

Prior to use, carefully read the instructions for use. **EN**

GC Fuji ORTHO™ BAND LC PASTE PAK (Automix Compatible)

DUAL CURED REINFORCED GLASS IONOMER ORTHODONTIC BAND CEMENT

For use only by a dental professional in the recommended indications.

- RECOMMENDED INDICATIONS**
- Cementation of orthodontic bands.
 - Cementation of appliances retained with stainless steel crowns (e.g., Herbst or expansion appliances).

CONTRAINDICATIONS

Avoid use of this product in patients with known allergies to glass ionomer cement, methacrylate monomer or methacrylate polymer.

- IDENTIFICATION OF PARTS (Fig. 1)**
- Paste Pak Cartridge
 - Cover 2. Inner plunger 3. Cartridge tip
 - Paste Pak Dispenser
 - Piston 5. Adjusting guide 6. Lever 7. Sliding block 8. Piston release
 - GC MIXING TIP For LC (Available separately)
 - Release tab 10. Grip 11. Guide Pin

- PASTE PAK CARTRIDGE LOADING**
- Make sure that the piston is completely retracted into the dispenser (Fig. 2). To retract the piston, push the piston release and at the same time pull the sliding block (on the underside of the dispenser) with fingers.
 - Load the cartridge into the Paste Pak Dispenser (Fig. 3). Ensure the ▲ mark on the cartridge line up with the Paste Pak Dispenser as illustrated. Then turn the cartridge fully to the right position.
 - After cartridge piston release forward until it stops (Fig. 4).
 - Push the piston release forward.
 - Do not push the upper slide.
- NOTE:**
- To remove the cartridge, retract the piston fully and turn the cartridge back to the marked positions.

- DIRECTIONS FOR USE**
- TOOTH PREPARATION**
 - Clean the tooth surfaces to be cemented with moisture and water.
 - Rinse thoroughly with water. Remove excess moisture by blotting with a cotton swab and blowing with oil-free air. DO NOT DESICCATE. Prepared surfaces should appear moist (glistening).

NOTE:

If the surface to be bonded contains porcelain, zirconium ceramic or metal, porcelain should be sandblasted and pre-treated with silane, and zirconium ceramic and metal should be sandblasted. Refer to manufacturer's instructions.

- 2. BAND PREPARATION**
- Make sure that the band is pretreated and handled according to the manufacturer's instructions.

- 3. DISPENSING AND HAND MIXING**
- Press the lever to dispense the required amounts of paste onto the mixing pad.

- NOTE:**
- Before dispensing the first time from a new cartridge or after a long interval between use, bleed the pastes from the cartridge.
 - The adjusting guide can be moved forwards or backwards to change the quantity of material to be dispensed (Fig. 5). Set the adjusting guide to the front of the cartridge tip.
 - Press the lever while moving the cartridge and dispenser backward (Fig. 6). Keep depressing the lever (Fig. 7), level and cut off the extruded paste from the cartridge tip by moving the cartridge and dispenser in an upright position on the mixing pad.

NOTE:

If the lever is released after dispensing, residual pastes at the cartridge tips are retracted into the cartridge. Clean the cartridge tip and the dispenser.

- 4. BAND APPLICATION**
- After dispensing, spread the two pastes thinly on the mixing pad using a plastic spatula. Mix thoroughly, with lapping strokes, for 10 seconds. Be careful not to incorporate air bubbles.

- 2. DISPENSING AND HAND MIXING**
- Before every use, check the two openings of the cartridge tip and confirm the amount of the sliding block on the underside of the dispenser.

- 3. ATTACH THE GC MIXING TIP FOR LC**
- Attach the GC MIXING TIP FOR LC correctly on the cartridge by aligning the guide pin on the cartridge tip with the guide pin on the mixing tip. Simultaneously pushing the tip until it clicks on the cartridge (Fig. 8-1).

