

# GC Fuji® VII EP CAPSULE

RADIOPAQUE GLASS IONOMER PROTECTION AND TEMPORARY RESTORATIVE MATERIAL WITH RECALDENT™ (CPP-ACP)  
RECALDENT™ (CPP-ACP): Casein Phosphopeptide - Amorphous Calcium Phosphate

Prior to use, carefully read the instructions for use.

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

## RECOMMENDED INDICATIONS

1. Root surface protection
2. Fissure protection
3. Hypersensitivity prevention and control
4. Protection for immature enamel
5. Temporary filling of endodontic access
6. Intermediate restorations

## CONTRAINDICATIONS

1. Pulp capping.
2. Avoid use of this product in patients with known allergies to glass ionomer cement.
3. Casein Phosphopeptides are derived from milk casein. Do not use this material on patients with a proven or suspected milk protein allergy or sensitivity.

## DIRECTIONS FOR USE

Powder / Liquid Ratio (g/g)	0.30 / 0.15
Mixing Time (sec.)	10"
Working Time (23°C/73°F) (min., sec.)	1'40"
Net Setting Time (37°C/99°F) (min., sec.)	2'30"
Finishing Time (37°C/99°F, from start of mixing) (min.,sec.)	6'00"
PINK, COMMAND SET technique	
Finishing Time (37°C/99°F, from start of mixing) (min.,sec.)	4'00"

## A. ROOT SURFACE PROTECTION, FISSURE PROTECTION, HYPERSENSITIVITY PREVENTION AND CONTROL, PROTECTION OF IMMATURE ENAMEL

### 1. SURFACE PREPARATION

- a) After cleaning the tooth surfaces (prophylaxis with pumice and water) in usual manner, rinse thoroughly with water.

Note:

If extra adhesion is desired, application of CAVITY CONDITIONER (10 seconds) or DENTIN CONDITIONER (20 seconds) is recommended. Rinse thoroughly with water.

- b) Blot away excess water with a cotton pellet or dry by gently blowing with oil-free air (Fig. A-1).

DO NOT DESICCATE. Prepared surfaces should appear moist (glistening).

### 2. CAPSULE ACTIVATION AND MIXING

- a) Before activation, shake the capsule or tap its side on a hard surface to loosen the powder (Fig. A-2).
- 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. A-3).

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. A-4).

### 3. RESTORATIVE TECHNIQUE

- a) Immediately remove the mixed capsule from the mixer. If needed, attach a GC Elongation Tip on the capsule nozzle firmly until it clicks. GC Elongation Tip can only be attached to Capsule with a retention ring on the nozzle (Fig. A-5). Do not attach the tip on other capsules.

- b) Immediately place the capsule into a GC CAPSULE APPLIER.

- c) Make two clicks to prime the capsule (Fig. A-6).

The working time is 1 minute 40 seconds from the start of mixing at 23°C (73°F). Higher temperature will shorten working time.

- d) Extrude the mixture onto the tooth surface (Fig. A-7) then use a brush to spread a thin film of GC Fuji VII EP directly over the surface to be treated. Keep the tip immersed in the cement while dispensing to avoid trapping air.

Note:

1) COMMAND SET: The initial set of GC Fuji VII EP PINK can be accelerated using the energy from a dental halogen light curing device. Place light guide as closely as possible to the cement surface and cure for 20-40 seconds. After light cure, protect the surface with GC Fuji VARNISH or GC Fuji COAT LC.

2) To adjust the direction of the nozzle, hold the applicator with the capsule towards you and turn the capsule body. If necessary, capsule nozzle can be bent.

3) To remove the used capsule, push the applicator release button. Twist the capsule and pull upwards.

- e) When set, immediately apply GC Fuji VARNISH (blow dry) or GC Fuji COAT LC (light cure for 10 sec) (A-8).

### 4. FINISHING

- a) Finishing under air water spray can be performed 6 minutes from start of mix (chemically set) or 4 minutes if light cured. Use a superfine diamond bur or a silicone finishing point (Fig. A-9).

- b) Apply a final coat of GC Fuji VARNISH (blow dry) or GC Fuji COAT LC (light cure for 10 sec.) (Fig. A-10).

Note:

For fissure protection, Section 4 is not necessary.

## B. TEMPORARY FILLING OF ENDODONTIC ACCESS

### 1. PULP CHAMBER PREPARATION

- a) After appropriate pulp treatment, clean and gently dry the pulp chamber with oil-free air (Fig. B-1).

- b) Fill the chamber with a cotton pellet (Fig. B-2).

### 2. CAPSULE ACTIVATION AND MIXING

- See directions in A (above), Section 2.

### 3. RESTORATIVE TECHNIQUE

- a) See directions in A, Section 3, a), b) and c).
- b) Extrude the mixture directly over the cotton pellet (Fig. B-3).

Note:

If a faster set is desired, use COMMAND SET technique.

See directions in A, Section 3.

### 4. FINISHING

- See directions in A, Section 4.

## C. INTERMEDIATE RESTORATIONS

### 1. SURFACE PREPARATION

- a) Remove caries and loose debris with hand instruments.

Note:

If extra adhesion is desired, application of CAVITY CONDITIONER (10 seconds) or DENTIN CONDITIONER (20 seconds) is recommended. Rinse thoroughly with water.

- b) Blot away excess water with a cotton pellet or dry by gently blowing with oil-free air (Fig. C-1). DO NOT DESICCATE. Prepared surfaces should appear moist (glistening).

### 2. CAPSULE ACTIVATION AND MIXING

- See directions in A (above), Section 2.

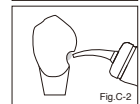
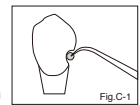
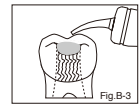
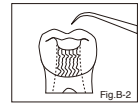
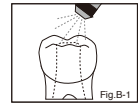
### 3. RESTORATIVE TECHNIQUE

- a) See directions in A, Section 3, a), b) and c).
- b) Extrude the mixture directly over the prepared lesion or tooth surface (Fig. C-2). Form the contour and if possible cover with a matrix.

Note:

If a faster set is desired, use COMMAND SET technique. See directions in A, Section 3.

- c) See directions in A, Section 4.



## SHADE

Pink, White

## STORAGE

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

## PACKAGE

50 capsules

Average contents per capsule: 0.30 g powder and 0.15 g (0.12 mL) liquid

Minimum net volume of mixed cement per capsule: 0.13 mL

## CAUTION

1. 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. Wear plastic or rubber gloves during use.
2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. 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.
4. 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.gcaustralasia.com>

They can also be obtained from your supplier.

## 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.

## NOTE

Recaldent™ (CPP-ACP) technology was developed by Melbourne Dental School, The University of Melbourne, Australia.

\*RECALDENT is a trademark used under licence. Recaldent™ (CPP-ACP) technology has related patents or patents pending in Australia, NZ, Europe, Canada and U.S.A.

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