

## Directions for Use

### Self Adhesive Luting Cement - Dual Cure

#### Product description

Oxford Cem SE is a self adhesive dual cure luting cement for permanent cementations. When Oxford Cem SE is used, conditioning and bonding of the tooth structure are not necessary. Oxford Cem SE is self neutralizing. Oxford Cem SE is based on methacrylate resin and inorganic fillers. The total filler load is 50% wt, the total filler volume is 45 %. The mixing ratio based on volume is 4 parts base and 1 part catalyst.

#### Indications/Intended use

Permanent cementing of:

- crowns and bridges made of metal and metal ceramic
- crowns and bridges of reinforced ceramics (e.g. Zirconia)
- all-ceramic crowns and bridges produced by using Cerec®
- inlays and onlays of ceramic, metal and composite posts
- metal, metal ceramic and reinforced ceramics (e.g. Zirconia) on implant abutments

#### Performance features

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

#### Contraindications

- Thin all-ceramic restorations of feldspathic ceramic or other low fusing ceramics, veneers, Maryland-bridges
- Pulp capping
- In singular cases, Oxford Cem SE 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 Cem SE the use of mixing cannulas type Oxford Mix TIP(S), Minimix 4:1/10:1, long or Oxford Mix TIP(O) Minimix 4:1/10:1 and intra oral tips Oxford Endo TIP.

Remove the MINIMIX-syringe from the seal-pack and discard the bag. Note the date of removal on the syringe label.

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.

**The working time (23°C/74°F) in the self cure mode is 1:30 minutes from start of mixing.**

#### Note:

Discard a peppercorn-size quantity of material. This has to be done for each new mix.

### APPLICATION

#### 1. Cementation of Inlays, Onlays, Crowns and Bridges

##### 1.1. Preparing

Prepare the luting side areas of the all-ceramic inlays, onlays, crowns and bridges according to manufacturer instructions and primed with a silane priming agent (e.g. Oxford CeraBond).

The luting side areas of metal, zirconia or composite restorations should be prepared according to manufacturer instructions.

##### 1.2. Cementing of the indirect restoration

###### 1.2.1. Preparation of cavity/tooth stump

For a sufficient retention the height of the prepared stump must be at least 4 mm with a steep preparation angle (maximum 6 degrees).

Prior to final cementation, clean the prepared stump or cavity thoroughly with pumice slurry, rinse with water and slightly dry in 2-3 intervals with oil free air. **Do not overdry!**

##### 1.2.2. Cementing of Inlays, Onlays, Crowns and Bridges

For cementing (preparation of the restoration see 1.1.) apply a uniform coat (0.5 mm) of Oxford Cem SE on the luting side of the inlays, onlays, crowns and bridges and on the prepared tooth areas. Seat the restoration under slight pressure. Remove excess material after brief light exposure (approx. 5 sec). Remove excess material after brief light exposure (approx. 5 sec). Light cure all marginal areas of the restoration from each direction (mesio-oral, disto-oral, mesio-buccal, disto-buccal) for **20 seconds** with a polymerization unit (wavelength range of 400-500 nm and light intensity of at least 1000mW/cm<sup>2</sup>). Net setting time in the self cure mode is **approx. 4:00 minutes**.

### 2. Cementation of Posts

#### 2.1. Preparing of the root canal

Use of a rubber dam to isolate the tooth is strongly recommended.

Prepare the selected post according to manufacturer directions.

Treat the root canal endodontically and clean it in the usual manner (e.g. with sodium hypochlorite solution, approx. 3%). Rinse with water and dry with paper points.

#### 2.2. Filling of the root canal

Prepare the MINIMIX-syringe as described above and attach an Endo-Tip to the mixing cannula. Insert the Endo-Tip as deep as possible into the root canal and apply Oxford Cem SE starting apically. Keep the end of the Endo-Tip in the material to avoid bubbles. When the root canal has been completely filled remove the Endo-Tip from the material.

If necessary apply a thin layer of Oxford Cem SE on the post. Place the post in the filled root canal and hold in position under moderate pressure. Light cure the coronal part of the cemented post for **20 seconds** with a polymerization unit (wavelength range of 400-500 nm and light intensity of at least 1000mW/cm<sup>2</sup>).

#### Storage

Store in the original seal-pack at 10-25 °C (50-77 °F). After opening of the seal-pack, use Oxford Cem SE within 6 months and before the end of expiry date. Avoid constantly high humidity. Do **not** store in the refrigerator.

Do not use after expiry date.

#### Additional Notes/Warnings

- Do not use any resin to adjust viscosity of luting cement.
- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.
- Catalyst paste: Contact with eyes may cause severe eye damage. Wear eye protection. In case of contact with eyes rinse immediately with plenty of water and seek medical advice.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Cerec® is not a registered trade mark of First Scientific Dental Materials GmbH
- Keep away from children!

#### Composition

Dimethacrylates, dental glass, silicon dioxide, phosphoric acid ester, 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.**