



## **uLab Systems Inc.**

### **Dental Aligner**

### **Patient Instructions for Use**

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



**MANUFACTURER:**  
uLab Systems Inc.  
7005 Appling Farms Pkwy, Suite 103  
Memphis, TN 38133 USA

**Australian Sponsor:**

Emergo Australia  
Level 20 Tower II  
Darling Park  
201 Sussex Street  
Sydney, NSW 2000  
Australia



## 1 Product Description

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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 your teeth at a different point of the treatment. Each subsequent aligner stage moves your teeth a small amount towards the final result. Aligners must be worn in sequence as prescribed by the dental practitioner to gradually move your teeth to the ideal position.

## 2 Indications for Use

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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

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

## 4 What's in the Box

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Each box of the uLab Systems Dental Aligner contains a series of pairs of individual dental aligners, in resealable bags, and an aligner storage case. Each resealable bag contains one stage of treatment, containing one upper aligner and/or one lower aligner, to be used in sequence according to the stage listed on the bag label.

## 5 Warnings and Cautions

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### 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 you 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:****ALIGNER CARE**

- Do not expose aligners to hot water and harsh chemicals.
- Leave aligners out of reach of young children and pets.
- Always store aligners in a cool, dry place.

**FIT & COMFORT**

- Treatment with aligners may cause dental tenderness.
- The aligners may irritate or scratch gums, cheeks, or lips.
- The aligner may temporarily cause speech impediment including lisp.
- 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.

**DURING COURSE OF TREATMENT**

- Attachments may fall off or wear out and require replacement by your doctor.
- 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 you do not brush and floss your teeth properly during treatment or if you consume foods or beverages containing sugar while wearing aligners.
- The treatment may not track to the prescription plan if aligners are not worn for the prescribed number of hours per day as directed by your doctor.
- Failure to wear the aligners for the prescribed number of hours per day and/or not using the aligners as directed by your doctor can lengthen the treatment time and affect the ability to achieve the desired results.

**TREATMENT COMPLETION**

- 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 position to shift position post treatment.

- After the treatment is completed, all attachments should be removed.

#### **GENERAL STATEMENTS ABOUT ORTHODONTIC TREATMENT**

- Aligners cannot move dental implants.
- 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.
- Orthodontic treatment may cause joint pain, headaches, or ear problems caused by problems in the temporo-mandibular joint (jaw joint).
- Orthodontic treatment may cause sharp pain or significant discomfort. If this occurs discontinue use of the aligners and contact your doctor as soon as possible.

## **6 Directions for Patient**

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### **6.1 General Aligner Guidelines**

6.1.1 Wear your aligners per your doctor's instructions, usually 20-22 hours per day.

6.1.2 Each aligner stage is usually worn for 1-2 weeks depending on your doctor's instructions.

6.1.3 Remove your aligners for all snacks and meals. Gum may stick to the aligners.

6.1.4 Wash your hands with soap and water before handling your aligners.

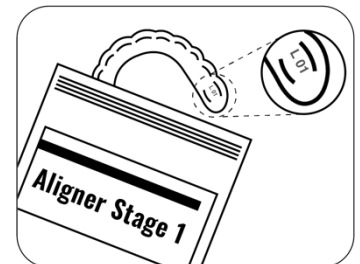
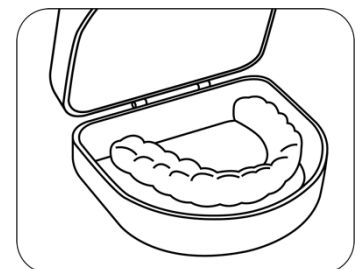
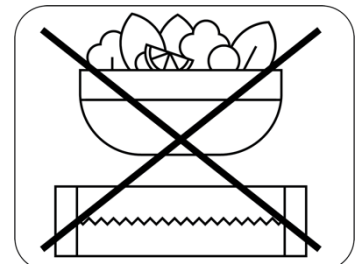
6.1.5 Rinse new aligners with cold water prior to using them.

6.1.6 Immediately rinse aligners with cold water after they are removed from teeth. See Section 9 Aligner Cleaning Instructions for more detail.

6.1.7 Store aligners in the protective case provided by your doctor to prevent damage or loss.

6.1.8 Immediately inform your doctor if you lose or break an aligner.

6.1.9 Your doctor may advise you to temporarily wear your last stage or next stage of aligners while ordering a replacement for you.

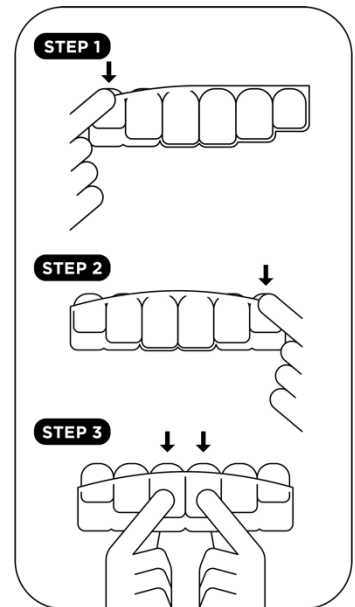
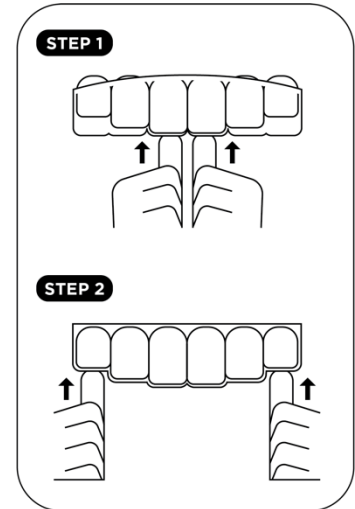


