



Glaslonomer Cement CX-Plus CAPSULE

For cementing

EN Instructions for use



single use



201307-02
SiA000002

Manufacturer

SHOFU INC.
11 Kamitakamatsu-cho, Fukuine,
Higashiyama-ku, Kyoto 605-0983,
Japan

SHOFU DENTAL ASIA-PACIFIC PTE.LTD.
10 Science Park Road, #03-12,
The Alpha, Science Park II, Singapore 117684
Singapore

SHOFU DENTAL CORPORATION
1225 Stone Drive, San Marcos,
California 92078-4059,
USA

Glaslonomer Cement CX-Plus CAPSULE is a radio-opaque glass ionomer luting material in capsules. Minimally 0.14 mL of the material can be extruded from each capsule.

INDICATIONS

Cementation of crowns, bridges, inlays


PRECAUTIONS

1. Do not use this product on patients with known allergies to this material and/or glass polyalkenoate cements.
2. Operators with known allergies to this material and/or glass polyalkenoate cements must not use this product.
3. If any inflammation or other allergic reactions occur on either the patient or operator, immediately discontinue use and seek medical advice.
4. Do not re-use the capsules.
5. Avoid contact with intraoral soft tissue, skin or eyes. In case of accidental contact with intraoral soft tissue or skin, immediately blot with alcohol moistened cotton ball and rinse with plenty of water. In case of contact with eyes, immediately flush the eyes with plenty of water and seek medical advice.
6. This product is intended for use by dental professionals only.

DIRECTIONS FOR USE

1. Cleaning of cavity and abutment tooth
Thoroughly remove the temporary sealing or cement. Rinse with water and dry.
2. Preparation of the capsule
Take out a capsule from an aluminum foil bag.
Shake it or tap its side to loosen the powder inside.
Press the plunger firmly and completely to ensure that all of the liquid is pressed into the powder. Insert the capsule mixer (frequency : 4000 rpm or more, eg, ultramat 2 (by SDI Limited)).
3. Mixing
Mix the capsule in a high-frequency capsule mixer for 10 sec. (Room temperature : 23±1 °C (73.4±1.8 °F))
4. Cementation
Insert the capsule in the applicator immediately after mixing. Extrude the cement mixture within 30 sec. after finish mixing (minimum deliverable amount : 0.14 mL). Then, apply the cement mixture following the conventional method.
Working time (23 °C/73.4 °F) : 3' 10" (from start of mixing)
Setting time (37 °C/98.6 °F) : 4' 10" (from start of mixing)

NOTE ON USE

1. When applying the cement mixture directly in patient's mouth, disinfect or sterilize the applicator following the instructions for use of the applicator in use in order to avoid cross-contamination.
2. Keep the capsule in the aluminum foil bag by the time it is used.
3. Insert the capsule securely into the capsule mixer or the applicator.
4. Follow the capsule mixer manufacturer's instructions for use.
5. When dispensing the cement mixture, care should be taken to avoid accidental flow out of the material.
6. Remove excess material quickly with wet gauze etc before it gets hardened.
7. In the case where pulp is exposed or the affected area is close to the pulp, cap the pulp with calcium hydroxide.
8. Do not use this product for any purposes other than specifically outlined in the INDICATIONS in these instructions for use.
9. Use this product within the expiration date indicated on the package.
(Example  YYYY-XX → Shelf life: at the end of XX month, YYYY year)

STORAGE

Store at room temperature (1-30 °C/34-86 °F). Avoid high temperature and high humidity. Keep away from direct sunlight.

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