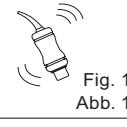




ND3702  
30001341  
IFU Fuji PLUS CAPSULE

Prior to use, carefully read the instructions for use.



## GC Fuji PLUS™ CAPSULE

RADIOPAQUE REINFORCED GLASS IONOMER LUTING CEMENT IN CAPSULE

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

### INDICATIONS FOR USE

- Cementation of metal-based inlays, onlays, crowns and bridges
- Cementation of resin inlays, onlays, crowns and bridges
- Cementation of all ceramic inlays
- Cementation of high strength (zirconia based) all ceramic crowns and bridges
- Cementation of metal, ceramic and fiber posts

### CONTRAINDICATIONS

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

### COMPOSITION

Powder: Fluor-alumino-silicate glass, initiator, pigment  
Liquid: Methacrylate, water, polyacrylic acid, dimethacrylate, carboxylic acid, stabilizer.

### DIRECTIONS FOR USE

Powder / Liquid ratio (g/g)	0.36 / 0.18
Mixing time (sec.)	10"
Working Time (23°C / 73°F) (min., sec.)	2'00"
Finishing time (37°C / 99°F, after seating the restoration) (min., sec.)	4'15"

ISO 9917-2 Class 1 / Luting

- TOOTH PREPARATION**  
a) Prepare tooth in usual manner. For direct pulp capping, use calcium hydroxide.  
b) Clean the prepared teeth with pumice and water.  
Note:  
Apply GC Fuji PLUS CONDITIONER for 20 seconds using a cotton pellet or sponge.
- RINSING**  
c) Rinse thoroughly with water. Remove excess moisture by blotting with a cotton pellet or gently bowing with an oil-free air. DO NOT DESCALICATE.
- RESTORATION PREPARATION**  
d) Best results are obtained when prepared surfaces appear moist (glistening).

### RESTORATION

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

### CAPSULE ACTIVATION AND MIXING

- Before activation, shake the capsule or tap its side on a hard surface to loosen the powder (Fig. 1).
- To activate the capsule, push the plunger until it is fully depressed with the main body and hold it down for 2 seconds (Fig. 2).
- Note:  
1) Ensure the plunger is fully pressed to avoid the incorrect mixing ratio of powder and liquid.  
2) The capsule should be activated just before mixing and used immediately.

c) Immediately set it into a mixer (or an amalgamator) and mix for 10 seconds (+/- 4,000 RPM) (Fig. 3).

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

- DISPENSING**  
a) Immediately remove the mixed capsule from the mixer and load it into the GC CAPSULE APPLIER.  
b) Make two clicks to prime the capsule (Fig. 4). To adjust the direction of the nozzle, hold the applier with the capsule towards you and turn the capsule body.  
c) Extrude directly into the restoration (Fig. 5).  
d) To remove the used capsule, push the applier release button. Twist the capsule and pull upwards.

### 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 will shorten working time.

Note:  
For more complex procedures requiring longer working time, it is recommended to refrigerate the capsules in the original aluminum foil.

- Maintain moderate pressure.  
c) Start removing excess cement when the excess cement feels rubbery (Fig. 6).

d) Finishing can be started 4 minutes 15 seconds after seating the restoration.

### STORAGE

Recommended for optimal performance, store the capsules in the original aluminum foil in a cool and dark place 4-25°C (39.2-77.0°F).

### SHADES

Yellow  
A3 (Vita® shade)

Vita® is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.

### PACKAGE

50 capsules

Average contents per capsule: 0.36 g powder and 0.18 g (0.16 mL) liquid

Minimum net volume of mixed cement per capsule: 0.19 mL

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. To avoid contact, a rubber dam and/or COCOA BUTTER can be used to isolate the operation field from the skin or oral tissue.

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

3. GC Fuji PLUS CONDITIONER contains 2% Ferric Chloride. It is not recommended to use GC Fuji PLUS CONDITIONER in combination with products containing Epinephrine as this may stain oral tissue.

