

Directions for Use

Semi-permanent Luting Cement for Crowns and Bridges on Implants

Product description

Oxford Cem IMPLANT is a dual cure semi-permanent luting cement. Oxford Cem IMPLANT is based on multifunctional methacrylic esters and contains zinc. Oxford Cem IMPLANT is suitable for semi-permanent cementing of implant abutment retained crowns and bridges. It shows good elastic behavior and good seal thanks to controlled slight expansion. Oxford Cem IMPLANT is delivered in 4:1 MINIMIX syringes, so it is very easy and comfortable to use. Oxford Cem IMPLANT does not influence the setting of resin-based filling and luting materials.

Indications/Intended use

- Cementing of crowns and bridges on implants

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.

APPLICATION

Preparing the MINIMIX-Syringe

First Scientific Dental Materials GmbH only recommends for Oxford Cem IMPLANT the use of mixing cannulas type Oxford Mix TIP(S), Minimix 4:1/10:1, Long.

Remove the cap of the MINIMIX-syringe and throw it away (**do not use it again!**). It is replaced by a 4:1 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.

Note:

Discard the first 2-3 mm of the extruded material. This must be done for each new mix.

Store used syringe with fixed used mixing cannula in a dark place.

Cementing

Before cementing degrease, clean (e.g. with alcohol) and dry abutment and restoration.

Oxford Cem IMPLANT is automatically mixed when dispensed with slight and even pressure. It can be applied directly into the restoration.

Apply a thin layer of Oxford Cem IMPLANT to the inside of the restoration. Position the restoration within **2 minutes** (working time at 23°C) cautiously but firmly over the implant abutments.

For a fast fixation of the restoration cure Oxford Cem IMPLANT at the marginal regions for 20 seconds per surface. In case of translucent materials it is also possible to expose to light through the material (40 seconds per surface).

Without any light Oxford Cem IMPLANT sets in the mouth within **approx. 4 minutes**.

After Oxford Cem IMPLANT has set remove any excess.

Notes

If the restoration has to be removed for inspection, this must be done gently with slight and permanent traction. **Avoid jerky removal!** The remaining cement can be extracted almost in one piece. Use water spray and suction to remove any remaining residue.

Clean and disinfect abutment and restoration with a cotton pellet soaked in alcohol or another disinfectant. Rinse thoroughly with water and dry.

Now the restoration can be fixed again with Oxford Cem IMPLANT (see Cementing).

Additional Notes/Warnings

- Contact of resin pastes with skin should be avoided, especially by anyone having known allergies to methacrylates.
- In case of contact with skin and eyes rinse immediately with plenty of water.
- If swallowed seek medical advice.
- Unpolymerized composite may have an irritant effect and can lead to sensitization against methacrylates.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

Storage

Do not store above 20 °C (68 °F)! Protect from direct sunlight. Do not use after expiry date.

Composition

Dimethacrylates, zinc-containing fillers, silicon dioxide, catalysts, photo initiators

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.