- NOTE:**
- Make sure GC MIXING TIP FOR LC is securely attached to the cartridge. If not, remove the GC MIXING TIP FOR LC and reattach (Fig. 8-2).

- 2. If the material has been refrigerated, leave the cartridge in room temperature for 10 minutes.**

- 3. Set the adjusting guide to the front of the lever (Fig. 9).**

- NOTE:**
- Before dispensing the material into the appliances, bleed a small amount of the mixed paste on a pad.

- 1) After dispensing, release the lever. To remove the GC MIXING TIP FOR LC,** push the Mixing Tip forward while depressing the release tab with one hand, and move the front part of the GC MIXING TIP FOR LC from side to side with the other hand (Fig. 10). Clean the cartridge tip and replace the cartridge cover.

- NOTE:**
- Do not leave the used GC MIXING TIP FOR LC on the cartridge for a long period of time.
 - The amount of residual material in the cartridge can be confirmed by the position of the sliding block on the underside of the dispenser. When using a small amount of paste remains in the cartridge, the paste may not be dispensed from the GC MIXING TIP FOR LC.

- 4. CEMENTATION TECHNIQUE**
- Coat the internal surface of the band with sufficient mixed material. The working time is 5 to 7 minutes from start of mixing at 23°C (73.4°F). Higher temperature will shorten working time.

- 2) Seat the bands.**
- Remove excess cement, light cure using a visible light curing unit (Halogen, GC G-Light, LED) for 2-4 seconds or allow the cement to self-cure until excess cement feels rubbery.
 - Remove excess cement with the GC MIXING TIP FOR LC. Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- 3) Remove excess cement, light cure using a visible light curing unit (Halogen, GC G-Light, LED) for 2-4 seconds or allow the cement to self-cure until excess cement feels rubbery.**

- 4) Remove excess cement with the GC MIXING TIP FOR LC.** Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- 5) Remove excess cement with the GC MIXING TIP FOR LC.** Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- 6) Appliances retained with stainless steel crowns**
- Apply a thin layer of the appliance, paste petroleum jelly on the occlusal surfaces of the teeth.
 - Fit the adapted crown with mixed material and cure. The working time is 4 to 7 minutes from start of mixing at 23°C (73.4°F). Higher temperature will shorten working time.

- 7) To remove excess cement, light cure using a visible light curing unit (Halogen, GC G-Light, LED) for 2-4 seconds or allow the cement to self-cure until excess cement feels rubbery.**

- 8) Remove excess cement with the GC MIXING TIP FOR LC.** Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- 9) Remove excess cement with the GC MIXING TIP FOR LC.** Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- 10) Remove excess cement with the GC MIXING TIP FOR LC.** Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- REMOVAL OF EXCESS CEMENT**
- Remove bonded bands/crowns from the buccal or lingual side using band/crown removers with residual material with adhesive removing pliers, scaler or rotary instrument.

- CLEANING / STERILIZATION OF PASTE PAK DISPENSER**
- For cleaning and sterilization of PASTE PAK DISPENSER, refer to the respective instructions for use.

- SHADE**
- Blue

- STORAGE**
- Refrigerated for optimal performance, store in a cool and dark place (4-25°C (39.2-77.0°F)). If not in use for a prolonged period of time, store in refrigerator.

- PACKAGE**
- GC Fuji ORTHO BAND LC PASTE PAK (Automix Compatible) Refill Package Paste Pak Cartridge (12.9 g / 7.2 mL) (2), mixing pad (No. 22) (1)
 - Paste Pak Dispenser (1)
 - GC MIXING TIP FOR LC (20)

- CAUTION**
- In case of contact with oral tissue or skin, remove immediately with a sponge or cotton soaked in alcohol. Flush with water. To avoid contact, a rubber dam and/or COCOA BUTTER can be used to isolate the operation field from the skin or oral tissue.

