

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

G-CEM LinkAce™

SELF-ADHESIVE RESIN CEMENT

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

RECOMMENDED INDICATIONS

- Cementation of all types of all ceramic, resin and metal-based inlays,onlays, crowns and bridges.
- Cementation of metal, ceramic, fiber posts, and cast post and cores.

CONTRAINDICATIONS

- Pulp capping.
- Avoid use of this product in patients with known allergies to methacrylate monomer or methacrylate polymer.

DIRECTIONS FOR USE

A. CEMENTATION TECHNIQUE for ceramics, indirect composites and metal-based restorations

1. TOOTH PREPARATION

- Prepare tooth in usual manner. For pulp capping, use calcium hydroxide.
- Clean the prepared tooth with pumice and water. A clean surface is paramount to an optimal adhesion.
- Rinse thoroughly with water. Dry thoroughly by gently blowing with oil free air. Prepared surface should be dry.

- NOTE:
- Do not use substances like H₂O₂, EDTA and/or disinfectants as these may lower the bond strength.
 - Special care should also be taken to remove imaging powders very thoroughly with pumice and water.

2. RESTORATION PREPARATION

Make sure that the restoration is pretreated and handled according to the manufacturer's instructions.

3. DISPENSING

- Before dispensing the first time from a new syringe or after a long interval in between use, bleed the pastes from the syringe.

- Remove the cap of the syringe by rotating 1/4 turn counterclockwise. Attach a GC Automix Tip by aligning the V shaped notch on the rim of the mixing tip with the V shaped notch between the syringe barrels. Push firmly to attach the mixing tip. Then rotate the colored collar of the mixing tip 1/4 turn clockwise.

- Extrude material directly into the restoration.

NOTE: The used mixing tip can be left on the syringe to serve as a storage cap until next use. For each application, place a new mixing tip.

4. CEMENTATION

- Coat the internal surface of the restoration with sufficient cement and seat immediately. The working time is 2 minutes 45 seconds from start of mix at 23°C (73,4°F). Higher temperatures will shorten the working time.

NOTE: Ambient light may shorten the working time. It is recommended to diminish the intensity or turn off your operation light during the cementation procedure.

- Maintain moderate pressure until final polishing is done.

5. EXCESS CEMENT REMOVAL

- Maintain moderate pressure and make sure the restoration remains in place.

- To remove excess cement, light cure using a visible light curing unit for 1 second or allow the cement to self-cure until the excess cement feels rubbery.

- Remove excess cement with appropriate instruments, holding the restoration in position.

NOTE: Protect the margins of the restoration with a glycerin gel after removing the excess cement to prevent oxygen inhibition.

6. FINAL SET

While maintaining moderate pressure, light cure all surfaces / margins for 20 seconds each (Halogen/LED, intensity: 700mW/cm², covering wavelength: 430 to 480 nm). In case of the following restorations, let the material set for 4 minutes after removing excess cement.

- Metal and metal coping restorations
- Metal-free dark and opaque restorations

- Translucent meta-free restorations greater than 2mm in thickness

7. FINAL POLISHING

If needed, finish and polish margins with appropriate instruments.

B. CEMENTATION TECHNIQUE for metal, ceramic, fiber posts, and cast post and cores

1. TOOTH PREPARATION

Prepare the post space according to manufacturer's instructions. The post space should be cleaned, rinsed and dried thoroughly using paper points. The post space should be dry.

- NOTE:
- a) Sodium hypochlorite solution is recommended to use for the chemical cleaning of the post space.
 - b) Do not use H₂O₂ and/or EDTA to chemically clean the post space as these products may lower the bond strength.

2. POST PREPARATION

Make sure that the post is pretreated and handled according to the manufacturer's instructions.

3. DISPENSING & CEMENTATION

- a) Before dispensing the first time from a new syringe or after a long interval in between use, bleed the pastes from the syringe.

- b) Attach a GC Automix Tip for endo. For details, see A 3b) above.

- c) Apply the extension tip to the mixing tip.

- d) Extrude material directly into the post space.

- e) Insert the post immediately into the post space within 1 minute after cement application.

NOTE: A low oral temperature accelerates the setting reaction of the cement.

