

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

GC Fuji™ I

RADIOPAQUE GLASS IONOMER LUTING CEMENT

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

INDICATIONS FOR USE

- Cementation of metal-based inlays, onlays, crowns, bridges and posts.
- Cementation of high strength (corona based) all ceramic crowns and bridges.

CONTRAINDICATIONS

- Direct pulp capping.
- Avoid use of this product in patients with known allergies to glass ionomer cement.

COMPOSITION

Powder: Fluoro-alumino-silicate glass, polyacrylic acid, pigment
Liquid: Water, polyacrylic acid, carboxylic acid

DIRECTIONS FOR USE

Powder / Liquid Ratio (g/g)	1,8/1,0
Mixing Time (min., sec.)	20*
Working Time (23°C/73°F) (min., sec.)	2'00"
Net Setting Time (37°C/99°F) (min., sec.)	4'30"
Finishing Time (37°C/99°F) after seating the restoration) (min., sec.)	2'30"

ISO 9917-1 Glass polyalkenoate cement, Luting

1) TOOTH PREPARATION

- Prepare tooth in usual manner. For pulp capping, use calcium hydroxide.
- Clean the prepared teeth with saline and water.
- 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 appear moist (glistening).

2) RESTORATION

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

3) POWDER AND LIQUID DISPENSING

- The standard powder to liquid ratio is 1.8g/1.0g (1 level scoop of powder to 2 drops of liquid).

- For accurate dispensing of powder, lightly tap the bottle against the hand. Do not shake or invert.

- Hold the liquid bottle vertically and squeeze gently.

Dispense powder and liquid onto the pad. Using the plastic spatula, add all the powder to the liquid. Mix rapidly for 20 seconds.

Note: When mixing larger amounts, divide the powder into two equal parts. Mix the first portion with all of liquid for 5 seconds. Incorporate the remaining portion and mix the whole thoroughly for 15 seconds (total 20 seconds).

4) CEMENTATION

- Coat the internal surface of the restoration with sufficient cement and seat immediately. The working time is 2 minutes from start of mixing at 23°C (73°F). Higher temperatures shorten working time.
- Maintain moderate pressure.
- Start removing excess cement when the excess cement feels rubbery.
- Finishing can be started 4 minutes 30 seconds after seating the restoration.

STORAGE

Recommended for optimal performance, store in a cool and dark place (4-25°C) (39-27,7°F, 0°).

SHADE

Light yellow

PACKAGES

- 1-1 package: 35g powder, 25g (20ml) liquid, powder scoop, mixing pads (No. 20).
- Bottle of 25g powder with scoop.
- Bottle of 25g (20ml) liquid.

CAUTION

- In case of contact with oral tissue or skin, remove immediately with a sponge or cotton swabbed in alcohol. Flush with water. To avoid contact, a rubber dam and/or occlusal 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 mix powder or liquid with components of other glass ionomer cements.
- This product is not indicated for filling or core build-ups.
- Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be used.
- 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.

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: https://www.gc.dental/europe.
They can also be obtained from your supplier.

CLEANING AND DISINFECTING:
MULTI-USE DELIVERY SYSTEMS: to avoid cross-contamination between patients the following steps should be followed:
Immediately after use inspect device and label for deterioration. Discard device if damaged.

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

For the Summary of Safety and Clinical Performance (SSCP) please see EUDAMED (https://ec.europa.eu/euotools/euamed) or contact us at Regulatory.gce@gc.dental

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/info/investors/medical-devices/contacts_en
as well as to the national vigilance system:
vigilance@gc.dental

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

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