

PRODUCT INFORMATION

OliBulk Fill Composite is a light curing, flowable, highly radiopaque (210 % Al) composite for posterior restorations, for direct filling and the „bulk fill“ technique.

The product complies with the guideline DIN EN ISO 4049.

COMPOSITION

Monomer matrix: diurethane dimethacrylate, butanediol dimethacrylate

Total filler: 77 % (by weight) inorganic filler (0.04 –15 µm).

INDICATIONS

- Fillings with layer thicknesses up to 4 mm in Black's class I and II cavities.
- Cavity lining – as a first (bottom) layer in Black's class I and II cavities.

APPLICATION**Preparatory measures**

Before beginning the treatment, clean the hard tooth substance with non-fluoride polishing paste.

1. CAVITY PREPARATION

Prepare the cavity with a minimally invasive method as generally required for adhesive techniques. All enamel margins in the anterior region must be bevelled. Do not bevel the margins in the posterior region and avoid slice preparations. Spray the cavity with water to clean it, remove all debris and dry it. Isolate the cavity to keep it dry. It is advisable to place a rubber dam.

2. APPROXIMAL CONTACT AREAS

For cavities with approximal sections, place a transparent matrix and fix it in place.

3. ADHESIVE SYSTEM

Etch and bond according to manufacturer's instructions. Avoid drying out the dentin. Dried, etched surfaces appear chalky white and must not be contaminated before the application of a bonding agent. In case of contamination with saliva, rinse and dry again. If necessary, etch once more.

4. APPLICATION OF OliBulk Fill

Place layers of max. 4 mm directly into the cavity.:

• Capsules

Insert the capsules in the dispenser and remove the sealing cap. Exert pressure slowly and uniformly to dispense the required amount of filling material from the capsules directly into the cavity.

Please note: For hygienic reasons capsules are for single use only.

• Syringes

Place layers of max. 4 mm of OliBulk Fill Composite directly into the cavity using the curved application tips supplied with the material. For hygienic reasons, these application tips must only be used once and then discarded. Avoid air bubbles when applying the material. Wet the prepared tooth surfaces thoroughly. Polymerize each layer with a conventional polymerization unit for 40 seconds, holding the light guide as close as possible to the surface. The polymerization time depends on the polymerization unit used. Check the compatibility of the polymerization unit. Ensure that the polymerization time is sufficient. Test the light output before each use. During polymerization, a dispersion layer forms on the material surface. This layer must not be touched or removed. It forms the bond with the layer of composite applied subsequently (e. g. with a universal or posterior composite) or for creating aesthetic cusps. Alternatively, OliBulk Fill Composite can be applied in a thin layer to form a liner on exposed dentin. The material can be polymerized in layers of up to 4 mm thickness.

5. FINISHING

OliBulk Fill Composite can be finished and polished directly after polymerization. To finish, use finishing diamond tools, flexible discs, silicone polishers and polishing brushes. Check occlusion and articulation. Grind down if necessary, thus avoiding premature or deflective contacts on the surface of the filling.

6. PLEASE NOTE

When creating large and time-consuming restorations either cover the material with a lightproof foil or temporarily move the operating light away from the site in order to avoid premature polymerization of the material.

For hygienic reasons, the curved application tips supplied with the material must only be used once, as a contamination of the material and a transfer of germs cannot be ruled out.

Use a polymerization unit with an emission spectrum of 350 – 500 nm to cure this material. As the required physical properties can only be achieved if the lamp is functioning correctly, its luminous intensity must be checked regularly as described by the lamp's manufacturer.

7. CONTRAINDICATIONS

Unpolymerized composite may cause skin allergies. The user must take adequate precautions (e. g. protective gloves). Do not use this material, if the user or patient should have known allergies against one of the components listed under „composition“.

8. SIDE-EFFECTS

With proper use of this medical device, unwanted side-effects are extremely rare. Reactions of the immune system (allergies) or local discomfort, however, cannot be ruled out completely. Should you learn about unwanted side-effects – even if it is doubtful that the side-effect has been caused by our product – please kindly contact us.

To prevent possible reactions of the pulp in cavities where the dentin is exposed, the pulp must be protected adequately (apply e. g. a calcium hydroxide preparation).

9. INTERACTION WITH OTHER SUBSTANCES

As phenolic substances (such as eugenol) inhibit polymerization, do not use cavity liners containing such substances (e. g. zinc Eugenol-cements).

10. STORAGE

Store at 10 – 25 °C (50 – 77 °F). Avoid direct sunlight. Close syringes tightly immediately after use. Let the material reach room temperature before use. After use, retract the plunger of the syringe slightly to prevent the apertures from becoming blocked. Do not use after the expiry date (refer to label on syringe). For use by dentists only. Keep out of children's reach. This product was developed specifically for the described range of application. It must only be used according to the above instructions. The manufacturer will not be held liable for damages caused by incorrect handling or incorrect processing of the material.

Keep away from children! For dental use only!

11. TROUBLESHOOTING

Trouble	Cause	Remedy
composite does not cure	Luminous intensity of the polymerization unit insufficient	check luminous intensity; replace light source, if necessary
	emitted spectral range of the polymerization unit insufficient	consult manufacturer of polymerization unit; recommended spectral range: 350 – 500 nm
composite seems to be too hard / firm inside the syringe / capsules	material was stored at temperatures below 10 °C for a longer period of time	let composite reach room temperature before use
	syringe was not closed tightly which caused part of the material to cure	close syringe tightly after each use
composite does not cure sufficiently	layer thickness per polymerization cycle too high	keep to max. layer thickness of 4 mm
restoration seems too yellow when compared to color reference	insufficient polymerization of the composite layers	repeat polymerization cycle several times, for a minimum of 40 sec

12. PACKAGING AND REFERENCE NUMBERS

1 syringe 2 g , 3 mixing tips, this instruction for use	OL095 - UD	OL117 - MD
20 compules 0,25 g , this instruction for use	OL096 - UD	OL118 - MD

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Reservation:

Olident Co. Ltd., L. P. warrants this product will be free from defects in material and manufacture. Olident Co. Ltd., L. P. 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 Olident Co. Ltd., L. P.'s sole obligation shall be repair or replacement of the Olident Co. Ltd., L. P. product.

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