

## Directions for Use

### Non-Eugenol Temporary Cement

#### Product description

**Oxford Temp CEM Universal** is a non-eugenol temporary crown and bridge cement suitable for cementing temporary crowns or bridges as well as for trial cementing of permanent restorations. It shows excellent adhesion to temporary crown and bridge materials, but it can easily be removed from prepared tooth stumps.

Oxford Temp CEM Universal is delivered in Minimix syringes, so it is very easy and comfortable to use.

Due to its non-eugenol formulation it does not influence the setting of resin-based filling and luting materials.

Oxford Temp CEM Universal is based on ZnO/organic acids. Especially in cases of allergies to eugenol it is strongly recommended to use this eugenol-free type of cement.

Oxford Temp CEM Universal meets the requirements of ISO 3107 and the ADA/ANSI Specification No. 30.

#### Indications/Intended use

- Temporary cementing of provisional crowns or bridges
- Trial cementing of permanent crowns and bridges

#### Performance features

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

#### Contraindications

Do not use Oxford Temp CEM Universal in cases where known allergies to the components exist.

#### 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

##### Preparing the Minimix-Syringe

First Scientific Dental Materials GmbH only recommends for Oxford Temp CEM Universal the use of mixing cannulas type Oxford Mix TIP(S), Minimix 1:1, transparent.

Remove the cap of the Minimix-syringe and throw it away (do not use it again!). Attach a 1:1 mixing cannula. 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.

#### Precautions

Oxford Temp CEM Universal should extrude easily from the Minimix-syringe. Do not use excessive force. Excessive pressure may result in an uncontrolled extrusion of the material and may cause rupture of the syringe.

#### Cementing

Apply Oxford Temp CEM Universal directly into the temporary crown or bridge under slight pressure.

Apply a thin layer to the inside of the temporary crown or bridge and. Position the temporary restoration within **1:30 minutes** (working time at 23°C/74°F) cautiously but firmly over the prepared tooth structures.

#### Note:

Do not dry stumps, best moisten them with some water. A humid milieu (humid stumps) additionally facilitates to remove the temporary crown or bridge later on.

Oxford Temp CEM Universal sets in the mouth within **2-3 minutes**. After Oxford Temp CEM Universal has set remove any excess.

#### Removing of the restoration

Remove the restoration with a suitable instrument. Residual PROVI CEM NE PLUS has to be removed completely with a suitable instrument (e.g. scaler, explorer or hand instrument before final cementing).

Clean dentine and enamel with a moist cotton pellet. Wash thoroughly with water spray and blot dry.

#### Storage

Store at 8 – 25 °C (47 – 77 °F). Protect from moisture! Do not use after expiry date.

#### Additional informations/Warnings

- In case of contact with skin and eyes rinse immediately with plenty of water and consult a physician if necessary.
- If swallowed seek medical advice.
- Keep away from children!

#### 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.

#### 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 exclusive 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.**

