



**Direct
Aligner®**

Medical Device User Guide



**Direct
Aligner®**



Direct Aligner 는 치아 교정을 위한 장치로 3D 프린터를 이용하여 제조되는 의료기기 제품입니다. (허가번호 : 제인 21-4949호)

www.itgraphy.com

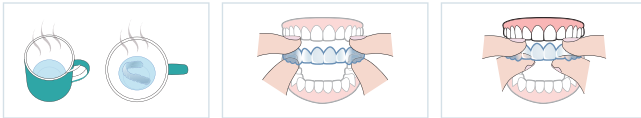
08501 서울특별시 금천구 가산디지털1로 225, 에이스가산포휴 6층 601호

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How to Wear Direct Aligner

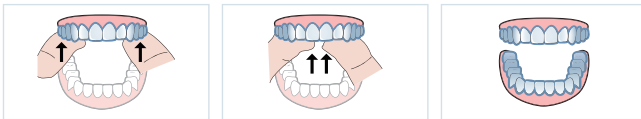
STEP 1 Submerge the device completely in hot water above 60°C for about 10 seconds.

STEP 2 Place the device on the teeth.



Tip. Be sure to wear the device before it cools down.

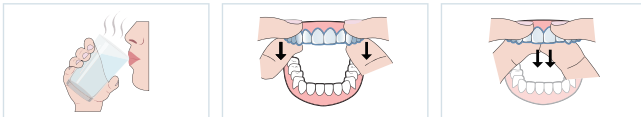
STEP 3 Fit in the device in the direction of the arrow.



How to Remove Direct Aligner

STEP 1 If the device is difficult to remove from the mouth, it can be easily removed by soaking in warm water.

STEP 2 Remove the device by pulling it from the molars to the anterior.



Tip. When removing, be careful not to apply excessive force.
Tip. Remove the device from the teeth, being careful not to deform the device.

STEP 3 If the device is removed from the oral cavity, wash it under running water and store it in a dedicated container out of light.



1 Preparation Before Use

- 1 Check for any damage or abnormalities, before use.
- 2 Check that the calibration steps of the device to be worn are correct.
- 3 Please read the user manual and precautions before use.
- 4 Use after checking the orthodontic stage and oral condition regularly according to the treatment plan established by the expert who treated the patient face-to-face.

2 How to Use & Operation Sequence

Wearing the Device

- 1 Before wearing the device, check for any damage or abnormalities.
- 2 Check that the calibration steps (steps) of the device to be worn are correct.
- 3 Place the clean device in warm or hot water (over 60°C) within 1 minute.
- 4 Place the device in your mouth with the inner surface facing your teeth.
- 5 After placing the device on the front teeth first, press the molar area so that the device is properly attached to the teeth and wear it.
Caution: After inserting the device into the tooth, do not bite it with a cotton roll, etc. The device will be seated accurately up to the cervical even if a cotton roll is not used.
- 6 Make sure the device is properly fitted to your teeth.
- 7 The device must be worn continuously for at least 20 hours a day, and if the recommended wearing time is insufficient, the desired corrective effect may not be achieved.

Removing the Device

- 1 Pull the inner of the molars of the device with your fingers to separate it from the teeth.
- 2 The inner of the molar in the opposite side is separated from the tooth by doing as in 1.
- 3 If the device floats slightly, gently grab the incisors with your hands and remove them.
- 4 When removing, be careful not to apply excessive force.
- 5 Remove the device from the teeth, being careful not to deform the device.



Do not eat while wearing the aligner



Do not give your aligner to others



Do not expose it to hot surfaces



Do not apply sharp objects to it



Wear at least 20 hours a day



Wash the aligner & Maintain good oral hygiene

3 Managing and Storing After Use

Washing

- 1 Unlike other aligners, the Direct Aligner can be sterilized. Place in hot water for 1 minute to sterilize the aligner.
- 2 Wash the aligner cleanly before and after use. Wearing an unclean aligner may cause inflammation and cavities.
- 3 Use toothpaste and toothbrush to cleanly brush the inside of the aligner under running water.
(*Caution: Do not use excessive force.)

