

Glaslonomer FX-LC CAPSULE



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en Instructions for use

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READ CAREFULLY BEFORE USE

en Light-cured Glass Ionomer Restorative

PRODUCT DESCRIPTION

Glaslonomer FX-LC CAPSULE is a self-adhesive resin-modified glass ionomer restorative.
Glaslonomer FX-LC Conditioner, a cavity conditioning agent, can be used to enhance adhesion to the tooth structure.

INTENDED PURPOSE

(Intended purpose)

Glaslonomer FX-LC CAPSULE is intended for restoration of teeth.

(Intended patient population)

From child to adult

(Clinical benefit)

For direct dental restorations in cavities and lesions in anterior and posterior teeth

INDICATIONS FOR USE

- Restorations of deciduous teeth
- Non-load bearing Class I and Class II restorations in permanent teeth
- Restorations of Class V cavities and wedge-shaped defects

PRECAUTIONS AND WARNINGS

1. Do not use this product if a patient or an operator is known to be allergic to this product or any of the material's ingredients.
2. If any inflammation or other allergic reactions occur on either the patient or operator while using this product, immediately discontinue use and seek medical advice.
3. Use medical (dental) gloves and protective glasses to avoid sensitization to this product. In case of accidental contact with oral soft tissue or skin, immediately blot with alcohol moistened cotton ball, and rinse with plenty of water. Medical (dental) gloves provide some protection against direct contact with this material; however, some monomers can penetrate through the gloves very quickly to reach the skin. Therefore, should this material contact even the gloves, immediately remove them and wash hands with plenty of water. In case of contact with eyes, immediately flush the eyes with plenty of water and seek medical advice.
4. Use Glaslonomer FX-LC Conditioner in well-ventilated area to avoid inhalation of acetone. If inhalation causes nausea or illness, take rest and keep warm in fresh air.
5. Avoid any source of ignition since Glaslonomer FX-LC Conditioner is flammable.
6. In case serious health hazards occur on a patient or an operator by use of this product, please report to local competent authority, our local distributor and sales company. Contact information on our sales companies is available on www.shofu.com.

DIRECTIONS FOR USE

1. Cleaning of tooth surface

Thoroughly clean the tooth surface to remove plaque.

2. Shade selection

Select the appropriate shade using a shade guide while the tooth is still moist.

3. Cavity preparation

Prepare the cavity following the standard method.

4. Isolation

Use a rubber dam etc., to isolate the restoration site.

5. Pulp protection

In the case of pulp exposure or deep cavities with close proximity to the pulp, cap the pulp with calcium hydroxide, etc.

- Do not use eugenol containing materials and hydrogen peroxide since they might inhibit polymerization or adhesion of this product.

6. Tooth surface conditioning

Use Glaslonomer FX-LC Conditioner as necessary. Dispense adequate

amount of the material on a disposable dish, apply to the prepared cavity with a disposable brush, and immediately dry with air blow.

- Close the bottle cap immediately after each dispensing as Glaslonomer FX-LC Conditioner contains volatile agents. Use the dispensed material promptly.
- Do not use phosphoric acid agent for tooth surface treatment since bond strength to the tooth structure may be impaired.
- Do not overdry the cavity after cavity preparation since bond strength to the tooth structure may be impaired.
- If the tooth surface is contaminated by saliva or blood, clean thoroughly with water or an ethanol moistened cotton ball and dry.
- Do not apply desensitizer and/or silver diamine fluoride to the restoration area since bond strength to the tooth structure may be impaired.

7. Mixing

Take out a capsule from the aluminium bag right before mixing. Depress the plunger firmly against the hard, flat surface of a desk etc., to insert the plunger fully into the capsule body to release the liquid. Then immediately set the capsule in the capsule mixer ($\geq 4,000$ rpm) and mix for 10 sec. Remove the capsule from the capsule mixer immediately after mixing and load it into a commercially available applier.

Type	LV (Low Viscosity)	HV (High Viscosity)	
Powder/Liquid content	0.43 g/0.135 g	0.50 g/0.135 g	
Mixing time (sec)*	10"	10"	
Working time (23 °C/73 °F) (min, sec)†	4'00"	3'00"	from the start of mixing
Working time (37 °C/99 °F) (min, sec)†	2'10"	2'00"	from the start of mixing
Setting time (37 °C/99 °F) (min, sec)†	4'00"	3'50"	from the start of mixing
Radio-opacity	The radio-opacity is greater than that of the same thickness of Al ⁺ .		from the start of mixing

Measurement is performed in compliance with ISO 9917-2 (Class 3).

