

Prior to use, carefully read the instructions for use.

EN

Před použitím, všechno
prostředek instrukce za upozor-
nění.

BG

GC Fuji PLUS™ EWT

RADIOPAQUE REINFORCED GLASS IONOMER LUTING CEMENT WITH EXTENDED WORKING TIME

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

- INDICATIONS FOR USE**
1) Dental restorative inlays, onlays, crowns and bridges
2) Cementation of resin inlays, onlays, crowns and bridges
3) Cementation of all ceramic inlays
4) Cementation of high strength (zirconia based) all ceramic crowns and bridges
5) Cementation of metal, ceramic and fiber posts

CONTRAINDICATIONS

- 1) Direct pulp capping.
2) Avoid use of this product in patients with known allergies to glass ionomer cement, methacrylate monomer or methacrylate polymer.

COMPOSITION
Prášek: Fluoro-alumino-silikátový iniciátor, pigment
Líquido: Metacrilátová voda, poliakrylová kyselina, dimetacrilát, karboksilová kyselina, iniciátor, stabilizátor.

DIRECTIONS FOR USE

Powder / Liquid Ratio (g/g)	2.0/1.0
Mixing Time (sec.)	20*
Working time (min., sec.) (at 23 °C)	3'30"
Setting Time (37°C/99°F) (min., sec.)	5'45"

Radio-opac: Its radiopacity is equivalent to 2.1 mm or 210% aluminum. (The radiopacity of aluminum is comparable to dentin.) ISO 9917-2 Class 1, Luting

- 1) **TOOTH PREPARATION**
a) Prepare tooth in usual manner. For pulp capping, use calcium hydroxide.
b) Clean the prepared teeth with pulio and water.

Note: Use GC Fuji PLUS CONDITIONER on the prepared tooth surface for 20 seconds for optimal adhesion.

2) **RESTORATION SURFACE**
a) Remove excess moisture by blowing with a dry air-free or DENTAL DESICATE. Prepared surface should appear moist (glistening).

3) **RESTORATION PREPARATION**
a) Remove debris that has been prepared and handled according to the manufacturer's instructions.

3) **POWER AND LIQUID DISPENSING**
Note: Use GC Fuji PLUS Liquid. Refer to instructions for use of GC Fuji PLUS.

a) The standard powder to liquid ratio is 2.0 g / 1.0 g (level large scoop of powder to 3 drops of liquid, or 1 level small scoop of powder to 1 drop of liquid).

b) For liquid dispensing of powder, lightly tap the bottle against the hand. Do not shake or invert.

c) Hold the liquid bottle vertically and squeeze gently.

d) Close bottles immediately after use.

4) **MIXING**
Dispense powder and liquid onto the pulp. Using the plastic spatula, add all the powder to the liquid. Mix thoroughly for 20 seconds. Note: When mixing, do not mix the first 2 equal parts of the first portion with all the liquid for 15 seconds. Incorporate the remaining portion and mix the whole thoroughly for 15-25 seconds (total 30-40 seconds).

5) **CEMENTATION**

- a) Coat the internal surface of the restoration with sufficient cement and seal immediately. The working time is 3 minutes 30 seconds after start mixing at 23°C (73.4°F). Higher temperatures will shorten working time.

b) Maintain moderate pressure.

c) Start removing excess cement when the excess cement feels rubbery.

d) Finishing can be started 5 minutes 45 seconds after sealing the restoration.

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

7) **SHADE**
A3 (Vita® shade)
Vita® is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.

8) **PACKAGE**
Powder 15g with scoop

9) **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 cotton cube butter can be used to isolate the restoration from the skin or oral tissue.

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

3) DO NOT mix powder or liquid with components of other glass ionomer cements.

4) GC Fuji PLUS CONDITIONER contains 2% Feric Fluoride. It is not recommended to use GC Fuji PLUS CONDITIONER in combination with products containing Epinephrine as this may stain oral tissue.

5) Do not use GC Fuji PLUS EWT in combination with eugenol containing materials as eugenol may hinder GC Fuji PLUS EWT from setting or bonding properly.

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

7) This product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.

8) 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>

They can also be obtained from your supplier.

9) **CLEANING AND DISINFECTION**

MUŽETE POUŽÍVAT VODNÉ STERILIZÁTORE, to avoid cross-contamination between patient/this device requires mid-level disinfection. Immediately after use, inspect device and label for deterioration. Discard device if damaged. DO NOT IMMERSIVE. 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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They can also be obtained from your supplier.

10) **FOR THE SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) PLEASE SEE EUDAMED database (<https://ec.europa.eu/tools/eudamed>) or contact us at Regulatory.gov@gc.dental**

11) **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 website: 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.

Last revised: 12/2023

12) **Post-revision up-to-date:**

The latest revision date: 12/2023

13) **EU: GC EUROPE N.V.**

Hausbachstrasse 10, 7430 Säckingen, Germany

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RADIOPAQUE KONTAKTNESTEN PODSÍLENÝ GLAS-IONOMEREM ZA ŠÍŘKOU 1 MM ZA UDĚLITÉ VČASEM

Da se používá samo od dantních lekářů, zvláštními instrukcemi za upozornění.

- INDIKACE A UPOTŘEBA**
1) Čimentiraní na inlegi, onlegi, korony a mostovce s metadním osnovou.
2) Čimentiraní všech typů keramických inlegi, onlegi, korunk a mostu.
3) Čimentiraní na izolaci keramického inlegu.
4) Čimentiraní všech korunk a mostovce s vysokou stabilitou až do 1000 hodin (bez zirkonu).

5) Čimentiraní na metalicki, keramicki a fibro-sifofitu.

KONTRAINDIKACE

- 1) Direktne pulpy. 2) Izolaci upotřebení na tomto produktu při pacientu s známou alergií na skloionomerem cement, metakrilátový monomer nebo metakrilátový polymer.

SČÍTAČ

Prašek: Fluoro-alumino-silikátový steklo, iniciátor, pigment

Těnost: Metakrilát, voda, poliakrylová kyselina, dimetacrilát, karboksilová kyselina, iniciátor, stabilizátor.

DIRECTIONS FOR USE

Prašek / tekutina pomér (g/g)	2.0/1.0
Mixing Time (sec.)	20*
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Radio-opac: Its radiopacity is equivalent to 2.1 mm or 210% aluminum. (The radiopacity of aluminum is comparable to dentin.)

ISO 9917-2 Class 1, Luting

1) **TOOTH PREPARATION**

a) Připravit vodou až užitelnou. Použít pulpo až užitelnou.

b) Čistit a vyčistit vodou až užitelnou.

c) Použít GC Fuji PLUS CONDITIONER na připravenou povrch po 20 sekund.

d) Odkrádat vodou až užitelnou.

e) Vymazat vodu až užitelnou.

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