

Directions for Use

Esthetic Glass Ionomer Cement for Luting

Product description

Oxford GI CEM E is a novel glass ionomer luting cement with improved esthetics and good physical properties in a universal shade. Beside its high fluoride release and good biocompatibility it has also good chemical bonding to dentine and enamel and to the restoration and a tight seal at the dental margins. Because of its radiopacity it ensures easy postoperative diagnosis.

Oxford GI CEM E meets the requirements of **ISO 9917-1**.

Indications/Intended use

- cementing of crowns, bridges, inlays and onlays (all types: metal, ceramic fused to metal and ceramic)
- liner under composite fillings

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

- Pulp capping
- Allergic reactions to glass ionomer cements

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Application

1. Tooth Preparation

Prepare the tooth in usual manner.

By using a cotton pellet apply a dentin conditioner for 20 sec to remove the smear layer. Rinse the dentin conditioner with water and dry it in an air stream, but **do not** desiccate.

For pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material (e.g. Oxford ActiveCal PC or Oxford Cal) or MTA cement (e.g. Oxford MTA).

Prepare the carefully cleaned restoration according to the instructions of the manufacturer.

2. Mixing

The **powder/liquid ratio** to achieve a suitable consistency is **1,8 / 1.0**. This can be obtained by mixing **one level (blue) scoop of powder and two drops of liquid**.

Note:

The spoon dosage is only an approximate reproduction of the nominal mixing ratio.

For accurate dispensing of **Oxford GI CEM E Powder** shake the bottle to loosen the powder. Overfill the spoon with the powder, level the powder by using the collar at the top of the bottle and carry it onto the mixing pad. **Avoid compressing** powder into the spoon with the inside wall of the bottle.

For dispensing of **Oxford GI CEM E Liquid** turn the bottle vertically with the tip about 5cm above the mixing pad. Steady your hand and squeeze the bottle gently to dispense the drops. If any bubbles are present, lightly tap the bottle with the fingers holding it. **Discount drops** that contain bubbles and are obviously not full-sized.

Use a small spatula to rapidly mix all the cement powder into the liquid. Usually one scoop powder/ 2 drops liquid should provide for sufficient amount of mixed cement. The mixed cement should be thixotropic and have a smooth consistency and glossy appearance. Total mixing time is **30 sec**.

After use, tightly close both liquid and powder bottles to prevent exposure to moisture.

3. Cementing

Avoid water and saliva contamination during application and setting of the cement.

Apply the mixed cement to the prepared bonding surface of the restoration and seat immediately (**working time 1:30 min** from start of mixing at 23°C). Net Setting time is approx. **5:00 min**.

Remove excess cement at the first setting stage.

Maintain isolation until the set of the cement is verified (ca. 5 min).

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.

4. Additional Notes/Warnings

- Do not use Oxford GI CEM E with patients who show an allergy to the material. In case of allergic reactions immediately stop the application, and advise the patient to consult a physician. An operator, who has a history of allergy to glassionomer cements, should not handle Oxford GI CEM E.
- 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.
- Avoid eye contact of the cement mixture. In case of contact, immediately flush with water and seek medical treatment.
- Do not mix the powder or liquid of Oxford GI CEM E with any other glass ionomer product.
- Shade: universal
- Keep away from children!

Composition

Dental glass, polyalkenoate acids

5. Storage

Store Oxford GI CEM E in a cool place at 4-25 °C (39-77 °F). Temperature should not exceed 25 °C (77 °F). Store protected from moisture. Do not use after expiry date.

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Note

The summary of safety and clinical performance of the medical device can be found in the European database on medical devices (EUDAMED – <https://ec.europa.eu/tools/eudamed>).

Warranty

First Scientific Dental Materials GmbH warrants this product will be free from defects in material and manufacture. First Scientific Dental Materials GmbH 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 exclusively remedy and First Scientific Dental Materials GmbH's sole obligation shall be repair or replacement of the First Scientific Dental Materials GmbH product.

Limitation of Liability

Except where prohibited by law, First Scientific Dental Materials GmbH 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.

Caution:

Federal law restricts the sale of this device to or by the order of a dentist.