- 2. In case of contact with eyes, flush immediately with water and seek medical attention.**

- 3. In rare cases metal may cause sensitivity to some people. If any such reactions are experienced, discontinue the use of Paste Pak Dispenser (nickel-plated aluminum) and refer to a physician.**

- 4. Store Paste Pak Dispenser away from chemicals such as iodine tincture containing halogens and refer to a physician.**

- 5. Do not use GC Fuji ORTHO BAND LC PASTE PAK in combination with eugenol-containing materials as eugenol may hinder GC Fuji ORTHO BAND LC PASTE PAK from setting or bonding properly.**

- 6. In rare cases the product may cause sensitivity to some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.**

- 7. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.**

- 8. Some products referred in the present IFU may be classified as hazardous according to GHS. Always familiarize yourself with the safety data sheets available at:**

- http://www.gceurope.com** for The Americas
http://www.gcamerica.com for Europe
http://www.gcamerica.com for Asia

- CLEANING AND DISINFECTING**
- MULTI-USE DELIVER SYSTEMS, avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. Discard device if damaged.

- DO NOT IMMERGE:** GC Fuji ORTHO BAND LC PASTE PAK in combination with disinfectants. Disinfect with a mid-level registered healthcare-grade infection control product according to regional/national guidelines.

- Undesired effects-Reporting:**
- If you become aware of any kind of undesired effect, reaction or similar events experienced by use of this product, which are not listed in this instruction for use, please report them directly through the relevant vigilance system, by selecting the contact authority of your country accessible through the following link:

- https://ec.europa.eu/growth/sectors/medical-devices/contacts_en** as well as to our internal vigilance system: **vigilance@gc.dental**

- In this way you will contribute to improve the safety of this product.**

- REVISIONS**
1. Revision 06/2019

Vor der Benutzung bitte die Gebrauchsanweisung gründlich lesen! **DE**

GC Fuji ORTHO™ BAND LC PASTE PAK (Automix Compatible)

DUALHÄRTENDER, KUNSTSTOFFVERSTÄRKTER GLASSIONOMER ZEMENT FÜR ORTHODONTISCHE BÄNDER

Nur von zahnärztlichem Fachpersonal für die genannten Anwendungsbereiche verwenden.

- EMPFOHLENE ANWENDUNGSBEREICHE**
- Befestigung von orthodontischen Bändern.
 - Befestigung von nicht edelmetallehaltigen Kronen.

GEGENZÄHNEN

Vermeiden Sie die Verwendung dieses Produkts bei Patienten mit bekannten Allergien gegen Glasionomer-Zementen, Methacrylat-Monomer oder Methacrylat-Polymer.

- BEZEICHNUNG DER TEILE (Fig. 1)**
- Paste Pak Kartusche
 - Deckel 2. Innerer Kolben 3. Kartuschenspitze
 - Paste Pak Dispenser
 - Kolbenstange 5. Justierhebel 6. Hebel 7. Gleitstück 8. Hebelverriegelung
 - GC MIXING TIP For LC (separat erhältlich)
 - Freigabe 10. Griff 11. Führungselement

- EINSETZEN DER PASTE PAK KARTUSCHE**
- Sicherstellen, dass die Pistone vollständig retracted sind (Fig. 2).
 - Pour rétracter le piston, poussez sur le piston de retrait et dans le même temps avec le doigt, le bloc coulissant (au-dessous du distributeur).
 - Chargez la cartouche de pâte (Fig. 3). Faites coïncider la marque ▲ de la cartouche avec la marque ▲ du bloc distributeur de pâte comme indiqué. Puis, tournez complètement la cartouche en position droite.
 - Après avoir chargé la cartouche, poussez le piston jusqu'à ce qu'il s'arrête. (Fig. 4).
 - Poussez le piston vers l'avant.
 - Né pas pousser pas sur la face supérieure.

- NOTE:**
- Enlever la cartouche, retirez entièrement le piston et tournez de nouveau la cartouche pour revenir à sa position initiale.