- 2) Ambient light may shorten the working time. It is recommended to diminish the intensity or turn off your operation light during the cementation procedure.

- 3) Keep the tip immersed in the cement while dispensing to avoid trapping air.

- 4) DO NOT use lentulo spirals to place the cement in the post space as this may shorten the working time.

- f) Maintain moderate pressure.

4. EXCESS CEMENT REMOVAL

Continue to maintain moderate pressure making sure the post remains in place, and remove excess cement with appropriate instruments. In case of a cast post and core, tack cure all surface for 1 second each with a visible light curing unit.

5. FINAL SET

- a) While maintaining moderate pressure, light cure all surfaces/margins for 20 seconds each (Halogen/LED, intensity: 700mW/cm², covering wavelength: 430 to 480 nm).

- b) Let the material set for another 4 minutes.

STORAGE

Recommended for optimal performance, store at room temperature away from heat, moisture and direct sunlight (4-25°C) (39.2-77.0°F).

SHADE

A2 (Vita® shade), A03 (opaque), B01 (opaque) and Translucent Vita® is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.

PACKAGE

- G-CEM LinkAce syringe 4.6 g (2.7 mL) (2), GC Automix Tip Regular (15), GC Automix Tip for endo with extension tip (5)
- GC Automix Tip Regular (20)
- GC Automix Tip Regular (10)
- GC Automix Tip for endo with extension tip (10)

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.

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

- Do not use G-CEM LinkAce in combination with eugenol containing materials as eugenol may hinder G-CEM LinkAce from setting or bonding properly.

- Use a protective light shield or similar protective eye wear during light curing.

- This product is not indicated for filling or core build-up.

- 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.

- Personal protective equipment (PPE) such as gloves, face masks and safety eyewear 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.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.

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SELBSTHAFTENDER BEFESTIGUNGSZEMENT

Nur zur Verwendung durch zahntechnisches Fachpersonal für die angegebenen Indikationen.

INDIKATIONEN

- Befestigung von allen metall-, keramik- oder kunststoffbasierten Inlays, Onlays, Kronen und Brücken.

- Einsetzen von Metall-, Keramik- und faserverstärkten Stiften, sowie gegossenen Stiftauftauben.

KONTRAINDIKATIONEN

- Pulpenabdeckung.

- Dieses Produkt darf nicht an Patienten verwendet werden, die eine Allergie gegen Methacrylatmonomer oder Methacrylatpolymer haben.

VERWENDUNG

A. ANWENDUNG für Keramik, indirekte Komposite und metallbasierten Restaurationen

1. PRÉPARATION DES ZAHNES

- a) Die Präparation des Zahnes wie üblich durchführen. Zur Pulpenabdeckung Calciumhydroxid verwenden.

- b) Den präparierten Zahn gründlich reinigen. Für eine optimale Haftung ist eine saubere Oberfläche wichtig.

- c) Gründlich mit Wasser spülen. Danach sorgfältig mit ölfreier Luft trocknen – die präparierten Oberflächen sollten trocken sein.

Bemerkung:

1. Verwenden Sie keine Substanzen wie H₂O₂, EDTA und/oder Desinfektionsmittel, da diese die Haftung verringern können.

2. Bitte entfernen Sie die "Scan-Pulver" (CAD/CAM Technik) sorgfältig mit Bismstein und Wasser.

2. PRÉPARATION DEL RESTAURATION

Stellen Sie sicher, dass die Restauration gemäß den Herstellerangaben vorbereitet und sauber ist.

3. AUSBRINGEN

- a) Vor der erstmaligen Benutzung einer neuen Spritze oder nach längerer Nichtbenutzung etwas Material aus den Spritzenöffnungen auspressen, um ein einheitliches Anmischverhältnis zu erzielen.

- b) Die Kappe von der Spritze durch eine Viertelrehung gegen den Uhrzeiger lösen. Den GC Automix Tip anbringen, dazu die V-förmige Nase am Rand des Mixing-Tips mit der V-förmigen Einkerbung in der Spritze in Übereinstimmung bringen, anschließend fest aufdrücken und den ungefärbten Rand des Mixing-Tips eine Viertelrehung im Uhrzeigersinn drehen.

