

English

Read these instructions before use

Before using Invisalign® aligners, patients (and, when applicable, their parents or legal guardians) should carefully read these Use and care instructions for important information about aligner wear including warnings and precautions, proper care and maintenance, and oral hygiene requirements during treatment. We recommend that you save these instructions for future reference. If you have questions or concerns, please contact your doctor.

What is the Invisalign® system?

The Invisalign system includes removable orthodontic appliances (aligners) and associated 3D orthodontic software and applicable supporting accessories. The 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 from their original state to a more optimal, treated state to address malocclusion. The optional mandibular advancement feature(s) positions the patient's jaw to address skeletal malocclusion. The system with Invisalign aligners is used in patients with primary (baby milk teeth), mixed (transitional) and permanent dentition (teeth). Invisalign aligners with mandibular advancement feature(s) are used in patients with mixed and permanent dentition.

For patients who are minors, your parent or guardian or another responsible adult should review these instructions and help you follow these directions.

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 active periodontal disease.

Note: this does not preclude, at the discretion of the doctor, treatment of patients with treated, controlled, or arrested periodontal disease and free of active disease.

Warnings

1. In rare instances, some patients may be allergic to the plastic aligner material.
2. 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.
3. Orthodontic appliances, or parts thereof, may be accidentally swallowed or aspirated and may be harmful. Note: If any of the above should occur, patient should discontinue use, seek medical attention immediately as necessary, and notify the Invisalign treating doctor. The doctor is required to notify Align Technology and the patient may also notify Align Technology, if needed.
4. Orthodontic treatment, including clear aligner treatments, is not effective in the movement of dental implants and should not be used to move implants. Treatment plans that involve implant movement may result in an implant failure.
5. Invisalign treatment with mandibular advancement features such as precision wings is neither tested nor approved for treatment of respiratory disorders, sleep apnea, and/or temporomandibular disorders (TMD).
6. Erupting, exfoliating and/or missing teeth under the mandibular advancement precision wing feature may affect the integrity of the feature. In addition, any erupting teeth which are located under the precision wing feature may not complete eruption during treatment with the precision wing feature.

Precaution: treatment considerations

1. Aligner treatment alone may not be adequate to achieve the desired result in patients with certain orthodontic issues. Your doctor will determine whether supplemental treatment is necessary and will discuss any associated risks and healing requirements prior to starting aligner treatment.
2. In patients with small, unusually - shaped or missing teeth, aligner retention and treatment duration may be impacted.
3. Dental restorations (which replace or restore part or all of a patient's tooth – for example, crowns or bridges) may become dislodged and require re-cementation or, in some instances, replacement.

4. A tooth that has been injured (for example, from a fall or blow) may be aggravated during orthodontic treatment. In rare instances, the life of the tooth may be reduced, the tooth may require additional dental treatment such as endodontic (root canal) and/or additional restorative work, and/or the tooth may be lost.
5. The root lengths of the teeth may be shortened (this is known as 'root resorption') during orthodontic treatment, causing a threat to longevity of the teeth.
6. Do not alter your aligners. The aligners should cover all your teeth; otherwise, 'supra-eruption' (in which an uncovered tooth can move above the 'occlusal' or chewing surface of the other teeth) may occur.
7. In rare instances, problems in the temporo-mandibular or jaw joint (temporo-mandibular disorder or dysfunction (TMD)) may result in joint pain, headaches, or ear problems. For patients in treatment with mandibular advancement features such as precision wings (which are used to shift the lower jaw forward), problems in the jaw joint may be exacerbated.
8. Certain medical conditions and use of certain medications may affect orthodontic tooth movement and treatment outcomes.

