

■ Precautions for users

1. This orthodontic appliance [Direct Aligner] is designed for individual orthodontic treatment according to the diagnosis and treatment plan of the expert (hereinafter referred to as the doctor in charge) and using this appliance during each step of the treatment plan must be followed by the prescription and guidelines of the doctor in charge.
2. According to the judgment of the doctor in charge, application of this orthodontic appliance, scope of alignment, treatment time, replacing or re-fabricating the aligners, etc. are determined, and as the treatment is progressing, the doctor in charge may modify the treatment.
3. Depending on malocclusion and/or patient compliance, fixed appliances may be added at the discretion of the doctor in charge.
4. Since it is an orthodontic appliance customized for orthodontic treatment of an individual patient, using this appliance other than the intended purpose is prohibited and must be used in accordance with the user manual of the appliance.
5. To maximize the efficacy of the orthodontic treatment with this appliance, the recommended amount of time for the appliance to be worn is at least 20 hours a day.
6. While the appliance is worn intraoral, the patient must refrain from chewing gum, eating food, and smoking. It is also advisable not to drink hot beverages nor colored drinks. However, water is acceptable.
7. When removing the appliance from the mouth, the patient must not use sharp objects and follow the instructions provided.
8. When storing the appliance, the patient must be sure to avoid direct sunlight and, it's best to keep it in its case.
9. The patient may feel pain when it's the first time to put the appliance on. This is only natural due to the force applied to move the teeth. Pain usually decreases as the teeth move. However, if the pain is severe or persists for more than 3 to 4 days, the patient must contact the doctor in charge. Also, because the appliance holds the teeth tightly, it can feel temporarily stuffy and uncomfortable. If it feels too uncomfortable, warming the appliance with warm water in the mouth may relieve the discomfort.
10. Doctor's instructions must precede intake of any medication to control pain, and usually acetaminophen (Tylenol) or non-steroidal anti-inflammatory drugs (NSAIDs) are prescribed.
11. If the patient feels discomfort wearing the appliance, or if the appliance becomes fractured or twisted, or the attachment(auxiliary appliance) gets damaged or lost, the patient must stop wearing it, and contact and consult the doctor in charge.

■ How to deal with problems during use

Q. What if the patient experiences pain while wearing the appliance?

A. The patient may feel pain if it's the first time to put the appliance on. This is only natural due to the force applied to move the teeth. In other words, it is a phenomenon accompanying the teeth movement process during orthodontic treatment. Pain usually decreases as the teeth move. However, if the pain is severe or persists for more than 3 to 4 days, the patient must contact the dentist in charge.

Also, the appliance can feel temporarily stuffy and uncomfortable because it holds the teeth tightly. The discomfort may be alleviated by warming the appliance in warm water in the mouth.

Q. What if the appliance is damaged (discolored, broken, etc.) or lost?

A. If the appliance is damaged or lost, the patient must request a new one from the doctor in charge. In this case, an additional charge set by the clinic may be incurred.

Q. What if the patient's gums are swollen or inflamed?

A. Direct Aligner has not only been certified as a **Level 2 medical device** by **the Ministry of Food and Drug Safety of Korea** but also has obtained **FDA 510(k) clearance from USA** and **CE certification from Europe** and is innocuous to the human body.

In medical terms, **inflammation** is 'one of the defense reactions of biological tissues to certain stimuli', which may include redness, swelling, burning sensation and pain, and currently defined as 'a type of defensive response in local tissue'.**[reference: "Doopedia", Doosan Encyclopedia, Encyclopedia of Physical Education]**

When wearing appliance, inflammatory reactions such as swelling around the gums may occur temporarily due to foreign body reaction. However, reactions may vary depending on individual characteristics or health conditions. In other words, there may be cases where an inflammatory reaction or an allergic reaction occurs, such as severe swelling of the gums. In such cases, the patient must immediately contact the doctor in charge to have guide about the cause and take an appropriate action.

■ Clinical guidelines for oral adverse reactions of the patient



Direct Aligner is an orthodontic appliance harmless to the human body that has passed all biosafety tests and obtained certification, and its biosafety is supported by several research papers.

However, if a patient experiences an oral adverse reaction, it can be resulted from several causes, for instance, any scratches the appliance has on its sharp edges that injures soft tissues touched by the edges, unhygienic handling of the appliance, uncured resin that provokes sensitization and stomatitis, etc.

Patients must avoid intake of any food other than water while wearing the Direct Aligner, and hygienic management of the appliance is essential for the patient's oral health. Therefore, explaining to the patient how to hygienically handle the appliance is very important.

In case the occlusal pressure is high due to a certain occlusion problem such as overbite, crossbite, etc., the appliance may be fractured in the posterior area or in some other parts. If this ever happens, adjusting the thickness of the appliance is recommended.

Since Direct Aligner is printed out from 3D printer with a great precision, any minor errors in the manufacturing process and any manipulations different from the instructions may result in defective appliances. The manufacturing process include all the following steps. Using and maintaining 3D printers, resins, 3D printer parts such as VAT, plate, etc., and designing the appliance to be directly printed out from a 3D printer(setting the right aligner margin and adjusting the thickness), putting the right amount of supports on right spots, centrifuging and removing the resins inside the aligners, post curing, cleaning the equipment and machines, etc. Each and every step of the manufacturing process must be executed correctly following the instructions, because each and every step may affect the result.

Graphy is doing our best to make sure the users manufacture their aligners correctly.

■ Notes on allergy

Allergy refers to the strange reactions of a body to a foreign substance and is also known as a hypersensitivity reaction. Although the term originally meant any altered reactivity, it is now commonly described as a hypersensitivity state. **[References: Lee Woo-joo Medical Dictionary]**

Allergy refers to various symptoms caused by an overreaction of the immune system to a substance that is not a particular problem for most people. These include hay fever, food allergies, atopic dermatitis, asthma, and other anaphylaxis, and show symptoms such as congested eyes, itchy skin rashes, runny nose, difficulty breathing and edema, etc.

The most common allergens that cause allergies are pollen and food. Also, insect stings and some medications cause severe allergic symptoms. **Allergy symptoms are caused by genetic and environmental factors.** Allergic reactions are triggered when **allergens that enter the body bind to the IgE antibodies** that are combined with IgE receptors in mast cells or basophils and activate the cells and **start secreting inflammatory substances such as histamine.** Treating the allergy symptoms includes **avoidance of contact with the allergen, the use of steroids or antihistamines,** or in severe cases, injections of adrenaline (epinephrine) may be required. Allergic disease is common in developed countries, with allergic rhinitis occurring in about 20% of people, as well as about 6% population of at least one food allergy, and it is also reported that about 20% of people have suffered from symptoms of atopic dermatitis at least once in a lifetime. Although there are differences between countries, about 1-18% of people suffer from asthma symptoms, and the number of allergic patients with various symptoms continues to increase. **[References: Encyclopedia of Molecular and Cellular Biology, Source of Information: Korean Society of Molecular and Cell Biology]**

■ About issues with allergies

A. Direct Aligner is the only 3D printed aligner that obtained FDA 510(k) Class II, CE Class II, and the KFD Safety Certification. FDA 510(k) Class II cleared Direct Aligner has been tested and proven to be innocuous in terms of reactivity in the intraoral environment, human body, intraoral temperature, reactivity with foreign substances. It is a safe material, and thus it is harmless to the human body, but if side effects ever occur due to the patient's biological characteristics, antihistamines can be prescribed.

"Graphy Inc. cannot be responsible for any side effects caused by not following the workflow and guidelines."

