

Keles™ Keyless Expander (KKE)



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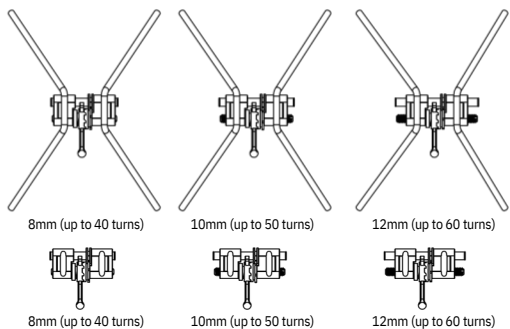
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A Rapid Palatal Expander Without a Key!

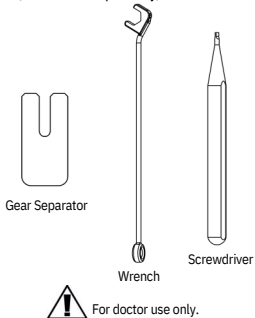
The Keles™ Keyless Expander (KKE) is a fixed rapid palatal expander used to treat maxillary transverse deficiency. Each activation expands by 0.2mm.

KKE Options



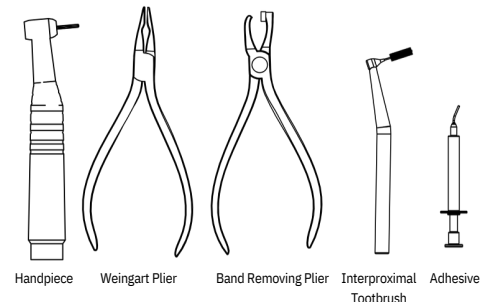
Reversal Kit

(Purchased separately)



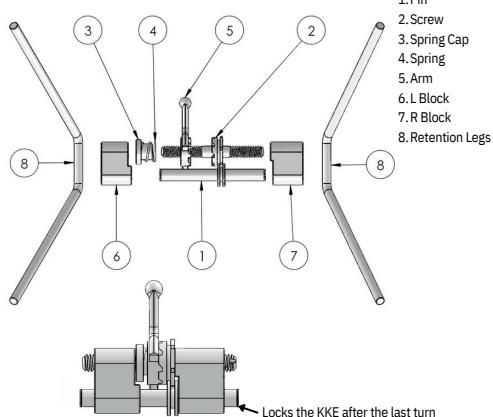
Other Tools

Commonly found in dental practices (not provided)