- MODE D'EMPLOI**
- PRÉPARATION DE LA DENT**
 - Nettoyez les surfaces de la dent à coller avec de l'eau et de la ponce.
 - Rincez soigneusement à l'eau. Retirez les excès d'humidité en tamponnant avec une boulette de coton ou avec une seringue à air. NE PAS DESHYDRATER. Les surfaces préparées doivent apparaître humides (glossantes).

- NOTE:**
- Si la surface à coller contient de la céramique, elle devra être sablée puis pré-traitée avec du silane. Si elle contient de la zircone ou du métal, il est nécessaire de réaliser un sablage. Référez-vous aux instructions du fabricant.

- 2. PRÉPARATION DES BANDES**
- Assurez-vous que les bagues sont pré-traitées et manipulées selon les instructions du fabricant.

- 3. DISTRIBUTION ET AUTOMELANGE**
- Retirez le capuchon de la cartouche.
 - Appuyez sur le levier pour distribuer la quantité de pâte désirée sur le bloc de mélange.

- NOTE:**
- Avant une première distribution d'une nouvelle cartouche ou après un long intervalle d'utilisation, faire sortir un peu de pâte de la cartouche.
 - Le guide d'ajustement peut être avancé ou reculé pour modifier la quantité de pâte distribuée. Déplacez-le vers l'avant pour coller une baguette.

- 3. DISTRIBUTION ET AUTOMELANGE**
- Appuyez sur le levier tout en déplaçant la cartouche et le distributeur vers l'arrière (Fig. 6). Gardez appuyé le levier (Fig. 7), égalisez et coupez la quantité de matériau extrudé des embouts de la cartouche en une seule manœuvre et le distributeur en position verticale sur le bloc de mélange (Fig. 7-2).
 - Lorsque le levier est relâché après distribution, les excédents de pâte au niveau des embouts se rétractent dans la cartouche.

- NOTE:**
- Nettoyez l'embout et replacez le capuchon de la cartouche.

- 4. APPLICATION**
- Après avoir distribué le matériau dans la cartouche, vérifiez la quantité de matériau restant dans la cartouche peut être vérifiée par la position du bloc coulissant sur le dessus du distributeur.

- NOTE:**
- Après extraction, incorporez d'abord le matériau en fine couche sur le bloc de mélange en utilisant une spatule en plastique.

- 2. DISPENSING AND HAND MIXING**
- Before every use, check the two openings of the cartridge tip and confirm the amount of the sliding block on the underside of the dispenser.

- 3. ATTACH THE GC MIXING TIP FOR LC**
- Attach the GC MIXING TIP FOR LC correctly on the cartridge by aligning the guide pin on the cartridge tip with the guide pin on the mixing tip. Simultaneously pushing the tip until it clicks on the cartridge (Fig. 8-1).

- NOTE:**
- Make sure GC MIXING TIP FOR LC is securely attached to the cartridge. If not, remove the GC MIXING TIP FOR LC and reattach (Fig. 8-2).

- 2. If the material has been refrigerated, leave the cartridge in room temperature for 10 minutes.**

- 3. Set the adjusting guide to the front of the lever (Fig. 9).**

- NOTE:**
- Before dispensing the material into the appliances, bleed a small amount of the mixed paste on a pad.

- 1) After dispensing, release the lever. To remove the GC MIXING TIP FOR LC,** push the Mixing Tip forward while depressing the release tab with one hand, and move the front part of the GC MIXING TIP FOR LC from side to side with the other hand (Fig. 10). Clean the cartridge tip and replace the cartridge cover.

- NOTE:**
- Do not leave the used GC MIXING TIP FOR LC on the cartridge for a long period of time.
 - The amount of residual material in the cartridge can be confirmed by the position of the sliding block on the underside of the dispenser. When using a small amount of paste remains in the cartridge, the paste may not be dispensed from the GC MIXING TIP FOR LC.

