

GC Fuji ORTHO™ LC

LIGHT-CURED ORTHODONTIC BONDING ADHESIVE

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

RECOMMENDED INDICATIONS

- Bonding metal brackets and attachments.
- Bonding ceramic brackets.
- Bonding porcelain appliances.
- Band cementation only on extra band retentive in desired.

CONTRAINDICATIONS

- Avoid use of this product in patients with known allergies to glass ionomer cement, methacrylic monomer or methacrylic polymer.
- Avoid use of this product on dentures.
- Cementation of stainless steel crown-retained appliances (e.g., Herbst Appliances).

DIRECTIONS FOR USE

- Etaminek megfelelően készítsék a fogakat:
 - Using a prophyl cup or brush, clean the bonding surfaces of the teeth with plain (non-fluorinated) pumice and water.
 - Rinse thoroughly with water.
 - Using a sponge or a cotton pellet, apply ORTHO CONDITIONER to the bonding surfaces of the teeth for 20 seconds.

Rinse thoroughly. Although successful results have been obtained with no enamel pretreatment, conditioning of the enamel bonding surfaces will increase the adhesive's bond strength. It is therefore recommended, especially for new uses of GC Fuji ORTHO LC.

OPTIONAL

Each the enamel bonding surfaces according to the etchant manufacturer's instructions. Rinse thoroughly. Note: The enamel bonding surfaces must be moist. An overly dry or desiccated enamel surface will adversely affect the bond strength. The liquid and the resin must be in contact with the enamel bonding surfaces for at least 10 seconds. Incorporate the remaining powder and mix thoroughly for an additional 10-15 seconds (total 20-25 seconds).

2. Apply the adhesive:
 - The standard powder to liquid ratio is 3.0g / 1.0g. Level large scope of powder to 20 seconds. For accurate dispensing of powder, tap the bottle gently. Do not shake the bottle. Hold the liquid bottle vertically and squeeze gently. Do not close bottles immediately after use.

For powder or a small mix, use the small scoop and one drop of liquid. Divide the powder into 2 equal parts. Mix the first portion with ALL the liquid and wait for about 10 seconds. Incorporate the remaining powder and mix thoroughly for an additional 10-15 seconds (total 20-25 seconds).

Note:

Working time is approximately 3 minutes from start of mixing at 23°C (73.4°F). Higher temperatures will shorten the working time, and lower temperatures will lengthen it.

Bonding Procedure

- Brackets
 - Coat the bonding surface of the bracket completely with the mixed resin.
 - Position the coated bracket on the tooth.
 - Press the bracket firmly against the enamel surface. Place an orthodontic scaler on the bracket for 20-30 seconds. Press the bracket again. Continue placing additional brackets. Place all brackets in the desired position. The use of a curing light or an adhesive may be necessary. If adhesive dries in a cement, "back" the bracket with a scaler for approximately 10 seconds.

AFTER REMOVING EXCESS ADHESIVE, BE CAREFUL NOT TO DISTURB THE BRACKETS BEFORE THE ADHESIVE IS CURED.

DECREASE THE BOND STRENGTH

1. **Use a curing light (or visible light)**, cure each bracket for 10-20 seconds each from the occlusal, mesial, distal and gingival aspects. This will reduce the bond strength. Use a curing light with a light meter to ensure adequate light output.
 - Insert leveling wire and complete initial procedures. A light cure wire (e.g., OTE NI) or equivalent is recommended for initial bonding.

1. Bonding ceramic brackets: Chemically retentive bases must be etched and silanated. If not etched and silanated, follow the manufacturer's directions for cleaning, anti-etching and silanating. No treatment is required for mechanically retentive bases.

2. Bonding to porcelain restorations: Prepare porcelain surfaces by etching and silanating according to manufacturer's directions. Some use of GC Fuji ORTHO LC.
 - Bonding brackets to amalgam/metal alloy restorations: Lightly roughen the metal surface with a fine diamond point before placing GC Fuji ORTHO LC.

B. Acrylic Appliances

- Use a scaler on the bracket or a rotary instrument, roughen and place relation holes in the internal surfaces of the appliance.
- Prepare the appliance as mentioned in section #1.
- To facilitate removal of the appliance, place petroleum jelly on the occlusal surfaces and a silanating agent on the lingual surfaces.
- Fit the internal surfaces of the appliance with GC Fuji ORTHO LC. Seal into proper position.

C. Removable orthodontic appliances

1. Apply adhesive during light curing in a distal-to-mesial direction, light-cure each side of the appliance for 30 seconds each on the buccal, palatal and lingual surfaces.
2. Appliance activation can begin at the patient's bedtime the same evening.

D. Debonding Procedure

- Brackets
 - Grasp the bracket with a ligature cutter and, while supporting the tooth with fingers from the lingual side, give a sharp clockwise rotation to the tooth. The resistance is met, by again holding in the opposite direction and after desiccating (using an air syringe) the tooth around the bracket. Remove any residual adhesive with a scaler or rotary instrument.

To remove bonded appliances, flex the appliance in multiple sites with hand pressure. If this does not remove the appliance, use a scaler or other appliance, desiccate the adhesive, and remove the appliance.

STORAGE

For optimum performance, store in a cool and dark place (4-25°C / 39-77.0°F).

PACKAGES

1. Introductory Package
 - 5g powder (1) / 8g (6.8ml) liquid (1) with a double-ended powder scoop, a plastic spatula, set of mixing pads (No. 22)
2. Standard Package
 - 40g powder (1) / 8g (6.8ml) liquid (2) with a double-ended powder scoop, a plastic spatula, set of mixing pads (No. 23)
3. Professional Package
 - 40g powder with a double-ended powder scoop (1) / 8g (6.8ml) liquid (1)

CAUTION

1. In case of contact with oral tissue or skin, remove immediately with a sponge or cotton swabbed in alcohol. Flush with water.
2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. In case of contact with or liquid with any other glass ionomer materials.
4. In rare cases the product may cause sensitivity to some persons. If such reactions are experienced, discontinue the use of the product and refer to a physician.
5. Personal protective equipment (PPE) such as gloves, face masks and eye protection should always be worn.

