

Directions for Use

Universal Etching Gel

Product description

Oxford Etch is a 37% phosphoric acid gel with an excellent thixotropy for use in the total etch technique.

Delivered in syringes with very thin application cannulas it can be applied very easily and safe on only that areas that are really desired to be etched.

Indications/Intended use

Enamel etch or total etch technique for:

- Composite restorations
- Sealing of fissures
- Adhesive cementation of inlays, onlays, crowns and bridges (with suitable composite-cement systems)

Performance features

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

Contraindications

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 a thin layer of pulp capping material.

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.

Warnings

Oxford Etch contains phosphoric acid and is corrosive. Avoid contact with eyes, skin and oral mucosa (safety glasses are recommended for both patients and dentists). After contact with eyes immediately rinse with copious amounts of water for at least 15 minutes and consult a physician/ophthalmologist. After skin contact immediately rinse with soap and water.

Preparation of Oxford Etch syringe

Screw off the cap and substitute it by the application needle. **Store the screw cap!**

Note:

The application needle might be bend in a slight arc, if desired, to facilitate application.

Handling precaution:

Squeeze out the first small drop on a pad to ensure proper handling and prevent "shooting" out of the etching gel by entrapped air.

Application of Oxford Etch

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**. 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.

After use replace disposable application cannula by the screw cap. Discard used application cannula. Application cannulas are for single use only due to hygienic reasons.

Application of an Adhesive

Apply a suitable adhesive (e.g. Oxford Bond TE Mono) with a brush on the etched saliva-free enamel and dentine surfaces according to the corresponding instructions.

Restorative placement, cure and finishing

Refer to manufacturer instructions for placement, curing and finishing of restorative materials.

Storage

Do not store above 25 °C (77 °F). Do not use after expiry date.

Additional Notes

- 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 GmbH 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 GmbH's sole obligation shall be repair or replacement of the First Scientific Dental Materials GmbH 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.