- 4. CEMENTATION TECHNIQUE**
- Coat the internal surface of the band with sufficient mixed material. The working time is 5 to 7 minutes from start of mixing at 23°C (73.4°F). Higher temperature will shorten working time.

- 2) Seat the bands.**
- Remove excess cement, light cure using a visible light curing unit (Halogen, GC G-Light, LED) for 2-4 seconds or allow the cement to self-cure until excess cement feels rubbery.
 - Remove excess cement with the GC MIXING TIP FOR LC. Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- 3) Remove excess cement, light cure using a visible light curing unit (Halogen, GC G-Light, LED) for 2-4 seconds or allow the cement to self-cure until excess cement feels rubbery.**

- 4) Remove excess cement with the GC MIXING TIP FOR LC.** Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- 5) Remove excess cement with the GC MIXING TIP FOR LC.** Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- 6) Appliances retained with stainless steel crowns**
- Apply a thin layer of the appliance, paste petroleum jelly on the occlusal surfaces of the teeth.
 - Fit the adapted crown with mixed material and cure. The working time is 4 to 7 minutes from start of mixing at 23°C (73.4°F). Higher temperature will shorten working time.

- 7) To remove excess cement, light cure using a visible light curing unit (Halogen, GC G-Light, LED) for 2-4 seconds or allow the cement to self-cure until excess cement feels rubbery.**

- 8) Remove excess cement with the GC MIXING TIP FOR LC.** Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- 9) Remove excess cement with the GC MIXING TIP FOR LC.** Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- 10) Remove excess cement with the GC MIXING TIP FOR LC.** Use the GC G-Light, LED (470 nm wavelength); 20 seconds

- REMOVAL OF EXCESS CEMENT**
- Remove bonded bands/crowns from the buccal or lingual side using band/crown removers with residual material with adhesive removing pliers, scaler or rotary instrument.

- CLEANING / STERILIZATION OF PASTE PAK DISPENSER**
- For cleaning and sterilization of PASTE PAK DISPENSER, refer to the respective instructions for use.

- SHADE**
- Blue

- STORAGE**
- Refrigerated for optimal performance, store in a cool and dark place (4-25°C (39.2-77.0°F)). If not in use for a prolonged period of time, store in refrigerator.

- PACKAGE**
- GC Fuji ORTHO BAND LC PASTE PAK (Automix Compatible) Refill Package Paste Pak Cartridge (12.9 g / 7.2 mL) (2), mixing pad (No. 22) (1)
 - Paste Pak Dispenser (1)
 - GC MIXING TIP FOR LC (20)

- CAUTION**
- In case of contact with oral tissue or skin, remove immediately with a sponge or cotton soaked in alcohol. Flush with water. To avoid contact, a rubber dam and/or COCOA BUTTER can be used to isolate the operation field from the skin or oral tissue.

- 2. In case of contact with eyes, flush immediately with water and seek medical attention.**

- 3. In rare cases metal may cause sensitivity to some people. If any such reactions are experienced, discontinue the use of Paste Pak Dispenser (nickel-plated aluminum) and refer to a physician.**

- 4. Store Paste Pak Dispenser away from chemicals such as iodine tincture containing halogens and refer to a physician.**

- 5. Do not use GC Fuji ORTHO BAND LC PASTE PAK in combination with eugenol-containing materials as eugenol may hinder GC Fuji ORTHO BAND LC PASTE PAK from setting or bonding properly.**

- 6. In rare cases the product may cause sensitivity to some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.**

- 7. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.**

- 8. Some products referred in the present IFU may be classified as hazardous according to GHS. Always familiarize yourself with the safety data sheets available at:**

- http://www.gceurope.com** for The Americas
http://www.gcamerica.com for Europe
http://www.gcamerica.com for Asia

- CLEANING AND DISINFECTING**
- MULTI-USE DELIVER SYSTEMS, avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. Discard device if damaged.