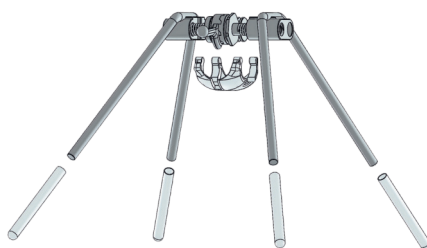


KKE Instruction For Use

1. COMPONENTS OF THE KKE

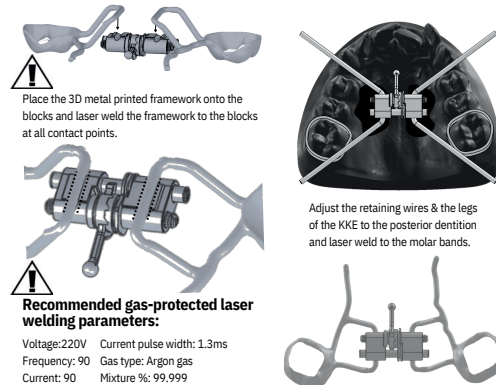


2. REMOVE THE PACKAGING



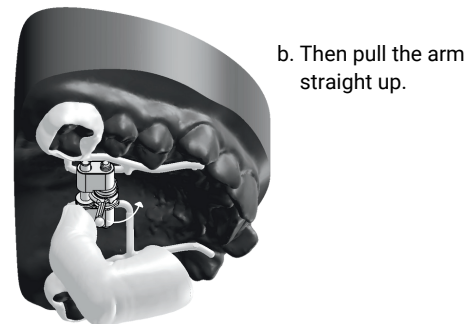
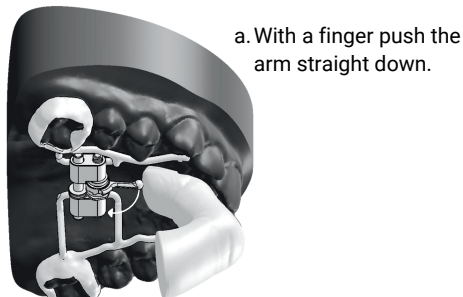
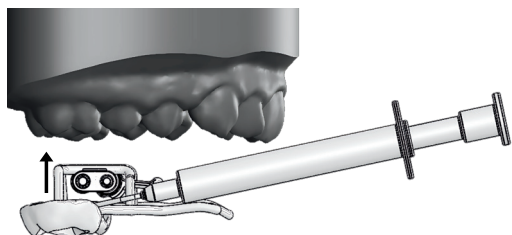
3. APPLIANCE DESIGN & CONSTRUCTION

3D Metal Printed framework & KKE Manual construction of the KKE



4. CEMENT THE KKE TO THE DENTITION

5. ACTIVATING THE KKE (The patient must follow the prescribed frequency and repeat for the number of turns as instructed by the doctor)

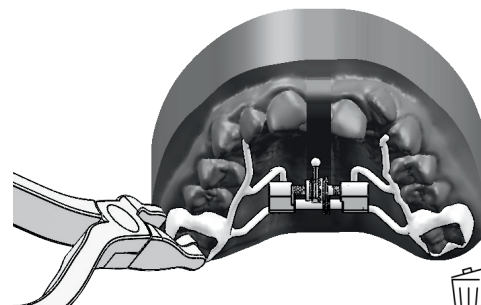
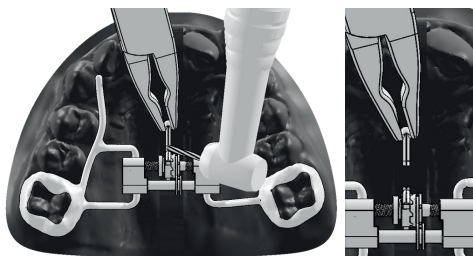
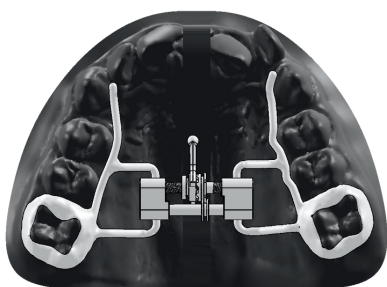


Can be performed either by the patient or by a guardian/parent.

This movement is passive and will bring the arm to its initial position for the next activation.

6. RETENTION PERIOD WITH THE KKE

7. CUT THE ARM USING A BUR (OPTIONAL) 8. REMOVE & DISCARD THE KKE

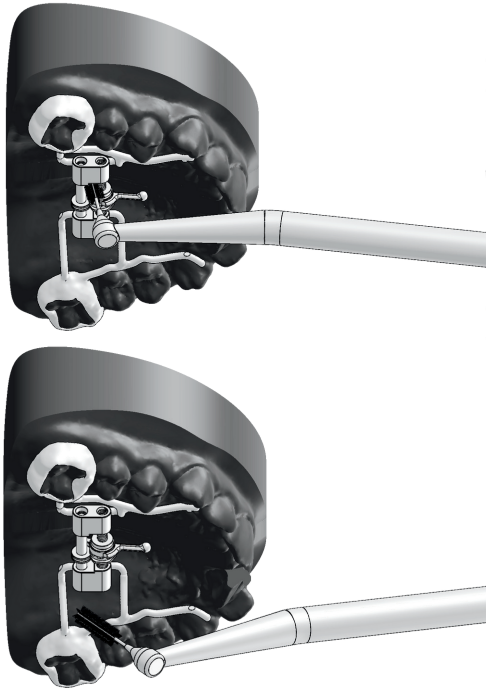


After completing the active phase of the treatment, the KKE should remain in the mouth for the duration decided appropriate by the doctor.

Disposal of Device. After the doctor completes the treatment, the KKE must be disposed of in compliance with national and local laws.