Some products referenced in the present IFU may be classified as hazardous according to GHS. Always familiarize yourself with the safety data sheets available at: <http://www.gcgroup.com>

CLEANING AND DISINFECTING

MULTI-USE DELIVERY SYSTEMS to avoid cross-contamination between patients. The device requires mid-level disinfection. Immediately after use remove device and label for destruction. Discard device if damaged.

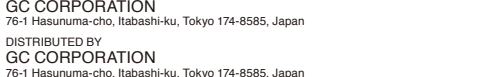
DO NOT IMMERSE. Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level regressive healthcare-grade infection control product according to regional/national guidelines.

Undesired effects/Reporting

If you experience any kind of undesired effect, reaction or similar events experienced by you or of this product, including those not listed in this document, please contact your local sales office or contact your nearest office as well as our internal vigilance system: vigilance@gc.dental

In any case you should always refer to the safety of this product.

Last revised: 06/2019



MANUFACTURED BY GC CORPORATION
7-1-1, Shinjuku-ku, Nishi-Shinjuku, Tokyo 163-8505, Japan
GC Fuji ORTHO™ LC
GC CORPORATION
7-1-1, Shinjuku-ku, Nishi-Shinjuku, Tokyo 163-8505, Japan
EU GC GROUP E.P.V.E.
Nieuwe Landerij 1, 3821 LE, The Netherlands
38201L Leven, Belgium TEL: +32 (0) 74 70 10 00



GC Fuji ORTHO™ LC

FOCOTIOLUWIZIRAJAĆI ORTOĐONTSKI CIMENT ZA ZALEPŪVANJE

Upotreba samo ot stomatolozi za preporuĉene indikacije.

PREPORUĀENI INDIKACIJE

- Zalepivanje metalnih braĉeta i prikljucak.
- Zalepivanje keramiĉkih braĉeta.
- Zalepivanje na metalni prikljucak.
- Ćimentiranje na prstima samo, kada je potrebna dodatna zatezna sila.

KONTRAINDIKACIJE

- Izbjegavati upotrebu na tozi produkti pacijenata s poznatom alergijom na akoinomerni cement, metakrilatni monomer ili metakrilatni polimer.
- Izbjegavati upotrebu na protezama.
- Cimentiranje nerđajućeg oĉelne konstrukcije od nerđajućeg oĉelika (npr. Herbst aparata).

NAOSNI ZA UPOTREBU

1. Etaminek odgovarajućim naĉinima pripremite zubne površine:
 - Izopolirajte polupirajni gumama ili četka, ponistite podloške na savršenom površnosti na zubima s obnovaiva (nesavršenja fluorid) pasta i voda.
 - Rinje temeljito.
 - Upotrijebite spužvu ili vlnicu, nanosite ORTHO CONDITIONER na površnosti zubiju za 20 sekundi.

Rinje temeljito. Iako su dobri rezultati dobiveni bez prethodne obrade površnosti, priprema površnosti zuba za zalepivanje pomoćno povećava jaĉinu vešnosti. Zbog toga se preporučuje, posebno za nove upotrebe materijala GC Fuji ORTHO LC.

OPTIONAL

Prema uputama proizvođaĉa etirajite zubne površnosti prema uputama proizvođaĉa sredstva za bojanje. Temeljito rinje. Note: Površnosti cakline za zalepivanje moraju biti vlažna. Prekomerna suha ili sušena površina cakline negativno će utjecati na čvrstoću spoja. Usprkos tome, usprkos dobrih rezultatima, priprema površnosti zuba za zalepivanje najviše povećava jaĉinu vešnosti. Zbog toga se preporučuje, posebno za nove upotrebe materijala GC Fuji ORTHO LC.

2. Dva dijela pripravka:
 - Standardni omjer praška i tekućine je 3,0 g / 1,0 g. U ravnomjerno raspršite prašak u 20 sekundi. Za precizno doziranje praška, lagano ključajte bočicu. Ne tresejte ni. Uvijek držite boĉicu vertikalno i lagano stisnite. Ne zatvarajte boĉicu odmah nakon upotrebe.

Prilikom upotrebe praška, lagano ključajte boĉicu. Ne tresejte ni. Uvijek držite boĉicu vertikalno i lagano stisnite. Ne zatvarajte boĉicu odmah nakon upotrebe.

Note:

Working time is approximately 3 minutes from start of mixing at 23°C (73.4°F). Higher temperatures will shorten the working time, and lower temperatures will lengthen it.

Bonding Procedure

- Brackets
 - Coat the bonding surface of the bracket completely with the mixed resin.
 - Position the coated bracket on the tooth.
 - Press the bracket firmly against the enamel surface. Place an orthodontic scaler on the bracket for 20-30 seconds. Press the bracket again. Continue placing additional brackets. Place all brackets in the desired position. The use of a curing light or an adhesive may be necessary. If adhesive dries in a cement, "back" the bracket with a scaler for approximately 10 seconds.

AFTER REMOVING EXCESS ADHESIVE, BE CAREFUL NOT TO DISTURB THE BRACKETS BEFORE THE ADHESIVE IS CURED.

DECREASE THE BOND STRENGTH

1. **Use a curing light (or visible light)**, cure each bracket for 10-20 seconds each from the occlusal, mesial, distal and gingival aspects. This will reduce the bond strength. Use a curing light with a light meter to ensure adequate light output.
 - Insert leveling wire and complete initial procedures. A light cure wire (e.g., OTE NI) or equivalent is recommended for initial bonding.

1. Bonding ceramic brackets: Chemically retentive bases must be etched and silanated. If not etched and silanated, follow the manufacturer's directions for cleaning, anti-etching and silanating. No treatment is required for mechanically retentive bases.

