

Informed Consent and Agreement for the ClearPath Patient

Your doctor has recommended the ClearPath Aligners for your orthodontic treatment. Although orthodontic treatment can lead to healthy teeth and provide important benefits, such as an attractive smile, you should also be aware that orthodontic treatment (including orthodontic treatment with ClearPath aligners) has limitations and potential risks that you should consider before undergoing treatment.

Device Description

ClearPath aligners, supplied by ClearPath Orthocare Australia Pty. Ltd, consist of a series of clear plastic, removable appliances that move your teeth in small increments. ClearPath products combine your doctor's diagnosis and prescription with sophisticated computer graphics technology to develop a treatment plan which specifies the desired movements of your teeth during the course of your treatment. Upon approval of a treatment plan developed by your doctor, a series of customized ClearPath aligners is produced specifically for your treatment.

Procedure

You will undergo a routine orthodontic pre-treatment examination including x-rays and photographs. Your doctor will take impressions of your teeth and send them along with a prescription to ClearPath. Our technicians will follow your doctor's prescription to create a virtual setup software model of your prescribed treatment. Upon approval of the virtual treatment plan by your doctor, ClearPath Orthocare Australia will dispatch a series of customized aligners to your doctor.

The total number of aligners will vary depending on the complexity of your doctor's prescription. The aligners will be individually numbered and will be dispensed to you by your doctor with specific instructions for use. Unless otherwise instructed by your doctor, you should wear your aligners for approximately 20 to 22 hours per day, removing them only to eat, brush and floss. As directed by your doctor, you will switch to the next aligner in the series every two weeks. Unless instructed otherwise, you should follow up with your doctor at a minimum of every 6 to 8 weeks. Some patients may require bonded aesthetic attachments on their teeth during treatment to facilitate specific dental movements. Patients may require additional refinement after the initial series of aligners.

Benefits

1. ClearPath aligners offer an aesthetic alternative to conventional braces.
2. Aligners are nearly invisible so many people won't realize you are in treatment.
3. Tooth movement can be visualized through the Virtual Setup software.
4. Aligners allow for normal brushing and flossing tasks that are generally impaired by conventional braces.
5. Aligners do not have the metal wires or brackets associated with conventional braces.
6. The wearing of aligners may improve oral hygiene habits during treatments.
7. ClearPath patients may notice improved periodontal (gum) health during treatment.

Risks and Inconveniences

Like other orthodontic treatments, the use of ClearPath product(s) may involve some of the risks outlined below:

- 1) Failure to wear the appliances for the required number of hours per day, not using the products as directed by your doctor, missing appointments, and atypically shaped teeth can lengthen the treatment time and affect the ability to achieve the desired results
- 2) Dental tenderness may be experienced after switching to the next aligner in the series
- 3) Gums, cheeks and lips may be scratched or irritated
- 4) Teeth may shift position after treatment.
- 5) Faithful wearing of retainers at the end of treatment should reduce this tendency;
- 6) Tooth decay, periodontal disease, inflammation of the gums or permanent markings (e.g. decalcification) may occur if patients consume foods or beverages containing sugar, do not brush and floss their teeth properly before wearing the ClearPath products, or do not use proper oral hygiene and preventative maintenance
- 7) The aligners may temporarily affect speech and may result in a lisp, although any speech impediment caused by the ClearPath products should disappear within one or two weeks
- 8) Aligners may cause a temporary increase in salivation or mouth dryness and certain medications can heighten this effect
- 9) Attachments may be bonded to one or more teeth during the course of treatment.
- 10) Teeth may require interproximal re-contouring or slenderizing in order to create space to allow tooth movement to occur
- 11) General medical conditions and use of medications can affect orthodontic treatment
- 12) Health of the bone and gums which support the teeth may be impaired or aggravated
- 13) Oral surgery may be necessary to correct crowding or severe jaw imbalances that are present prior to wearing the ClearPath product. If oral surgery is required, risks associated with anesthesia and proper healing must be taken into account prior to treatment
- 14) 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 the tooth may be lost
- 15) Existing dental restorations (e.g. crowns) may become dislodged and require re-cementation or in some rare instances, replacement
- 16) Short clinical crowns can pose appliance retention issues and inhibit tooth movement
- 17) The length of the roots of the teeth may be shortened during orthodontic treatment and may become a threat to the useful life of teeth
- 18) Product breakage has a higher probability in cases with multiple missing teeth
- 19) Orthodontic appliances or parts thereof may be accidentally swallowed or aspirated
- 20) In rare instances, problems may also occur in the jaw joint, causing joint pain, headaches or ear problems
- 21) Allergic reactions may occur
- 22) Teeth that are not at least partially covered by the aligner may undergo supra-eruption

INFORMED CONSENT

I have been given adequate time to read and have read the preceding information describing orthodontic treatment with ClearPath aligners. I understand the benefits, risks and inconveniences associated with treatment. I have been sufficiently informed and have had the opportunity to ask questions and discuss concerns about orthodontic treatment with ClearPath products with my doctor from whom I intend to receive treatment. I understand that I should only use the ClearPath products after consultation and prescription from a ClearPath certified doctor, and I hereby consent to orthodontic treatment with ClearPath products that have been prescribed by my doctor.

Due to the fact that orthodontics is not an exact science, I acknowledge that my doctor and ClearPath Orthocare Australia have not and cannot make any guarantees or assurances concerning the outcome of my treatment. I understand that ClearPath is not a provider of medical, dental or health care services and does not and cannot practice medicine, dentistry or give medical advice.

No assurances or refunds or guarantees of any kind have been made to me by my doctor or ClearPath, its representatives, successors, assigns, and agents concerning any specific outcome of my treatment.

I authorize my doctor to release my medical records, including, but not be limited to, radiographs (x-rays), reports, charts, medical history and photographs.

Please contact to your dentist whenever your last aligners will be finished for any arch (Upper or Lower) within one week. Please note no refinement can be claimed after two weeks of last aligners finished.

Patient's Signature:

Patient Name:

Address:

Date:

Witness:

Signature of Parent/Guardian

If signatory is under 18, the parent or Legal Guardian must also sign to signify agreement.