

EN
Please use, carefully read the instructions for use.

GC Fuji™ IX GP EXTRA

RADIOAPAOE POSTERIOR GLASS IONOMER RESTORATIVE CEMENT IN CAPSULES

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

RECOMMENDED INDICATIONS

- Class II restorations in deciduous teeth.
- Non-load bearing Class I and Class II restorations in permanent teeth.
- Intermediate restorations for heavy stress situation in Class I and Class II cavities using sandwisch laminate technique.
- Class V and root surface restorations.
- Cure build-up.

CONTRAINDICATIONS

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

DIRECTIONS FOR USE

Powder / Liquid Ratio (g/g)	0,40 / 0,12
Mixing Time (sec.)	10"
Time of initial extrusion after mixing	10 seconds maximum
Working Time (min., sec.)	1'15"
Net Setting Time (min., sec.)	2'00"
Final Finishing Commencing Time (37 °C)	2'30"
Use, after starting mix (min., sec.)	4'00"
Test conditions: Temperature (23 ±1 °C), Relative humidity (50 ±4%)	

1. CAVITY PREPARATION

- Prepare tooth using standard techniques. Extensive mechanical retention is unnecessary. For pulp capping use calcium hydroxide.
- Apply GC CAVITY CONDITIONER (10 seconds) or GC DENTIN CONDITIONER (20 seconds) to the bonding surfaces using a cotton pellet or sponge (Fig. 1).

- Rinse thoroughly with water. Blot away excess water with a cotton pellet or dry gently blowing with an air syringe. Do NOT DESICATE. Prepared surfaces should appear moist (glistening).

2. CAPSULE ACTIVATION AND MIXING

- Before activation, shake the capsule or put its side on a hard surface to loosen the powder (Fig. 2).
- To activate the capsule, push the plunger until it is fully depressed with the main body and hold it down for 2 seconds (Fig. 3).

- Ensure the plunger is fully pressed to avoid the incorrect mixing ratio of powder and liquid.
- The capsule should be activated just before mixing and used immediately.
- Immediately set it into a mixer (or an amalgamator) and mix for 10 seconds (+/-4.000 RPM) (Fig. 4). Note: When using a rotational mixing unit, it is recommended not to use the centrifuge option.

3. RESTORATIVE TECHNIQUE

- Immediately remove the mixed capsule from the tray and load it into the GC Capsule Applier.
- Make two dds to prime the capsule then syringe (Fig. 5). The working time is 1 minute 15 seconds from start of mixing at 23°C (73.4°F). Higher temperatures will shorten working time.
- Within 10 seconds maximum after mixing, start to load the mixture directly into the preparation (Fig. 6).
- Form the preliminary contour, and cover with a matrix if required.
- During the first 2 minutes 30 seconds from start of mix extra care should be taken to avoid moisture contamination or drying out. In case this cannot be guaranteed, immediately apply or GC Fuji Varnish (blow dry) or GC Fuji Coat LC (light cure).

- Apply the direction of the nozzle, hold the applicator with the capsule towards you and turn the capsule body.
- To remove the used capsule, push the applicator release button. Twist the capsule and pull upwards.

4. FINISHING

- Final finishing under water spray using standard technique should begin approximately 2 minutes 30 seconds after start of mixing (Fig. 8).
- Apply a final coat of GC G-COAT PLUS and light cure for 20 seconds.
- Alternatively, apply GC Fuji VARNISH (blow dry) or GC Fuji Coat LC (light cure) Refer to the respective instructions for use.
- Instruct the patient not to apply pressure for 1 hour.

STORAGE

- Recommended for optimal performance, store capsules in the original aluminium foil in a cool and dark place (+22°C) (39,2-77,0°F).

SHADES

- A1, A2, A3, A3.5, B1, B2, B3, C4
Shade numbers according to Vita® shade guide. Vita® is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.

PACKAGES

- Single Amalgam package: 50 capsules.
- Assortment package: 50 capsules (10 each of A2, A3, A3.5, B1, B3).
- Average contents per capsule: 0.40g powder and 0.12g (0.10mL) liquid. Mixed cement volume of each capsule per capsule: 0.14mL.
- Option: GC CAPSULE APPLIER (1 piece).

CAUTION

- In case of contact with oral tissue or skin, remove immediately with a sponge or cotton soaked in alcohol. Flush with water.
- In case of contact with eyes, flush immediately with water and seek medical attention.
- Personal protective equipment (PPE) such as gloves, face masks and eyeglasses should always be worn.
- In case of severe reactions, 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: <http://www.georgroup.com>. They can also be obtained from your supplier.

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

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Пред použitím si dôkladne prečítajte návod na použitie.



GC Fuji™ IX GP EXTRA

RADIOOPAKÝ SKLOJONOMERNÝ VÝPLŇOVÝ MATERIÁL V KAPSULÁCH PRE VÝPLŇVE V LATERÁLNOM ÚSEKU

Na použitie len v stomatologickej praxi v doporučených indikáciách.

DOPORUČENÉ INDIKÁCIE

- Výplne I a II triedy vodorovného chrbtu.
- Nepríliš zatažené výplne I a II triedy stehého chrbtu.
- Dôcasné výplne a báze pre silno zatažené výplne I a II triedy za zubných sennýchvých techniky.
- Výplne V triedy a povrchu koreňa.
- Dostavky.