2. Bonding to porcelain restorations: Prepare porcelain surfaces by etching and silanating according to manufacturer's directions. Some use of GC Fuji ORTHO LC.
 - Bonding brackets to amalgam/metal alloy restorations: Lightly roughen the metal surface with a fine diamond point before placing GC Fuji ORTHO LC.

B. Acrylic Appliances

- Use a scaler on the bracket or a rotary instrument, roughen and place relation holes in the internal surfaces of the appliance.
- Prepare the appliance as mentioned in section #1.
- To facilitate removal of the appliance, place petroleum jelly on the occlusal surfaces and a silanating agent on the lingual surfaces.
- Fit the internal surfaces of the appliance with GC Fuji ORTHO LC. Seal into proper position.

C. Removable orthodontic appliances

1. Apply adhesive during light curing in a distal-to-mesial direction, light-cure each side of the appliance for 30 seconds each on the buccal, palatal and lingual surfaces.
2. Appliance activation can begin at the patient's bedtime the same evening.

D. Debonding Procedure

- Brackets
 - Grasp the bracket with a ligature cutter and, while supporting the tooth with fingers from the lingual side, give a sharp clockwise rotation to the tooth. The resistance is met, by again holding in the opposite direction and after desiccating (using an air syringe) the tooth around the bracket. Remove any residual adhesive with a scaler or rotary instrument.

To remove bonded appliances, flex the appliance in multiple sites with hand pressure. If this does not remove the appliance, use a scaler or other appliance, desiccate the adhesive, and remove the appliance.

STORAGE

For optimum performance, store in a cool and dark place (4-25°C / 39-77.0°F).

PACKAGES

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3. Professional Package
 - 40g powder with a double-ended powder scoop (1) / 8g (6.8ml) liquid (1)

CAUTION

1. In case of contact with oral tissue or skin, remove immediately with a sponge or cotton swabbed in alcohol. Flush with water.
2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. In case of contact with or liquid with any other glass ionomer materials.
4. In rare cases the product may cause sensitivity to some persons. If such reactions are experienced, discontinue the use of the product and refer to a physician.
5. Personal protective equipment (PPE) such as gloves, face masks and eye protection should always be worn.

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CLEANING AND DISINFECTING

MULTI-USE DELIVERY SYSTEMS to avoid cross-contamination between patients. The device requires mid-level disinfection. Immediately after use remove device and label for destruction. Discard device if damaged.

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Undesired effects/Reporting

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GC Fuji ORTHO™ LC

SVEĀOTIOLUWIZIRAJAĆI ORTOĐONTSKI CIMENT ZA ZALEPŪVANJE

Upotreba samo ot stomatolozi za preporuĉene indikacije.

PREPORUĀENI INDIKACIJE

- Zalepivanje metalnih braĉeta i prikljucak.
- Zalepivanje keramiĉkih braĉeta.
- Zalepivanje na metalni prikljucak.
- Ćimentiranje na prstima samo, kada je potrebna dodatna zatezna sila.

KONTRAINDIKACIJE

- Izbjegavati upotrebu na tozi produkti pacijenata s poznatom alergijom na akoinomerni cement, metakrilatni monomer ili metakrilatni polimer.
- Izbjegavati upotrebu na protezama.
- Cimentiranje nerđajućeg oĉelne konstrukcije od nerđajućeg oĉelika (npr. Herbst aparata).

NAVOK K POUŽITJU

1. Priprema cakline:
 - Gunjom ili katom oĉistite površine zuba za zalepivanje obimim (ne-fluoriranim) fluoridom i vodom.
 - Temeljito isprati vodom.
 - Spužvicom ili komadom vune nanosite ORTHO CONDITIONER na površnosti zuba za zalepivanje u trajanju od 20 sekundi. Temeljito isprati. Iako se dobri rezultati dobiveni bez prethodne obrade površnosti, priprema površnosti zuba za zalepivanje najviše povećava jaĉinu vešnosti. Zbog toga se preporučuje, posebno za nove upotrebe materijala GC Fuji ORTHO LC.

Priprema cakline za zalepivanje moraju biti vlažna. Prekomerna suha ili sušena površina cakline negativno će utjecati na čvrstoću spoja. Usprkos tome, usprkos dobrih rezultatima, priprema površnosti zuba za zalepivanje najviše povećava jaĉinu vešnosti. Zbog toga se preporučuje, posebno za nove upotrebe materijala GC Fuji ORTHO LC.

OPTIONAL

Prema uputama proizvođaĉa etirajite zubne površnosti prema uputama proizvođaĉa sredstva za bojanje. Temeljito isprati. Note: Površnosti cakline za zalepivanje moraju biti vlažna. Prekomerna suha ili sušena površina cakline negativno će utjecati na čvrstoću spoja. Usprkos tome, usprkos dobrih rezultatima, priprema površnosti zuba za zalepivanje najviše povećava jaĉinu vešnosti. Zbog toga se preporučuje, posebno za nove upotrebe materijala GC Fuji ORTHO LC.

2. Dva dijela pripravka:
 - Standardni omjer praška i tekućine je 3,0 g / 1,0 g. U ravnomjerno raspršite prašak u 20 sekundi. Za precizno doziranje praška, lagano ključajte boĉicu. Ne tresejte ni. Uvijek držite boĉicu vertikalno i lagano stisnite. Ne zatvarajte boĉicu odmah nakon upotrebe.

Prilikom upotrebe praška, lagano ključajte boĉicu. Ne tresejte ni. Uvijek držite boĉicu vertikalno i lagano stisnite. Ne zatvarajte boĉicu odmah nakon upotrebe.

Note:

Working time is approximately 3 minutes from start of mixing at 23°C (73.4°F). Higher temperatures will shorten the working time, and lower temperatures will lengthen it.

