INSTRUCTIONS FOR USE

solafil® B40

solafil B40 is alightcuring, flowable(Bulkfil), highly radiopaque(210% Al) composite with a high viscosity. The guidelines and requirements of DIN EN ISO 4049apply. solafil B40 is available in syringes and compules. The compules are for single use only. Please do not reuse them, as this makes impossible to rule out contamination and germ formation.

Composition:
Monomer matrix: Diurethane dimethacrylate, 1,4-butanediol dimethacrylate
Total filler: 77% by weight (57% by volume) inorganic filler (0.005–40 µm)

Indications:
• Fissure sealing and Extensive fissure sealing on molars and premolars
• Fillings in Black's class V (cervical caries, root erosions, v-shaped lesions)
• Minimally invasive fillings in Black's classes I, II and III
• Corrections of enamel defects
• Blocking out undercuts
• Small corrections of shape and colour of the enamel

Procedure:
Pre-treatment
Before starting the treatment, clean the hard tooth substance with a fluoride-free polishing paste. Select the correct colour with help of the shade guide while the tooth is still moist.
1. Cavity preparation: Prepare the cavity according to the general rules of the adhesive technique. Use a procedure that is gentle on the hard tooth substance. Bevel the incisal edges on anterior teeth. Do not bevel the edges on posterior teeth. Avoid irregular edges. Next, clean the cavity with water spray, remove all residue and dry. It is necessary to dry the site completely.
2. Pulp protection/liner: The use of a liner can be foregone if an enamel dentin adhesive is used. In case of very deep cavities that come close to the pulp, cover according to surfaces with a calcium hydroxide compound.
3. Design of the approximal contacts: For cavities in approximal areas, insert and fix a transparent matrix.
4. Adhesive system: Etch (e.g. solaetch) and bond (e.g. solabond) according to manufacturer's instructions.
5a. Application of solafil FLOW Composite syringes: Fill solafil FLOW Composite in thin layers (max. 2 mm) directly into the cavity. Use the disposable curved application tips included with the material. For hygiene reasons, do not use the application tips more than one time.
Avoid introducing air bubbles into the material during application with the tip. Ensure that the prepared hard tooth substance is well-coated
Polymerise each layer with a conventional polymerisation lamp for 40 sec. A dispersion layer will form on the surface of the material during polymerisation. This dispersion layer forms the chemical bond between the layers and must not be touched or removed.
5b. Application of solafil B40 Composite compules: Insert the compule into the dispenser. Remove the sealing cap. Place the compule in the correct angle towards the cavity. Inject the material into the cavity. Apply slow and steady pressure to the compule. Do not use excessive force! To remove the compule from the dispenser after use, retract the plunger. Next, remove the compule. Please note: For hygiene reasons, compules are intended for single use only.
6. Finishing solafil B40 Composite is ready to be finished and polished directly after polymerisation Suitable tools are finishing diamonds, flexible wheels, silicone polishers and polishing brushes.

Special notes:
• In case of extensive restorations, the surgical light should be moved away from the working area temporarily to avoid premature curing of the composite. Alternatively, the material can be covered with a light-tight foil.
• For hygiene reasons, do not use the curved application tips included with the product more than once. Dispose of the tips directly after use. Use a light polymerisation system with an emission range of 350–500 nm to polymerise the material. The required physical properties are only reached if the polymerisation light functions properly. Therefore, it is necessary to check the light intensity regularly according to the manufacturer's instructions.

Light intensity for curing	≥ 650 mW/cm^2
Wavelength for curing	350-500 nm
Curing time	40 sec

Hazard statement/precautionary statement:
Contains Tetramethylene dimethacrylate
Warning: May cause an allergic skin reaction.
Wear protective gloves/protective clothing/eye protection/face protection. If skin irritation or rash occurs: Get medical advice/attention.

Contraindications
If a patient has known hypersensitivities towards a

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component of this product, we recommend not to use it or to do so only under strict medical supervision. The dentist should consider known interactions and cross-reaction of the product with other materials already in the patient's mouth before using the product.

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. In case of exposed dentin in a cavity, ensure proper protection of the pulp to avoid possible pulp reactions (e.g. line the cavity with a calcium hydroxide compound).

Cross-reactions with other substances:
Phenolic substances (e.g. eugenol) inhibit polymerisation. Therefore, these materials (e.g. zinc oxide eugenol cements) must not be used as liners.

Disinfection/Protection from cross-contamination:
Place the functioning syringe with application tip into a suitably shaped barrier sheath; pierce the end of sheath with cannula, exposing the cannula for use. Using a barrier sheath facilitates cleaning and disinfection of the syringe between patients. After use of sheathed syringe, remove delivery tip and sheath by grasping on the hub of the delivery tip through the sheath, twist and remove tip along with sheath.
Discard used tip and sheath in an appropriate waste stream. Replace syringe storage cap.
Disinfect – After removal of the delivery tip and sheath, disinfect this product using an intermediate level disinfection process (liquid contact) as recommended by the Centres for Disease Control and endorsed by the American Dental Association, Guidelines for Infection Control in Dental Health-Care Settings–2003 (Vol. 52; No. RR-17), Centres for Disease Control and Prevention (USA).

Storage:
Store at temperatures between 10°C and 25°C (50°F to 77°F). Avoid direct sunlight. Screw the cap back onto the syringe tightly after each use.
Let the material reach room temperature before use.
Withdraw the plunger slightly after use to keep the outlet from becoming plugged. Do not use after the expiration date (see the label on the syringe).
The only for use in dentistry. Keep out of children's reach. This product has been developed for the specific use illustrated above. Only process as described in these instructions. The manufacturer will not be held liable for any damages that result from improper use or improper processing.

Trouble shooting

Trouble	Cause	Remedy
Composite does not cure	Luminous intensity of the polymerisation unit insufficient	Check luminous intensity; replace light source, if necessary
	Emitted spectral range of the polymerisation unit insufficient	Consult manufacturer of polymerisation unit; recommended spectral range: 350 – 500 nm
Composite seems to be too hard/ firm inside the syringe	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 correctly with the cap after each use
Composite does not cure sufficiently	Layer thickness per polymerisation cycle too high	Keep to max. layer thickness of 2 mm
Restoration seems too yellow when compared to colour reference	Insufficient polymerisation of the composite layers	Repeat polymerisation cycle several times, for a minimum of 40 sec.



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