

**GC Fuji TEMP LT™**

GLASS IONOMER PROVISIONAL LUTING CEMENT

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

RECOMMENDED INDICATIONS

- Temporary (provisional) cementation of all types of all-ceramic, resin and metal-based crowns and bridges
- Temporary (provisional) cementation of all types of all-ceramic, resin and metal-based crowns and bridges on implant abutments

CONTRAINDICATIONS

Avoid use of this product in patients with known allergies to glass ionomer cement.

IDENTIFICATION OF PARTS (Fig. 1)

- A. Paste Pak Cartridge
1. Cover 2. Inner plunger 3. Cartridge tip
B. Paste Pak Dispenser
4. Piston 5. Adjusting guide 6. Lever 7. Sliding block 8. Piston release

PASTE PAK CARTRIDGE LOADING

- Make sure that the piston is completely retracted into the dispenser (Fig. 2). NOTE:

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 lines up with the mark (▲) on the Paste Pak Dispenser as illustrated. Then turn the cartridge fully to the right position.

- After cartridge loading, push the piston release forward until it stops (Fig. 4).

- Push the piston release forward.

- Do not push the upper side.

NOTE:

To remove the cartridge, retract the piston fully and turn the cartridge back to the marked positions.

DIRECTIONS FOR USE

Paste / Paste Ratio (g/g)	0.7 / 1.0
Mixing Time (sec.)	10"-15"
Working Time (23°C / 73°F) (min., sec.)	2'00"
Finishing Time (37°C / 99°F, after removing excess) (min., sec.)	3'00"

1. ABUTMENT PREPARATION

- Clean the tooth/abutment surfaces with pumice and water. For pulp capping, use calcium hydroxide.
- Rinse thoroughly with water. Remove excess moisture by blotting with a cotton pellet or gently blowing with an oil-free air. DO NOT DESICCATE. Prepared surfaces should be moist (glistening). Overdrying may cause difficulties in cleaning the residual cement after debonding.

NOTE:

- When a moderate retention is desired and especially when the fit of restoration is tight, a thin layer of separation medium like petroleum jelly can be applied on the abutment surface. Prior to final cementation remove petroleum jelly with alcohol first then water, as petroleum jelly may hinder setting or bonding of the permanent cement.

- The use of desensitizer may lower the bonding of GC Fuji TEMP LT.

It is recommended to sandblast the internal surface of the restoration when increased retention is desired. For sandblasting procedure, refer to the respective manufacturer's instructions. Before cementation, apply a thin layer of petroleum jelly to the outer marginal surface of the restoration. This will ease the clean-up of excess cement.

3. DISPENSING

- Remove the cartridge cover.
- Depress the lever to dispense the required amounts of paste onto the mixing pad.

NOTE:

- For dispensing the first time from a new cartridge or after a long interval in 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).

- Position of adjusting guide for one inlay.

- Position of adjusting guide for one crown.

- The paste may be dispensed in the shape of a rod, but this does not affect the quality of the paste.

- Depress the lever while moving the cartridge and dispenser backward (Fig. 6). Keep depressing the lever (Fig. 7-1), level and cut off the extruded material from the cartridge tips by moving the piston and dispenser to an upright position on the mixing pad (Fig. 7-2).

- When the lever is released after dispensing, residual pastes at the cartridge tips are retracted into the cartridge. Clean the cartridge tip and replace the cartridge cover.

NOTE:

- The amount of residual material in the cartridge can be confirmed by the position of the sliding block on the underside of the dispenser.

4. MIXING

- First spread the yellow paste alone and then mix the two pastes together with a spatula. Spread pastes thinly on the mixing pad and spatulate vigorously and thoroughly with lapping strokes for 10 seconds. Be careful not to incorporate air bubbles.

NOTE:

- A larger amount of paste requires a longer mixing time (15 seconds).

- Do not mix GC Fuji TEMP LT with other materials.

5. CEMENTATION

- Apply a thin layer of mixed GC Fuji TEMP LT on the internal rim of the restoration. The working time is 2 minutes from start of mixing at 23°C (73°F). Higher temperature will shorten working time.

