

IFU FUJI IX GP FAST CAPSULE
NW4105_3000639Prior to use, carefully read
the instructions for use.Před použitím si pečlivě přečtěte návod
k použití.

BG

GC Fuji™ IX GP FAST

RENTGENOKONTRASTNÝ POSTERIORNÝ GLAS-IONOMERENÝ VÝPLŇOVÝ MATERIÁL V KAPSULÍ

GC Fuji IX GP FAST je červeno-hnědá verzia GC Fuji IX GP CAPSULE. Dá sa použiť vo stomatologickej praxi v doporučených indikacijach.

INDIKACIE NA UPOŽTENIA

- Výplň klase I a II na vremenni zbyti.
- Bézvýznamová klasa I a II bez okzulzánu natovarované, pri postojnom zubu.
- Medzinárodný výstavoznam a osnova sa sandvich technika pri I a II klase kavárov.
- Významová V klasa a defekty po korénkovata povrchosť.
- Ingrediaty na výplňtu.

KONTRAINDIKACIE

- Direktné pulpo porfirie.
- Neupoužiť tento produkt u pacientu se znáom alergii na skloionomerový výplňový materiál.

SČSTAV

Prášok: Fluor-hlinno-kfemičký sklo, kyselina poliakrylová, pigment, pigment.

Tekutina: Destilovaná voda, poliakrylná kiselina, karboksílová kiselina.

NAVOD K UPOŽTENIA

	Fast	Original
Powder / Liquid Ratio (g/g)	0.40/0.11	0.40/0.11
Mixing Time (sec.)	10*	10*
Time of initial extrusion after mixing	10 seconds maximum	
Working Time (min., sec.)	1'15" 2'00"	
Net Setting Time (min., sec.)	2'00" 2'20"	
Final Finishing Comming Time (min., sec.)	3'00" 6'00"	
Test conditions: Temperature (23 +/- 1°C), Relative humidity (50 +/- 5%)		
ISO 9917-1 Glass polyalkenový cement, Výplň		

Test conditions: Temperature (23 +/- 1°C), Relative humidity (50 +/- 5%)

COMPOSITION

Powder: Fluoro-alumino-silikátne sttko, poliakrylná kiselina, pigment.

Liquid: Distilled water, poliakrylic acid, carboxylic acid.

DIREKCIJE ZA UPORABO

Fast	Original
Powder / Liquid Ratio (g/g)	0.40/0.11
Time of initial extrusion after mixing	10*
Working Time (min., sec.)	1'15" 2'00"
Net Setting Time (min., sec.)	2'00" 2'20"
Final Finishing Comming Time (min., sec.)	3'00" 6'00"

Test conditions: Temperature (23 +/- 1°C), Relative humidity (50 +/- 5%)

INDICATIONS FOR USE

- Class I and II restorations in deciduous teeth.
- Intermediate restorative and base material for heavy stress situation in Class I and Class II cavities using sandwich laminate technique.
- Class V and root surface restorations.
- Core build-up.

CONTRAINDICATIONS

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

COMPOSITION

Powder: Fluoro-alumino-silikátne sttko, poliakrylná kiselina, pigment.

Liquid: Distilled water, poliakrylic acid, carboxylic acid.

DIRECTIONS FOR USE

Fast	Original
Powder / Liquid Ratio (g/g)	0.40/0.11
Time of initial extrusion after mixing	10*
Working Time (min., sec.)	1'15" 2'00"
Net Setting Time (min., sec.)	2'00" 2'20"

Test conditions: Temperature (23 +/- 1°C), Relative humidity (50 +/- 5%)

ISO 9917-1 Glass polyalkenový cement, Restoration.**1. CAVITY PREPARATION**

- Prepare tooth using standard techniques.
- Extensive mechanical retention is unnecessary.
- Apply G.C. CAVITY CONDITIONER (10 seconds) or G.C. 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 by gently blowing with an air syringe. DO NOT DISCULATE. Prepared surface should appear moist (glossy).

2. CARRIER ACTIVATION AND MIXING

- Before activation, shake the capsule or tap it 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).
- Note:

1) Ensure the plunger is not pressed to avoid the incident loss of powder and liquid.