- c) Die Spritzenspitze in die Präparation halten und vorsichtig das Material ausbringen.

Anm.: Benutze die Mixing-Tip kann auf der Spritze verbleiben, um als Schutzkappe zu dienen. Für jede Anwendung muss jedoch ein neuer Mixing-Tip verwendet werden.

4. ZEMENTIEREN

- a) Die Oberfläche der zu zementierenden Restauration mit einer ausreichenden Zementmenge versehen und sofort einsetzen. Die Verarbeitungszeit beträgt 2 Minuten 45 Sekunden ab Anmischbeginn bei einer Temperatur von 23°C. Höhere Umgebungstemperaturen verkürzen die Verarbeitungszeit.

Anm.: Umgebungslicht kann die Verarbeitungszeit verkürzen; es wird deshalb empfohlen, das OP Licht zu dimmen oder auszuschalten, um die maximale Wirkung zu erzielen.

- b) Die Kuppe von der Spritze durch eine Viertelrehung gegen den Uhrzeiger lösen. Den GC Automix Tip anbringen, dazu die V-förmige Nase am Rand des Mixing-Tips mit der V-förmigen Einkerbung in der Spritze in Übereinstimmung bringen, anschließend fest aufdrücken und den ungefärbten Rand des Mixing-Tips eine Viertelrehung im Uhrzeigersinn drehen.

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5. ENTFRENNUNG DES ÜBERSCHÜSSIGEN MATERIALS

- a) Behalten Sie einen moderaten Druck bei und stellen Sie sicher, daß die Restauration nicht mehr bewegt wird.

- b) Den die Zementreste zu entfernen diese für 1 Sekunde mit einer Polymertastlampe leuchten lassen, oder abwarten bis der Zement chemisch abgebunden ist, und einen gummiartigen Zustand erreicht hat.

- c) Entfernen Sie die Zementreste mit geeigneten Instrumenten, während Sie die Restauration in Position halten.

Anm.: Schützen Sie die Ränder der Restauration nach dem Entfernen des überschüssigen Zements mit einem Glycerin-Gel um eine Sauerstoffinhibition zu verhindern.

6. ENDGÜLTIGE ABHÄRTUNG

Während Sie einen moderaten Druck auf die Restauration ausüben, bitte alle Oberflächen/Ränder für 20 Sekunden lichthärten (Halogen/LED, Intensität: 700mW/cm², Wellenlänge:430-480nm). Falls Sie noch weitere Restaurationen einsetzen, das Material 4 Minuten nach Entfernen der Zementreste aushärten lassen .

- Restaurationen aus Metall und Metallkappen
- Metallfreie dunkle und opaque Restaurationen

- Transluzente metallfreie Restaurationen mit einer Schichtstärke die mehr als 2mm beträgt

7. ENDPOLITUR

Falls notwendig, die Übergänge wie gewohnt finieren und polieren.

B. TECHNIQUE DE SCÉLLEMENT pour tenons métallique, céramique ou en fibre de verre et inlays core coulés.

1. PRÉPARATION DE LA DENT

- a) Préparer l'espace du tenon selon les instructions du fabricant. Le canal doit être propre, rincé et séché soigneusement avec une pointe papier. L'espace canalinaire doit être sec.

NOTE: Protéger les marges de la restauration avec un gel de glycérine après élimination de l'excès de ciment pour empêcher l'inhibition de l'oxygène.

6. PRISE FINALE

Tout en maintenant une pression modérée, photopolymériser chaque surface/margins pendant 20 secondes (Halogène/LED, intensité: 700mW/cm², longueurs d'onde: 430 à 480 nm). Pour les restaurations suivantes, laissez le matériau prendre 4 minutes supplémentaires après le retrait des excès de ciment.

- Restauration et chape métalliques
- Restauration opaque et sans métal

- Restauration translucides sans métal d'une épaisseur supérieure à 2mm

7. POLISSAGE FINAL

Si nécessaire, finir et polir avec un instrument approprié.

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NOTE: Protéger les marges de la restauration avec un gel de glycérine après élimination de l'excès de ciment pour empêcher l'inhibition de l'oxygène.

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