- DO NOT IMMERGE:** GC Fuji ORTHO BAND LC PASTE PAK in combination with disinfectants. Disinfect with a mid-level registered healthcare-grade infection control product according to regional/national guidelines.

- Undesired effects-Reporting:**
- If you become aware of any kind of undesired effect, reaction or similar events experienced by use of this product, which are not listed in this instruction for use, please report them directly through the relevant vigilance system, by selecting the contact authority of your country accessible through the following link:

- https://ec.europa.eu/growth/sectors/medical-devices/contacts_en** as well as to our internal vigilance system: **vigilance@gc.dental**

- In this way you will contribute to improve the safety of this product.**

- REVISIONS**
1. Revision 06/2019

Avant toute utilisation, lire attentivement les instructions d'emploi. **FR**

GC Fuji ORTHO™ BAND LC PASTE PAK (Automix Compatible)

CIMENT VERRE IONOMERE RENFORCÉ A PRISE DUALE POUR LE COLLAGÉ DE BAGUE ORTHODONTIQUE

A utiliser par un professionnel de l'Art Dentaire selon les recommandations d'utilisation.

- INDICATIONS**
- Collage des bagues orthodontiques.
 - Collage d'appareils sur couronnes en acier inoxydable (ex. : Herbst ou appareils Herbst ou expansion).

CONTRE INDICATIONS

Évitez l'utilisation de ce produit chez des patients souffrant d'allergies connues aux verre ionomère, au monomère méthacrylate ou au polymère méthacrylate.

- IDENTIFICATION DES ÉLÉMENTS (Fig. 1)**
- Cartouches de pâte
 - Capuchon 2. Piston interne 3. Embout de la cartouche
 - Distributeur de pâte
 - Piston 5. Guide d'ajustement 6. Levier 7. Bloc coulissant 8. Piston de retrait
 - GC MIXING TIP For LC (disponible séparément)
 - Freinage 10. Griff 11. Ergot de positionnement

- CHARGEMENT DE LA CARTOUCHE PASTE PAK**
- Sicherstellen, dass die Pistone vollständig retracted sind in den Distributeur. (Fig. 2).
 - Pour rétracter le piston, poussez sur le piston de retrait et dans le même temps avec le doigt, le bloc coulissant (au-dessous du distributeur).
 - Chargez la cartouche de pâte (Fig. 3). Faites coïncider la marque ▲ de la cartouche avec la marque ▲ du bloc distributeur de pâte comme indiqué. Puis, tournez complètement la cartouche en position droite.
 - Après avoir chargé la cartouche, poussez le piston jusqu'à ce qu'il s'arrête. (Fig. 4).
 - Poussez le piston vers l'avant.
 - Né pas pousser pas sur la face supérieure.

- NOTE:**
- Enlever la cartouche, retirez entièrement le piston et tournez de nouveau la cartouche pour revenir à sa position initiale.

- MODE D'EMPLOI**
- PRÉPARATION DE LA DENT**
 - Nettoyez les surfaces de la dent à coller avec de l'eau et de la ponce.
 - Rincez soigneusement à l'eau. Retirez les excès d'humidité en tamponnant avec une boulette de coton ou avec une seringue à air. NE PAS DESHYDRATER. Les surfaces préparées doivent apparaître humides (glossantes).

- NOTE:**
- Si la surface à coller contient de la céramique, elle devra être sablée puis pré-traitée avec du silane. Si elle contient de la zircone ou du métal, il est nécessaire de réaliser un sablage. Référez-vous aux instructions du fabricant.

- 2. PRÉPARATION DES BANDES**
- Assurez-vous que les bagues sont pré-traitées et manipulées selon les instructions du fabricant.

- 3. DISTRIBUTION ET AUTOMELANGE**
- Retirez le capuchon de