Attachments and interproximal reduction (IPR)

1. Attachments (bumps which are attached to your teeth during aligner treatment to help your aligners move your teeth) may be temporarily bonded to one or more teeth during the course of treatment to help hold your aligners in place and to aid tooth movement.
2. Attachments may fall off and require replacement. Failure to have attachments replaced may impact a patient's treatment duration or treatment outcome.
3. All attachments should be removed when your aligner treatment is complete. Failure to remove attachments at the end of treatment could lead to tooth decay (cavities) and soft tissue irritation.
4. Interproximal reduction (IPR) (filing in between your teeth) may be prescribed to create space as part of treatment. You may experience temporary sensitivity and your doctor will discuss any associated risks and remedies.

Treatment experience

1. Aligners with cracks the size of the height of the tooth should not be used.
2. Dental tenderness or sensitivity may be experienced following initial aligner placement and after switching to each new aligner in the series.
3. Patients may experience a temporary loosening of their teeth during the treatment.
4. The product may temporarily affect speech and may result in a lisp, although any speech impediment associated with clear aligner treatment usually disappears within one or two weeks.
5. A temporary increase in salivation or dryness of mouth may occur.
6. Gums, cheeks, or lips may be scratched or irritated by the product and its associated features.
7. Tooth decay (cavities), periodontal disease (gum disease), and permanent markings from stains and decalcification (white spots) may occur if patients do not brush and floss their teeth properly during treatment or if they consume foods or beverages containing sugar or acids while wearing aligners.
8. The bite may change during treatment; this may result in temporary discomfort.
9. At the end of treatment, the bite may require adjustment by the doctor.
10. Teeth may shift position (relapse) after treatment. Consistent wearing of retainers at the end of treatment should reduce this tendency.
11. For aligners with mandibular advancement feature(s) such as precision wings, biting directly on the features or positioning them incorrectly may increase the chance of aligner deformation or breakage, which may lengthen the treatment.

Aligner care and compliance

1. Aligners are intended to be removed only for eating, drinking, and oral care. Unnecessary and excessive removal and insertion of aligners may prematurely damage and/or break the aligners.
2. Failure to properly store, insert or remove aligners can lead to damage. Patients should read all instructions carefully and should use proper techniques for aligner insertion and removal. Aligners should always be stored in a cool, dry place and in their applicable cases. Attempting to store aligners with mandibular advancement features such as precision wings in a standard Invisalign aligner case may damage the aligners.
3. Keep aligners away from hot water and harsh chemicals and carefully follow the patient instructions below. Do NOT use denture cleaners to clean aligners, and do not soak them in mouthwash. These products can damage the surface of the aligner, causing it to become dull and more visible.
4. Keep aligners out of reach of young children and pets. For children in treatment, a supervising adult should monitor aligner use, storage and care.
5. Tobacco use, smoking, and/or vaping while wearing aligners may lead to discoloration or damage. In general, tobacco use has been shown to increase gum disease and to delay tooth movement during orthodontic treatment.
6. Orthodontic treatment (including aligner treatment) may impair the health of the bone and gums which support the teeth and may aggravate the gums.
7. The length and success of treatment depends on the patient's compliance, cooperation in keeping appointments, maintaining good oral hygiene, avoiding loose or broken appliances and following the doctor's instructions carefully.
8. Failure to wear the appliance for the prescribed number of hours per day and/or not using the product as directed by the doctor can lengthen the treatment time and affect the ability to achieve the desired results.
9. Regardless of the patient's compliance, due to the variation in the size and shape of the teeth and other factors, achievement of an ideal result may not always be possible. Restorative dental treatment may be indicated.

Wearing and using your Invisalign aligners

Here are some instructions to help ensure proper use and avoid damaging your aligners.

Always remember to

1. Wear your aligners per your doctor's instructions, usually 20-22 hours per day. Aligners are designed to be changed every 1-2 weeks or at doctor's discretion.
2. Wash your hands thoroughly with soap and water before handling your aligners.
3. Handle only ONE aligner at a time.
4. Rinse your aligners when removing them from the packaging.

Use proper technique described below when inserting and removing aligners to avoid damaging aligners.

