

## Directions for Use

### Esthetic Glass Ionomer Cement for Filling

#### Product description

**Oxford GI FILL E** is a classical glass ionomer filling cement with improved esthetic and good physical properties. Besides its excellent fluoride release and excellent biocompatibility as glass ionomer cement Oxford GI FILL E also has good chemical bonding to dentine and enamel and a tight seal at the dentinal margins. Therefore it requires no enamel and dentine etching. Because of its radiopacity it ensures easy postoperative diagnosis. Oxford GI FILL E meets the requirements of: DIN EN ISO 9917-1 (Specification for Dental Water based Cements).

#### Indications/Intended use

- Class I and II restorations in deciduous teeth
- Non-load bearing small class I and class II restorations in permanent teeth
- Intermediate restorative material for heavy stress situations in class I and class II cavities
- Base material for class I and II cavities according to sandwich technique
- Class V restorations
- Core build-ups

#### 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 using standard techniques. Do not prepare thin edges.

If desired, place a matrix band.

Apply a conditioner according to the corresponding instructions to the bonding surfaces to remove the preparation smear layer. Rinse the conditioner thoroughly with water and dry gently. 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).

##### 2. Mixing

The **powder/liquid ratio** to achieve a suitable consistency is **3.6 /1.0**. This can be obtained by mixing **1 level (blue) scoop of powder and 1 drop of liquid**.

For accurate dispensing of **Oxford GI FILL 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 FILL E Liquid** turn the bottle vertically with the tip about 5 cm 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/ one drop 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. Filling

Mix the required amount of Oxford GI FILL E and apply it into the prepared cavity by using a suitable placement instrument. Please see to it, that no air bubbles will be incorporated.

**Oxford GI FILL E** should be placed in the cavity within the **working time (1:15 minutes from start of mixing at 23 °C or 74°F)**. If desired, a matrix band may be used to form the contour.

Net setting time is about **3:30 minutes**.

After setting, immediately apply Oxford GI COAT. Immediately light cure for 20 seconds.

**Close bottle immediately after use.**

#### 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 dentine.**

Remove the matrix when the cement has achieved clinical set (approx. **3:30 minutes** after application).

##### 4. Finishing

Final finishing and polishing can begin from about **6 minutes** after start of mixing. Smooth with fine diamond burs, then polish with finishing and polishing discs with graded grain size.

Apply a thin layer of **Oxford GI COAT** to the final finished surface of the restoration. Immediately light cure for 20 seconds.

**Close bottle immediately after use.**

**Instruct the patient not to expose the restoration to any pressure for one hour.**

##### 5. Additional Notes/Warnings

- Do not use Oxford GI FILL 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 FILL 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 FILL E with any other glassionomer product.
- Keep away from children!

##### Composition

Dental glass, polyalkenoate acids

##### 6. Storage

Store **Oxford GI FILL E** at room temperature (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

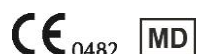
First Scientific Dental Materials GmbH warrants this product will be free from defects in material and manufacture. First Scientific Dental Materials GmbH makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining 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 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.**



First Scientific Dental Materials GmbH,  
Robert-Bosch-Strasse 2, 25335 Elmshorn, Germany