

Directions for Use

Light Cure Condensable Composite

Product description

Oxford Ceram P is a visible light cure microhybrid composite for posterior restorations. It is based on BIS-GMA-resin and inorganic filler particles of 0.05-0.9 µm. The total filler load is 82 %; the total filler volume is 64 %. Radiopacity of Oxford Ceram P is 220 % aluminium (radiopacity of enamel: ~200 % aluminium, of dentine: ~100 % aluminium).

Oxford Ceram P meets the requirements of ISO 4049, type 1, class 2, group 1.

Indications/Intended use

- Class I and II restorations according to Black
- Fabrication of inlays and onlays

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 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 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.

Application

1. Isolation

Rubber dam is the recommended method of isolation.

2. Color Matching

Clean the tooth with a fluoride-free polishing paste (e.g. flour of pumice with water) prior to preparation and color matching.

Ascertain the tooth shade while teeth are still moist and select the appropriate Oxford Ceram P shade.

Oxford Ceram P is shaded according to VITA®-Shades.

3. Cavity Preparation

After isolation prepare the cavity with minimal tooth reduction.

For pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material (e.g. Oxford ActiveCal PC or Oxford Cal).

Apply an adhesive for enamel and dentine bonding (e.g. Oxford Universal Bond, Oxford Bond SE Mono, Oxford Bond TE Mono) according to the corresponding instructions.

The application of the universal adhesive Oxford Universal Bond is recommended. Oxford Universal Bond can be used in combination with an etching gel (e.g. Oxford Etch) or as a self-etching adhesive. Follow the instructions for Oxford Universal Bond.

4. Application and Curing of Oxford Ceram P

Apply Oxford Ceram P in the selected shade. Oxford Ceram P is easy to model. Place it by using a suitable instrument. Matrix strips may be used.

In case of deep and extended cavities best results are obtained with a build-up of a base liner using a light cure resin modified cement or a

light cure flowable composite (e.g. Oxford Flow), followed by the application of Oxford Ceram P.

In case of small cavities Oxford Ceram P can be applied directly.

For an optimum result apply Oxford Ceram P in **layers of max. 2 mm**. Light cure each increment separately.

By using a polymerization unit with a light intensity of at least 1000 mW/cm² and a wavelength range of 400 to 500 nm (blue light) cure each increment as follows:

Lighter shades (e.g. A1, A2, C2) **20 seconds**

Darker shades (e.g. A3.5, B3) **30 seconds**

Hold the light emission window as close as possible to the filling material.

5. Finishing

Depending on the shape of the area contour with finishing diamonds, flexible grinding discs or carbide burs.

Polish to high gloss with polishing discs or polishing brushes.

Storage

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

Close syringe immediately after use to avoid exposure to light.

Additional Notes/Warnings

- The ambient light of the dental lamp may start polymerization of the composite.
- Do not use any resin to adjust viscosity of composite restorative material.
- Avoid contact with skin, mucous membrane and eyes.
- Unpolymerized composite may have an irritant effect and can lead to sensitization against methacrylates.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- VITA® is a registered trade mark of the VITA-Zahnfabrik, Bad Säckingen, Germany.
- Keep away from children!

Composition

Dimethacrylates, dental glass, silicon dioxide, 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 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.

