

## Directions for Use

### Total Etch Adhesive – Light Cure

#### Product description

Oxford Bond TE Mono is a simple to use light cure one component bonding agent. It is designed for strong bonding of light cure composites and compomers to etched enamel and dentine and to nonprecious and precious metals.

Its strong adhesion to etched enamel or dentine proceeds on principles similar to that occurring with glassionomer cements. Good, long lasting adhesive strength and good biocompatibility are attained by polycarboxylic acids.

Oxford Bond TE Mono is compatible with all current brands of visible light cure composite materials. It is ethanol-based and hydrophilic. Oxford Bond TE Mono can be used on slightly moist dentin surfaces (wet bonding technique).

If a dual or self cure bonding system is recommended, Oxford Bond TE Mono can be mixed with Oxford Bond TE Dual Activator and applied in a similar way (see directions for use for Oxford Bond TE Dual Activator).

#### Indications/Intended use

Adhesive for:

- Restorations with light cure composites

#### 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.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with pulp capping material (e.g. Oxford ActiveCal PC or Oxford Cal).

#### 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 Oxford Bond TE Mono. Neither store the material in proximity of eugenol containing products, nor let the material allow coming into contact with materials containing eugenol.

#### Application

##### 1. Isolation

Rubber dam is the recommended method of isolation.

##### 2. Cavity Preparation

Clean the tooth with flour of pumice and water prior to preparation. Prepare the cavity with minimal tooth reduction. Margins should have a slight (**0.5 - 1.0 mm**) bevel placed in the enamel to increase the surface area for greater bond strength.

##### 3. Pulp Protection

Cavity floor of deep excavations should be covered with a thin layer of calcium hydroxide material.

##### 4. Enamel and Dentine Conditioning

Recommended is the total etch technique. Apply Oxford Etch onto the enamel and dentine surfaces beginning with the enamel bevels. Condition **the enamel for at least 15 seconds and the dentine for 15 seconds**. (This results in 20–30 seconds etching of enamel and 15 seconds of dentine). Deciduous teeth are etched correspondingly longer. Rinse for 20 seconds with water. Dry it in a water and oil-free airstream, but **do not** desiccate. A slightly wet dentine surface is important for the function of Oxford Bond TE Mono. The etched enamel bevel should have a chalky white appearance.

#### Etching precaution:

It is essential, that etched areas are not contaminated by anything. If contamination occurs, re-etch, rinse with water and dry as above. Avoid etching gel contact with oral soft tissues, eyes and skin. If accidental

contact occurs, flush immediately with copious amounts of water.

**For the typical indications of compomers** etching is mostly not recommended, but it improves considerably the bonding with tooth material.

#### 5. Application of Oxford Bond TE Mono

Apply Oxford Bond TE Mono generously with a brush onto the enamel and dentine surfaces for **30 seconds** with agitation. The material should build a homogeneous layer. Remove excess material carefully. Dry cautiously with oil free air for about 15 seconds to remove all volatile components and to disperse the adhesive to an even layer. Do not desiccate the dentine.

Cure the Oxford Bond TE Mono coating by exposing its entire area to a dental halogen light unit for **20 seconds** before application of a second layer of Oxford Bond TE Mono.

**Notes:** Do not rinse off the Oxford Bond TE Mono! If not used immediately, place dispensed Oxford Bond TE Mono in subdued light to prevent premature polymerization by incident light. The Oxford Bond TE Mono will **not** selfcure.

#### 6. Application of a **Second** Layer of Oxford Bond TE Mono

Apply again the Oxford Bond TE Mono generously with a brush onto the adhesive surfaces as described under **point 5**. before placement of a light cure composite.

#### 7. Restorative Placement

Apply the restorative material according to the instructions of the manufacturer.

Best results are obtained with application of a thin layer of a flowable composite (e.g. Oxford Flow) followed by the application of a moldable composite (e.g. Oxford Ceram NANO). Light cure each composite layer separately according to the corresponding user instructions.

#### Storage

Do not store above 25 °C (77 °F)! Protect from direct sunlight. Do not use after expiry date.

#### Additional Notes/Warnings

- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates
- 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.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

#### Composition

Hydrophilic methacrylates, modified acrylic acids, 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.**



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