- Seal the restoration with a thin film of cement.

- Do not remove excess cement, allow the cement to self-cure until excess cement feels rubbery (approx. 1 minute).

- Remove excess cement with a scalpel, probe and/or floss.

- Maintain isolation until the cement has set. Finishing can be started approx. 3 minutes after excess cement removal.

6. RESTORATION REMOVAL

- Using a suitable crown removal instrument, remove provisionally cemented restoration. Avoid undue forces that could damage the preparation or restoration.

- After removal of the restoration, residual cement remaining on the preparation and/or internal surfaces of the restoration, may be removed with a ultrasonic scaler, explorer or other suitable hand instrument such as a sharp scalpel. Gently drying the residual cement by air helps the clean-up easier.

- Treat the preparation and proceed to final cementation according to the cement manufacturer's instructions or repeat provisional cementation with GC Fuji TEMP LT Cement by following initial cementation procedure noted at the beginning of this instruction for use document.

CLEANING / STERILIZATION OF PASTE PAK DISPENSER

For cleaning and sterilization of PASTE PAK DISPENSER, refer to the respective instructions for use.

SHADE

Universal

STORAGE

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

PACKAGE

- 1) GC Fuji TEMP LT Cartridge (13.3g / 7.2mL) (2), mixing pad (1)
- 2) Paste Pak Dispenser (1)

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. Wear plastic or rubber gloves for protection.

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

- Avoid getting material on clothing.

- 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.geurope.com> or for The Americas <http://www.gcamerica.com>. They can also be obtained from your supplier.**CLEANING AND DISINFECTION**

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 IMMERSE. 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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Rx Only

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EMPFOLHENE INDIKATIONEN

- Temporäre (provisorische) Zementierung aller Arten von Kronen und Brücken auf Vollkeramik-, Kunststoff- und Metallbasis.
- Temporäre (provisorische) Zementierung aller Arten von Kronen und Brücken aus Vollkeramik-, Kunststoff- und Metallbasis auf Implantatfests.

KONTRAINDIKATIONEN

Dieses Produkt nicht bei Patienten mit bekannten Allergien gegenüber Glasionomer-Zement.

BESCHREIBUNG DER INZELTEILE (Abb. 1)

- A. Paste-Pak-Kartrusche
1. Verschluss 2. Innenstempel 3. Kartuschenspitze
- B. Paste-Pak-Applikator
4. Kolben 5. Einstellhülse 6. Hebel 7. Gleitstück 8. Kolbenentriegelung

EINLEGEN DER PASTE-PAK-KARTUSCHE

- Der Kolben muss vollständig in den Applikator zurückgezogen sein (Abb. 2).

HINWEIS:
Um den Kolben zurückzuziehen, die Kolbenentriegelung drücken und gleichzeitig mit den Fingern am Gleitstück (auf der Unterseite des Applikators) ziehen.

- Kartusche in den Paste-Pak-Applikator einlegen (Abb. 3). Die Markierung (▲) auf der Kartusche muss (wie abgebildet) genau auf die Markierung (▲) auf dem Paste-Pak-Applikator ausgerichtet sein. Die Kartusche muss vollständig in die korrekte Position drehen.

- Nach dem Einlegen der Kartusche die Kolbenentriegelung bis zum Halt vorschieben (Abb. 4).

- a) Kolbenentriegelung vorschieben.

- b) Nicht auf die Oberseite drücken.

HINWEIS:
Um die Kartusche herauszunehmen, den Kolben vollständig zurückziehen und die Kartusche zurück in die Position drehen, wo die Markierungen übereinstimmen.**ANWENDUNGSHINWEISE**

- Clean the tooth/abutment surfaces with pumice and water. For pulp capping, use calcium hydroxide.

- Rinse thoroughly with water. Remove excess moisture by blotting with a cotton pellet or gently blowing with an oil-free air. DO NOT DESICCATE. Prepared surfaces should be moist (glistening).

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4. MIXING