2) The capsule should be activated just before mixing and used immediately.

3) Immediately set it into a mixer (or amalgamator) and mix for 10 seconds (~4,000 RPM) (Fig. 4).

Note: VV11en using a rotational mixing device, it is recommended not to use the centrifuge option.

3. RESTORATIVE TECHNIQUE

- Immediately apply the mixed capsule from the start of mixing at 23°C (73.4°F). Higher temperatures will shorten working time.
- Wait 10 seconds maximum after mixing, start to extrude the mixture directly into the preparation (Fig. 5).
- Form the initial temporary contour, and cover with a rubber-dam (Fig. 6).

During the first 3 minutes from start of mix extra care should be taken to avoid moisture contamination and drying-out. In case this cannot be guaranteed, immediately apply or GC Fuji Varnish (blue dry) or GC Fuji Coat LC (light cure).

Note:

1) To adjust the direction of the nozzle, hold the applicator with the capsule towards you and turn the capsule body.

2) Turn the used capsule, push the applicator release button. Twist the capsule and pull upwards.

4. FINISHING

- Final finish using water spray using standard techniques (not recommended for approximately 3 minutes after start of mixing) (Fig. 7).
- Apply a final coat of G.C. COAT PLUS and light cure for 20 seconds (Fig. 8).

After mixing, apply GC Fuji VARNISH (blue dry) or GC Fuji COAT LC (light cure) Refer to the respective instructions for use.

c) Instruct the patient not to apply pressure for 1 hour.

5. STORAGE

Recommended for optimal performance, store in a cool and dark place (4-25°C) (39-77.0°F).

SHADES

Shade numbers according to Vita® shade guide. Vita® is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.

PACKAGES

- Single shade package : 50 capsules.
- Assortment package (10 each of A2,A3,A5,B2,B3).

Average weight per capsule: 0.40g (0.09ml).

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 see medical physician.

3. Protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.

4. In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of product and refer to a physician.

Some products mentioned 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>. They can also be obtained from your supplier.For the Summary of Safety and Clinical Performance (SSCP) please see EUDAMED database (<https://ec.europa.eu/europa/eudamed>) or contact us at Regulatory.gce@gc.dental.

Undesired effects- Reporting:

If you become aware of any kind of undesired effect, reaction or similar event caused 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:

http://www.geurope.com/growth/sectors/medical-devices/contacts_en as well as to our internal vigilance system:[vigilance@gc.dental](http://www.vigilance.gc.dental).

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

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Last revised : 03/2023

Postledna redakcia : 03/2023

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For the Summary of Safety and

Для получения юридической информации о безопасности и клинической эффективности (SSCP), пожалуйста, обратитесь к базе данных EUDAMED (<https://ec.europa.eu/tools/eudamed>) или свяжитесь с нами по адресу Regulatory.gce@gc.dental

Информация о некоторых субстанциях, которые имеют признаки неизвестного соединения/вещества, при использовании высвобожденного материала на территории Российской Федерации, может быть направлена уполномоченному представителю производителя в РФ, ООО «Крайтфарм»:
e-mail: derm@krfarm.ru
129262, г. Москва, 3-я Мышинская, д. 16, строение 60, комната 30, помещение 1, этаж 5, к. 8-495 232-69-33.

Последняя редакция : 03/2023

Pred použitím si dôkladne prečítejte návod na použitie.

GC Fuji™ IX GP FAST

RADIOOPÁPNÝ SKLJONOMERNÝ VÝPLŇOVÝ MATERIÁL V KAPSULÍKU PRE VYPLENIE V LATERÄROM NÁSKA
GC Fuji IX GP FAST je rýchlo-hnútka verzia GC Fuji IX GP CAPSULE. Uprabovala sa ako profesionálne lenamene v prípravenej indikácii.

INDIKÁCIE ZA UPORABO
1. Restaurácie I a II razredu pri mliečnih zubech.
2. Restaurácie I a III razredu pri stálini zubech, ktorí sú obremjenené.
3. Vmesi restatívami v bázovi materiale pri restatívach I a II razredu, ktorí sú močno obremjenené ktorí sú močno obremjenené.
4. Restatívna výzera v hraniciach na korenskú površinu.
5. Izgrevanie jednotlivých zubov.

