

This form is to be signed by your SPARK Clear Aligner patients prior to treatment and kept in your records.

WHY SPARK CLEAR ALIGNERS?

100% of Spark patients would recommend Spark to a friend.*

Compared to the leading aligner brand*, Spark is:

- More Clear
- More Comfortable
- Stains Less

CUSTOM-MADE DEVICE

The Ormco™ Spark™ Clear Aligner System consists of a series of doctor-prescribed, custom manufactured, 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.

CONTRAINDICATIONS

If you have active periodontal disease, treatment with clear aligners should be avoided or delayed until you are free from symptoms of 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. Ormco must also be notified.
- Orthodontic appliances, or parts thereof, may be accidentally swallowed or aspirated, which may be harmful.

PRECAUTIONS

- 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.

*Data on file

- 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.

INFORMED CONSENT

I understand the benefits and risks associated with Spark Clear Aligner orthodontic treatment and have been offered the option of no treatment. I have had the opportunity to discuss and ask questions regarding the Spark Clear Aligner treatment. I understand I should only use Spark Clear Aligners following discussion and consultation with a trained doctor. I acknowledge that my doctor and Ormco cannot and have not made any guarantees or assurances concerning the specific outcome of my treatment. I agree to read and follow all the instructions for use that come with my Spark Clear Aligner treatment.

I hereby consent to the Spark Clear Aligner orthodontic treatment that has been prescribed by my doctor. I hereby represent that I am either 18 years of age or older and competent to sign this consent or, if a minor, that my guardian is 18 years of age or older and competent to sign this consent on my behalf. I agree that this consent shall be binding on me, my legal representatives, heirs, assigns and personal representatives. I have read, understand and agree to the terms set forth in this consent.

Signature or Signature of Parent / Guardian

Print Name

Address

Date



Image Consent and Release

As a user of the Spark Clear Aligner System, I grant Ormco Corporation and its authorized agents, affiliates and employees (“Ormco”), permission to record on photography film, digital form and/or video, my image, voice and/or likeness, in any record on photography film, digital form or video, including my case images, intraoral, extraoral, and software treatment plans, in any and all of its publications, including advertisements, promotional flyers, brochures, social media, videos, websites, derivative works or otherwise, to promote Ormco products or for any other lawful purpose. I further agree that such use shall be without any payment of fees, royalties, special credit or other compensation, and shall occur without notice, and that Ormco shall own the copyright over such material. I agree to release Ormco and its successors, assigns, representatives and licensees from any liability whatsoever of any nature in connection with their use of such material, including claims based on libel, breach of privacy or copyright.

I am at least 18 years old and have the right to contract in my own name. This agreement shall be binding upon me and my heirs, legal representatives and assigns.

I have read the above consent and release and fully understand the contents thereof.

Signature: _____

Printed Name: _____

Institutional Affiliation: _____

Date: _____