ENGLISH

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ProGlass™ *Two LC*

Radiopaque Light Cured Reinforced Glass Ionomer Restorative

ProGlass™ Two LC is a light cured reinforced glass ionomer filling cement, providing good chemical bonding to dentine and enamel and a tight seal at the dental margins. ProGlass Two LC has high fluoride release & excellent biocompatibility. Due to its radiopacity easy postoperative diagnosis is ensured.

INDICATIONS

Direct dental restorative material in the treatment of dental caries.

CONTRAINDICATIONS

- Pulp capping
- 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

ESSENTIAL INGREDIENTS

Aluminosilicate glass powder ,Dried poly (acrylic acid), Aqueous solution of polyacids and methacrylates, Camphorquinone

DIRECTIONS FOR USE

Tooth Preparation

1. Clean the cavity preparation with pumice and water.
2. Rinse thoroughly and dry but do not desiccate. If desired, place a matrix band.

Optional: apply a 20% polyacrylic acid with a brush onto the wet enamel and dentin surfaces for 30 secs. Air dry gently for 10 seconds to remove the volatile components and to disperse the material. For pulp capping, apply a small amount of calcium hydroxide liner.

Mixing and Dispensing

Capsule System

1. Prior to activation, slightly shake capsule or tap its side on a hard surface to loosen the powder. (Figure 1)
2. To activate the capsule, gently press the plunger on the bottom of the capsule until it is flush with the main body. (Figure 2)
   Note: The capsule should be activated just before mixing and used immediately.
3. Place capsule into amalgamator and mix for 15-20 sec (Figure 3).
   Note: Mixing time is affected by amalgamator. If you find the mixed material to be too loose or dry, increase or reduce mixing time by 2 secs. at a time in order to achieve the desired consistency.
4. Remove the capsule from amalgamator and place tip (Optional, if removed. Figure 4). Load into capsule applicator.
5. Place capsule into capsule applicator and extrude onto designated surface. Click trigger of applicator 2 times to prime the capsule. Click once more to extrude material. No need for excess force. (Figure 5)

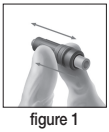
figure 1

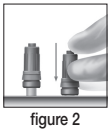
figure 2


figure 3

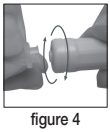
figure 4

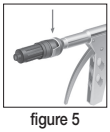
figure 5

SPECIAL ATTENTION: To ease insertion of capsule into amalgamator, application tip can be unscrewed prior to placing. Screw tip back on capsule immediately after triturating

Powder / Liquid System

1. To obtain a suitable consistency, mix powder and liquid according to the quantities indicated on the powder cap using the spoon included.
2. Shake the bottle to loosen the powder. Overfill the spoon with the powder, level the spoon and place onto the mixing pad. Avoid compressing powder into the spoon.
3. Turn the liquid bottle vertically with the tip about 5 cm above the mixing pad. Steady your hand and squeeze the bottle gently to dispense drops. If any bubbles are present, lightly tap the bottle with the fingers holding it. Discard drops that are obviously not full sized.
4. After use, tightly close both bottles.
5. Divide liquid and powder into 2 equal parts. Spread the liquid across the mixing pad and mix the first half with the whole of the liquid for 15 sec. add the second part and mix for 15 sec to obtain a homogeneous mixture. The mixed cement should be thixotropic and have a smooth consistency and glossy appearance. Total mixing time is 30 secs.
   Note: Higher temperatures will shorten the working time, lower temperatures will prolong the working time. An overextended working time will cause the loss of adhesion to the dental enamel and the dentin.

Filling and Finishing

1. Apply the mixed material into the prepared cavity by using a suitable placement instrument. Ensure that no air bubbles are incorporated.
2. Form the cement with a placement or forming instrument within the working time (3-4 mins) and use a matrix. A celluloid strip or matrix may be used and removed after the material has set.
3. Cure for 20 secs with a visible light cure device. Setting time without any light is 5-7 minutes (depending on environmental conditions). If the cavity is more than 2mm deep, curing in thin incremental layers is strongly recommended. After material has set, perform finishing under water spray using standard techniques.

ProGlass Two LC s suitable to be cured by all light-curing units (Halogen, Led & plasma) that have a luminous intensity of min. 550 mW/cm² (with higher intensity curing time can be reduced by half), emit at 400 -515nm, and that their performance is checked regularly.
Observe the light-curing unit manufacturer's instructions before use with ProGlass Two LC

SHELF LIFE

The lot number & expiry date are indicated on the product. Do not use after expiry date.

PRECAUTIONARY INFORMATION FOR PATIENTS

Avoid use of this product in patients with known allergies to Glass Ionomers, Polyacrilic Acid or methacrylates.
If prolonged contact with oral soft tissues occurs, flush with large amounts of water.

PRECAUTIONARY INFORMATION FOR DENTAL PERSONNEL

Do not mix the powder or liquid of ProGlass Two LC with any other glass ionomer products.
Use of protective gloves and a no touch technique is recommended.
In case of allergic reactions immediately stop the application and advise the patient to consult a physician.
Do not allow the cement mixture to contact the oral tissues or skin. In case of contact, remove the material with absorbent cotton soaked in alcohol and rinse with water.
In case of eye contact, immediately flush with water and seek medical treatment.
Direct contact with eugenol-based products is to be avoided. Eugenol slows the setting of glass ionomer cements.

CAUTION

U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

EU NOTICE

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
Summary of Safety and Clinical Performance (SSCP) is available at following website:
https://ec.europa.eu/tools/eudamed
Basic UDI-DI: 7290013DMR3XJ

STORAGE & DISPOSAL

Store in a cool and dark place / room temperature (5-30°C / 41-86°F) away from direct sunlight.
Do not store material in proximity to eugenol containing material.
Protect powder from moisture and carefully close powder bottle after use.
See the Safety Data Sheet (available at www.silmetdental.com or through your local subsidiary) for disposal & safety information.

WARRANTY

Silmet Ltd. will replace product that is proven to be defective. Silmet Ltd. does not accept liability for any damage or loss, direct or consequential, arising from the use of or inability to use the product described. It is the responsibility of the dentist to determine before use, the suitability of the product for its intended use. The dentist assumes all risk and liability in connection therewith.

For instructions in additional languages:

FR Pour des instructions dans d'autres langues:
DE Die Anleitung in weiteren Sprachen:
ES Para obtener las instrucciones en otros idiomas:
IT Per istruzioni in altre lingue:

www.silmetdental.com/downloads/downloads_instruction

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