INSTRUCTIONS FOR USE

solafil® BULKFIL

solafil BULKFIL

1 Intended Purpose

Dental filling materials on composite basis are used to build up or to preserve tooth structures.

2 Product description and user

2.1 Product description

solafil Bulkfil is a light-curing, flowable, highly radiopaque (210% Al) composite for posterior restorations, direct filling and processing with the bulk fill technique.
solafil Bulkfil is available in syringes and compules. The compules are for single use. Please do not reuse them since contamination and germ formation otherwise cannot be excluded.

2.2 Patient target group

All patients requiring tooth substance to be replaced or built up in order to restore or maintain dental function.

2.3 Users

Dental filling materials on composite basis are used in dental practice or in a dental hospital by dental professionals.

3 Composition

Glass powder, silicon dioxide, 1,4-butanediol dimethacrylate
Filler content: 77% by weight (57% by volume) inorganic fillers (0.005 - 40 µm)

4 Indications

- Fillings with layer thicknesses up to 4 mm in class I cavities
- Base fillings with layer thicknesses up to 4 mm in class II cavities. Class II cavities require coating with a composite suitable for class II cavities.
- Cavity lining, as a first (bottom) layer in class I and II cavities

5 Contraindications

If a patient has allergies or hypersensitivities to a component of this product, it should not be used or used only under the strict supervision of the attending physician/dentist.

6 Warnings

Contains: di-urethane dimethacrylate, tetramethylene dimethacrylate
Important: May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.

7 Safety instructions

Wear protective gloves. Avoid breathing vapours und spray.

8 Interactions with other materials

Phenolic substances (such as eugenol) inhibit polymerisation. Therefore, do not use any lining materials (such as zinc oxide-eugenol cements) which contain substances of this type. The dentist should consider known interactions and cross-reactions of the medical product with other materials already in the patient's mouth before using the product.

9 Application

Prior to the treatment, clean the hard tooth tissue with a fluoride-free polishing paste.

9.1 Cavity preparation

Preparation of the cavity with protection of the hard tooth tissue according to the general rules of adhesive technique. In the region of the anterior teeth, all enamel edges must be bevelled. In the region of the posterior teeth, by contrast, do not bevel the edges and avoid feather edges. Then clean the cavity with water spray, remove all residues, and dry it. Isolation is necessary. The use of a rubber dam is recommended.

9.2 Pulp protection/lining

Lining is not necessary if an enamel-dentin adhesive is used. If there are very deep cavities near the pulp, cover corresponding areas with a calcium hydroxide preparation.

9.3 Approximal contact areas

For cavities with approximal sections, a transparent matrix must be created and fixed in place.

9.4 Adhesive system

Etching and bonding according to the manufacturer's instructions.

9.5 Application of composite

9.5.1 Application from syringes

Rotate the delivery tip clockwise until it lock in place on the syringe and dispense solafil Bulkfil Composite in thin layers (max. 4 mm) directly into the cavity. Use the curved delivery tips included with the kit for application. For hygiene reasons, tips are intended only for single use. Avoid introducing air bubbles during application with the tip. Ensure the prepared hard tooth tissue is thoroughly wetted.

9.5.2 Application from compules

Insert the compule in the dispenser. Remove the cap. Secure the compule such that the opening is aligned at the correct angle for application into the cavity. Introduce the material into the cavity using slow, even pressure. Do not use excessive force! The layer thickness must not exceed 4 mm. When finished, pull back the spindle to remove the compule from the dispenser. Then remove the compule.
Note: For hygiene reasons, compules are intended only for single use.

9.6 Curing

Cure each layer after coating for 20 seconds using a commercially available polymerisation unit. The light guide must be held as close as possible to the surface of the filling. A dispersion layer forms on the surface during polymerisation which should not be touched or removed. It bonds to the next composite layer (e.g. a universal or posterior dental composite) or the aesthetic cusp onlay. Alternatively, a thin layer of Bulk Fill Composite can be applied to exposed dentine as a liner. Polymerisation can be applied incrementally up to 4 mm.

9.7 Finishing

solafil Bulkfil can be finished and polished immediately after polymerisation. Finishing diamonds, flexible discs, silicone polishers, and polishing brushes can be used for finishing. Check the occlusion and articulation and grind so that no early contacts or undesirable paths of articulation remain on the surface of the restoration.

10 Special information

- In case of time-consuming restorations, the surgical lamp should be temporarily moved away from the working area to prevent the composite from curing too early or the material should be covered with an opaque foil.
- The curved delivery tips supplied with the kit are intended for single use only since contamination of the materials and spread of germs cannot be ruled out.

turn over ▸

• A light polymerisation unit with an emission spectrum in the range of 350 - 500 nm is to be used for polymerisation. The physical properties required are achieved only with properly working lamps. For this reason, it is necessary to regularly check the light intensity according to the manufacturer's instructions.

Light intensity for curing	≥ 1200 mW/cm^2
Wavelength for curing	350-500 nm
Curing time	20 sec.

11 Troubleshooting

Fault	Cause	Corrective action
Composite does not cure	Light output of the polymerisation lamp is inadequate	Check the light output clean light guide if soiled. Replace the light source, if necessary
	Emitted wavelength range of the polymerisation lamp is inadequate	Consult the manufacturer of the polymerisation lamp. Recommended wavelength range: 350 - 500 nm
Composite appears to be too hard and solid in the syringe	Material stored for a longer period of time at temperatures < 10°C	Allow composite to warm up to room temperature before use
	Syringe not closed correctly, composite polymerised	Close the syringe correctly with the cap each time after removing composite
Composite does not correctly cure (dark or opaque shades)	Composite layer too thick per curing cycle	Maintain max. layer thickness of 4.0 mm per layer
Restoration appears too yellow in comparison to the colour reference	Inadequate polymerisation of the composite layering	Repeat exposure cycle several times, min. 20 sec.

12 Information on storage and handling

Store at 10 - 25°C (50 - 77°F). Close syringes tightly immediately after use. The material should be at room temperature before use. Retract the syringe spindle slightly after use to prevent the discharge opening from becoming clogged.

13 Shelf life

The maximum shelf life is printed on the label of each syringe. Do not use after the expiry date.

14 Side effects

With proper preparation and use of this medical product, adverse effects are extremely rare. However, immune reactions (such as allergies) or local discomfort cannot in principle be ruled out completely. All serious incidents which occur in connection with the use of this product are to be reported to the manufacturer indicated below and the competent authority in each case.

15 Disposal

Leftover quantities and packaging materials are to be disposed of according to the local and/or statutory regulations.

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