KONTRAINDIKÁCIE
1. Drukovej trhlej pulpe.
2. Izbezpečuje uporelégia proizvodu pri pacientoch z znano alergiou na skljonomerový restatívny cement.

SESTAVA
Práh: Fluor-aluminiový silikátový sklo, poliakrylná kisílna, barvilo. Tekočina: Destilovaná voda, poliakrylná kisílna, karboksílna kisílna.

NAVODILA ZA UPORABO

Fast	Original
Razmerje práh / tekočina (g/g)	0,40 / 0,11 0,40 / 0,11
Cas mešanja (sek.)	10* 10*
Cas začiatku ekstrusie po mešanju	Maksimalno 10 sekund
Delovní čas (min., sek.)	1'15" 2'00"
Neto čas strivajania (min., sek.)	2'00" 2'20"
Pribeh časa za odberanie	3'00" 6'00"

Testovacie podmienky: Teplota: (23+/-1°C),
Relativná vlhkosť (50+/-5%)

ISO 9917-1 Stekleni polialkenovaty cement, Restauracia.

PRÍPRAVA KAVITÉTE
a) Zub prípravu s pomocou običajnej techniky. Obecná mechanická referencia ni potrebná. Za začiatku pulpe uporabite kalidic hidskrid.

b) Nameste GC CAVITY CONDITIONER (10 sekund) alebo GC DENTIN CONDITIONER (20 sekund) na výzbrovou plôchu z držiteľa.

c) Pracovný čas (min., sek.)* 1'15" 2'00"

d) Čistý čas (min., sek.)* 2'00" 2'20"

Zadotok konečného opracovania (37°C, po batom mešaní) (min., sek.) 3'00" 6'00"

Testovacie podmienky: Teplota: (23+/-1°C),
Relativná vlhkosť (50+/-5%)

ISO 9917-1 Sklo polalkenočtový cement, Výplň.

1. PRÉPARATION DE LA CAVITÉ

a) Zub préparer avec la technique standardisée de l'outil. Veiller à l'absence mécanique de référence ni la nécessité. Pour la préparation de la cavité pulpausez avec calidic hidrosid.

b) Appliquer GC CAVITY CONDITIONER (10 secondes) ou GC DENTIN CONDITIONER (20 secondes) sur la surface de travail avec un gobelet.

c) Temps de travail (min., sec.)* 1'15" 2'00"

d) Temps de nettoyage (min., sec.)* 2'00" 2'20"

2. ACTIVATION DU CAPSULE ET MISE EN PLACE

a) Pré aktivier le capsule et l'insérer dans l'outil de travail pour la pulpe. Appliquer la pulpe à la surface de travail.

b) Activer le capsule jusqu'à ce qu'il entre dans le dentine.

c) Utiliser le gobelet pour dégager la pulpe de la cavité.

d) Utiliser le gobelet pour dégager la pulpe de la cavité.

e) Utiliser le gobelet pour dégager la pulpe de la cavité.

f) Utiliser le gobelet pour dégager la pulpe de la cavité.

3. TECHNIQUE DE RESTAURATION

a) Zmesávanie kapsulu takto zanzimejte z mesáca vo jeho súčasnosti.

b) Nameste GC Capsule Applier.

c) Delovní čas je 1 minuta a 15 sekund od početka

d) Čistý čas je 1 minuta a 15 sekund od začiatku

e) Pracovný čas je 1 minuta a 15 sekund od začiatku

f) Početky času: 1'15" 2'00"

g) Početky času: 2'00" 2'20"

3. TECHNIQUE DE RESTAURATION

a) Zmesávanie kapsulu takto zanzimejte z mesáca vo jeho súčasnosti.

b) Nameste GC Capsule Applier.

c) Delovní čas je 1 minuta a 15 sekund od početka

d) Čistý čas je 1 minuta a 15 sekund od začiatku

e) Pracovný čas je 1 minuta a 15 sekund od začiatku

f) Početky času: 1'15" 2'00"

g) Početky času: 2'00" 2'20"