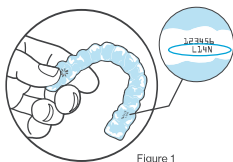


Figure 1

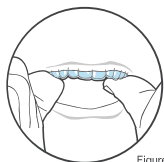


Figure 2

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. Caution on aligners with cracks the size of the height of the tooth should not be used.
Note: A parent or guardian should inspect aligners of children.
2. Make sure you have the proper aligner – the upper for your top teeth and the lower for your bottom teeth.
3. To help avoid confusion, each aligner is engraved with your unique case number, a "U" for upper and an "L" for lower, followed by the stage number. (Figure 1)
4. You may insert either the upper or lower aligner first. When inserting each aligner, gently push the aligners over your front teeth. Then apply equal pressure, using your fingertips, to the tops of your left and right molars (back teeth) until the aligner snaps into place. (Figure 2)

5. Do NOT bite your aligners into position. This may damage them. For aligners with precision wings (Figures 3a and 3b, precision wings circled), do NOT bite down on precision wings. The lower precision wings should be positioned in front of the upper precision wings when the aligners are in the mouth.

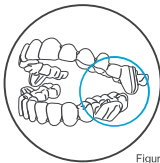


Figure 3a

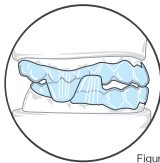


Figure 3b

Note: If you experience sharp pain or significant discomfort, discontinue use of the aligners and contact your doctor.

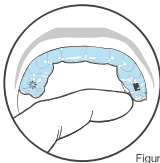


Figure 4

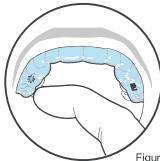


Figure 5

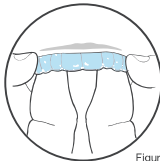


Figure 6

Aligner removal

1. On one side of your mouth, use your fingertip on the inside of your back molar to slowly pull the aligner from your molars. (Figure 4)
2. Repeat this process on the other side of your mouth before trying to completely remove the aligner. (Figure 5)
3. Once aligner is disengaged from the back molars on both sides of your mouth, you should be able to slowly work your way forward gently prying the aligner away from your teeth with your fingertips. (Figure 6)

Note:

- Aligners should be rinsed/brushed and dried prior to storage in a protective case.
- Aligners are intended to be removed only for eating, drinking, smoking, and oral care. Unnecessary and excessive removal/ insertion of aligners with precision wings may prematurely damage and/or break the aligners.

- Take care in removing your aligners, especially if multiple attachments are being used.
- Do NOT use excessive force to bend or twist an aligner to get it off.
- Do NOT use any sharp object to remove your aligners. Consider an aligner removal tool if needed.
- Consult with your doctor if your aligners are extremely difficult to remove.

Daily care and maintenance of your Invisalign aligners

1. Clean your aligners prior to each insertion. Use a soft bristle toothbrush with water and a small amount of toothpaste. You may find it easiest to clean the outside of your aligners by brushing them while they are still on your teeth (Figure 7), then remove your aligners to clean the inside surfaces (Figure 8).

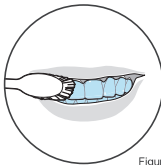


Figure 7

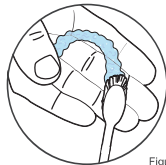


Figure 8

Note: Be sure to rinse each aligner thoroughly with water after each cleaning. Use Invisalign cleaning products as needed.

2. 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: A parent or guardian should inspect aligners of children.
3. Do NOT use denture cleaners to clean aligners or soak them in mouthwash. These products can damage the surface of the aligner, causing it to become dull and more visible.
4. Aligner cases may be hand washed with soap and water. Do not use dish washing machines to clean the cases.

Proper oral hygiene

1. Remove your aligners for eating and drinking. (You do not need to remove your aligners to drink cool or tepid water.)
2. Brush and floss your teeth after each meal or snack prior to re-inserting your aligners. If you don't have access to a Invisalign cleaning system or a toothbrush, you can simply rinse your mouth, and then clean your aligners by holding them under warm running water. Be sure to thoroughly clean your aligners at your earliest convenience.
3. If you have any questions regarding hygiene techniques, please consult your doctor.
4. Regular dental checkups and cleaning are recommended for the continued health of your teeth and gums.