Bonding Procedure

- Brackets
 - Coat the bonding surface of the bracket completely with the mixed resin.
 - Position the coated bracket on the tooth.
 - Press the bracket firmly against the enamel surface. Place an orthodontic scaler on the bracket for 20-30 seconds. Press the bracket again. Continue placing additional brackets. Place all brackets in the desired position. The use of a curing light or an adhesive may be necessary. If adhesive dries in a cement, "back" the bracket with a scaler for approximately 10 seconds.

AFTER REMOVING EXCESS ADHESIVE, BE CAREFUL NOT TO DISTURB THE BRACKETS BEFORE THE ADHESIVE IS CURED.

DECREASE THE BOND STRENGTH

1. **Use a curing light (or visible light)**, cure each bracket for 10-20 seconds each from the occlusal, mesial, distal and gingival aspects. This will reduce the bond strength. Use a curing light with a light meter to ensure adequate light output.
 - Insert leveling wire and complete initial procedures. A light cure wire (e.g., OTE NI) or equivalent is recommended for initial bonding.

1. Bonding ceramic brackets: Chemically retentive bases must be etched and silanated. If not etched and silanated, follow the manufacturer's directions for cleaning, anti-etching and silanating. No treatment is required for mechanically retentive bases.

2. Bonding to porcelain restorations: Prepare porcelain surfaces by etching and silanating according to manufacturer's directions. Some use of GC Fuji ORTHO LC.
 - Bonding brackets to amalgam/metal alloy restorations: Lightly roughen the metal surface with a fine diamond point before placing GC Fuji ORTHO LC.

B. Acrylic Appliances

- Use a scaler on the bracket or a rotary instrument, roughen and place relation holes in the internal surfaces of the appliance.
- Prepare the appliance as mentioned in section #1.
- To facilitate removal of the appliance, place petroleum jelly on the occlusal surfaces and a silanating agent on the lingual surfaces.
- Fit the internal surfaces of the appliance with GC Fuji ORTHO LC. Seal into proper position.

C. Removable orthodontic appliances

1. Apply adhesive during light curing in a distal-to-mesial direction, light-cure each side of the appliance for 30 seconds each on the buccal, palatal and lingual surfaces.
2. Appliance activation can begin at the patient's bedtime the same evening.

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To remove bonded appliances, flex the appliance in multiple sites with hand pressure. If this does not remove the appliance, use a scaler or other appliance, desiccate the adhesive, and remove the appliance.

STORAGE

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CAUTION

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2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. In case of contact with or liquid with any other glass ionomer materials.
4. In rare cases the product may cause sensitivity to some persons. If such reactions are experienced, discontinue the use of the product and refer to a physician.
5. Personal protective equipment (PPE) such as gloves, face masks and eye protection should always be worn.

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- Ćimentiranje na prstima samo, kada je potrebna dodatna zatezna sila.

KONTRAINDIKACIJE

- Izbjegavati upotrebu na tozi produkti pacijenata s poznatom alergijom na akoinomerni cement, metakrilatni monomer ili metakrilatni pol

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

Vor der Benutzung bitte die Anweisungen sorgfältig lesen! **DE**

GC Fuji ORTHO™ LC

LIGHT-CURED ORTHODONTIC BONDING ADHESIVE

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

1. Bonding metal brackets and attachments.
2. Bonding ceramic brackets.
3. Bonding acrylic appliances to teeth with a moistened cotton roll immediately after band cementation only when extra band retention is desired.

CONTRAINDICATIONS

1. Avoid use of this product in patients with known allergies to glass ionomer cement, methacrylic monomer or methacrylic polymer.
2. Bonding polycarbonate brackets.
3. Cementation of stainless steel crown-retained appliances (e.g., Herbst Appliances).

DIRECTIONS FOR USE

1. Enamel Preparation
 - a) Using a prophyl cup or a brush, clean the bonding surfaces of the teeth with plain (non-fluoriated) pumice and water.
 - b) Rinse thoroughly with water.
 - c) Using a sponge or a cotton pellet, apply ORTHO CONDITIONER to the bonding surfaces of the teeth for 20 seconds. Rinse thoroughly. Although successful results have been obtained with no enamel pretreatment, conditioning of the enamel bonding surfaces will increase the adhesive's bond strength. It is therefore recommended, especially for new users of GC Fuji ORTHO LC.

OPTIONAL: Etch the enamel bonding surfaces according to the etchant manufacturer's instructions. Rinse thoroughly.

NOTE: The enamel bonding surfaces must be moist. An overly dry or desiccated enamel surface will adversely affect the bond strength. The optimum level of surface moisture can be obtained by wiping the bonding surfaces of the teeth with a moistened cotton roll immediately prior to bonding procedure. If the bonding surfaces become desiccated during the bonding procedure, rehydrate by wiping them with the moistened cotton roll before bonding with GC Fuji ORTHO LC.

2. Powder and Liquid Dispensing
 - a) The standard powder to liquid ratio is 3.0 g / 1.0 g. 1 level large scoop of powder to 2 drops of liquid.
 - b) For accurate dispensing of powder, tap the bottle gently. Do not shake or invert.
 - c) Hold the liquid bottle vertically and squeeze gently.
 - i) Close bottles immediately after use.

For rebonds or a small mix, use the small scoop and one drop of liquid.

3. Mixing
 - a) Divide the powder into 2 equal parts. Mix the first portion with ALL the liquid and mix for about 10 seconds. Incorporate the remaining powder and mix thoroughly for an additional 10-15 seconds (total 20-25 seconds).

NOTE: The working time is approximately 3 minutes from start of mixing at 23°C (73.4°F). Higher temperature will shorten the working time, and lower temperatures will extend it.

4. Bonding Procedure
 - a) Coat the bonding surface of the bracket completely with the mixed adhesive.
 - b) Position the coated bracket on the tooth.
 - c) Press the bracket firmly against the enamel surface. Using an explorer or a scaler, remove the excess adhesive at this time. Press the bracket again. Continue placing additional brackets. Place all brackets in a quadrant or in the full arch. More than one mix of adhesive may be necessary. If bracket drift is a concern, "tack" the brackets by light curing for approximately 5 seconds.

