

Tune Clear Aligner System

| Product | Part # |
|---------------------|---------|
| Tune Clear Aligners | AP-G100 |

Custom-made device. For professional use only. (Rx only)

Device Description

Tune Clear Aligners are sequential orthodontic aligners manufactured from clear thin thermoformed plastic. Tune Clear Aligners progressively reposition the teeth in order to align teeth and correct malocclusion in patients with permanent dentition.

Indications for Use

The Tune Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The aligner system repositions teeth by way of continuous gentle force.

Clinical Benefits

Clinical benefits of orthodontic treatment include improvement of tooth health, improvement of dental function, and correction of malocclusion.

Warnings

1. Patients with hereditary angioedema (HAE), a genetic disorder, may experience rapid local swelling of subcutaneous tissues including the larynx. HAE may be triggered by mild stimuli including dental procedures.
2. Device may on rare occasion cause allergic reaction in some users. In such cases, discontinue use and consult a healthcare professional immediately.

Cautions

1. Treatment time may exceed estimates. Failure to wear the appliances for the required number of hours per day, not using the product as directed by your doctor, missing appointments, and erupting or 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. Consistent wearing of retainers at the end of treatment should reduce the tendency.
5. 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 Tune Clear Aligner products, or do not use proper oral hygiene and preventative maintenance.
6. The aligners may temporarily affect speech and may result in a lisp, although any speech impediment caused by the Tune Clear Aligner products should disappear within one or two weeks.
7. Aligners may cause a temporary increase in salivation or mouth dryness and certain medications can heighten this effect.
8. Attachments may be bonded to one or more teeth during the course of treatment to facilitate tooth movement and/or appliance retention. These will be removed after treatment is completed.
9. Attachments may fall off and require replacement.
10. Teeth may require interproximal recontouring or slenderizing in order to create space needed for dental alignment to occur.
11. The bite may change throughout the course of treatment and may result in temporary patient discomfort.

12. In rare instances, slight superficial wear of the aligner may occur where patients may be grinding their teeth or where the teeth may be rubbing and is generally not a problem as overall aligner integrity and strength remain intact.
13. At the end of orthodontic treatment, the bite may require adjustment (“occlusal adjustment”).
14. Atypically-shaped, erupting, and/or missing teeth may affect aligner adaptation and may affect the ability to achieve the desired results.
15. Treatment of severe open bite, severe overjet, mixed dentition, and/or skeletally narrow jaw may require supplemental treatment in addition to aligner treatment.
16. Supplemental orthodontic treatment, including the use of bonded buttons, orthodontic elastics, auxiliary appliances/ dental devices (e.g. temporary anchorage devices, sectional fixed appliances), and/or restorative dental procedures may be needed for more complicated treatment plans where aligners alone may not be adequate to achieve the desired outcome.
17. Teeth which have been overlapped for long periods of time may be missing the gingival tissue below the interproximal contact once the teeth are aligned, leading to the appearance of a “black triangle” space.
18. Aligners are not effective in the movement of dental implants.
19. General medical conditions and use of medications can affect orthodontic treatment.
20. Health of the bone and gums which support the teeth may be impaired or aggravated. Oral surgery may be necessary to correct crowding or severe jaw imbalances that are present prior to wearing the Tune Clear Aligner product. If oral surgery is required, risks associated with anesthesia and proper healing must be taken into account prior to treatment. 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.
21. Existing dental restorations (e.g. crowns) may become dislodged and require recementation or in some instances, replacement.
22. Short clinical crowns can pose appliance retention issues and inhibit tooth movement.
23. 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.
24. Product breakage is more likely in patients with severe crowding and/or multiple missing teeth.
25. Orthodontic appliances or parts thereof may be accidentally swallowed or aspirated.
26. In rare instances, problems may also occur in the jaw joint, causing joint pain, headaches or ear problems.
27. Teeth that are not at least partially covered by the aligner may undergo super-eruption.
28. Aligners worn out of sequence can delay treatment and result in complications including (but not limited to) patient discomfort. Always wear aligners in the order specified by the doctor.
29. A successful treatment outcome cannot be guaranteed. After the final planned aligners have shipped, some case may require refinement with additional clear aligners, traditional orthodontic techniques, and/or cosmetic procedures. There may be additional costs to the patient if such procedures are required. Follow aligner direction for use to achieve best results.

Directions for Use









- Aligners should be rinsed under cold water upon initial removal from packaging.
- Aligners should be inserted over the front teeth first using even, gentle pressure, working backwards until the aligner clicks into place over the molars.
- Aligners will fit tightly and apply pressure to the teeth. This pressure will decrease over time with normal wear.
- Excessive twisting or bending forces should not be used to remove aligners.
- Sharp objects should not be used to remove aligners.
- Aligners should be worn for at least 22 hours per day. All doctor’s instructions should be followed.
- Retainers must be worn following treatment to prevent teeth from shifting.

- When it is time to move on to the next aligner always keep the previous aligner. If current aligner is ever lost or broken, it is recommended to go back to the previous aligner to maintain the results, while a replacement is being fabricated.

Daily Care, Maintenance, and Proper Oral Hygiene

- Aligners must be removed prior to eating.
- Aligners should be cleaned before each insertion with a dental appliance cleaner. Aligners should not be cleaned with abrasive toothpaste, or mouthwash as this can scratch or dull the plastic, adversely affecting the product's clarity.
- A proper oral hygiene routine should be maintained during treatment. Brush and floss after each meal and snack prior to re-inserting aligners.
- Regular dental checkups should be maintained throughout your aligner treatment.
- Aligners should be changed every 2 weeks (10-14 days) or as directed by a doctor.
- Please dispose of worn aligners in the household trash.

Symbols

| Symbol | Title of Symbol | Description of Symbol |
|---|-------------------------------|---|
|  | Manufacturer | Indicates medical device manufacturer |
|  | Medical device | Indicates that the item is a medical device |
|  | Batch Code | Indicates the manufacturer's batch code so that the batch or lot can be identified |
|  | Date of Manufacture | Indicates the date when the medical device was manufactured |
|  | Country of Manufacturer | Identifies the country of the manufacturer |
|  | Consult Instruction For Use | Indicates the need for the user to consult the instructions for use |
|  | Prescription Use | Federal law restricts this device to sale by or on the order of a licensed dental professional. |
|  | Single Patient – Multiple Use | Indicates that a medical device may be used multiple times on a single patient |

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State.