KONTRAINDIKÁCIE

- Príame priručie pulpy.
- Tento výrobok nepoužívajte u pacientov s preukázanou alergiou na skloionomerný cement.

NÁVOD NA POUŽITIE

Prášok / tekutina pomor (g/g)	0,40 / 0,12
Miešací čas (sek.)	10"
Čas do začiatku vytlačenia materiálu	
od premiešania	maximálne 10 sekúnd
Pracovný čas (min., sek.)	1"15"
Čistý čas tuhnutia (min., sek.)	2'00"
Začiatok konečného opracovania	
(37°C, po začatí miešania) (min., sek.)	2'30"
Testovacie podmienky: Teplota (23±1 °C),	
Relatívna vlhkosť (50+/-5%)	

- PREPARÁCIA KAVITY**
 - Zub preparujte pomocou štandardných techník. Nie je nutná rozsiahla mechanická retencia. Na vytváranie pulpy použite hydroxid videný.
 - Naneste GC CAVITY CONDITIONER (10 sekúnd) alebo GC DENTIN CONDITIONER (20 sekúnd) na vzhľadov plochy za použitia vodorovného tampóna alebo špongie (obr. 1). Dôkladne opláchnite vodou.
 - Prebytký vlhkosti
 - Vysušte vatovým tampónom alebo jemne vyfúknute vzduchom.NEPRESUSUJATE. Preparovaný povrch by sa mal javiť vlnky (tekia).
- AKTIVÁCIA KAPSYLA A MIEŠANIE**
 - Pred aktiváciou kapsuly zatrasťte alebo s ňou krepitne o tvrdý povrch, aby sa uvoľnili prášok (obr. 2).
 - Kapsulu aktivujte U plným zatažením piesta do hlavného telesu kapsuly a podržte ho 2 sekundy (Silka 3).
 - Poznámka:
 - Skontrolujte, či je miest úplne zatažený, aby sa zabránilo nesprávnej zmiešaniu prášku a tekutiny.
 - Kapsulu aktivujte tesne pred miešaním a potom v rámci použitia.
 - Kapsulu ihneď vložte Do miešacieho prístroja (amalgamátor) a pri vysokej rýchlosti (+12-4 000 otáčok za minútu) miešajte po dobu 10 sekúnd (obr. 4).
 - Poznámka:
 - Ak používate rotačný zmiešavací prístroj, nepoužívajte možnosť cyberty.
 - TECHNIKA VÝPLNE**
 - Zmiešavací kapsulu okamžite vberte z miešacieho prístroja a vložte do aplikátora GC Capsule Applicator.
 - Dvakrát stlačte, potom je materiál v kapsule (obr. 5).
 - Pracovný čas je 1 minúta a 15 sekúnd od začiatku miešania a pri teplote 23°C (73,4°F). Vyššia teplota skracuje pracovný čas.
 - V priebehu maximálne 10 sekúnd od premiešania začnite s vytlačovaním materiálu priamo do prípravenej kavity (obr. 6).
 - Vytvárajte vlnu a pokiaľ je potreba umiestnite kapsulu.
 - Práca prvých 2 minút a 30 sekúnd od začiatku miešania treba venovať zvýšenú pozornosť tomu, aby nedošlo ku kontaminácii vlhkom alebo vysušeniu. V prípade, že toto nie je možné zaradiť innej naneste GC Fuji Varnish (okúľajte) alebo GC Fuji COAT LC (vytvrdzte svetlom).
 - Zníženie
 - Šmyr tržky nastavte tak, že aplikátor s kapsulou pridržte smerom k sebe a odtlačte Opichnite vodu.
 - Použite kapsle vyberiete stlačením uvoľňovacieho tlačítka na aplikátore. Kapsulu odstráňte a vyhodte ju do odpadu.
 - KONEČNÁ ÚPRAVA**
 - S konečnou úpravou pod vodným sprajom s pomocou štandardných techník môžete začať približne po 2 minútach a 30 sekundách od začiatku miešania (obr. 8).
 - Naneste finálnu vrstvu G-COAT PLUS (vytvrdzte svetlom po dobu 20 sek.) (obr. 8.9)
 - Alternatívne, aplikujte GC Fuji VARNISH (okúľajte) alebo GC Fuji COAT LC (vytvrdzte svetlom).
 - Pozrite príslušné návody na použitie.
 - Upozornite pacienta, aby 1 hodinu nevyvíjal tlak na ošetrované miesto.

SKLADOVANIE
Pre zachovanie optimálnych vlastností skladujte kapsule v originálnej alumínovej fólii na tmavom a chladnom mieste 4-25°C (39-77,0°F).

OTIETIE
A1, A2, A3, A3.5, B1, B2, B3, C4
Číslo odtieňový podľa vzorkníka Vita®
Vita® je registrovaná obchodná značka spoločnosti Vita Zahnfabrik, Bad Säckingen, Nemcko.

BALENIE
S jedným odtieňom: 50 kapsul.
2. Výberové balenie: 50 kapsul (po 10 kusoch z A2, A3, A3.5, B1, B3).
Prírodný obsah kapsule: 0,40g prášku o 0,12g (0,10mL) tekotiny.
Minimálny neto volumen zmiešaného cementu na kapsulu: 0,14ml.
Možnosť GC CAPSULE APPLIER (1 kus).

OPOROZILLO
1. V prvej miske je 50 kapsul.
2. Asortiment: 50 kapsul (10 kusov z A2, A3, A3.5, B1, B3).
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