

Directions for Use

Dual Cure Flowable Composite Cement

Product description

Oxford Flo CEM is a dual cure easy flowing composite cement for permanent cementations. Oxford Flo CEM is a strongly radiopaque and relatively high filled composite of very high strength.

Oxford Flo CEM is based on methacrylate resin and inorganic filler particles of 0.05-1 µm. The total filler load is 61 % and the total filler volume 41 %. Oxford Flo CEM meets the requirements of ISO 4049.

Indications/Intended use

Permanent cementation of:
inlays, onlays, crowns, bridges and veneers

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.

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.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Preparing the MINIMIX-Syringe

First Scientific Dental Materials GmbH only recommends for Oxford Flo CEM the use of mixing cannulas type Oxford Mix TIP(S)12.

Remove the cap of the MINIMIX-syringe and throw it away (**do not use it again!**). It is replaced by a special 1:1 mixing cannula. Bleed the MINIMIX-syringe before applying the mixing cannula. Gently press the plunger until both components (base and catalyst) begin to flow out evenly. Make sure that the guidance of the MINIMIX-syringe is aligned with that of the mixing cannula and turn the cannula 90° clockwise until it locks in position. The material is now ready for application.

The working time (23°C (74°F)) in the self cure mode is 2:00 minutes from start of mixing.

Note:

Discard the first 3-5 mm of the extruded material. This must be done for each new mix.

Store used syringe with fixed used mixing cannula in the dark.

Application

Cementing of Inlays, Onlays, Crowns, Bridges and Veneers

1. Preparing

Prepare the luting side areas of the restoration (inlay, onlay, crown, bridge or veneer) with a suitable bonding agent:
Restorations made from:

- Zirconia with e.g. Oxford ZirBond
- Silicate ceramics with e.g. Oxford CeraBond
- Metal (precious or non-precious metal) with a suitable metal primer

2. Cementing of the indirect restoration

2.1. Cementing of Inlays, Onlays, Crowns and Bridges

Prepare the tooth surface and apply a bonding agent (e.g. Oxford Bond SE Dual) according to the corresponding user instructions. For cementing (preparation of the restoration see 1.) apply a uniform coating (0.5 mm) of Oxford Flo CEM on the luting side of the inlays, onlays, crowns and bridges and – if necessary - on the prepared tooth areas. Seat the restoration under

light pressure. Have the patient bite slowly into the habitual occlusion. Remove excess material. Light cure all marginal areas of the restoration for 20 seconds with a polymerization unit (wavelength range 400-500 nm) with a light intensity of at least 1000mW/cm². The dual cure cement system will auto cure within **4 minutes**.

2.2. Cementing of Veneers

Optional try-in the veneers with Try-in Gel. Clean try-in Gel off the enamel surfaces, using pumice in a rubber cap. Avoid gingival contact to prevent bleeding. Rinse with water and dry with oil-free air. Isolate the teeth to be veneered with interproximal strips to protect adjacent teeth (not being veneered) from the etchant and bonding agent.

Apply Oxford Bond SE Dual according to the corresponding directions for use onto the enamel areas to be veneered.

Apply Oxford Flo CEM onto the prepared tooth surface in a thin layer.

Remove matrix strips prior to placing the veneers on the teeth.

After placement of the veneer, light cure for **20sec** with a polymerization unit (wavelength range 400-500 nm) with a light intensity of at least 1000mW/cm² through tooth structures and the veneer material. If the light through the veneer material is not sufficient or a light cure cannot guaranteed to be sufficient, Oxford Flo CEM selfcures within **4 minutes**. After curing finish and polish margins in the usual manner.

Storage

Do not store above 20 °C (68 °F). Protect from direct sunlight. Store unopened material in the refrigerator.

Opened cartridges have to be used up within 3 months.

Do not use after expiry date.

Additional Notes/Warnings

- The ambient light of the dental lamp may start polymerization of the composite.
- Do not use any resin to adjust viscosity of composite.
- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Unpolymerized composite may have an irritant effect and can lead to sensitization against methacrylates.
- Color stability meets the requirements of DIN EN ISO 4049.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

Composition

Dimethacrylates, dental glass, silicon dioxide, photo initiators, catalysts

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

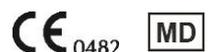
First Scientific Dental Materials GmbH warrants this product will be free from defects in material and manufacture. First Scientific Dental Materials makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the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



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