings, biting directly on the precision wings or positioning them on top of each other may increase the chance of aligner deformation or cracking.
- Keep aligners away from hot water and harsh chemicals.
- Keep aligners out of reach of young children and pets.
- Always store aligners in a cool, dry place.
- Treatment of severe open bite, severe overjet, mixed dentition, and/or skeletally narrow jaw may require supplemental treatment in addition to aligner treatment.
- Skeletal expanders, bonded auxiliaries, elastics, and other fixed and/or removable orthodontic appliances, may be needed for more complicated treatment plans where aligners alone may not be adequate to achieve the desired outcome.
- Oral surgery may be necessary to correct severe crowding or jaw imbalances. If oral surgery is required, risks associated with anesthesia and proper healing must be taken into account prior to treatment.
- Atypically-shaped, erupting, and/or missing teeth may affect aligner adaptation and may affect the ability to achieve the desired results.
- Existing dental restorations (e.g., crowns, bridges) may become dislodged and require re-cementation or, in some instances, replacement.
- Aligners are not effective in the movement of dental implants.
- Certain medical conditions and use of certain medications may affect orthodontic treatment outcomes.

- Dental tenderness may be experienced following initial aligner placement and after switching to each new aligner in the series.
- The product may temporarily affect speech and may result in a lisp, although any speech impediment associated with the product usually disappears within one or two weeks.
- Failure to wear the appliances for the prescribed number of hours per day and/or not using the product as directed by your doctor can lengthen the treatment time and affect the ability to achieve the desired results.
- Gums, cheeks, or lips may be scratched or irritated by the product.
- Attachments may be temporarily bonded to one or more teeth during the course of treatment to facilitate aligner retention and/or tooth movement.
- Attachments may fall off and require replacement.
- All attachments should be removed upon completion of treatment.
- Risks associated with interproximal reduction, which may be prescribed to create space for tooth movement as part of treatment must be taken into account.
- Tooth decay, periodontal disease, and permanent markings from stains and decalcification may occur if patients do not brush and floss their teeth properly during treatment or if they consume foods or beverages containing sugar while wearing aligners.
- The bite may change throughout the course of treatment and may result in temporary patient discomfort.
- At the end of treatment, the bite may require adjustment by the doctor.
- Teeth may shift position after treatment. Consistent wearing of retainers at the end of treatment should reduce this tendency.
- It is recommended that all teeth should be at least partially covered to help prevent supra-eruption.
- Temporary increase in salivation or dryness of mouth may occur.
- 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/or the tooth may be lost.
- The health of the bone and gums which support the teeth may be impaired or aggravated.
- The length of the roots of the teeth may be shortened during orthodontic treatment, which may become a threat to the longevity of the teeth.
- In rare instances, problems in the temporo-mandibular joint (jaw joint) may result in joint pain, headaches, or ear problems.

**Directions for use**

1. Rinse new aligners with cold water prior to using them.
2. If an extraction has been performed as a part of treatment, retain the space while the area is healing. Attachments should be bonded only after the extraction site has completely healed.
3. Review the "Use and care instructions for your Invisalign aligners" brochure with your patient.
4. Each set of aligners is designed to be replaced after 1-2 weeks of 20-22 hours of wear per day or at doctor's discretion.
5. Seat aligner #1 on the patient's teeth and visually inspect for soft tissue impingement. If necessary, trim the aligners. Following trimming, polish the aligners using the EZ-Trim™ Polishing Wheels (or similar product).

6. For aligners with precision wings, the precision wings are especially designed to position the mandible forward to help correct the bite. It is important to make sure that the precision wings are in the proper engaged position (lower wings in front of upper wings) when the aligners are worn.
7. Complete any attachment placement; perform any necessary interproximal reduction (IPR) procedures using the Invisalign Interproximal Reduction Kit (or similar product).
8. Add pontics to the aligners, if applicable, using the Invisalign Pontic System (or similar product).
9. Provide the patient with Invisalign aligner storage cases. Instruct patient to store aligners in a case when not in the mouth to protect them from loss or damage.
10. At each appointment, check teeth for tight interproximal contacts and, if needed, perform IPR as prescribed. Check for appropriate aligner stage and their fit, and review the ClinCheck setup to monitor treatment progress as needed.
11. Dispense the next set of aligner stages. The patient should be allotted enough aligners to last until the next appointment.
12. If additional aligners are needed, new impressions may be required.
13. At the end of treatment, retainer wear is highly recommended.
14. For other procedural details, consult the Invisalign training materials.

**Daily care and maintenance of the Invisalign aligners**

1. Prior to each insertion and before bed, inspect aligners for cracks and deformation. Severe cracks or deformities should be reported to the doctor immediately. Aligners with cracks the size of the height of the tooth should not be used.

**Note:** Parent or guardian should inspect aligners of pediatric patients.

2. Aligners should be cleaned prior to each insertion using a soft bristle toothbrush with water and a small amount of toothpaste.

**Note:** Be sure that each aligner is rinsed thoroughly with water after each cleaning. We also recommend that Invisalign aligner cleaning products are used once a week, or as needed.

3. Do NOT use denture cleaners to clean aligners. Do NOT soak them in mouthwash. These products can damage the surface of the aligner, causing it to become dull and more visible.
4. Aligner storage case(s) are included in the starter kit. Invisalign aligners should be stored in a case when not in use. Aligners with precision wings should be stored in the appropriate aligner case that is designed with more space to accommodate this product.
5. Aligner cases may be hand washed with soap and water. Do not use dish washing machines to clean the cases.

**Proper oral hygiene**









1. Aligners should be removed for eating and drinking. (Patients do not need to remove aligners to drink cool water.)
2. Patients should brush and floss their teeth after each meal or snack prior to re-inserting their aligners. If they don't have access to a Invisalign cleaning system or a toothbrush, they can simply rinse their mouth, and then clean the aligners by holding them under warm running water. Aligners should be thoroughly cleaned at the patient's earliest convenience.
3. If patients should have any questions regarding hygiene techniques, please have them consult their doctor.
4. Regular dental checkups and cleaning are recommended for the continued health of a patient's teeth and gums.

**How supplied**

Each aligner is cleaned, and packaged prior to delivery. Each aligner contains the Invisalign logo and a number which identifies the patient ID number and treatment stage.

For professional dental use - Rx only.

**Symbol glossary**

Symbol	Title	Explanatory text	Standard reference
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	EN ISO 15223-1*, 5.4.3
	Date of manufacture	Indicates the date when the medical device was manufactured.	EN ISO 15223-1*, 5.1.3
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	EN ISO 15223-1*, 5.4.4
	Patient number	Indicates a unique number associated with an individual patient	EN ISO 15223-1*, 5.7.1
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directive 93/42/EEC.	EN ISO 15223-1*, 5.1.1
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	EN ISO 15223-1*, 5.1.2
	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.	US Code of Federal Regulations, Title 21, Part 801.109(b)(1)
	CE marking Conformité Européenne Notified Body Reference no. 0344	Signifies European technical conformity.	MDD 93/42/EEC Articles 4,11,12,17, Annex II

\*Medical devices- Symbols to be used with medical device labeling and information to be supplied- Part 1: General requirements.