INSTRUCTIONS FOR USE

solafil® M90

solafil M90 Micro Hybrid

1 Intended purpose

Dental filling materials on composite basis are used to build-up or maintain tooth substance.

2 Product description and user

2.1 Product description

solafil M90 Micro Hybrid is a light curing, hybrid composite containing an ultrafine, radiopaque glass filler and is indicated for placing fillings using adhesive techniques. 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.
solafil M90 Micro Hybrid 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.

2.2 Target patient group

All patients who require replacement or build-up of tooth structure to restore or maintain tooth function.

2.3 Users

Dental filling materials on composite basis are applied by the dentist in the dental office or in a dental clinic.

3 Composition

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

4 Indications

- Anterior and posterior restorations in Black's classes I, II, III, IV, and V cavities.
- Inlays, onlays and veneers
- Extended fissure sealing in molars and premolars
- Core build-up
- Splinting of loose teeth
- Corrections of shape and color to improve aesthetics

We recommend using the color smart shade (Universal) in the posterior region. An opaque color (opaque) is also offered to cover stronger discolorations.

5 Contraindications

If the patient is allergic or hypersensitive to one of the components, this product must not be used or only under the strict supervision of the attending doctor / dentist. Cavity liners containing eugenol are contraindicated.

6 Hazard and Precautionary statements

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

7 Safety instructions

Avoid breathing vapors/spray. Wear protective gloves. If skin irritation or rash occurs: Get medical advice / attention.

8 Interaction with other materials

As phenolic substances (such as eugenol) inhibit polymerization, do not use cavity liners (such as zinc-oxide eugenol cements) containing such substances.
Well-known cross-reactions or interactions of the medical device with other materials already in the patient's mouth must be considered by the dentist before using the product.

9 Application

9.1 Restorations of the anterior teeth and incisors

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

9.1.1 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 residue and dry it. The cavity must be isolated. It is advisable to place a rubber dam.

9.1.2 Pulp protection / Cavity liner

If an enamel-dentin 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.

9.1.3 Approximal contact areas

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

9.1.4 Adhesive system

Etch and bond according to manufacturer's instructions.

9.1.5 Application of composite

9.1.5.1 Application from 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 2 mm.

9.1.5.2 Application from compules

Place the compule in the dispenser. Remove the sealing cap. Position the compule in such a way that 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! The layer thickness must not exceed 2 mm. Once finished, pull back the punch in order to remove the compule from the dispenser. The compule can then be removed.
Note: For hygiene reasons, the compule are only intended for single use.

9.1.6 Curing

The curing time for all shades is 40 seconds per layer with a conventional dental curing lamp (Universal shade: 20 seconds). Hold the waveguide as close to the surface of the filling as possible. Fillings with more than one surface must be cured from the direction of each surface separately. Due to the effect of the oxygen in the air, a thin smear layer of unpolymerized material remains on the surface of each layer. This bonds the layers chemically and must not be touched or contaminated with moisture.

9.1.7 Finishing

solafil M90 Micro Hybrid can be finished and polished immediately after curing using finishing diamonds, flexible discs, 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.

9.2 Inlays, Onlays, Veneers

9.2.1 Cavity preparation

The cavity should be prepared as minimally invasively as

turn over ▸

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.

9.2.2 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.

9.2.3 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 polymerization 90 seconds/ final polymerization 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.

9.2.4 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.

9.2.5 Fixing the restoration

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

10 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 polymerization 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.

Only color smart shade (Universal):

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

11 Troubleshooting

Problem	Cause	Remedy
Composite does not cure properly	Light output of the light-curing lamp is inadequate	Control of the light output. Clean the light guide if it is dirty.
		Replace the light source if necessary
	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, colorless 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 in a syringe warmer for more than one hour per application
Composite appears too hard and firm in the syringe	Material stored at temperatures < 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. (color smart shade: 20 sec.)

12 Use and 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.

13 Shelf life

The maximum shelf life is printed on the label of the syringe or directly on the compule. Do not use the product after the expiration date.

14 Side effects

Unwanted side effects of this medical product are to be expected extremely rarely when properly processed and used. All serious incidents that occur in connection with the use of this product must be reported to the manufacturer specified below and the relevant competent authority.

15 Disposal

Remaining quantities and packaging material must be disposed of in accordance with local and / or legal regulations.

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