Storing your Invisalign aligners

1. Aligner storage case(s) are included in your starter kit. We recommend that you store your Invisalign aligners in a case when they are not in your mouth (Figures 9 and 10). This will help protect them from loss and damage. Keep aligner cases clean by hand washing them with soap and water. Do not wash them in dish washing machines.
2. The case represented on Figure 10 is designed for aligners that have “wings” on the sides of aligners. Trying to place these aligners into the standard aligner case shown in Figure 9 may damage the aligners, which could impact treatment efficacy.



Figure 9



Figure 10

Always keep the most recently used aligners (or more stages as directed by your doctor). If your current aligner is lost or broken, your doctor may recommend that you temporarily go back one stage while a replacement is being made.

After the treatment is complete as deemed by the doctor, Invisalign aligners should be disposed of in compliance with national and local laws.

Note: Keep all of your older aligners in a clean plastic bag, or as instructed by your doctor. Keep them out of reach of young children and pets. For children, instruct patient to keep aligners under adult supervision.

Frequently asked questions and answers

What if I lose or break an Invisalign aligner?

In the event that an aligner is lost or broken, you should immediately inform your doctor. Your doctor will probably tell you to start wearing your last set or next set of aligners immediately. He or she will possibly order you a new set of aligners to replace the ones you just lost, which should arrive in a few days.

For patients undergoing mandibular advancement, why do some of my aligners have 'wings' on them?

The 'wings' on the sides of aligners are called precision wings, and are especially designed to position the lower jaw forward to help correct the bite.

Will the treatment be painful?

Most people experience tooth soreness for a few days after starting each new stage. This is normal. It is a sign that the Invisalign aligners are working, moving your teeth to their final destination. This soreness should gradually go away a couple of days after inserting the new aligner in the series. If it doesn't, promptly call your doctor.

What should I do if my new Invisalign aligner doesn't snap onto my teeth?

Minor discrepancies between the new aligner and the current tooth position are normal, since the teeth need time to conform to the new aligner position. In the event of significant problems with aligner fit, inform your doctor.

Are there restrictions on what I can eat?

In general, no. Unlike traditional orthodontics, you can usually eat and drink whatever you desire because you remove your aligners while eating. Thus, there is no need to restrict your consumption of any of your favorite foods and snacks, unless otherwise instructed by your doctor.

Is it OK to drink hot or cold beverages while wearing Invisalign aligners?

Except for cool or tepid water, we recommend that you do not drink while wearing the aligners. This is to avoid formation of cavities and stains or warping of the aligners with hot drinks and hot water.

Can I chew gum while wearing Invisalign aligners?

NO. Gum will stick to the aligners. We recommend removing your aligners for all snacks and meals.

Will smoking or chewing tobacco stain the aligners?

We discourage tobacco use while wearing aligners because of the possibility of aligner discoloration.

Why do some of my aligners have bumps or ridges on them?







Depending on your specific treatment, some of the movements may require either “attachments” or “ridges” to help the aligner grip the teeth. These bumps, or wells, are where the aligner grips the attachment the doctor places on your teeth. The attachments are actually small pieces of composite the doctor affixes to your teeth that are then gripped by bumps on your aligners. The ridges are slim indentations in your aligners. Your doctor will use one or both of these features to attempt to achieve the desired movement.

What if I lose or break an attachment?

In the event that an attachment is lost or broken, you should immediately contact your doctor.

Note: If you have additional questions after reading this pamphlet, please consult with your doctor.

Symbols glossary

Symbol	Title	Explanatory text	Standard reference
	Consult instructions for use or consult electronic 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	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	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
Rx only	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)

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

For professional dental use – **Rx only**