

Directions for use

Radiopaque Resin Based Glassionomer Liner

Product description

Oxford Iono VLC is a light cure, radiopaque resin-based glassionomer liner for light cure composites.

Indications

- lining of cavities for following filling procedures
- lining of cavities to improve marginal behaviour

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

Application

Clean and dry the cavity.

Remove the cap from the Oxford Iono VLC-syringe and attach a NeedleTip. Squeeze out the first small drop on a pad to ensure safe handling of Oxford Iono VLC.

Before applying Oxford Iono VLC paste use of a pulp capping material e.g. Oxford ActiveCal PC or Oxford Cal in areas in proximity of the pulp (pulp protection) is recommended. Dentin should be primed with a suitable dentin priming agent (e.g. Oxford Bond TE Mono).

Apply then Oxford Iono VLC in a thin layer (max. 1 mm). Do not apply to the cavity edges and remove any paste sticking to them. Light cure Oxford Iono VLC for **20 seconds** by using a polymerization unit (wavelength range 400-500 nm) with a light intensity of at least 1000mW/cm². Then proceed with light cure composites, e.g. Oxford Ceram NANO.

After use discard the NeedleTip and attach the cap to the syringe again.

NeedleTips are for single use only due to hygienic reasons!

Storage

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

Additional Notes/Warnings

- Do not use any resin to adjust viscosity of Oxford Iono VLC.
- 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

Dimethacrylates, dental glass, 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.