AFTER REMOVING EXCESS ADHESIVE, BE CAREFUL NOT TO DISTURB THE BRACKETS BEFORE THE ADHESIVE IS CURED. MOVEMENT OF THE BRACKETS AT THIS POINT MIGHT DECREASE THE BOND STRENGTH.

- a) Using a curing light (470nm wavelength), cure each bracket for 10 seconds each from the occlusal, mesial, distal and gingival aspects. It is very important that the curing light be tested periodically with a light meter to ensure adequate light output.
- b) Insert leveling wire and complete initial procedures. A light force wire (e.g., .016 NiTi or equivalent) is recommended at the initial bonding. **Notes:**
 - 1) Bonding ceramic brackets: Chemically retentive bases must be etched and silanated. If not etched and silanated by the manufacturer, etch and silanate before bonding with GC Fuji ORTHO LC. If bracket bases become contaminated, follow the manufacturer's directions for cleaning, and/or etching and silanating. No treatment is required for mechanically-retentive bases.
 - 2) Bonding brackets to porcelain restorations: Prepare porcelain surfaces by etching and silanating according to manufacturer's directions. Bond with GC Fuji ORTHO LC as per above.
 - 3) Bonding brackets to amalgam/metal alloy restorations: Lightly roughen the metal surface with a disc or a fine diamond point before placing GC Fuji ORTHO LC.

- a) Using a microetcher or a rotary instrument, roughen and place retention holes in the internal surfaces of the bracket and petiole.
- b) Prepare the teeth as mentioned in section #1.
- c) To facilitate removal of the appliance, place petroleum jelly on the occlusal surfaces of the teeth.
- d) Fill the internal surfaces of the appliance with GC Fuji ORTHO LC.
- e) Seat into proper position.
- f) Immediately remove excessive adhesive from the periphery of the appliance.
- g) Moving the curing light pin in a distal-to-mesial direction, light-cure each side of the appliance for 30 seconds each on the buccal, palatal and occlusal surfaces.
- h) Appliance activation can begin at the patient's bedtime the same evening.

5. Bonding Procedure
 - A. Brackets
 - i) Grasp the bracket with a ligature cutter and, while supporting the tooth with fingers from the lingual side, give a sharp clockwise rotation to the bracket. If resistance is met, try again by twisting in the opposite direction after desiccating (using an air syringe) the tooth around the bracket. Remove any residual adhesive with a scaler or rotary instrument.
 - B. Appliances
 - i) To remove bonded appliances, flex the appliance in multiple sites with band removing pliers. If this does not remove the appliance, section the appliance, desiccate the adhesive, and remove the appliance.

STORAGE: Recommended for optimal performance, store in a cool and dark place (4-25°C / 39.2-77.0°F).

1. Introductory Package: 15 g powder (1), 8 g (6.8 mL) liquid (1) with a double-ended powder scoop, a plastic spatula, a set of mixing pads (No. Z2)
2. Standard Package: 40 g powder (1), 8 g (6.8 mL) liquid (2) with a double-ended powder scoop, a plastic spatula, a set of mixing pads (No. Z3)

3. Replacement Packages:
 - a) 40 g powder with a double-ended powder scoop
 - b) 8 g (6.8 mL) liquid

4. CAUTION
 1. In case of contact with oral tissue or skin, remove immediately with a sponge or cotton soaked in alcohol. Flush with water.
 2. In case of contact with eyes, flush immediately with water and seek medical attention.
 3. Do not mix powder or liquid with any other glass ionomer materials.
 4. In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.
 5. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.

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> or for The Americas <http://www.gcamerica.com>

They can also be obtained from your supplier.

CLEANING AND DISINFECTING

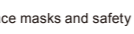
MULTI-USE DELIVERY SYSTEMS: to avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. Discard device if damaged.

DO NOT IMMERGE: Thoroughly clean device to prevent drying and accumulation of contaminants. 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, including those not listed in this instruction for use, please report them directly through the relevant vigilance system, by selecting the proper 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.

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MANUFACTURED BY
GC CORPORATION
781 Hasunuma-cho, Tabatahri-ku, Tokyo 176-8685, Japan
REGULATORY AUTHORITY
GC AMERICA, INC.
3737 West 127th Street, Anso, IL 60863 U.S.A.

REGULATORY AUTHORITY
GC CORPORATION
781 Hasunuma-cho, Tabatahri-ku, Tokyo 176-8685, Japan
REGULATORY AUTHORITY
EU: GC EUROPE N.V.
Huisvestingweg 10, 3810 Lelystad, The Netherlands
3-9001 Leuven, Belgium TEL: +32 37 74 10 00
USA: GC AMERICA, INC.
3737 West 127th Street, Anso, IL 60863 U.S.A.
TEL: +1 708-597-0000
www.gcamerica.com

GC SOUTH AMERICA
Rua Heliópolis, 378 - Jardim - São Paulo, SP, BRAZIL
CEP: 06022-051 - TEL: +55 11-2925-0965
CNPJ: 06.708.717/0001-00
RESP. TEC: Mayara de Sales Ribeiro - CRDOSP 105.982

GC ASIA DENTAL PTE. LTD.
11 Tampines Central 1, #04-01, Singapore, Singapore 529541
TEL: +65 6546 7588

GC AUSTRALASIA DENTAL PTY. LTD.
170 Bayswater Road, Bayswater, VIC 3009 Australia
TEL: +61 3 9391 8200

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GC Fuji ORTHO™ LC

LICHTHÄRTENDER GLAS IONOMER ZEMENT FÜR KIEFERORTHOPÄDISCHE BEFESTIGUNGEN

Nur von zahnärztlichem Fachpersonal für die genannten Anwendungsbereiche verwenden.

EMPOFOHLENE ANWENDUNGSBEREICHE

1. Befestigung von Metall-Brackets und Halteelementen.
2. Befestigung von Keramik-Brackets.
3. Befestigung von Kunststoff-Apparaten.
4. Befestigung von Bändern nur wenn extreme Haftfestigkeit gefordert ist.

