

solafil ONE Micro Hybrid Composite is a light curing composite containing an ultrafine, radiopaque glass filler and is indicated for placing fillings using adhesive techniques. It can be polished to a high lustre. Due to the ultrafine particle filler, extremely homogeneous restorations can be placed which are easily polished to a high lustre. The chameleon effect matches the shade of the filling perfectly to the tooth structure. The guidelines of EN ISO 4049 have been complied with. solafil ONE Micro Hybrid Composite is available in syringes and compules. The compules are for single use. Please do not reuse them, as this makes it impossible to rule out contamination and germ formation.

Composition

Glass powder, diurethane dimethacrylate, silicon dioxide, Bis-GMA, tetramethylene dimethacrylate. Total filler: 75% by weight (53% by volume) inorganic filler (0.005-3.0 µm)

Indications

- Direct anterior and posterior restorations in Black's class I, II, III, IV, and V cavities
- Inlays, onlays and laminate veneers
- Extended fissure sealing in molars and premolars
- stump build-up
- Splinting loose teeth
- Adjusting the contours and shades to improve aesthetics

Application—Pretreatment

Before commencing the treatment, clean the tooth with non-fluoride polishing paste. Use a shade guide to select the shade while the tooth is still moist.

1. Cavity preparation: Minimal-invasive preparation of the cavity 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. The cavity must be isolated. It is advisable to place a rubber dam.

2. Pulp protection/Cavity liner: If an enamel-dentine adhesive is used, no cavity liner is required.

In very deep cavities those areas in close proximity to the pulp must be coated with a calcium hydroxide material.

3. Approximal contact areas: When filling cavities with approximal sections, place a transparent matrix and fix it in place.

4. Adhesive system: Etch (e.g. solaetch) and bond (e.g. solabond) according to manufacturer's instructions.

5a. Application of solafil ONE Micro Hybrid Composite (syringes): Take the required amount of composite from the syringe, place it in the cavity with conventional metal instruments and contour. The layer thickness must not exceed 2mm

5b. Application of solafil ONE Micro Hybrid Composite (compules): Place the compules in the dispenser. Remove the sealing cap. Position the compules in such the opening is at a suitable angle for application

within the cavity. Insert the material into the cavity while slowly and evenly applying pressure. Do not use excessive force! Once finished, pull back the punch in order to remove the compules from the dispenser. The compules can then be removed. Note: for hygiene reasons, the compules are only intended for single use.

6. Curing: The curing time for all shades is 40 sec. per layer with a conventional halogen curing lamp or an LED curing lamp. With a plasma curing system, the curing time is 2 x 3 seconds. Hold the waveguide as close to the surface of the filling as possible.

Fillings with more than one surface must be cured of the direction of each surface separately. Due to the effect of the oxygen in the air, a thin smear layer of unpolymerised material remains on the surface of each layer. This bonds the layers chemically and must not be touched or contaminated with moisture

7. Trimming: solafil ONE composite can be trimmed and polished immediately after curing using finishing diamonds, flexible disks, silicone polishers and polishing brushes.

Check the occlusion and articulation and spot grind to eliminate high spots or undesirable paths of articulation from the surface of the filling.

Cavity preparation: Inlays, Onlays, Veneers

The cavity should be prepared as minimally invasively as possible with only slightly diverging sides. To prevent the material fracturing, the layer must have a minimum thickness of 1.5 mm in the lateral and vertical aspects. All internal edges and angles must be rounded. Avoid slice preparations. Prepare a flat cervical shoulder – do not bevel it. Any unavoidable undercuts must be blocked out with glass ionomer cement. Use slightly tapering diamonds with rounded tips for the preparation. Coat those areas of dentin in close proximity to the pulp with a thin layer of calcium hydroxide material. Cavity liners containing eugenol are contraindicated.

