



Clarity™

Esthetic Orthodontic Solutions

NOTICE FOR DOCTOR'S OFFICE: The following document is an informed consent for 3M™ Clarity™ Aligner treatment to be used in addition to your office's standard patient forms. This form is not adequate for full patient notice of privacy practices as required by the Health Insurance Portability and Accountability Act (HIPAA). This form is to be signed by the patient before treatment. It should be kept on file for your records and not returned to 3M.

Patient's informed consent and agreement: 3M™ Clarity™ Aligner treatment

Your doctor has recommended 3M™ Clarity™ Aligners for your orthodontic treatment. The aligners are prescribed for correcting malocclusions with crowding and spacing. More complicated cases may require supplemental treatment in addition to aligner treatment. While considering the benefits of a healthier and improved smile, you should also be aware that any orthodontic treatment has warnings and precautions that you should recognize before beginning treatment. Your doctor will review any specific risks and limitations for your personalized orthodontic treatment plan.

WARNINGS

- Care should be taken to not swallow or breathe in the aligner, attachments or other auxiliaries wholly or in pieces. Doing so may be harmful. Consult physician if the aligner or parts of the aligner are swallowed or aspirated.
- Single Patient Use Only. Reuse by another patient may result in compromising product integrity or may create risk of patient infection or cross-contamination.
- Some adhesives used for bonding attachments contain acrylate monomers, which are known to produce allergic skin reactions in certain sensitive individuals. May cause eye and skin irritation.
- Care should be used when using instruments or tools to seat and/or remove aligners so that aligners do not become damaged. Any resulting rough edges or cracks can irritate the gums, cheeks and lips.

PRECAUTIONS:

- Keep aligners out of reach of young children and pets.
- Gums, cheeks and lips may be abraded or irritated by the aligners.
- Caries, decalcification, periodontal disease and permanent stains may occur if consistent and proper oral hygiene, such as brushing and flossing, is not performed as recommended.
- Eating and/or drinking sugary foods and beverages while wearing the aligners may also lead to caries, decalcification, and periodontal disease.
- Ensure that there is no hard debris, i.e. food or other foreign material in the aligner before inserting. Foreign material may lead to damage of the enamel.
- The alignment of your teeth and the way they fit together may change during the course of treatment, resulting in temporary discomfort.
- In rare instances, aligner treatment may result in temporomandibular joint (TMJ) pain, headaches or ear problems.

INFORMED CONSENT

I hereby acknowledge that I have read and completely understand the treatment considerations and warnings/precautions presented in this form. I understand the benefits, risks and limitations associated with treatment using 3M™ Clarity™ Aligners. In addition, the option of having alternative treatment or no treatment performed has also been discussed with me.

I understand that 3M has not and cannot make any guarantees or assurances regarding my treatment's outcome. Furthermore, I acknowledge that 3M is not a provider of medical, health or dental care services. Therefore, 3M neither practices dentistry or medicine nor gives medical advice of any kind. No assurances or guarantees of any kind have been made to me by 3M, its representatives or other respective parties associated with 3M regarding any specific outcomes that would result from the treatment plan being undertaken by my doctor.

I authorize my doctor to release to 3M my dental and medical records required to assist in treatment planning and for fabricating 3M prescription appliances and oral care products for orthodontic treatment. I hereby give my permission for the use of such records, including x-ray images, photographs, digital images and reports that are made during examinations, treatment and retention for the purposes of education and research. 3M may de-identify my personal health information (PHI) in accordance with the standards set forth in 45 CFR § 164.514(b). 3M may use or disclose such de-identified data.

An electronic copy of this consent shall be considered just as effective and valid as an original version of the document. As indicated by my signature below, I have read, understand and agree to the terms set forth in this consent.

SIGNATURE OF PATIENT

PRINT PATIENT NAME

ADDRESS

CITY

STATE

ZIP

DATE

SIGNATURE OF PARENT/GUARDIAN

PRINT PARENT/GUARDIAN NAME (If signatory is under 21, the parent of legal Guardian must also sign to signify agreement)



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NOTICE TO PATIENT: Please keep this form for your personal records as a reference for your 3M™ Clarity™ Aligners and Retainers. Consult your orthodontist with any questions or concerns about your aligners, your treatment or treatment progress.

WARNINGS:

- Care should be taken to not swallow or aspirate the aligner, attachments or other auxiliaries wholly or in pieces. Doing so may be harmful. Consult physician if the aligner or parts of the aligner are swallowed or aspirated.
- Single Patient Use Only. Reuse by another patient may result in compromising product integrity or may create risk of patient infection or cross-contamination.
- Some adhesives used for bonding attachments contain acrylate monomers, which are known to produce allergic skin reactions in certain sensitive individuals. May cause eye and skin irritation.
- Care should be used when using instruments or tools to seat and/or remove aligners so that aligners do not become damaged. Any resulting rough edges or cracks can irritate the gums, cheeks and lips.

