

Directions for use

Light Cure Calcium Hydroxide Liner

Product description

Oxford Cal VLC is a light cure, radiopaque liner with calcium hydroxide.

Indications

- indirect pulp capping
- lining of cavities for following filling procedures

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 the liner. Neither store the liner in proximity of eugenol containing products, nor let the liner allow coming into contact with materials containing eugenol.

Application

Clean and dry the cavity thoroughly. Avoid contamination

Screw off the cap of the syringe and substitute it by a NeedleTip. After use discard the NeedleTip and attach the cap to the syringe again. NeedleTips are for single use only.

Note:

For direct proximity to the pulp (direct pulp capping) application of an aqueous calcium hydroxide liner or the pulp capping material Oxford ActiveCal PC is recommended. is recommended.

To enhance bonding of Oxford Cal VLC use a bonding agent. Etching and application of Oxford Bond TE Mono according to the corresponding user instructions is recommended. In areas with a thin dentin layer over the pulp do without bonding (pulp protection).

Then Oxford Cal VLC can be applied directly from the syringe. Screw off the cap of the syringe and substitute it by a NeedleTip.

Apply Oxford Cal VLC in a thin layer (max. 1 mm) and light cure for **40 seconds** by using a polymerization unit

(wavelength range 400-500 nm) with a light intensity of at least 1000mW/cm².

After curing apply the filling material according to manufacturer instructions.

Storage

Store at 4 - 25 °C (39 - 77 °F) protected from light and moisture. Close syringe immediately after use.

Do not use after expiry date.

Warnings

- When using Oxford Cal VLC wear protective glasses and cover the patient eyes.
- In case of contact with eyes, rinse with copious amounts of water and consult a physician immediately.
- Unpolymerized materials may have an irritating effect and may lead to a sensitizing reaction against methacrylates.
- Avoid contact with skin and mucous membrane. If accidental contact occurs, wash immediately with water.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Do not use any resin to adjust viscosity of Oxford Cal VLC material.
- Keep away from children!

Composition

Dimethacrylates, dental glass, calcium hydroxide, 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.