GEGENANZEIGEN

1. Vermeiden Sie die Verwendung dieses Produkts bei Patienten mit bekannten Allergien gegen Glasionomer-Zementen, Methacrylat-Monomer oder Methacrylat-Polymer.
2. Befestigen von Polycarbonat-Brackets.
3. Befestigen von kieferorthopädischen Apparaten an Stahlkronen (e.g., Herbst Applian-ces).

GERAUCHSANWEISUNG

- a) Die Zahnoberfläche mit Bismepulver (nicht fluoridiert) und Wasser unter Verwendung eines Prophyl-Cup oder einer Bürste reinigen.
- b) Gründlich mit Wasser abspülen.
- c) Mit einem Schwämmchen oder einer Watte Pellet ORTHO CONDITIONER auf die zu befestigende Zahnoberfläche auftragen, 20 sec. einwirken lassen und gründlich mit Wasser abspülen. Auch bei nicht vorbehandelten Schmelzoberflächen wurden in klinischen Anwendungen ein erhöhter Zahneinbaueffekt erzielt. Trotzdem wird eine Schmelzconditionierung empfohlen da diese die Haftfestigkeit erhöht.

OPTION: Etch the enamel bonding surfaces according to the etchant manufacturer's instructions. Rinse thoroughly.

NOTE: Die Zahnoberfläche muss feucht sein. Eine ausgetrocknete oder trockene Schmelzoberfläche beeinflusst die Haftfestigkeit negativ.

- a) Die Standard Pulver / Flüssigkeitsverhältnis ist 3,0 g / 1,0 g; dies entspricht 1 Dosierviertel Pulver und 2 Tropfen Flüssigkeit.
- b) Pulverglas vor der Entnahme leicht aufklopfen. Nicht schütteln oder auf den Kopf stellen.
- c) Die Flüssigkeitflasche zum Dosieren senkrecht nach unten halten und leicht drücken.
- d) Nach dem Gebrauch Pulverglas und Flüssigkeitflasche sofort verschließen.

Achtung: Zum Wiederbefestigen oder für geringe Anmischmengen, den kleinen Rest in 1 Tropfen Flüssigkeit verwenden.

3. Mischen
 - a) Das Pulver auf einem Anmischblock in 2 gleiche Teile aufteilen. Die erste Portion mit dem gesamten Flüssigkeit für 10sec. mischen. Dann den Rest hinzugeben und für weitere 10-15 sec mischen (totale Mischzeit 20-25 sec).

Anmerkung: Die Verarbeitungszeit beträgt etwa 3min. ab Mischbeginn bei 23°C (73,4°F). Höhere Temperaturen verkürzen, tiefere Temperaturen (z. B. Anmischen auf einer gekühlten Glasplatte) verlängern die Verarbeitungszeit.

4. Zementieren
 - A. Brackets
 - i) Die Zahnoberfläche der Brackets komplett mit dem angemischten Zement bedecken.
 - ii) Das präparierte Bracket mit dem Zahn positionieren.
 - iii) Das Bracket vollständig gegen die Schmelzoberfläche pressen.
 - iv) Überschüssigen Zement mit einer Sonde oder einem Scaler entfernen. Das Bracket noch einmal anpressen. Mit dem Plazieren des Brackets auf dem Zahn, entfernen Sie überschüssigen Zement oder in einem vollen Zahnhagen. Dafür könnte mehr als eine Mischung notwendig sein. Wird ein "Weggleiten" des Brackets beobachtet, so kann dieses durch 5 sec. Lichthärtung stabilisiert werden.
 - B. Kunststoff-Apparate
 - i) Nach dem Aufkleben der Brackets mit dem angemischten Zement bedecken.
 - ii) Die Zähne wie unter Punkt 3 beschrieben vorbereiten.
 - iii) Ummittelbar nach dem Abbinden einen Nivellierdraht einsetzen und anschließendes Arbelten kompletieren. "Light Force Wire" (z. B. Nitinol oder ähnliche Verfahren) verwenden.
 - iv) Anmerkung:
 - 1) Befestigen von Keramikbrackets: Chemisch retentive Brackets müssen getätzt und silanisiert werden. Ist es nicht vom Hersteller getätzt und silanisiert, muss vor dem Befestigen mit GC Fuji ORTHO LC getätzt und silanisiert werden.
 - 2) Wird die Oberfläche des Metalls vor dem Plazieren von GC Fuji ORTHO LC mit einer Disc oder einem feinen Diamanten leicht anrauhern.
 - v) Bei mechanisch retentiven Brackets ist keine Behandlung erforderlich.
 - vi) Beim Kleben von Brackets an Amalgam oder Metallrestorationen die Oberfläche des Metalls vor dem Plazieren von GC Fuji ORTHO LC mit einer Disc oder einem feinen Diamanten leicht anrauhern.

NOTE: Les zones de liaison chimique doivent être mordancées puis silanisées. Si ces opérations n'ont pas été réalisées par le fabricant, mordancer puis silanier le bracket avant son collage avec GC Fuji ORTHO LC. Si les zones concernées ont été contaminées, suivre les instructions du fabricant pour le nettoyage et / ou le mordantage et la silanisation. Un traitement particulier n'est requis pour les zones de rétention mécaniques.

Collage de brackets sur restaurations céramique: Les zones de liaison chimique doivent être mordancées et silanisées. Si ces opérations n'ont pas été réalisées par le fabricant, mordancer puis silanier le bracket avant son collage avec GC Fuji ORTHO LC. Si les zones concernées ont été contaminées, suivre les instructions du fabricant pour le nettoyage et / ou le mordantage et la silanisation. Un traitement particulier n'est requis pour les zones de rétention mécaniques.

Collage sur amalgam ou alliage métallique: polir la surface du métal avec un disque ou une fraise diamantée avant de placer GC Fuji ORTHO LC.