PRECAUTIONS:

- Keep aligners out of reach of young children and pets.
- Gums, cheeks and lips may be abraded or irritated by the aligners.
- Caries, decalcification, periodontal disease and permanent stains may occur if consistent and proper oral hygiene, such as brushing and flossing, is not performed as recommended.
- Eating and/or drinking sugary foods and beverages while wearing the aligners may also lead to caries, decalcification, and periodontal disease.
- Ensure that there is no hard debris, i.e. food or other foreign material in the aligner before inserting. Foreign material may lead to damage of the enamel.
- The alignment of your teeth and the way they fit together may change during the course of treatment, resulting in temporary discomfort.
- In rare instances, aligner treatment may result in temporomandibular joint (TMJ) pain, headaches or ear problems.

FOR YOUR INFORMATION:

- Aligners are designed to be worn for 22 hours per day.
- The aligners are marked with the sequencing order. The aligners should be worn in the order prescribed, usually in increasing numerical order.
- Aligners should be replaced approximately every 2 weeks or as instructed by your orthodontist.
- Aligners should be inserted one at a time.
- When it is time for your next aligner in the series, we recommend placing it just before going to bed for the night. This will help alleviate the initial discomfort you may experience.
- Keep aligners away from hot water and harsh chemicals.
- Store aligners in a cool, dry place.
- Small amounts of dental composite, commonly referred to as attachments, may be bonded to one or more teeth to facilitate aligner retention and teeth movement. These attachments are temporary.
- Attachments may prematurely come off and will need to be replaced, otherwise treatment time may be affected.
- All attachments will be removed at the end of treatment.
- Gingival tissue (your gums) and teeth may become sore and tender after initial aligner placement and when placing each sequential aligner.
- Speech may be affected when initially beginning treatment but effects should be minimized in one to two weeks after beginning to wear the aligners.
- Failure to wear the aligners for the prescribed number of hours per day or in the prescribed order and/or not using the aligners as directed may lengthen the treatment time and affect the final treatment outcome.
- The alignment of your teeth and the way they fit together may require additional adjustments by your doctor at the end of treatment.
- Temporary increase in the amount of saliva or dryness of mouth may occur.
- At the end of treatment, wear your retainer as directed. Failure to do so may result in your teeth shifting from their final positions.

ALIGNER INSERTION:

1. Be sure that you have the correct aligner. The aligner intended for your upper teeth is marked with a U. The aligner for your lower teeth is marked with an L.
2. To insert an aligner, gently push the aligners over your front teeth. Then apply pressure at the same time with your fingertips to the back teeth on both sides of the aligner until the aligner snaps into place.
3. Do not bite your aligners in to place. They should seat well with finger pressure.
4. Your doctor may provide a tool or instrument to assist with aligner insertion. Follow the instructions provided by your doctor or the instructions that may accompany the tool or instrument.

ALIGNER REMOVAL:

1. Place your fingertips on the inside of last molar to slowly pull the aligner from your molars. Do this one side at a time.
2. After the aligner has been loosened from the molars, gently pry the aligner away from your teeth, working your way toward your front teeth.
3. Do not use excessive force or twist your aligner to remove it.
4. Your doctor may provide a tool or instrument to assist with aligner removal. Follow the instructions provided by your doctor.
5. After removing your aligners rinse them with water, shake them dry and store them in the case provided to help prevent loss or damage to your aligners or the instructions that may accompany the tool or instrument.

DAILY CARE AND MAINTENANCE OF 3M™ CLARITY™ ALIGNERS:

1. Prior to inserting an aligner, it should be cleaned with a soft bristle toothbrush and running water. **NOTE:** Be sure that each aligner is thoroughly rinsed with water after cleaning and before reinstalling.
2. Do not use denture cleaners to clean aligners. Do not soak them in mouthwash. Doing so may alter the finish of the aligners making them more visible.
3. An aligner carrying case is included in your starter kit. We recommend storing your aligners in the case when they are not in your mouth. This will help protect them from damage or loss.

PROPER ORAL HYGIENE:

1. It is recommended that you wash your hands with soap and water before handling your aligners.
2. The aligners should be removed for eating and drinking. You may drink water with the aligners inserted.
3. Brush your teeth (and floss if necessary) after eating and before reinserting the aligner. If it is not possible to brush, rinse your mouth with water before reinserting the aligner.
4. If you have any questions regarding hygiene protocols, please consult your doctor.
5. Regular dental checkups and hygiene appointments are recommended during aligner treatment.

3M CLARITY RETAINERS:

1. After your aligner treatment has been completed, your doctor will likely prescribe a retainer. The retainer will help keep your teeth in their new positions.
2. Retainers are typically worn for up to 22 hours a day for the first six (6) months after treatment and then nightly thereafter. Follow the protocol prescribed by your doctor.
3. Replace your retainer as suggested by your doctor. Consult your doctor if your retainer is broken or no longer fits comfortably.
4. Follow the protocol suggested by your doctor to keep your retainers clean. At a minimum, clean with a soft bristle toothbrush and running water.