



Glaslonomer FX ULTRA CAPSULE

en Instructions for use



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READ CAREFULLY BEFORE USE

en Packable radiopaque direct restorative for anterior and posterior

PRODUCT DESCRIPTION

Glaslonomer FX ULTRA CAPSULE is a newly developed packable type enhanced general purpose restorative glass ionomer with higher translucency.

INTENDED PURPOSE

- Restoration of deciduous teeth
- Non-load bearing Class I and Class II restorations in permanent teeth
- Restoration of Class III and Class V cavities and wedge shaped defects
- Core build-up

PRECAUTIONS AND WARNINGS

1. Do not use this product on patients with known allergies to this material and/or glass polyalkenoate cements.
2. In case of inflammation or allergic reactions in either patient or operator, immediately discontinue use and seek medical advice.
3. Use protective gloves and 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.
4. In case of contact with eyes, immediately flush eyes with plenty of water and seek medical advice.
5. Follow the instructions for use of each material, instrument or equipment to be used in conjunction with this product.
6. Do not use this product for any purposes other than specifically outlined in these instructions for use.
7. Use this product within the expiration date indicated on the package or container. (Example ☐ YYYY-MM-DD→Year-Month-Date of the expiration date)
8. This product is intended for use by dental professionals only.

DIRECTIONS FOR USE

A. Filling

- A-1. Tooth surface cleaning
Thoroughly clean the tooth surface to remove plaque/
surface stains.
- A-2. Shade selection
Select one shade optimal for the patient.
- A-3. Cavity preparation
Prepare the cavity following the standard method.
- A-4. Isolation
Use a rubber dam etc to isolate the restoration site.
- A-5. Pulp protection
In the case of pulp exposure or deep cavities with close
proximity to pulp, cap the pulp with calcium hydroxide etc.
- A-6. Tooth surface treatment
Use cavity cleaning agent (example: TOOTH CONDITIONER)
as necessary.
 - 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.

A-7. Mixing

Take out a capsule from the aluminum bag right before
mixing.
Press the plunger firmly into the capsule body to release the
liquid. Then immediately set the capsule in the capsule mixer
(≥ 4,000 rpm) and mix for 10 seconds. Remove the capsule
from the capsule mixer immediately after mixing and load it
into a commercially available applicator.

Mixing time	10"	
Working time (23 °C/73 °F)	2' 30"	from the start of mixing
Setting time* (37 °C/99 °F)	2' 20"	from the end of mixing

※Measurement is performed in compliance with
ISO9917-1:2007.

- When using the RotoMix™ rotating mixer (3M-ESPE),
set the mixing time at 9 seconds. (including 3 seconds. of
centrifugation time).
- Use caution when the room temperature is higher than
23 °C/73 °F for it shortens working time.

A-8. Filling and moisture control

Dispense the cement mixture within 30 seconds from the
end of mixing (minimum amount: 0.17 mL) directly into
the prepared cavity that has previously been rinsed with
water and dried, then create the intended shape using an
instrument. When the cement mixture loses luster, apply
cocoa butter, varnish or light-cured resin coat (example:
COAT-IT) to the restored area.

- When restored area cannot be protected from moisture
completely, the surface of the set material might become
whitish after contouring. Thus, apply the material oversized
by about 0.5 mm.
- When using a strip, apply some cocoa butter before
placing it.

A-9. Contouring and polishing

Perform contouring and polishing under running water
after about 2 minutes 30 seconds from the start of mixing
cement. Airdry cement surface immediately after polishing,
then reapply cocoa butter, varnish or light-cured resin
coat (example: COAT-IT).

B. Core build-up

B-1. Tooth abutment preparation

Prepare the tooth abutment following the standard method.
Perform isolation, pulp protection, tooth surface
treatment and preparation of cement mixture following
the instructions under A-4 through A-7 above.

B-2. Core build-up and moisture control

Build up the core following the standard method. Then
apply cocoa butter when the cement mixture loses luster.

B-3. Abutment preparation

Prepare the abutment following the standard method.

NOTE ON USE

- Do not reuse a capsule.
- Do not click a capsule with an applicator before mixing.
- Press the plunger into the capsule body right before mixing and
fill the mixture promptly after mixing.

SHADES

A2, A3, A3.5

COMPOSITION

POWDER: Fluoroaluminosilicate glass, Pigments

LIQUID: Acrylic acid tricarboxylic acid co-polymer solution,
Tartaric acid

STORAGE

Store at room temperature (1-23 °C/34-73 °F).

Avoid high temperatures and high humidity.

Keep away from direct sunlight.

Keep a capsule in the aluminum bag until just before use.

**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/