

Directions for Use

AirFlex™ - 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.

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 and OrthoFX Customer Service.
2. Wear AirFlex aligners for a minimum of 12 hours continuously each day, or as prescribed by 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.
6. Do not wear OrthoFX aligners while eating, drinking, chewing gum or using tobacco products.
Brush and floss after eating before reinserting your aligners.

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7. Clean your aligners daily after brushing your teeth, by gently brushing your aligners using a toothbrush and soap and rinsing with cool water.

Complications: OrthoFX Clear Aligners can cause serious side effects; however, these side effects occur in only a small number of people. Your doctor can monitor you for them. Potential complications may include:

- 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.

Recommended Procedure:

1. Carefully remove the OrthoFX aligners and any additional accessories from the OrthoFX package and examine them for defects. Do not use defective appliances.
2. Rinse the OrthoFX aligners thoroughly with cool water.
3. Place the upper or lower OrthoFX stage 01 aligners on your upper or lower teeth respectively and push them over your teeth with your fingers.

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4. Wear these stage 01 aligners for at least 12 hours each day for one week.
5. OrthoFX aligners will fit tightly and will apply pressure to your teeth. This pressure will lessen over time as you wear your aligners.

Note: 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.

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 aligner packages are sequentially numbered for easy identification. Once you have worn the aligner stage for one week, move to your next aligner stage.
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.

Period of Use/Storage:

1. The aligner should be worn at least 12 hours per day.
2. Do not wear aligner after expiration date printed on the bag it came in.
3. Store your aligners in the provided OrthoFX aligner case when not wearing them.

Included Items: AirFlex Aligners, aligner case

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Contacts:

- **US:** OrthoFX - 48890 Milmont Drive, Fremont, CA 94538
- **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:** EU REP 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	Jennifer Day	Initial draft of the clinicians DFU for Nightwear Aligners.
2	Jennifer Day	Updating indication for use statement to specify permanent dentition and complications.
3	Jennifer Day	Updating warnings, period of use descriptions and device description.
4	Mariel Chavez	Updated product name as response to ECO 041

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	The bag labels will be updated to reflect this change as well.
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

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Approval	Name	Maria Volpato
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