

## Directions for Use

### Dual Cure Core Build-up and Post Cementing Composite

#### Product description

**Oxford Flo CORE** is a dual cure radiopaque flowable composite material for core build-up and cementation of posts. Oxford Flo CORE is also suitable for cementing of crowns and bridges, inlays and onlays. For all indications the use of a dual cure bonding agent (e.g. Oxford Bond SE Dual) is required before application of the composite.

Oxford Flo CORE is based on poly- and difunctional methacrylates and inorganic filler particles of 0.05-2.5 µm. The total filler content is 66 % by weight and 46 % by volume. Delivered in 1:1 MINIMIX-syringes Oxford Flo CORE can be easily dispensed and applied directly. Oxford Flo CORE exhibits a short setting time without high heat generation and shows excellent thixotropic behavior. The dual cure properties enables the dentist, also to carry out cementations and core build-ups in cases where light cure cannot be guaranteed to be sufficient.

Oxford Flo CORE meets the requirements of **ISO 4049**, type 2, class 3.

#### Indications/Intended use

- Cementing of posts
- Core build-up
- Cementing of crowns and bridges, inlays and onlays

#### Performance features

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

#### Contraindications

The placement of Oxford Flo CORE is contraindicated if a dry working area or the recommended application technique are not possible.

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 (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.

#### Preparing the MINIMIX-Syringe

First Scientific Dental Materials GmbH only recommends for Oxford Flo CORE the use of mixing cannulas type Oxford Mix TIP(O) Minimax 1:1 and intra oral tips Oxford EndoTIP Minimax.

Remove the cap of the MINIMIX-syringe and throw it away (**do not use it again!**). Bleed the MINIMIX-syringe before applying the mixing cannula. Gently press the plunger until both components (base and catalyst) begin to flow out evenly. Attach a 1:1 mixing cannula. 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 intra-oral tip to the mixing cannula. The material is now ready for application.

#### Note:

Discard the first 3-5 mm of the extruded material. This must be done for each new mix.

Store used syringe with fixed used mixing cannula in the dark.

**The working time (23°C / 74°F) of Oxford Flo CORE in the self cure mode is 1:30 minutes from start of mixing.**

### 1. Post Cementation

#### 1.1. Isolation

Use of a rubber dam to isolate the tooth is strongly recommended.

#### 1.2. Root Canal Preparation

Refer to directions of the selected post manufacturer.

Remove all existing old restorations and decay from the tooth. Prepare and clean the root canal with e.g. sodium hypochlorite solution, rinse and remove excess solution from the canal with a soft paper tip.

Apply a dual cure bonding agent to the clean surfaces.

The self-etching bonding agent Oxford Bond SE Dual is recommended.

One drop of Oxford Bond SE Dual Part A and one drop of Oxford Bond SE Dual Part B were combined in a mixing pallet and mixed for 5-10 seconds.

#### Note:

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

Apply the homogeneous mixture generously with a suitable brush onto the slightly wet root canal walls for 15 seconds with agitation. Repeat procedure 1–2 times. All the dentine surfaces must kept wet with the primer over the specified time

Remove excess Oxford Bond SE Dual with dry paper points. Dry the root canal cautiously with oil free air for 15 seconds to remove all volatile components and to disperse the adhesive to an even layer. Light cure all areas that are available for a dental curing unit for 20 seconds.

**For a maximal adhesion it is strongly recommended to use the light cure mode.**

If light cure is absolutely impossible, the adhesive will also cure in the autocure mode. After application of the adhesive air thin to **remove all volatile components**. There must remain a sticky layer.

#### 1.3. Post Cementation

Prepare the selected post according to manufacturer directions.

Oxford Flo CORE is applied into the prepared root canal and onto the post. Seat the post careful into the canal and maintain firm pressure until the post is seated. Oxford Flo CORE self-cures within **3:30 minutes**. For post stabilization light cure the coronal part of the cemented post for **20 seconds** with a polymerization unit in the wavelength range 400-500 nm and a light intensity of at least 1000mW/cm<sup>2</sup>.

As soon as the Oxford Flo CORE has set proceed with the core build-up procedure.

## 2. Core Build-up

### 2.1 Isolation

Use of a rubber dam to isolate the tooth is strongly recommended.

### 2.2. Cavity Preparation

Remove all existing old restorations and decay from the tooth. If necessary place any pins or posts. Refer to directions of the selected post manufacturer.

### 2.3. Pulp Protection

Cavity floor of deep excavations should be covered with a thin layer of calcium hydroxide material.

### 2.4. Application of a Bonding Agent

Apply a dual cure bonding agent to the clean surfaces.

The self-etching bonding agent Oxford Bond SE Dual is recommended.

One drop of Oxford Bond SE Dual Part A and one drop of Oxford Bond SE Dual Part B were combined in a mixing pallet and mixed for 5-10 seconds.

#### Note:

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

Apply the homogeneous mixture generously with a suitable brush onto the slightly wet enamel- and dentin surfaces for 30 seconds with agitation. The material should build a homogeneous layer. Air thin for 10 seconds to remove the volatile components and to disperse the adhesive. Then light cure with a dental halogen light unit for 20 seconds and place the restorative material.

**For a maximal adhesion it is strongly recommended to use the light cure mode.**

If light cure is absolutely impossible, the adhesive will also cure in the autocure mode. After application of the adhesive air thin to **remove all volatile components**. There must remain a sticky layer.

#### Note:

It is essential that the primed dentine and enamel surfaces are dry and contaminant free for the application of Oxford Flo CORE.

### 2.5. Application

Place the mixing cannula directly into the preparation and press out the paste.

Oxford Flo CORE is automatically mixed when dispensed with slight and even pressure. Filling should occur from bottom upwards to prevent voids.

To facilitate placement of Oxford Flo CORE place a matrix band around the prepared tooth.

Oxford Flo CORE may be contoured by using a composite instrument. A flat-ended interproximal carver is recommended.

Place Oxford Flo CORE directly into the preparation and allow the system to self cure for **3:30 minutes**. After that the material should be light-cured for **40 seconds** with a polymerization unit in the wavelength range 400-500 nm and a light intensity of at least 1000mW/cm<sup>2</sup>. With this technique an optimum of physical properties will be obtained.

An explorer can be used to test that the Oxford Flo CORE has completely set. Remove the matrix not earlier than the material has set.

Final core preparation on the Oxford Flo CORE can be carried out by using crown preparation burs.

### 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 the composite.
- 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.
- Unpolymerized composite may have an irritant effect and can lead to sensitization against methacrylates.
- Color stability meets the requirements of DIN EN ISO 4049.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

### Composition

Dimethacrylates, dental glass, silicone dioxide, photo initiators, catalysts

### Storage

Do not store above 20 °C (68 °F). Protect from direct sunlight. Store unopened material in the refrigerator.

Opened syringes have to be 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.

### 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 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 exclusive remedy and First Scientific Dental Materials GmbH' 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.**