* When using the RotoMix™ rotating mixer (Solventum), set the mixing time at 11 sec (including 3 sec of centrifugation time).

† When light-curing is not done.

‡ Aluminium has a radio-opacity equivalent to that of dentine.

- Use caution when the room temperature is higher than 23 °C/73 °F for it shortens working time.

8. Filling

Immediately after the mixing, dispense the cement mixture (minimum amount: 0.2 mL) directly into the prepared cavity that has previously been rinsed with water and dried, then create the intended shape.

- For a deep cavity, place the cement mixture incrementally in layers with each layer up to 4 mm thickness, and light-cure each layer separately. For light-curing of a large surface area, divide the area into several sections and light-cure each section separately.
- After clicking the applicator's handle twice, the cement mixture will be pushed out into the capsule's nozzle during the third or fourth click. Therefore, it is recommended to click slowly from the third time onwards.
- Avoid applying excessive force to the capsule (capsule body, nozzle etc.) when extruding the cement mixture from the capsule.

9. Light-curing

Light-cure for 10 sec using a light-curing unit.

Light-curing unit	Halogen	LED
Light-curing time	10 sec	10 sec
Wavelength	400-500 nm	440-490 nm
Light intensity	≥ 500 mW/cm ²	$\geq 1,000$ mW/cm ²

- Use light-curing unit with the above specifications.
- Operators must use protective glasses or light-shielding plate to avoid direct exposure to curing light. Operators must also protect patients' eyes from direct exposure to the curing light.
- Disinfect the light-curing unit with alcohol after each use to avoid cross-infection.

10. Contouring and polishing

After light-curing, contour, finish, and polish the restoration following the standard method.

(Notes)

- Capsules are intended for a single use only. Do not reuse.
- Do not click the capsule with an applicator before mixing.
- Press the plunger into the capsule body right before mixing and fill the mixture promptly after mixing.
- Polymerization may be started by ambient light or the dental operating light.
- Use the capsule immediately after opening the aluminium bag. After removing the capsule from the bag, the material inside deteriorates over time due to ambient light.
- Use saliva ejector or vacuum during the procedure to eliminate water or saliva contamination.
- Use all the dispensed material only for one patient to avoid cross-infection.
- If Glaslonomer FX-LC Conditioner comes in contact with oral soft tissue, the tissue may turn whitish, however it should resolve in 2 or 3 days. Avoid touching or brushing the area.
- To avoid incomplete insertion of the plunger, do not press the plunger with fingers alone.
- Follow the instructions for use of each dental material, instrument, or equipment to be used in conjunction with this product.
- Do not use this product for any purposes other than specifically outlined in these instructions for use.
- This product is intended for use by dental professionals only.

POSSIBLE SIDE EFFECTS/RESIDUAL RISKS

- This product contains substances that may cause allergic reactions.

COMPOSITION**Glaslonomer FX-LC CAPSULE Powder**

Composition	% by weight
Fluoroaluminosilicate glass	80-90
Inorganic filler	10-20
Pigment	< 1

Glaslonomer FX-LC CAPSULE Liquid

Composition	% by weight
Methacrylate monomer	60-70
Polyacrylic acid solution	30-40
Others	< 1

Glaslonomer FX-LC Conditioner

Composition	% by weight
Water	40-50
Acetone	30-39
Carboxylic acid monomer	5-15
Phosphoric acid ester monomer	< 5
Others	< 1

SHADES

LV : BW, Pedo, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C2, C4, D2, CV

HV : BW, Pedo, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C2, C4, D2, CV

STORAGE

- Store at 1-25 °C/34-77 °F.
- Avoid high temperature and high humidity.
- Keep away from direct sunlight and any source of ignition.
- Keep a capsule in the aluminium bag until just before use.

DISPOSAL

Dispose the contents and containers in accordance with relevant local and national regulations.

CAUTION: US Federal law restricts this device to sale by or on the order of a dental professional.

Location of the symbols glossary: https://www.shofu.com/en/symbols_glossary/