Management and Storage

- 1 When storing the aligner after use, avoid direct sunlight and store in an aligner case or in an airtight container.
- 2 Do not expose the aligner to hot surfaces, such as heaters or stoves.

4 Precautions

Warning

- 1 The company is not responsible for any problems caused by use other than the intended use, so be sure to refer to the user manual before using it.
- 2 Do not chew gum, eat, or smoke while wearing the device in mouth. Hard and chewy foods, should be avoided. (However, water is fine)
- 3 Since it is designed for each patient, it is forbidden to be worn by others.
- 4 Do not use sharp objects to remove the device.
- 5 The device should not be exposed to heat for long periods of time, such as in products that are heated.

Precautions During Use

- 1 This device must be used under the prescription and supervision of the doctor.
- 2 According to the expert diagnosis and treatment plan, the application of this device, the scope of correction, the period, replacement, and remanufacturing are implemented.
- 3 The range, method, and period of calibration of this device are determined by the judgment of the expert and may be changed according to the progress of treatment.
- 4 Depending on various conditions such as patient cooperation and condition, additional use of fixed orthodontic devices may be required.
- 5 Using this device according to the malocclusion aspect must be discussed with a doctor.
- 6 If you experience discomfort during wearing, fracture or distortion, misalignment of teeth, or collapse of teeth, stop wearing it and be sure to consult with your doctor.
- 7 Symptoms such as inflammation and swelling around the gums may occur temporarily due to a foreign body sensation. However, there may be various causes depending on the characteristics of the patient, and it is imperative to consult with a specialist.
- 8 To control pain, steroids and other medications can affect tooth movement, so we recommend taking acetaminophen (Tylenol) and non-steroidal anti-inflammatory drugs (NSAIDs).
- 9 If the attachment (auxiliary device) is damaged or falls off during orthodontic treatment, please visit the dentist immediately.
- 10 Temporary pain is the process of tooth movement during treatment, so no need to worry. Also, it can be temporarily stuffy and uncomfortable because it holds the teeth tightly.
- 11 Discomfort may be relieved by soaking in warm water while wearing the device.

? FAQ

Q1



What is a Direct Aligner?

A1

Direct aligner is a patient-tailored orthodontic device manufactured by direct printing with a 3D printer. It was developed by GRAPHY for the first time in the world and obtained domestic and international patents and medical device certifications.

Q2



How many hours a day should I wear it?

A2

The treatment effect is expected the more you wear it as much as possible, excluding mealtime. It is recommended to wear it for at least 20 hours a day.

Q3



I have pain when wearing the device, is that ok?

A3

You may experience pain when you put on the device for the first time. This is natural because force is applied to the teeth to move. Pain is reduced as the tooth moves. If the pain is severe or persists after 3 to 4 days, contact your dentist.

Q4



Please tell us in detail how to clean, disinfect, and store.

A4

Direct Aligner can be used by using toothpaste or tooth cleaner under running water, and it can also be sterilized with hot water at high temperature. When the device is not being worn, put it in the separately supplied storage case and store it in a cool place.

Q5



For children or the elderly, is there an age range that can be treated?

A5

There is no age limit for treatment as long as the teeth are healthy. If you are a child or an elderly, please follow the guidance of the hospital to decide whether to receive treatment.

Q6



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

A6

If the device is damaged or lost, you must contact the dentist to provide a new device. In this case, a separate fee set by the hospital may be incurred.

Q7



Can I eat while wearing the device?

A7

Eat after removing the device. After eating, clean the dental appliance and put it on before putting it on.

Q8



How often should I visit the hospital?

A8

This may vary depending on your treatment plan.

Q9



What if my gums are swollen or inflamed?

A9

Direct Aligner is CE certified and harmless to human body. However, depending on the individual's health condition and reaction, severe swelling of the gums, inflammation, and allergic reactions may occur. In this case, contact your dentist immediately for the necessary treatment.