

Directions for Use

Temporary Crown & Bridge Material 10:1

Product description

Oxford Temp is an automatically mixed two component material in cartridges based on multifunctional methacrylic esters. The temporary material is a very easy and comfortable material for creating short- and long-term temporary crowns or bridges, onlays and veneers. Because of its flexibility, the material is especially suitable for longer bridge spans.

Oxford Temp is free of methyl methacrylate. Its temperature derived while curing is lower than 40 °C (104 °F). As a temporary crown or bridge it protects the prepared teeth against external influences and preserves the occlusion. It shows increasing transverse strength, good abrasion resistance and low polymerization shrinkage. It fits perfect. Showing good polishability, good color stability and fluorescence it looks perfect.

Indications/Intended use

- Fabrication of temporary crowns, bridges, inlays, onlays and veneers

Performance features

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

Contraindications

Do not use for patients with allergic reactions against acrylates. Oxford Temp should not be used any more, if allergic reactions are observed.

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

1. Impression taking

Before preparing of stumps or before a planned extraction of a tooth a situation impression is made by addition curing silicones (long storage stability!) or by alginates. For better stability of the temporary interdental areas are carved out. In molar areas with teeth absent it may be necessary to cut a groove in the impression between the abutments to create a bridge-like connection between the tooth units.

Note:

In the silicone impression block out undercuts and if necessary cut grooves into the impression.

2. Preparing of the Automix-cartridge

First Scientific Dental Materials GmbH only recommends for Oxford Temp the use of mixing cannulas type Oxford Mix TIP(S) Automix 4:1/10:1.

Remove the cap of the Automix-cartridge and throw it away (**do not use it again!**). Bleed the Automix-cartridge before applying the mixing cannula. Gently press the plunger until both components (base and catalyst) begin to flow out evenly. Attach a 10:1 mixing cannula. Make sure that the guidance of the Automix-cartridge is aligned with that of the mixing cannula and turn the cannula 90° clockwise until it locks in position. The application gun is loaded with the prepared cartridge and is ready for application.

Note:

The initial extrusion from the mixing cannula (about the size of a pea) should be discarded. Then the following mix will be perfect. This must be done for each new mix.

Leave the used mixing cannula on the cartridge. It serves as a cap.

3. Forming of the temporary crowns / bridges

Oxford Temp is automatically mixed when dispensed with slight and even pressure directly into the situation impression made before. Filling should occur from bottom upward to prevent voids.

Working time of Oxford Temp is 50 seconds (at 23 °C/74 °F)

a. Application in the mouth

Load the situation impression with Oxford Temp. Seat the impression within the working time (50 seconds at 23 °C/74 °F) onto the prepared areas of the teeth.

After 1-2 minutes (setting time in mouth 37 °C/98 °F) the material shows hardened but still elastic condition and can be removed from the teeth together with the situation impression.

b. Application on the model

Load the situation impression with Oxford Temp. Seat the impression within the working time (50 seconds at 23 °C/74 °F) onto the prepared areas of the model.

After 3-4 minutes (setting time at 23 °C/74 °F) the material shows a hardened but still elastic condition and can be removed from the model together with the situation impression.

Note:

The setting reaction has to be checked with excess material intra-orally (e.g. with a scaler) resp. on the model. Temperature in mouth has a significant effect on setting reaction and the temporary can only be removed without destruction during the elastic state.

4. Post curing and finishing

If possible, leave the temporary in the situation impression during post curing. Optimally the temporary is post cured in warm (45-55 °C /113-131 °F) water (e.g. in a hot cure polymerization device) until reaching its final hardness (approx. 4:30 min from start of mixing). Post curing at room temperature is completed after about 6 minutes from start of mixing.

After removal from the impression excess material and proximal undercuts are removed. Then the temporary acrylic can be worked out with rotary instruments and can be polished to high gloss.

Do not breathe polishing dust; use suitable mouth protective device, safety glasses and aspiration!

Note:

The oxygen inhibited smear layer on the surface caused by the acrylic system can not be fully avoided and should be removed before working out. It can easily be removed by alcohol or other suitable solvents.

5. Cementing of the temporary

Oxford Temp temporary crowns or bridges preferably should be cemented with an eugenol-free temporary cement (e.g. Oxford Temp CEM Universal). In case of using eugenol-containing cements it should be considered that later used acrylate based cements could be hindered in hardening (inhibition of curing reaction by traces of remained eugenol).

6. Repairs

Oxford Temp temporaries show high mechanical strength. However, if a temporary breaks the following procedures are recommended:

a) Fracture shortly after production

Both ends of the fracture are refixed with freshly extruded Oxford Temp.

b) Fracture of longer existing temporary

The areas of fracture are cleaned and roughened and provided with some mechanical retentions. Thus prepared, the fractured areas can be joint with freshly extruded Oxford Temp. To enhance the curing place for some minutes in warm water.

7. Special hints

Non hardened Oxford Temp can easily be removed with alcohol or other suitable solvents.

8. Storage

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

9. Additional notes/Warnings

- Oxford Temp is free of methyl methacrylate but contains other acrylates.
- 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.
- For sensitive persons, sensitization to the material cannot be excluded. The material should not be used any more, if allergic reactions are observed. Do not use for persons with allergic reactions against acrylates.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

Composition

Unsaturated esters, multifunctional methacrylates, multifunctional malonyl urea derivatives, dental glass, silicon dioxide, catalysts

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

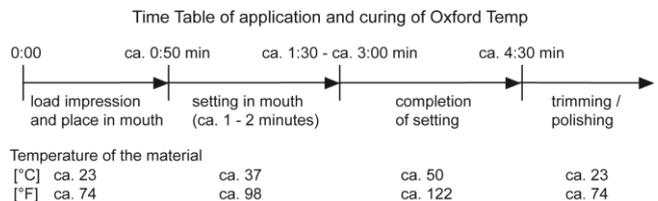
First Scientific Dental Materials GmbH warrants this product will be free from defects in material and manufacture. First Scientific Dental Materials makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your 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.



If the completion of setting takes place at room temperature, trimming / polishing can be done after 6 minutes (from start of mixing)

