

SheepMedical

KiyoClear™ Aligners Instruction for Use

CAUTION: United States Federal Law restricts this device to sale to, or on the order of, a licensed dentist or physician.

NOTE: Instructions for Use are available in other languages on demand.



CONSULT ACCOMPANYING DOCUMENTS



BY PRESCRIPTION ONLY



SINGLE USE ONLY



NON-STERILE



CONSULT INSTRUCTIONS FOR USE; READ THE INSTRUCTIONS FOR USE DILIGENTLY PRIOR TO USING THE *DEVICE*

REQUEST THE INSTRUCTIONS OF USE IN AN APPROPRIATE LANGUAGE IN ORDER TO FULLY UNDERSTAND THE CONTENT PROVIDED; DO NOT USE THE *DEVICE* IF YOU DO NOT FULLY UNDERSTAND THE INSTRUCTIONS FOR USE

THIS *DEVICE* MAY ONLY BE USED FOR ITS INTENDED USE ACCORDING TO THE GENERAL RULES FOR DENTAL AND ORTHODONTIC TREATMENT, OCCUPATIONAL SAFETY AND ACCIDENT PREVENTION

THE INSTRUCTIONS PROVIDED HEREIN ARE NOT SUFFICIENT TO ALLOW INEXPERIENCED DENTISTS AND DENTAL SPECIALISTS TO PROVIDE ORTHODONTIC DENTISTRY; IT IS RECOMMENDED THAT A DENTIST OR DENTAL SPECIALIST EXPERIENCED WITH ORTHODONTIC DENTISTRY PROVIDES PROPER CLINICAL INSTRUCTIONS, TRAINING AND SUPERVISION TO INEXPERIENCED CLINICIANS; IMPROPER TECHNIQUE CAN LEAD TO ORTHODONTIC FAILURE AND HARM TO PATIENTS AND BYSTANDERS.

INTENDED USE

The “KiyoClear™ Aligners”, herein also referred to as the “*DEVICE*”, are indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.

QUANTITY AND CONDITION OF CONTENTS

Please see the enclosed Packing List/ Bill of Delivery.

CLINICAL USE

The “Kiyoclear™ Aligners” are custom-made clear plastic trays which when worn in a sequential series, will reposition patient teeth.

Each aligner of the *DEVICE* is made of medical-grade transparent thermoplastic material. Brackets or other attachments, already placed on the teeth, could serve as aligner attachments.

Based on the digital representation of the dentition and dental situation of the patient when starting or switching to the treatment with the *DEVICE*, the “Kiyoclear™ Aligners” are produced according to the treatment plan, approved by the treating clinician.

The number of sequential aligners depends on the treatment plan. The forces applied to the teeth of the dentition by each aligner are determined by a set of target tooth positions per stage also defined by the treatment plan.

Each aligner must be worn and removed in sequence by the patient as prescribed by the dental practitioner. The patient needs to be able to comfortably place and remove the aligners before leaving the practice.

CONTRAINDICATIONS

Inadequate patient oral hygiene, patients not prepared to undergo oral rehabilitation, patients that show insufficient patient compliance, allergic sensitiveness and/ or reaction to orthodontic materials, illness and underlying conditions which preclude orthodontic treatment, existing root resorption, intraoral infection or inflammation e.g. periodontitis, gingivitis, existing decalcification of tooth enamel.

WARNINGS

DO NOT USE THE *DEVICE* WITH KNOWN ALLERGIES TO PLASTIC OR OTHER DENTAL MATERIALS
DISCONTINUE USE, IF SIGNS OF A SIGNIFICANT ALLERGIC OR ADVERSE REACTION BECOMES PRESENT

MISHANDLING OF THE *DEVICE* OR ITS COMPONENTS INSIDE THE MOUTH OF A PATIENT CARRIES A RISK OF ASPIRATION AND/OR SWALLOWING; APPLY DILIGENT CARE WHEN HANDLING SMALL COMPONENTS INSIDE THE MOUTH OF A PATIENT

DAMAGED OR BROKEN ALIGNERS SHOULD NOT BE USED

IMPROPER DEBONDING OF ATTACHMENTS MAY RESULT IN DAMAGE TO THE ENAMEL OR TOOTH RESTAURATION MATERIALS

SIDE EFFECTS / PRECAUTIONS

It is the primary responsibility of the dental professional and/or orthodontist to identify any possible risk of injury and/or contraindications that may arise during treatment, relay any possible unwanted side effects to the patient and to individualize treatment accordingly.

During treatment, unwanted side effects may include: tooth discolorations, decalcification, root resorption, periodontal complications, allergic reactions, difficulties in oral hygiene maintenance, discomfort and pain.

Do not apply excessive force when placing or removing of the aligners.

Provide the patient with instructions on how to conduct thorough oral hygiene, as tartar or food debris may impair the function of the aligners.

Aligners may stain.

Provide the patient with instructions how to place and remove the aligners.

Aligners are intended to only be removed for eating, drinking, and for oral care. Unnecessary and excessive removal and insertion of aligners may prematurely damage and/or break the aligners.

Keep aligners away from hot water and harsh chemicals. Keep aligners out of reach of young children and pets. Always store aligners in a cool, dry place.