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

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

5. 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.

7. 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.

For the Summary of Safety and Clinical Performance (SSCP) please see EUAMED database (<https://ec.europa.eu/tools/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 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/growth/sectors/medical-devices/contacts\\_en](https://ec.europa.eu/growth/sectors/medical-devices/contacts_en)

as well as to our internal vigilance system:

[vigilance@gc.dental](mailto:vigilance@gc.dental)

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

UK Responsible Person  
GC UNITED KINGDOM Ltd.  
Coopers Court Newport Pagnell Buckinghamshire  
MK16 8JS United Kingdom

Last revised: 05/2023

Vor der Benutzung bitte die Gebrauchsanweisung gründlich lesen! DE

## GC Fuji PLUS™ CAPSULE

RONTGENSICHTBARER VERSTÄRKTER GLAS IONOMER-BEFESTIGUNGSCHEMEL IN KAPSLEN

Nur zur Verwendung durch zahnärztliches Fachpersonal gemäß den Anwendungshinweisen.

### INDIKATIONEN ZUR ANWENDUNG

- Befestigung von metallbasierten Inlays, Onlays, Kronen und Brücken
- Befestigung von kunststoffbasierten Inlays, Onlays, Kronen und Brücken
- Befestigung von vollkeramischen Inlays
- Befestigung von hochfesten (Zr-basierten) vollkeramischen Kronen und Brücken
- Befestigung von Metall-, Keramik- und Faserstiften

### KONTRAINDIKATIONEN

- Directe Pulpaabdeckung
- Vermeiden Sie die Verwendung dieses Produkts bei Patienten mit bekannten Allergien gegen Glasionomer-Zemente, Methacrylat-Monomer oder Methacrylat-Polymer.

### KOMPOSITION

Pulver: Fluor-alumino-Silikatglas, Initiator, Pigment  
Flüssigkeit: Methacrylat, Wasser, Polyacrylsäure, Dimethacrylat, Karboxylic Acid, Stabilisator.

### DIREKTIONEN FÜR USE

Powder / Liquid ratio (g/g)	0.36 / 0.18
Mixing time (sec.)	10"
Working Time (23°C / 73°F) (min., sec.)	2'00"
Finishing time (37°C / 99°F, after seating the restoration) (min., sec.)	4'15"

ISO 9917-2 Klasse 1 / Luting

### 1. TOOTH PREPARATION

- a) Prepare tooth in usual manner. For direct pulp capping, use calcium hydroxide.  
b) Clean the prepared teeth with pumice and water.  
Note:  
Apply GC Fuji PLUS CONDITIONER for 20 seconds using a cotton pellet or sponge.
- b) Den fertig präparierten Zahn gründlich mit Wasser und Bims reinigen.  
Anm.: Durch Anwendung von GC Fuji PLUS CONDITIONER (20 sek.) wird eine optimale Adhäsion erreicht.
- c) Rinse thoroughly with water. Remove excess moisture by blotting with a cotton pellet or gently bowing with an oil-free air. DO NOT DESCALICATE.
- d) Best results are obtained when prepared surfaces appear moist (glistening).

### 2. RESTORATION

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

### 3. CAPSULE ACTIVATION AND MIXING

- a) Before activation, shake the capsule or tap its side on a hard surface to loosen the powder (Fig. 1).
- b) To activate the capsule, push the plunger until it is fully depressed with the main body and hold it down for 2 seconds (Fig. 2).
- Note:  
1) Ensure the plunger is fully pressed to avoid the incorrect mixing ratio of powder and liquid.

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

c) Immediately set it into a mixer (or an amalgamator) and mix for 10 seconds (+/- 4,000 RPM) (Fig. 3).

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

- d) To remove the used capsule, push the applier release button. Twist the capsule and pull upwards.