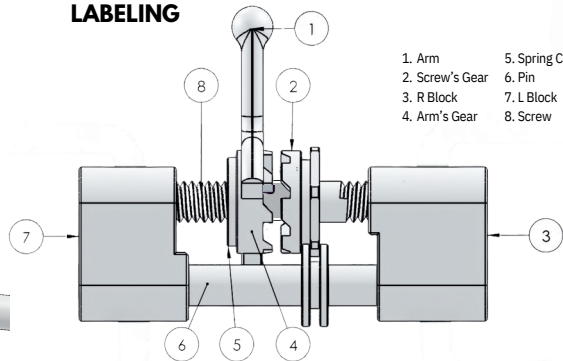
Cleaning The KKE

USE AN INTERPROXIMAL TOOTHBRUSH TO CLEAN AROUND THE DEVICE AND ITS MECHANISM.

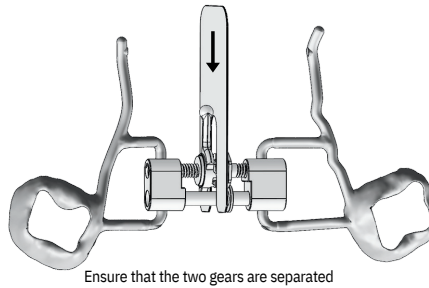


Reversing the KKE Extraorally

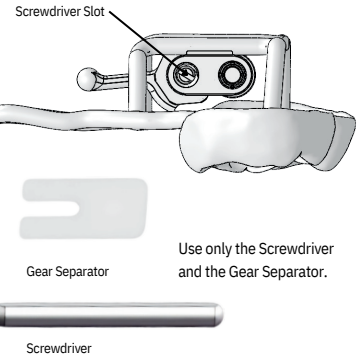
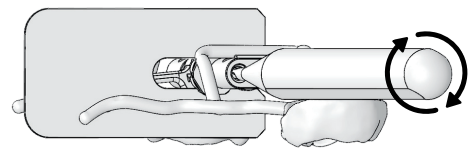
1. FAMILIARIZE YOURSELF WITH THE LABELING