- a) Appareils acryliques
 - i) En utilisant un micro-broyeur ou un instrument rotatif, rendre la surface rugueuse et mordançer des trous de rétention dans la surface interne de l'appareil.
 - ii) Préparer la surface interne de l'appareil de la vaseline sur les surfaces occlusales internes de la dent.
 - iii) Enduire la surface interne de l'appareil de GC Fuji ORTHO LC.
 - iv) Positionner correctement l'appareil.
 - v) Retirer aussitôt les excès de ciment des bords de l'appareil.
 - vi) Diriger le pince à l'arrière du moule et appliquer le ciment distale vers méseale, photopolymériser chaque face buccale, palatine et occlusale de l'appareil pendant 30 secondes.
 - vii) Le traitement orthodontique peut démarrer le soir même.

TECHNIQUE DE DEPOSE
A. Brackets
1. Saisir les brackets avec des pinces. Tandis que l'on maintient la dent avec les doigts sur sa face linguale, faire effectuer une rotation au bracket dans le sens des aiguilles d'une montre. Si l'on rencontre une résistance, déshydrater la dent autour du bracket en utilisant une seringue ou à le tourner dans la direction opposée. Enlever le résidu de matériau avec un instrument à détacher ou un instrument rotatif.

5. Conservation
 - a) Pour enlever l'appareil collé, piler l'appareil en plusieurs endroits avec une pince à déposer les bagues. Si cela ne suffit pas, le couper puis déshydrater le ciment et enlever l'appareil.

CONSERVATION
Pour des performances optimales, conserver dans un endroit frais et à l'abri de la lumière (4-25°C/39,2-77,0°F).

CONDITIONNEMENT
1. Coffret Introductif: 15 g de poudre (1) - 8 g (6,8 mL) de liquide (1) - une cuillère double dosage pour la poudre - une spatule en plastique - un bloc de mélange (N° 22)

2. Conditionnement régulier: 40 g de poudre (1) - 8 g (6,8 mL) de liquide (2) - une cuillère double dosage pour la poudre - une spatule en plastique - un bloc de mélange (N° 23)

3. Réassortiment:
a) 40 g de poudre avec une double cuillère doseuse
b) 8 g (6,8 mL) de liquide.

AVERTISSEMENTS
1. En cas de contact avec les tissus oraux ou la peau, retirer immédiatement avec une éponge ou un coton imbibé d'alcool. Rincer avec de l'eau.

2. Eviter tout contact du liquide ou du mélange avec les yeux. En cas de contact, rincer immédiatement à l'eau et procéder à des soins médicaux.

3. Ne pas mélanger le liquide de GC Fuji ORTHO LC avec tout autre CVI.

4. Dans de rares cas, ce produit peut entraîner, chez certaines personnes, une réaction allergique. Si cela se produit, cessez d'utiliser ce produit et consultez un médecin.

5. Un équipement de protection individuel (PPE) comme des gants, masques et lunettes de sécurité doit être porté.

Certains produits mentionnés dans le présent mode d'emploi peuvent être classés comme dangereux selon le GHS. Familiarisez-vous avec les fiches de données de sécurité disponibles sur: <http://www.gceurope.com> ou pour l'Amérique <http://www.gcamerica.com>

Elles peuvent également être obtenues auprès de votre fournisseur.

NETTOYAGE ET DESINFECTATION
Systèmes de distribution multi-usage: pour éviter toute contamination croisée entre les patients, ce dispositif nécessite une désinfection de niveau intermédiaire. Immédiatement après utilisation, inspecter le dispositif et l'étiquette. Jeter le dispositif s'il est endommagé.

NE PAS IMMÉRGER. Nettoyer soigneusement le dispositif pour prévenir l'assèchement et l'accumulation de contaminants. Désinfecter avec un produit de contrôle de l'infection de niveau intermédiaire selon les directives régionales / nationales.

Déclaration d'effets indésirables:
Si vous avez connaissance d'effets indésirables, de réactions ou d'événements de ce type résultant de l'utilisation de ce produit, y compris ceux non mentionnés dans cette notice, veuillez les signaler à votre système de vigilance approprié, en sélectionnant l'autorité compétente de votre pays accessible via le lien suivant:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en ainsi qu'à notre système de vigilance interne: vigilance@gc.dental

Vous contribuerez ainsi à améliorer la sécurité de ce produit.

Dernière mise à jour: 06/2019

Unerwünschte Wirkungsberichte:
Wenn Sie sich einer unerwünschten Wirkung, Reaktion oder ähnlichen Vorkommnisse bewusst werden, die durch die Verwendung dieses Produktes erlebt werden, einschließlich derer, die nicht in dieser Gebrauchsanweisung aufgeführt sind, melden Sie diese bitte direkt über das entsprechende Meldebehoörde, indem Sie die richtige Autorität Ihres Landes zugänglich über den folgenden Link auswählen:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en sowie zu unserer internen Meldezentrale: vigilance@gc.dental

Auf diese Weise tragen Sie dazu bei, die Sicherheit dieses Produktes zu verbessern.

Zuletzt aktualisiert: 06/2019

GC Fuji ORTHO™ LC

CIMENT VERRE IONOMÈRE PHOTOPOLYMERISABLE POUR COLLAGE ORTHODONTIQUE

Ce produit est réservé à l'Art Dentaire selon les recommandations d'utilisation.

UTILISATIONS

1. Collage des brackets et attaches métalliques.
2. Collage de brackets céramiques.
3. Collage d'appareils en résine acrylique.
4. Collage de bagues seulement lorsqu'une rétention élevée est souhaitée.

CONTRE INDICATIONS

1. Évitez l'utilisation de ce produit chez des patients souffrant d'allergies connues au verre ionomère, au monomère méthacrylate ou au polymère méthacrylate.
2. Collage de brackets polycarbonates.
3. Collage des appareils avec couronne en acier inoxydable (ex: Appareils Herbst).