4. KONČÍ ČAS

a) S končením obdelovania pod vodním sprejem je obmedzení výkonu zlepšené.

b) Dvojkrátky výtržky výkonu v kapsule.

c) Pracovný čas (min., sek.) 1'15" 2'00"

d) Čistý čas (min., sek.) 2'00" 2'20"

e) Početky času: 1'15" 2'00"

f) Početky času: 2'00" 2'20"

5. TEHNOLOGIA VÝPLNE

a) Zmesávanie kapsulu výplňového zlepšeného.

b) Nameste GC Capsule Applier.

c) Delovní čas je 1 minuta a 15 sekund od začiatku

d) Čistý čas je 1 minuta a 15 sekund od začiatku

e) Pracovný čas je 1 minuta a 15 sekund od začiatku

f) Početky času: 1'15" 2'00"

g) Početky času: 2'00" 2'20"

6. KONČÍ ČAS

a) S končením obdelovania pod vodním sprejem je obmedzení výkonu zlepšené.

b) Dvojkrátky výtržky výkonu v kapsule.

c) Pracovný čas (min., sek.) 1'15" 2'00"

d) Čistý čas (min., sek.) 2'00" 2'20"

e) Početky času: 1'15" 2'00"

f) Početky času: 2'00" 2'20"

7. VYPLŇOVACÍ VÝPLŇ

a) Početky času: 1'15" 2'00"

b) Početky času: 2'00" 2'20"

c) Početky času: 1'15" 2'00"

d) Početky času: 2'00" 2'20"

e) Početky času: 1'15" 2'00"

f) Početky času: 2'00" 2'20"

8. VYPLŇOVACÍ VÝPLŇ

a) Početky času: 1'15" 2'00"

b) Početky času: 2'00" 2'20"

c) Početky času: 1'15" 2'00"

d) Početky času: 2'00" 2'20"

e) Početky času: 1'15" 2'00"

f) Početky času: 2'00" 2'20"

9. VYPLŇOVACÍ VÝPLŇ

a) Početky času: 1'15" 2'00"

b) Početky času: 2'00" 2'20"

c) Početky času: 1'15" 2'00"

d) Početky času: 2'00" 2'20"

e) Početky času: 1'15" 2'00"

f) Početky času: 2'00" 2'20"

10. VYPLŇOVACÍ VÝPLŇ

a) Početky času: 1'15" 2'00"

b) Početky času: 2'00" 2'20"

c) Početky času: 1'15" 2'00"

d) Početky času: 2'00" 2'20"

e) Početky času: 1'15" 2'00"

f) Početky času: 2'00" 2'20"

11. VYPLŇOVACÍ VÝPLŇ

a) Početky času: 1'15" 2'00"

b) Početky času: 2'00" 2'20"

c) Početky času: 1'15" 2'00"

d) Početky času: 2'00" 2'20"

e) Početky času: 1'15" 2'00"

f) Početky času: 2'00" 2'20"

12. VYPLŇOVACÍ VÝPLŇ

a) Početky času: 1'15" 2'00"

b) Početky času: 2'00" 2'20"

c) Početky času: 1'15" 2'00"

d) Početky času: 2'00" 2'20"

e) Početky času: 1'15" 2'00"

f) Početky času: 2'00" 2'20"

13. VYPLŇOVACÍ VÝPLŇ

a) Početky času: 1'15" 2'00"

b) Početky času: 2'00" 2'20"

c) Početky času: 1'15" 2'00"

d) Početky času: 2'00" 2'20"

e) Početky času: 1'15" 2'00"

f) Početky času: 2'00" 2'20"

14. VYPLŇOVACÍ VÝPLŇ

a) Početky času: 1'15" 2'00"

b) Početky času: 2'00" 2'20"

c) Početky času: 1'15" 2'00"

d) Početky času: 2'00" 2'20"

e) Početky času: 1'15" 2'00"

f) Početky času: 2'00" 2'20"

15. VYPLŇOVACÍ VÝPLŇ

a) Početky času: 1'15" 2'00"

b) Početky času: 2'00" 2'20"

c) Početky času: 1'15" 2'00"

d) Početky času: 2'00" 2'20"