



uLab Systems Inc.

Dental Aligner

Clinician Instructions for Use

Caution: USA Federal law restricts this device to sale by or on the order of a licensed dental practitioner.



MANUFACTURER:

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1 Product Description

The uLab Systems Dental Aligner is an orthodontic treatment system, that consists of doctor prescribed, clear, thin, plastic removable aligners. The aligners are designed by dental professionals using uLab Systems proprietary technology and manufactured by uLab Systems Inc.. The aligners are made of aesthetic and medical grade materials. Each aligner stage, consisting of one upper aligner and/or one lower aligner, is preformed to fit the patient's teeth at a different point of the treatment. Each subsequent aligner stage moves the teeth a small amount towards the final result. Aligners must be worn in sequence as prescribed by the dental practitioner, to gradually move the teeth to the ideal position.

2 Indications for Use

The uLab Systems Dental Aligner is indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.

3 Contraindications and Side Effects

uLab Systems Dental Aligner is contraindicated for use in patients with active dental or periodontal disease.

4 What's in the Box

Each box of the uLab Systems Dental Aligner contains up to 24 pairs of individual dental aligners, or 48 individual devices, in resealable bags and an aligner storage case.

5 Warnings and Cautions

Definitions:

A **WARNING** is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

A **PRECAUTION** is a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property. The caution statement includes the precaution that should be taken to avoid the hazard.

Carefully read and review this entire manual to fully understand the Dental Aligner, its operation, and the potential risks. Illustrations shown in this manual are intended to familiarize the user with the device.

WARNINGS:

- In the case that patients are allergic to the plastic aligner material, discontinue use and consult a health care professional immediately. uLab Systems must also be notified as soon as possible.
- Patients with hereditary angioedema (HAE), a genetic disorder, may experience rapid local swelling of subcutaneous tissues including the larynx. Discontinue use and consult a health care professional immediately. uLab Systems must also be notified as soon as possible.

- Orthodontic aligners, or parts thereof, may be accidentally swallowed or aspirated and may cause harm to the patient.

PRECAUTIONS:

- Do not expose aligners to hot water and harsh chemicals.
- Leave aligners out of reach of young children and pets.
- Tooth shape, erupting, and/or missing teeth may affect aligner fitting and the tracking of the treatment.
- Treatment with aligners may cause existing dental restorations (e.g., crowns, bridges) to become loose or dislodged and require re-cementation or replacement.
- Aligners cannot move dental implants.
- Treatment with aligners may cause dental tenderness.
- The aligner may temporarily cause a speech impediment, including a lisp.
- The treatment can become off track if aligners are not worn for the prescribed number of hours per day and/or as directed by the doctor.
- The product may irritate or scratch gums, cheeks, or lips.
- Attachments may fall off or wear out and require replacement.
- After the treatment is completed, all attachments should be removed.
- Interproximal reduction may be prescribed by doctor to create space for tooth movement as part of treatment.
- Tooth decay, periodontal disease, and permanent markings from stains and decalcification may occur if patients do not brush and floss their teeth properly during treatment or if they consume foods or beverages containing sugar while wearing aligners.
- The doctor may need to adjust the bite at the end of treatment.
- Consistent wearing of retainers at the end of treatment is recommended to reduce the tendency of teeth to shift position post-treatment.
- Orthodontic treatment may cause the bite to change and result in temporary discomfort.
- Orthodontic treatment with aligners may cause a temporary increase in salivation or dryness of the mouth.
- Orthodontic treatment may aggravate a previously traumatized or significantly restored tooth, which may reduce the longevity of the tooth and require additional dental treatment.
- Orthodontic treatment may impair or aggravate the health of the bone and gums which support the teeth.
- Orthodontic treatment may shorten the length of the roots of the teeth and become a threat to the longevity of the teeth.
- Temporomandibular (Jaw) joint symptoms, including joint clicking, pain, headaches, or ear problems may arise during orthodontic treatment.
- Orthodontic treatment may cause sharp pain or significant discomfort. If this occurs, have the patient discontinue use of the aligners -.
- Treatment of severe open bite, severe overjet, and/or a skeletally narrow jaw may require supplemental treatment in addition to aligner treatment.

- Other fixed and/or removable orthodontic appliances, may be needed for more complicated treatment plans where aligners alone may not be adequate to achieve the desired outcome.
- Oral surgery may be necessary to correct severe crowding or jaw imbalances.

6 Directions for Clinician

- 6.1 Perform a dental examination and scan the patient for orthodontic treatment planning. Review and approve treatment plan. Perform any necessary interproximal reduction (IPR) procedures. Risks associated with interproximal reduction, which may be prescribed to create space for tooth movement as part of treatment must be considered.
- 6.2 Rinse new aligners with cold water prior to using them.
- 6.3 Seat first aligner stage of the series on the patient's teeth and visually inspect for soft tissue impingement.
- 6.4 Trim the aligners using standard trimming tool, if needed.
- 6.5 If applicable, bond temporary attachments to one or more teeth during the course of treatment to facilitate aligner retention and/or tooth movement.
- 6.6 Perform any necessary interproximal reduction (IPR) procedures if not performed in previous visits.
- 6.7 Review the Instructions for Use with the patient.
- 6.8 Each set of aligners can be worn for approximately 2 weeks of 20-22 hours of wear per day or according to doctor's prescription.
- 6.9 If applicable, add a pontic paint or fill to the aligners.
- 6.10 Provide the patient with the aligner storage case.
- 6.11 At each appointment, check teeth for tight interproximal contacts and, if needed, perform IPR as prescribed. Check for appropriate aligner fit and potential soft tissue impingement at the current stage and the next stage to monitor the treatment progress. If needed, re-scan the patient to update the treatment progress with current teeth position and order the next set of aligners based on the updated treatment plan.
- 6.12 Give the patient the next series of aligner stages, enough of which should be sufficient to reach the next appointment.
- 6.13 At the end of treatment, wearing a retainer (s) is highly recommended.
- 6.14 For other procedural details, consult uLab Systems' training materials.

7 Cleaning Instructions

- 7.1 Aligners should be rinsed with cold water prior to each insertion. If needed, clean aligners using a soft bristle toothbrush with cold water and a small amount of toothpaste. Then rinse aligners with cold water thoroughly.
- 7.2 Avoid denture cleaners or mouthwash to help prevent damage to aligners.

8 Symbols

The following symbols may be found on the product packaging:



Manufacturer



Single patient multiple use



Consult Clinician Instructions
for Use



Batch code



Use-by date



Catalog number

9 Additional Products & Accessories

Please contact your uLab Systems Inc. representative to order additional products or accessories.



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