### 4. DISPENSING

- a) Immediately remove the mixed capsule from the mixer and load it into the GC CAPSULE APPLIER.
- b) Make two clicks to prime the capsule (Fig. 4). To adjust the direction of the nozzle, hold the applier with the capsule towards you and turn the capsule body.
- c) Extrude directly into the restoration (Fig. 5).
- d) To remove the used capsule, push the applier release button. Twist the capsule and pull upwards.

### 5. CEMENTATION

- a) 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 will shorten working time.

Note:  
For more complex procedures requiring longer working time, it is recommended to refrigerate the capsules in the original aluminum foil.

- b) Maintain moderate pressure.

c) Start removing excess cement when the excess cement feels rubbery (Fig. 6).

d) Finishing can be started 4 minutes 15 seconds after seating the restoration.

### 6. STORAGE

Recommended for optimal performance, store the capsules in the original aluminum foil in a cool and dark place 4-25°C (39.2-77.0°F).

### SHADES

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### PACKAGE

50 capsules

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Minimum net volume of mixed cement per capsule: 0.19 mL

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. To avoid contact, a rubber dam and/or COCOA BUTTER can be used to isolate the operation field from the skin or oral tissue.

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3. GC Fuji PLUS CONDITIONER contains 2% Ferric Chloride. It is not recommended to use GC Fuji PLUS CONDITIONER in combination with products containing Epinephrine as this may stain oral tissue.

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

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

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[https://ec.europa.eu/growth/sectors/medical-devices/contacts\\_en](https://ec.europa.eu/growth/sectors/medical-devices/contacts_en)

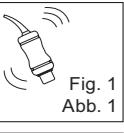
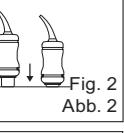
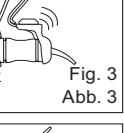
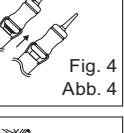
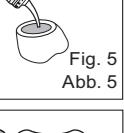
as well as to our internal vigilance system:

[vigilance@gc.dental](mailto:vigilance@gc.dental)

**ADVARSLER**

- Hvis materialet kommer i kontakt med oral blæddelsvæv eller huden: så fjernes det umiddelbart med en svamp eller bomuldsstøtte, fugtet med vand. Skyld rigtigt med vand. Vi anbefaler at anvende kofferdam og/eller kokos smør som isolering af operationsområdet.
- I tilfælde af at materialet kommer i øjenene skyldes omhyggeligt med vand og læge konsekvens.
- GC Fuji PLUS CONDITIONER indeholder 2% jernklorid. Dérfor anbefuleres der ikke anvende GC Fuji PLUS CONDITIONER i kombination med produkter som inneholder adrenalín då det kan resultere i mifasfaring af oral væv.
- Anvend ikke GC Fuji PLUS CAPSULE i kombination med materialer som inneholder eugenol. Eugenol kan forhånd GC Fuji PLUS CONDITIONER til steina og det kan også orsaka et binding til tanden inte blir av.
- Denna produkt är inte indicerad för fyllningar eller perlepryppygna.
- I saltsyntetisk kan produkten framkalla allergi hos känsliga personer. Ifallsdåta reaktioner skall upptäckta, avbryt användningen av produkten och se till läkare.
- Använd alltid handskar, mundskydd och skyddsglasögon eller annan personlig skyddsutrustning.
- Vissa produkter som härvässar till i nuvarande Brusavarsning kan anses som farliga i enlighet med GHS. Därmed, här är alltid uppdaterade med varå aktuella Säkerhetsdatablad. Dessa finner ni på:

  - <http://www.gceurope.com>
  - Dessa kan också erhållas från din leverantör.

Fig. 1  
Abb. 1Fig. 2  
Abb. 2Fig. 3  
Abb. 3Fig. 4  
Abb. 4Fig. 5  
Abb. 5

Läs bruksanvisningen noggrant före användning.