MODE D'EMPLOI

1. Préparation de l'émail
 - a) Utilizating una prophyl cup or un spaazzolino, pulire le superficiali del dente con pomice semplice (non fluorata) e acqua.
 - b) Sciacquare accuratamente con acqua.
 - c) Utilizzando una spugnetta o un pellet di cotone, applicare ORTHO CONDITIONER sulla superficie del dente per 20 secondi. Sciacquare bene.
2. Rinocer soigneusement à l'eau.
3. Rinocer soigneusement à l'eau.
4. Rinocer soigneusement à l'eau.
5. Rinocer soigneusement à l'eau.

NOTE: Garder la surface humide. Une surface trop sèche ou trop déshydratée affectera la force d'adhésion. Le niveau d'humidité parfait peut être obtenu en humidifiant les surfaces à coller de la dent avec un coton humide préalablement au collage du bracket. Si la surface devient trop sèche pendant la procédure de collage, réhydrater en humidifiant la surface avec une boulette de coton humide avant de coller avec GC Fuji ORTHO LC.

2. Préparation de la poudre et du liquide
a) Le ratio standard Poudre/Liquide est de 3,0 g / 1,0 g. Cette consistance peut être obtenue avec 1 grande cuillère de poudre et 2 gouttes de liquide.

3. Réassortiment:
a) Pour un dosage plus précis de la poudre, taper légèrement le flacon. Ne pas secouer ni retourner le flacon.

4. Procédure de collage
A. Brackets
1. Enduire complètement la surface des brackets avec le mélange obtenu.

2. Positionner le bracket sur la dent.
3. Presser le bracket fermement contre la surface de l'émail. Enlever à ce moment l'excès de colle avec un instrument à détacher ou un scalair.

4. Répéter la procédure. Un II Nitinol 0,10 ou équivalent est recommandé à ce stade.

5. Préparation de la poudre et du liquide
a) Le ratio standard Poudre/Liquide est de 3,0 g / 1,0 g. Cette consistance peut être obtenue avec 1 grande cuillère de poudre et 2 gouttes de liquide.

6. Procédure de collage
A. Brackets
1. Enduire complètement la surface des brackets avec le mélange obtenu.

2. Positionner le bracket sur la dent.
3. Presser le bracket fermement contre la surface de l'émail. Enlever à ce moment l'excès de colle avec un instrument à détacher ou un scalair.

4. Répéter la procédure. Un II Nitinol 0,10 ou équivalent est recommandé à ce stade.

7. Préparation de la poudre et du liquide
a) Le ratio standard Poudre/Liquide est de 3,0 g / 1,0 g. Cette consistance peut être obtenue avec 1 grande cuillère de poudre et 2 gouttes de liquide.

8. Procédure de collage
A. Brackets
1. Enduire complètement la surface des brackets avec le mélange obtenu.

2. Positionner le bracket sur la dent.
3. Presser le bracket fermement contre la surface de l'émail. Enlever à ce moment l'excès de colle avec un instrument à détacher ou un scalair.

4. Répéter la procédure. Un II Nitinol 0,10 ou équivalent est recommandé à ce stade.

9. Préparation de la poudre et du liquide
a) Le ratio standard Poudre/Liquide est de 3,0 g / 1,0 g. Cette consistance peut être obtenue avec 1 grande cuillère de poudre et 2 gouttes de liquide.

10. Procédure de collage
A. Brackets
1. Enduire complètement la surface des brackets avec le mélange obtenu.

2. Positionner le bracket sur la dent.
3. Presser le bracket fermement contre la surface de l'émail. Enlever à ce moment l'excès de colle avec un instrument à détacher ou un scalair.

4. Répéter la procédure. Un II Nitinol 0,10 ou équivalent est recommandé à ce stade.

11. Préparation de la poudre et du liquide
a) Le ratio standard Poudre/Liquide est de 3,0 g / 1,0 g. Cette consistance peut être obtenue avec 1 grande cuillère de poudre et 2 gouttes de liquide.

12. Procédure de collage
A. Brackets
1. Enduire complètement la surface des brackets avec le mélange obtenu.

2. Positionner le bracket sur la dent.
3. Presser le bracket fermement contre la surface de l'émail. Enlever à ce moment l'excès de colle avec un instrument à détacher ou un scalair.

4. Répéter la procédure. Un II Nitinol 0,10 ou équivalent est recommandé à ce stade.

13. Préparation de la poudre et du liquide
a) Le ratio standard Poudre/Liquide est de 3,0 g / 1,0 g. Cette consistance peut être obtenue avec 1 grande cuillère de poudre et 2 gouttes de liquide.

14. Procédure de collage
A. Brackets
1. Enduire complètement la surface des brackets avec le mélange obtenu.

2. Positionner le bracket sur la dent.
3. Presser le bracket fermement contre la surface de l'émail. Enlever à ce moment l'excès de colle avec un instrument à détacher ou un scalair.

4. Répéter la procédure. Un II Nitinol 0,10 ou équivalent est recommandé à ce stade.

15. Préparation de la poudre et du liquide
a) Le ratio standard Poudre/Liquide est de 3,0 g / 1,0 g. Cette consistance peut être obtenue avec 1 grande cuillère de poudre et 2 gouttes de liquide.

16. Procédure de collage
A. Brackets
1. Enduire complètement la surface des brackets avec le mélange obtenu.

2. Positionner le bracket sur la dent.
3. Presser le bracket fermement contre la surface de l'émail. Enlever à ce moment l'excès de colle avec un instrument à détacher ou un scalair.

4. Répéter la procédure. Un II Nitinol 0,10 ou équivalent est recommandé à ce stade.

17. Préparation de la poudre et du liquide
a) Le ratio standard Poudre/Liquide est de 3,0 g / 1,0 g. Cette consistance peut être obtenue avec 1 grande cuillère de poudre et 2 gouttes de liquide.

18. Procédure de collage
A. Brackets
1. Enduire complètement la surface des brackets avec le mélange obtenu.