## 6.2 Aligner Insertion

- 6.2.1 Make sure you are wearing the proper aligner(s)— refer to the stage number and identification of upper or lower jaw on the packaging bag and on the aligner(s) itself for the proper aligner(s) to wear. Start with stage #1 and proceed sequentially according to your doctor's instructions.
- 6.2.2 When inserting each aligner, gently and slowly engage the aligner onto your front teeth. Using your fingertips, gently and slowly push on to your left and right back teeth. And when the aligner snaps onto the back teeth, work toward the front teeth in the same way until the aligner snaps into place.
- 6.2.3 Avoid biting your aligners into position to help prevent damage to them.
- 6.2.4 Inform your doctor of any significant discomfort, poor fit and/or tissue impingement.

## 6.3 Aligner Removal

- 6.3.1 Starting on the inside of your back teeth on one side of your mouth, use your fingertip to gently and slowly pull the aligner off your back teeth so it is disengaged from the back teeth.
- 6.3.2 Repeat this process on the back teeth from the other side of your mouth so the aligner is disengaged from the back teeth.
- 6.3.3 Keep gently and slowly pulling aligner off from the back teeth toward the front teeth with your fingertips, alternating from one side to the other of the mouth.
- 6.3.4 If your aligners are extremely difficult to remove, consult with your doctor.
- 6.3.5 When removing the aligner, do not use excessive force to bend or twist it or use any sharp tool.
- 6.3.6 Avoid unnecessary removal to help prevent damage to the aligners.
- 6.3.7 If multiple attachments are being used, remove your aligners gently and slowly according to the instructions listed above.
- 6.3.8 Please consult with your doctor if you have additional questions after reading these instructions.



## **7 Initial Treatment Expectations**

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- 7.1 Aligners should fit snugly over your teeth without significant discomfort. If you are unable to insert the aligner without significant force or discomfort, contact your dental practitioner.
- 7.2 If the edge of the aligner is rough or causing significant discomfort, contact your dental practitioner to see if an adjustment can be made to the aligner causing the discomfort.
- 7.3 Some soreness is expected but should decrease as your teeth gently move to fit within the aligner over the course of each stage. If soreness persists or increases, consult your dental practitioner.
- 7.4 You may experience a slight lisp as your mouth adapts to speaking with aligners, this is normal and should subside over time.

## **8 Treatment Progression & Completion**

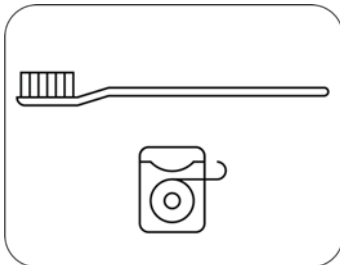
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- 8.1 Continue to wear your aligners as directed; usually 20-22 hours per day, and progress to the next stage in sequence every 1-2 weeks as directed by your doctor.
- 8.2 Evaluate aligner fit with each subsequent stage and contact your doctor with any significant issues that would prevent continued treatment.
- 8.3 Complete all stages in your prescription unless indicated by your dental practitioner.
- 8.4 The length of your treatment varies on the endpoint you are trying to achieve, and how consistent your daily wear is throughout treatment.
- 8.5 Maintain your new smile by wearing your retainers as directed by your dental practitioner.

## **9 Cleaning Instructions**

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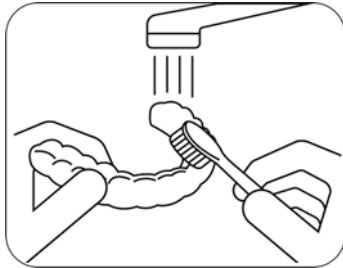
- 9.1 Aligners should be rinsed with cold water prior to each insertion. If needed, clean aligners using a soft bristle toothbrush with cold water and a small amount of toothpaste. Then rinse aligners with cold water thoroughly.
- 9.2 Avoid denture cleaners or mouthwash to help prevent damage to aligners.



## 10 Proper Oral Hygiene

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- 10.1 Patients should not wear aligners when eating and drinking, with the exception of cold water.
- 10.2 Patients should maintain good oral hygiene during the treatment with aligners by brushing and flossing their teeth after each meal or snack prior to re-inserting their aligners. If brushing is not possible, patients should at a minimum, rinse their mouth and the aligners with cold water and then brush their teeth and aligners as soon as possible.
- 10.3 Patients should maintain good health of their teeth and gums by regular dental checkups and cleaning.
- 10.4 Patients should consult their doctor if they have any questions regarding hygiene techniques.



## 11 Symbols

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The following symbols may be found on the product packaging:



Manufacturer



Consult Patient Instructions  
for Use



Use-by date



Single patient multiple use



Batch code



Catalog number

## 12 Additional Products & Accessories

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



7005 Appling Farms Pkwy, Suite 103  
Memphis, TN 38133  
866-900-8522  
info@ulabsystems.com