2. PLACE THE GEAR SEPARATOR BETWEEN THE GEARS



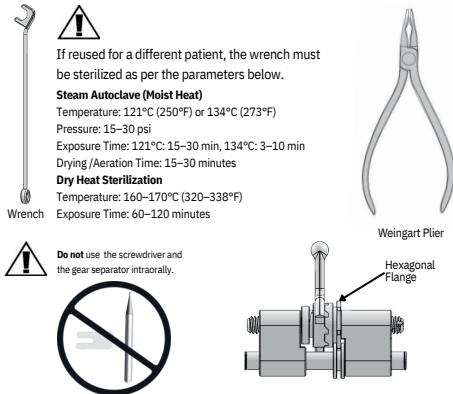
3. PLACE SCREWDRIVER IN THE SLOT & TURN CLOCKWISE TO THE DESIRED AMOUNT



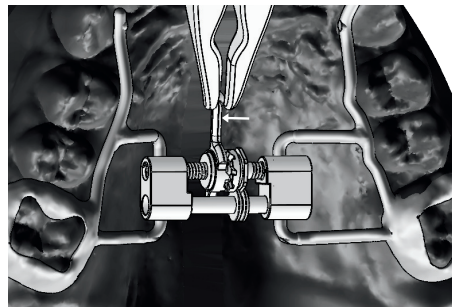
Reversing the KKE Intraorally

The reversing process should be conducted only by the doctor

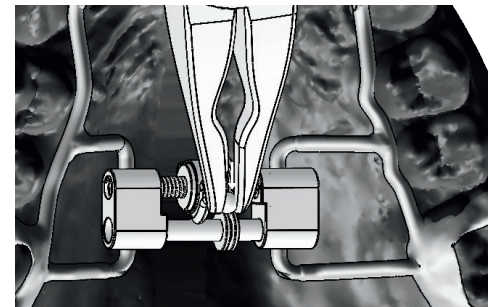
1. FAMILIARIZE YOURSELF WITH THE LABELING



2. HOLD THE ARM WITH A PLIER & MOVE THE ARM TO THE LEFT

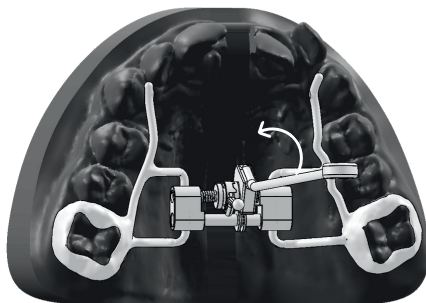


3. MOVE THE ARM DOWN 90°

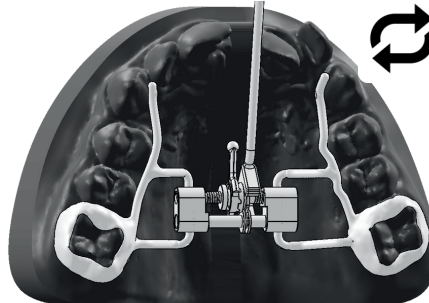


On the way down, ensure that the two gears do not engage

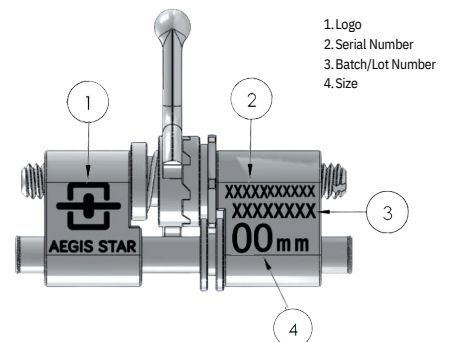
4. PLACE THE WRENCH ON THE HEXAGONAL FLANGE & TURN THE WRENCH UPWARDS



5. ONCE THE ARM IS ALL THE WAY UP, REPEAT PREVIOUS STEPS UNTIL DESIRED POSITION IS REACHED



Labeling



Symbol Glossary

	Consult instructions for use		Manufacturer		Country of manufacture		Date of manufacture		Lot number/batch number		Catalog Number
	Serial number		Warning		Professional use only		For single use only		Contains nickel and chromium		Do not use if package is damaged

Intended User. KKE is a prescription-only device for professional dental use. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. It can only be purchased by dental technicians, laboratories, distributors, and accredited dental professionals. Placement and cementing of the expander must be performed by a certified doctor. Patients or guardians can activate the device as prescribed by the doctor. The reversal of the expander must be performed by the doctor using the reversal kit.

Indications for Use. The KKE is indicated to be used in treatment of maxillary transverse constriction. It is designed to expand the palate in primary, mixed, or permanent dentition patients. This device can be used in children and adolescents. For adults, the KKE may be utilized alongside surgical procedures or other necessary interventions.

Contraindications. Patients who have recently experienced, are currently experiencing, or are prone to periodontal disease, dental caries, poor oral hygiene, root resorption, osteoporosis or other bone disorders, previous trauma to the teeth, temporomandibular joint disorders (TMD), uncontrolled medical conditions, hereditary angioedema (HAE), and allergies to metals or materials used in dental devices may not be suitable candidates to be treated with the KKE.

Warnings, Precautions, & Undesirable Side Effects. Patients must follow American Dental Association (ADA) oral hygiene guidelines and avoid hard, sticky foods, as well as sugary or acidic beverages, to prevent tooth decay, gum disease, permanent staining, and damage to the expander. The expander is designed for single use and should not be reused. The doctor must determine the activation frequency and duration based on the patient's needs and educate the patient/guardian on proper usage. It is crucial for patients/guardians to follow the prescribed protocol by their doctor, as incorrect use may result in complications such as tooth dislocation, gum damage, exposed roots, bone erosion, or tooth loss. Patients may experience tenderness, difficulty eating, minimal speech impediments, and soft tissue irritation as they adjust to the device. In rare cases, patients may experience tooth sensitivity, increased salivation or dry mouth, headaches or jaw tension, root resorption, infection. In adults, tooth movement may be observed. In adults or individuals with fused palatal sutures, expansion may be less effective and could require surgical assistance. Allergic reactions to expander materials may rarely occur.

Packaging & Handling. Inspect the packaging for any signs of damage upon receipt. Before use, carefully examine the KKE for visible issues such as bends, wear, or dents that could affect safety. Always handle with clean gloves to prevent contamination.