**GC Fuji PLUS™ CAPSULE**

RÖNTGENKONTRASTERANDE FÖRSTÄRKT GLASJONOMER FOR CEMENTERING I KAPSLEAR

Får endast användas av tandvårdspersonal enligt indikationerna för användning.

**INDIKATION FÖR ANVÄNDNING**

- Cementering av metallbaserade inlägg, onlays, kronor och broar
- Cementering av resinbaserade inlägg, onlays, kronor och broar
- Cementering av helkeramiska inlägg
- Cementering av högfärgstarka (zirkoniumdioxidbaserade) keramiska kronor och broar
- Cementering av metall-, keramik- och glasfiberpelare

**KONTRAINDIKATIONER**

- Direkt pulpaöverkapping.
- Undvik användning av denna produkt på patienter med känd allergi mot glasjonomercement, metakrylat monomerer eller metakrylat polymerer.

**INNEHÅLL**

Pulver: Fluoro-aluminium-silikatglas, initiatör, pigment. Vätske: Metakrylat, vatten, polyakrylsyra, dimetylakrylat, karboksylsyra, stabilisator.

**BRUKSANVISNING**

Pulver / vätske relation (g/g)	0,36 / 0,18
Blandningsstd (sek.)	10"
Arbetsstd (vid 23°C/73°F) (min., sek.)	2'00"
Slutlig finishing kan påbörjas (37°C/99°F, efter fastsättning av restaurerationen) (min., sek.)	4'15"

**ISO 9917-2 Klass 1 / Luting****1. PREPARATION AV TANDEN**

- Preparer tanden på svedligt sätt. Ifall önskvärt, använd kalciumpolymer för direkt pulpaöverkapping.
- Rengör och preparera tanden med pimsten och vatten.
- Använd GC Fuji PLUS CONDITIONER under 20 sekunder på den preparerade tanden för optimal adhesion.
- Skölj noggrant med vatten. Torka fysiskt med bomulspellet eller blästra fysiskt med oljeft luft. DEHYDRERA INTE. De preparerade ytorna ska se lätt fuktiga ut (glittrande).

**2. PREPARATION AV ERSÄTTNINGEN**

Försäkra dig om att ersättningen är förbehållad enligt tillverkarens instruktioner.

**3. AKTIVERING AV KAPSELN OCH BLANDNING**

- Skaka kapseln eller knacka den mot bordskivan i syfte att frigöra pulvert. (Fig. 1)

Aktivera kapseln genom att trycka in knappen så att den kommer i ett nära så jämt läge i förlängning till kapselkroppen, här i ett sekunder. (Fig. 2)

Notera: 1) Kontrollera att kolven är helt intykt för att undvika felaktiga blandningsförhållanden mellan pulver och vätska.

2) Kapseln ska aktiveras direkt före tillblandningen och användas omedelbart.

3) Sätt omedelbart kapseln i blandningsapparaten (eller amalgamblandare). Blanda under 10 sekunder (+/- 4.000 RPM). (Fig. 3)

Notera: Om en roterande blandare används för G-Cem kapslar rekommenderar vi att inte använda blandaren centrifugfunktion.

**4. APPLICERING AF CEMENTET**

a) Tag kapseln från blandningsmaskinen och placera den åter i GC CAPSULE APPLIER.

b) Pressa samman hållaren två gånger så atttvå "klick hör". (Fig. 4). Kapseln spets kan vridas efter önskemål genom att hela kapseln vrider i hållaren.

c) Applicera cement direkt från kapseln i restaurerationen (Fig. 5).

d) Avlägsna kapseln från hållaren efter att spärknappen trycks in. Vrid kapseln och drag den sedan ur hållaren.

**5. CEMENTERING**

a) Täck den irre ytan på ersättningen med tillräckligt mycket cement och sätt omedelbart på plats. Arbetstiden är 2 minuter från blandningstart vid 23°C (73°F). Högre temperatur förkortar arbetstiden. Eftl längre arbetstid önskas förvara patronen i kylskåp.

