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 1639

# Glass Ionomer Cement-Filling I Instructions for Use

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

## RECOMMENDED INDICATIONS

1. Restoration of primary teeth.
2. Restorations of Class III, V and limited Class I cavities.
3. Base linings under composite and amalgam.
4. Core build-up.

Powder/Liquid ratio (g/g)	2.3~2.9/1.0
Mixing time (min., sec.)	1'00"
Working time (min., sec.) (at 23°C) (from start of mixing)	1'00"~2'00"
Net setting time (min., sec.) (from end of mixing)	1'30"~6'00"

## CONTRAINDICATIONS

1. Pulp capping.
2. 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.

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## DIRECTIONS FOR USE

1. POWDER AND LIQUID DISPENSING
  - a) The standard powder to liquid ratio is 2.3g ~ 2.9g: 1.0g (slightly adjusted according to use habit and environmental temperature), 1 level scoop of powder to 1 drop of liquid.
  - b) For accurate 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.
2. MIXING  
 Dispense powder and liquid onto the pad. Using the plastic spatula, divide the powder into 2 equal parts. Mix the first portion with all of the liquid. Incorporate the remaining portion and mix the whole thoroughly (total time within 60 seconds);
3. RESTORATIVE TECHNIQUE
  - a) Prepare tooth using standard techniques. Only remove the carious substance; no extensive mechanical retention required.
  - b) Blow the cavity dry in only 2-3 short intervals with water and oil-free air or dab dry with cotton pellets. Do not over-dry!

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- c) Mix the required amount of cement. Working time is 1-2 minutes at 23°C (73.4°F). Higher temperatures will shorten working time.
- d) Remove surface moisture, but DO NOT DESICCATE.
- e) Transfer cement to the preparation using a syringe or suitable placement instrument.
- f) Form the contour during the first 2 minutes of setting.
- g) Setting time is 1.5-6 minutes from start of mixing depending on powder to liquid ratio (23°C).

## 4. FINISHING

- a) One visit treatment
  - 1) 7-10 minutes after initial set, correct the contour, finish and polish WITHOUT WATER SPRAY using standard techniques.
  - 2) Apply standard GIC water-proofing agent or Vaseline on surface of restoration to proof water.
- b) Standard method  
 24 hours after placement, finish and polish the restoration under water spray using standard techniques.

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## STORAGE

Store in a cool and dark place (4-25°C) (39.2-77.0°F).  
 (Shelf life: 3 years from date of manufacture)

## SHADE

A1, A2, A3

## PACKAGES

1. powder
2. liquid
3. powder measure
4. mixing pads

## 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.
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.

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4. Notification of any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in your country.

## Warranty

HUGE warrants this product will be free from defects in material and manufacture. HUGE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and HUGE's sole obligation shall be repair or replacement of the HUGE product.

## Limitation of Liability

Except where prohibited by law, HUGE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

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## Symbols for use in the labelling

- Temperature limit - Keep away from sunlight

- Keep dry - Caution - Use-by date

- Batch code - Manufacturer - Recycling

- Authorized representative in the European Community

- Consult instructions for use

- Caution: U.S. Federal Law restricts this device to sale by or on the order of a dentist or professionals.

- Country of manufacture

- Medical device

- Unique device identifier

- Model number

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