Oxford Bond SE Dual

Oxford Scientific

Directions for Use

Self Etching Adhesive – Dual Cure

Product description
Oxford Bond SE Dual is a simple to use self-etching dual cure adhesive. It is designed for strong bonding of composites, compomers and resin modified glass ionomer cements to enamel and dentine

Oxford Bond SE Dual consists of the components PART A and PART B that were mixed before application. It is bonding to dual cure, self-cure and light cure composite restorative materials.

Indications/Intended use
Adhesive for:
- Core build-ups and cementing of posts with dual and self cure composites (e.g. Oxford Zircore NANO, Oxford Flo CORE)
- Cementing of posts with dual and self cure composite cements (e.g. Oxford Flo CEM)
- Cementing of inlays, onlays, crowns and bridges with dual and self cure composite cements (e.g. Oxford Flo CEM)
- Restorations with dual cure, self cure and 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 SE Dual. 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. Application of Oxford Bond SE Dual
One drop of Oxford Bond SE Dual PART A and one drop of Oxford Bond SE Dual PART B were combined in a mixing pallet and mixed for 5-10 seconds.

Apply the homogeneous mixture generously with a brush onto the slightly wet enamel and dentine surfaces for 30 seconds with agitation. The material should build a homogeneous layer. Air thin for 10 seconds to remove the volatile components and to disperse the adhesive. Then light cure for 20 sec with a dental halogen light unit or an LED (wavelength 400–500 nm, light intensity min. 1000 mW/cm^2) and place the restorative material.
For a maximal adhesion it is strongly recommended to use the light cure mode.

If light cure is absolutely impossible, the adhesive will also cure in the autocure mode. After application of the adhesive air thin gently to **remove all volatile components**. There must remain a sticky layer. Then apply the restorative material directly.

Notes:
Do not interchange lids of the bottles, because this can lead to a cross-contamination of the liquids.

5. Restorative Placement
Best results are obtained with application of a thin layer of a flowable composite followed by the application of a moldable composite. 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, MDP, photo initiators,
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.

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