Notera: Då komplexa protetiska ersättningar, som kräver längre arbetstid, ska cementeras rekommenderas att kylskåpservera cementkläpparna i originaltillverkning av aluminium.

b) Behåll ett mättigt tryck på restaureringen.

c) Avlägsna överskötselmeden med en scaler när cementet är gummiklätt (Fig. 6).

d) Finishing kan påbörjas 4 minuter 15 sekunder efter att ersättningen är på plats.

**FÖRVARING**

For optimala resultat, förvaras kallt och mörkt (4-25°C) (39,2-77,0°F).

**FÄRGER**

Gu

A3 (färger enligt Vita® skalan)

Vita® är ett av Vita Zahnfabrik, Bad Säckingen, Tyskland, registrerat varumärke.

**FÖRPACKNINGAR**

50 kapslar

Genomsnittligt innehåll per kapsel: 0,36 g pulver och 0,18 g (0,16 mL) vätska

Minimum nettoyrom blandat cement per kapsel: 0,19 mL

Tilval: GC CAPSULE APPLIER (1 ST)

**VARNING**

1. Om materialet kommer i kontakt med oralia mjukvävader eller huden: avlägsna omedelbart materialet med svamp eller bomull som fuktats i alkohol. Spola riktigt med vatten. Vi rekommenderar att

**CUIDADO**

- Em caso de contacto com o tecido oral ou pele, retire imediatamente com uma esponja ou algodão embebido em álcool. Lave com água. Para evitar o contacto, pode usar um dique de borraça ou COCOA BUTTER para isolar o campo operatório da pele e tecido oral.
- Em caso de contacto com os olhos, lave imediatamente com água e consulte o médico.
- O CONDICIONADOR GC Fuji PLUS contém 2% de cloreto férmico. Não se recomenda a utilização do CONDICIONADOR GC Fuji PLUS em combinação com produtos que contenham epinefrina, pois poderá tingir o tecido oral.
- Não utilize o GC Fuji PLUS CAPSULE em combinação com materiais que contenham eugenol, pois o eugenol pode impedir que o GC Fuji PLUS CAPSULE endureça ou adira adequadamente.
- Este produto não é indicado para obturações ou reconstruções.
- Em casos raros, o produto pode provocar reações de sensibilidade emalgumas pessoas. Caso se observem reações desse género, interrompa o uso do produto e consulte um médico.
- Equipamentos de proteção individual (EPI) tais como tovas, máscaras e óculos de segurança devem ser sempre utilizados.

Vissa produkter som härvässar till i nuvarande Brusavarsning kan anses som farliga i enlighet med GHS. Därmed, här är alltid uppdaterade med varå aktuella Säkerhetsdatablad. Dessa finner ni på:

<http://www.gceurope.com>

Dessa kan också erhållas från din leverantör.

För sammanfattingen av Säkerhet och Klinisk prestation (SSCP) var vanlig se EU-DAMED databases (<https://ec.europa.eu/tools/eudamed>) eller kontakta oss: Regulatory@gc.dental

Rapportering av oönskade effekter:

Om du upptäcker något av förmånen för att rapportera dem direkt till Lagmeddelningsrådet eller via detta link [https://ec.europa.eu/growth/sectors/medical-devices/contacts\\_en](https://ec.europa.eu/growth/sectors/medical-devices/contacts_en)

Samt till viktige övervägningssystem: vigilance@gc.dental

Herved hjälper du med till att förbedra säkerheten för denna produkt.

Reviderad senast: 05/2023

Sist redigerad: 05/2023

Ultima revisão: 05/2023

Sist oppdatert: 05/2023

Värmestis päivitys: 05/2023

Värmestis parantaama tänään tuotteen turvalisuutta.

Värmestis tekninen tieto: 05/2023

Värmestis tekninen tieto: 05/2023