Impression and temporary restoration

Once the impression has been taken, a composite temporary restoration is fabricated. This may only be cemented with a non-eugenol cement

Fabricating an inlay, onlay or laminate veneer

Cast the impression with hard stone plaster. Allow the model to set and pull off the impression. Block out the undercuts and apply an oil-free separating agent to the model. Build up the inlay on the model layer-by-layer. Build up the approximal and deep occlusal sections first. Each individual layer may not be thicker than 2 mm and is cured separately with a commercially available light curing lamp (e.g. HiLite Power, Heraeus Kulzer, intermediate polymerisation 90 seconds/final polymerisation 180 seconds). The finished inlay is then released from the die. Trim and polish to a high lustre. Clean the inlay thoroughly with soap and water rinse with air/water spray and dry

Placing the inlay, onlay or laminate veneer

Remove the temporary restoration and clean the cavity. Place a rubber dam before cleaning and drying the prepared surfaces of the tooth. Exert gentle pressure on the inlay to check for fitting accuracy. Do not use force. If necessary, trim the fitting surfaces to improve the fit. The occlusion and articulation may not be checked when trying to fit the inlay as this could cause fractures. Etching and bonding according to the manufacturer's instructions

Fixing the restoration

The restoration is fixed with a commercially available dual-curing fixing composite. Please adhere to the manufacturer's instructions.

Special notes

- The working time under a surgical lamp is approximately 2 minutes
- In case of time-consuming restorations, the surgical lamp should be either temporarily moved away from the working area or the material should be covered by an opaque foil in order to prevent the composite from curing too early
- Use a light-curing unit with an emission spectrum of 350-500 nm for the polymerisation of this material. As the required physical properties can only be achieved when the lamp works correctly, its luminous intensity must be checked regularly as described by the manufacturer.

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

Hazard and Precautionary statements

Contains tetramethylene dimethacrylate

Warning: May cause an allergic skin reaction. Avoid breathing vapours/ spray. Wear protective gloves/ protective clothing/eye protection/face protection. If skin irritation or rash occurs: Get medical advice/attention.

Contraindications/interactions.

If a patient has known allergies against or hypersensitivities to a component of this product, it may not be used or only under strict medical supervision by the doctor/dentist. The dentist should consider known interactions and cross-reactions 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. To prevent possible reactions of the pulp in cavities where the dentin is exposed, the pulp must be protected adequately (e.g. calcium hydroxide preparation)

Interactions with other substances

As phenolic substances (such as eugenol) inhibit polymerisation, do not use cavity liners (such as zinc-oxide eugenol cements) containing such substances

Storage

Storage Store at 10-25°C (50-77°F). Close the screw syringes tightly immediately after use. The material should be at room temperature before use. Retract the plunger of the syringe slightly to prevent the apertures from becoming blocked. Do not use after expiry date (refer to label on syringe). For use by dentists only. Keep out of reach of children. This product was developed specifically for the described range of applications. It must be used as described in the instructions. The manufacturer is not liable for damage caused by handling or processing the material incorrectly

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Trouble shooting

Problem does not	Cause	Remedy
Composite does not cure properly.	Light output of the light-curing lamp is inadequate	Check the light output and change the light source if required
	Emitted wavelength range of the light-curing lamp is inadequate	Consult the manufacturer of the light-curing lamp. Recommended wavelength range: 350 - 500 nm
Composite in the syringe is sticky and soft, colourless liquid separates in the syringe.	Material has been stored for a longer period at > 25°C (77°F)	Adhere to storage temperature. Store at 10-25°C (50-77°F).
	Material has been kept in a syringe warmer for too much time	Never keep a syringe longer in a syringe warmer for more than one hour per application
Composite appears too hard and firm in the syringe.	Material stored at temperature < 10°C (50°F) for a longer period of time	Allow the composite to heat to room temperature before use; use a syringe warmer if necessary
	Syringe not properly sealed, composite partially cured	Always seal the syringe properly with the cap after taking out composite
Inlay / onlay is not properly retained when fitted.	Restoration is too opaque to be cemented using only light-curing composite	Use dual-curing luting composite
Composite does not cure completely (dark or opaque shades)	Composite layers applied too thickly for each curing cycle	Adhere to a max. thickness of 2.0 mm per layer
Restoration appears too yellow compared with the shade guide.	Inadequate curing of the composite layer	Repeat the exposure cycle several times min. 40 sec.



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Date of issue: Dec 2021

Rev no: 03