

Directions for Use

Dual Cure Permanent Root Canal Filling Material

Product description

Oxford Root FILL is a **dual cure** flowable root canal filling material based on methacrylates. The hydrophilic properties of Oxford Root FILL allow a very good adaptation to the root canal walls. Sealing of the root canal is excellent due to the very low shrinkage during setting of Oxford Root FILL. Oxford Root FILL shows an excellent radiopacity, which makes easier radiological examination possible. In case of revisions of the root canal filling, Oxford Root FILL can be removed easily from the root canal.

Indications/Intended use

Permanent root canal sealing of the secondary dentition with or without the aid of root canal points.

Performance features

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

Contraindications

In cases where the root canal has been treated with eugenol containing products, do **not** use Oxford Root FILL. Do not use for patients with allergic reactions against methacrylates.

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.

Application

Isolation

Rubber dam is the recommended method of isolation.

1. Preparation of the Root Canal

Prepare the root canal mechanically. Use of Oxford Root PREP in combination with sodium hypochlorite solution (NaOCl) gives excellent results.

Clean and disinfect the root canal using an antibacterial agent (e.g. sodium hypochlorite NaOCl). Thoroughly rinse the antibacterial solution from the root canal with EDTA solution or bacteria-free water before application of Oxford Root FILL.

Note:

Do not use any lubricant or irrigants that are not specifically designed for endodontic use.

Remove excess liquid with dry paper points but do not desiccate the root canal.

2. Conditioning of the Root Canal

To achieve an optimal obturation, apply the self etching dual cure sealer Oxford Root SEAL to the prepared root canal. One drop of Oxford Root SEAL PART A and one drop of Oxford Root SEAL PART B were combined in a mixing pallet and mixed for 5-10 seconds.

Notes:

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

Use the supplied Oxford Endo BRUSH and apply the homogenous mixture to the root canal walls for 10 seconds with agitation. Repeat procedure 1-2 times.

Remove excess sealer with dry paper points. Light cure all areas that are available for a dental curing unit for 20 seconds.

3. Application of Oxford Root FILL

3.1. Preparing the MINIMIX-Syringe

First Scientific Dental Materials GmbH only recommends for Oxford Root FILL the use of mixing cannulas Oxford Mix TIP(O)12 and intra oral tips Oxford Endo TIP.

Remove the cap of the MINIMIX-syringe and throw it away (**do not use it again!**). It is replaced by a special 4:1 mixing cannula. Bleed the MINIMIX-

syringe before applying the mixing cannula. Gently press the plunger until both components (base and catalyst) begin to flow out evenly. Make sure that the guidance of the MINIMIX-syringe is aligned with that of the mixing cannula and turn the cannula 90° clockwise until it locks in position. Attach an endo tip to the mixing cannula. The material is now ready for application.

Note:

Discard the first 2-3 mm of the extruded material, which must have a pale pink color. This must be done for each new mix. Store the used MINIMIX-syringe with fixed used mixing cannula.

3.2. Application

Oxford Root FILL can be used in combination with gutta percha points. Trial fit the gutta percha points to the desired length.

Apply Oxford Root FILL with the endo tip directly into the root canal. Depending on the preferred technique, e.g. with a lentulo ensure that Oxford Root FILL is brought to the apex.

Place the gutta percha point cautiously. Trim excess gutta percha at the canal orifice with a hot instrument.

Oxford Root FILL has a **working time of 10-15 minutes** (at 23 °C / 74 °F).

Light cure Oxford Root FILL at the orifice for 40 seconds with a dental curing unit. Light curing will create a slightly hardened surface.

Note: Full polymerization in the root canal will occur within 1 – 2 hours.

After light curing the surface of the root canal filling proceed with core build-up or filling with a bonding or composite.

4. Additional Notes/Warnings

- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.
- In case of contact with eyes, rinse with copious amounts of water and consult a physician immediately. In case of skin contact wash immediately with water.
- Neither store the composite material in proximity of eugenol containing products, nor let the composite allow to come into contact with materials containing eugenol. Eugenol inhibits the polymerization of the composite.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

Zusammensetzung

Dimethacrylates, zinc oxide, radiopaque glass filler, silicon dioxide, catalysts, photo initiators

5. Storage

Store at room temperature (25 °C / 77 °F), protected from direct sunlight. Opened syringes have been used up within 3 months.

Do not use after expiry date!

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.

Hinweis

Kurzberichte über Sicherheit und klinische Leistung für das Medizinprodukt sind in der Europäischen Datenbank für Medizinprodukte (EUDAMED – <https://ec.europa.eu/tools/eudamed>) hinterlegt.

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.