

Handmix

Directions for Use

Light Cure Ultra Fine Resin Modified Glass Ionomer Cement for Luting

Product description

Oxford GI Resin CEM UF is a light cured resin reinforced glass ionomer luting cement. Beside its high fluoride content and the excellent biocompatibility as glass ionomer cement Oxford GI Resin CEM UF has also good chemical bonding to dentine and enamel and a tight seal at the dental margins. Because of its radiopacity it ensures easy postoperative diagnosis.

Indications

- cementing of crowns, bridges, inlays and onlays (all types: metal, resin, ceramic fused to metal and ceramic)

Performance features

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

Contraindications

- In singular cases, the material may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used further on.
- Direct and indirect pulp capping

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.

Interaction with other materials

Avoid direct contact with products containing eugenol since eugenol impairs the setting of Oxford GI Resin CEM UF.
Do not mix the powder or liquid of Oxford GI Resin CEM UF with any other glassionomer product.

Application

1. Tooth Preparation

Prepare tooth in usual manner.

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).

Optional: To improve adhesion particularly in case of deeper cavities the light cure bonding agent Oxford GI Resin PRIME VLC can be applied.

2. Mixing

The **powder/liquid ratio** to achieve a suitable consistency is **2.0 /1.0**. This can be obtained by mixing **one level (blue) scoop of powder and 3 drops of liquid**.

Note:

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

For accurate dispensing of Oxford GI Resin CEM UF 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 Resin CEM UF 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/ 3 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. Rubber dam is the best way of achieving tooth isolation.

Prepare the restoration according to manufacturer instructions.

Mix the required amount of Oxford GI Resin CEM UF and apply a thin layer (1 mm or less) to the prepared bonding surface of the restoration and seat immediately (**working time 2:30 min** from start of mixing at 23°C). Net setting time without any light is approx. 4:00 min.

Remove excess cement at the first setting stage.

Maintain isolation until the set of the cement is verified (ca. 4:00 minutes). Setting can be optimized with **20 seconds** light cure with a suitable dental light cure unit (wavelength range 400–500 nm, light intensity min. 1000 mW/cm²).

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 enamel and dentine.

4. Additional Notes/Warnings

- The material can also be used as liner under composite restorations.
- Unpolymerized material may have an irritant effect and can lead to sensitization against methacrylates.
- Avoid contact with skin, mucous membrane and eyes
- If the material comes into contact with skin, In case of contact, remove the material with absorbent cotton soaked in alcohol and rinse with water. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

5. Storage

Store Oxford GI Resin CEM UF in a cool and dark place at 4-25 °C (39-77 °F). Temperature should not exceed 25 °C (77 °F).
Do not use after expiry date.

Composition

Powder: Dental glass, photo initiators
Liquid: polyalkenoate acid, methacrylates

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.