Treatment of severe open bite, severe overjet, mixed dentition, and/or skeletally narrow jaw may require supplemental treatment in addition to aligner treatment.

Skeletal expanders, bonded auxiliaries, elastics, and 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. If oral surgery is required. Risks associated with anesthesia and proper healing must be taken into account prior to treatment.

Atypically-shaped, erupting, and/or missing teeth may affect aligner adaptation and may affect the ability to achieve the desired results.

Existing dental restorations (crowns, bridges) may become dislodged and require re-cementation or, in some instances, replacement.

Aligners are not effective in the movement of dental implants.

Certain medical conditions and use of certain medications may affect orthodontic treatment outcomes.

The product may temporarily affect speech and may result in a lisp, although any speech impediment associated with the product usually disappears within one or two weeks.

Failure to wear the appliances for the prescribed number of hours per day and/or not using the product as directed by your doctor can lengthen the treatment time and affect the ability to achieve the desired results.

Gums, cheeks, or lips may be scratched or irritated by the product.

Attachments may be temporarily bonded to one or more teeth during the course of treatment to facilitate aligner retention and/or tooth movement.

Attachments may fall off and require replacement.

All attachments should be removed upon completion of treatment.

Risks associated with interproximal reduction, which may be prescribed to create space for tooth movement as part of treatment must be taken into account.

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 bite may change throughout the course of treatment and may result in temporary patient discomfort.

Teeth may shift position after treatment. Consistent wearing of retainers at the end of treatment should reduce this tendency.

It is recommended that all teeth should be at least partially covered to help prevent super-eruption.

Temporary increase in salivation or dryness of mouth may occur.

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/or the tooth may be lost.

The health of the bone and gums which support the teeth may be impaired or aggravated.

The length of the roots of the teeth may be shortened during orthodontic treatment, which may become a threat to the longevity of the teeth.

In rare instances, problems in the temporo-mandibular joint (jaw joint) may result in joint pain, headaches, or ear problems.

At the end of treatment, the bite may require adjustment by your doctor.

DIRECTIONS FOR USE:

Upon receipt of aligners, open bag and rinse well with cold water or toothpaste and water before putting into mouth.

Snap the aligners onto your teeth, making sure to put the upper arch aligner on your upper teeth, and lower arch aligner on your lower teeth.

To remove your aligners, use your fingers to grasp the aligner edge and gently pull away from your teeth. If resistance is felt, it may be necessary to repeat the previous step in several locations. Do not bend, twist, or use excessive force when removing aligners or they may distort or be damaged. Do not use sharp objects to remove your aligners.

Wear aligners for at least 22 hours every day during treatment.

It is normal for new aligners to fit tightly and apply pressure to your teeth. This pressure should lessen the longer you wear each step.

Contact your doctor or office who supplied treatment if you experience any fitting issues or severe pain.

Remove the aligners before eating and drinking. You don't have to remove aligners to drink cold/room temperature water. Do not chew gum while wearing your aligners.

After removing your aligners, make sure to clean them with a toothbrush and cool water.

Brush and floss-after every meal to prevent food and drink from getting trapped under the aligners. Do not use denture cleaners, do not soak aligners in mouthwash as these products can damage the surface of the aligners.

While wearing your aligners you may experience dry mouth. Drink plenty of water.

When directed by your doctor, advance to the next step.

Make sure to bring your previous set of aligners with you to any checkups.

If you lose an aligner, do not use another one and contact your doctor immediately for assistance.

Attachments may fall off and require replacement. If so, please contact your doctor immediately for assistance.

Dispose of used and completed aligners in household garbage. Aligners are for one-time use only and should not be re-used after advancing to the next stage.

When removed, store your aligners in the provided carrying case.

Store your upcoming aligners in their original packaging, in a cool, dry place.

If you suspect an adverse reaction, discontinue use immediately and consult your doctor. Your doctor, not Kiyoclear technician, is responsible for managing your orthodontic treatment.

MAGNETIC RESONANCE (MR) SAFETY

The *DEVICE* has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the *DEVICE* in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

SYMBOLS GLOSSARY

 Attention: points out the necessity for the operator to check the operating instructions for important safety-related information such as warnings and precautions which cannot be applied to the medical device itself due to a variety of reasons.

 Operating instructions: refers to the necessity of the operator to consult the operating instructions.

 By prescription only. Do not use for another patient than labeled.

 Single use only, not for re-use: indicates that a medical device is designed for single use or use for a single patient during a single procedure.

 Non-sterile device.

 Do not use if packaging is damaged: indicates a medical device that should not be used if the packaging is damaged or opened.

 Use by: shows the date after the medical device should no longer be used.

 Article number: indicates the article number of the manufacturer, so that a specific medical device can be identified.

 Serial number: displays the manufacturer's serial number so that a specific medical device can be identified.

 Matrix Code: displays the manufacturer's matrix code number so that a specific medical device can be identified.

 Manufacturer: indicates the legal manufacturer of the medical device.

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Made in U.S.A • Kiyoclear™ is a trademark of SheepMedical • All other trademarks are the property of their respective owners • U.S. Patent Pending • Foreign patents issued.

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