

Directions for Use

AirFlex™ with PrecisionFinish™ Aligners - English

Device Description: AirFlex™ Aligners are custom made thermoplastic orthodontic braces.

Indication for Use: AirFlex™ Aligners are indicated for the alignment of permanent teeth during orthodontic treatment of malocclusion.

Caution: Rx only. Federal law restricts this device to sale by or on the order of a physician.

Recommended Procedure:

1. Carefully remove your aligners and any additional accessories from the package and examine them for defects. Do not use defective aligners.
2. Rinse your aligners thoroughly with cool water.
3. Place the upper or lower stage 01 aligners on your upper or lower teeth respectively and push them over your teeth with your fingers.
4. Wear these stage 01 aligners for at least 12 hours each day for one week or as prescribed by your doctor.
 - Wear **AirFlex™ Aligners** for a minimum of 12 hours continuously each day, or as prescribed by your doctor.
 - During the last stages of treatment, you will wear special aligners called "**PrecisionFinish™ Aligners.**" Wear your Precision Finish Aligners for 22 hours each day, or as prescribed by your doctor.
5. AirFlex Aligners with PrecisionFinish will fit comfortably and apply gentle pressure to your teeth. This gentle continuous pressure will guide your teeth to the planned destination for each stage of treatment.
6. Wear each stage of aligners for one week before advancing to the next stage of aligners, or as prescribed by your doctor.
7. Your aligners and aligner packages are sequentially numbered for easy identification. Once you have worn the aligner stage for one week, move to your next aligner stage, or as prescribed by your doctor.
8. Once you have moved onto the next aligner stage in your treatment, keep your previously worn aligner in the package it came in just in case you lose or break your current set. Before storing the aligner, rinse thoroughly with cool water.
9. After treatment is complete, dispose of aligners in accordance with local government policy.

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Period of Use/Storage:

1. The aligner should be worn for the time prescribed as described below:
 - a. Wear **AirFlex™ Aligners** for a minimum of 12 hours continuously each day, or as prescribed by your doctor.
 - b. During the last stages of treatment, you will wear special aligners called "**PrecisionFinish™ Aligners.**" Wear your Precision Finish Aligners for 22 hours each day, or as prescribed by your doctor.
2. Do not wear aligners after the expiration date printed on the bag that they came in.
3. Store your aligners in the provided OrthoFX aligner case when not wearing them.

Included Items: AirFlex Aligners with PrecisionFinish aligner case

Contraindications:

1. Patients whose permanent teeth or second molars have not yet erupted
2. Patients with poor oral hygiene
3. Patients with active periodontal disease
4. Patients with dental prosthetics or implants

Warnings:

1. If you have an allergic reaction, please discontinue use, and contact your doctor.

Precautions:

1. Aligners are non-sterile, rinse before use.
2. Accidental swallowing of aligners may be harmful.
3. Keep your aligners away from children and pets.
4. Keep your aligners away from hot, acidic, sweet, or colored liquids.
5. Keep your aligners out of excessive heat.

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6. Do not wear your aligners while eating, drinking, chewing gum or using tobacco products. Brush and floss after eating before reinserting your aligners.
7. Clean your aligners daily after brushing your teeth, by gently brushing your aligners using a toothbrush and soap and rinsing with cool water.
8. Do not use hydrogen peroxide, baking soda or ultrasonic bath to clean your aligners.
9. Do not use chewies with AirFlex Aligners as they may break.
10. You may notice a slight lisp when you initially start wearing your aligners. This typically goes away after a few days. You may experience dry mouth during aligner treatment; if so, please drink water.

Complications: Orthodontic treatments including aligners may cause serious side effects; however, these side effects occur in only a small number of people. During treatment your doctor can help to monitor potential complications including:

- Discomfort
- Tissue damage
- Relapse (tooth movement post treatment)
- Extractions (tooth removal)
- Decalcification and Dental Caries
- Root Resorption
- Nerve Damage
- Periodontal Disease
- Temporomandibular (Jaw) Joint Dysfunction
- Occlusal Adjustment
- Allergies
- General Health Problems
- Complications due to Third Molars
- Complications due to the Use of Tobacco Products

If any of the complications mentioned above do occur, a referral may be necessary to your family dentist or another dental or medical specialist for further treatment.

Contacts:

- **US:** OrthoFX - 48890 Milmont Drive, Fremont, CA 94538

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- **Australia:** OrthoFX Pty Ltd. Level 6 200 Adelaide St. Brisbane, QLD, 4000, Australia
- **UK:** Obelis UK LTD Sandford Gate, East Point Business Park OX4 6LB, Oxford England, UK
- **Europe:**  Obelis-Boulevard General Wahis, 53 1030, Brussels Belgium 060
- **India:** OrthoFX Private Limited, Floor 17, Trans Asia Cyber Park, Infopark Kochi Phase 2, Ambalamedu, Puthencruz, Ernakulam, Kerala, 682303.

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History of Changes and Document Approvals

Revision	Autor	Changes
1	Mariel Chavez	Initial draft of the clinicians DFU for AirFlex with PrecisionFinish Aligners.

Impact of Change	Decision	Rationale
QMS	No	This is not a significant change, there is no impact on the QMS.
Product(s)	Yes	This change affects the labeling of the product.
Risk Management	No	This is not a significant change, there is no impact on risk management.
Other Document(s)	No	No documentation should be affected by the changes developed
Training Required?	No	Training is not required to the IFU, it is for patient use and made accessible to all aligner users.

Revision	Name	Breanne Butler
	Department(s)	Quality and Regulatory
	Signature	In Q Suite
	Date	In Q Suite

Approval	Name	Dr. Carla Mora
	Department(s)	Clinical/Medical Oversight
	Signature	In Q Suite
	Date	In Q Suite

Approval	Name	Maria Volpato
	Department(s)	Marketing
	Signature	In Q Suite

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	Date	In Q Suite
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