INSTRUCTIONS FOR USE

solafil® N50

solafil N50 Nano

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 N50 is a light-curing nano composite which has an ultrafine, radiopaque glass filler for adhesive restorations. Because of the ultrafine filler, extremely homogeneous restorations can be created which enable ideal colour adaptation of the restoration through a precisely adjusted chameleon effect.

Solafil N50 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, diurethane dimethacrylate, BisGMA, splitter polymerizate, tetramethylene dimethacrylate

Filler content: 83.5% by weight (66.5% by volume) inorganic fillers (28 nm - 40 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

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. Linings containing eugenol are contraindicated.

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

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

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

9.1 Restorations of the anterior teeth and incisors

Prior to the treatment, clean the hard tooth tissue with a fluoride-free polishing paste. Select colours when still wet using the Vita* Shade Guide.

9.1.1 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.

9.1.2 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.

9.1.3 Approximal contact areas

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

9.1.4 Adhesive system

Etching and bonding according to the manufacturer's instructions.

9.1.5 Application of composite

9.1.5.1 Application from syringes

Remove the amount of composite needed from the screw syringe, introduce into the cavity using the usual metal instruments, and model it. The layer thickness must not exceed 2 mm.

9.1.5.2 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 2 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.

9.1.6 Curing

The exposure time is 20 seconds per layer for all colours with a conventional dental polymerisation device. The light guide is to be kept as close as possible to the surface of the restoration. Expose multisurface restorations from every side. Due to the effect of atmospheric oxygen, a thin, non-polymerisable film – the dispersion layer – remains on the surface of each layer. This creates the chemical bond between the layers and should not be touched or contaminated with moisture.

9.1.7 Finishing

solafil N50 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.

9.2 Inlays, onlays and veneers

9.2.1 Cavity preparation

The preparation should preserve tooth substance as much as possible, with only slightly diverging cavity walls. A minimum layer thickness of 1.5 mm in the lateral and vertical direction is needed to prevent fracturing of the material. All internal edges and angles must be round. Avoid feather edges. Create a flat cervical

turn over ▸

shoulder and do not bevel it. Block out unavoidable undercuts with glass ionomer cement. Use slightly tapered diamond grinders with rounded ends for the preparation. Cover areas of dentin near the pulp with a thin layer of compounds containing calcium hydroxide. Linings containing eugenol are contraindicated.

9.2.2 Impression and temporary restoration

After taking the impression, a synthetic temporary restoration is created. Secure this only with a cement that does not contain eugenol.

9.2.3 Producing inlays, onlays and veneers

Cast the impression using super hard plaster. When the model is hard, remove the impression from the model. Block out undercuts and separate the model using an oil-free separating agent. Build up the inlay on the model in layers. Build up the approximal and deep occlusal sections first. Each layer should be a maximum of 2 mm thick. The polymerisation takes place with a commercially available polymerisation device (such as HiLite Power, Heraeus Kulzer intermediate polymerisation 90 seconds/final polymerisation 180 seconds). Remove the finished restoration from the stump, finish, and polish to a high gloss. Clean the restoration thoroughly with soap and water, rinse with air/water spray and dry.

9.2.4 Incorporating inlays, onlays or veneers

Remove the temporary restoration and clean the cavity. Place a rubber dam, clean and dry the prepared tooth surface. Check the fitting accuracy of the restoration using gentle pressure. Do not insert using force. If necessary, improve the fit by grinding the inner surface. The occlusion should not be checked when trying in the restoration since this could risk a fracture.
Etching and bonding according to the manufacturer's instructions.

9.2.5 Fixing the restoration

The restoration is fixed using a commercially available dual-curing fixing composite. Please follow the corresponding manufacturer's instructions.

10 Special Notes

• The processing time under the surgical light is in the range of 2 minutes.
• In case of time-consuming restorations, the surgical light should be temporarily moved further away from the work area to prevent premature curing of the composite or the material should be covered with an opaque foil.
• 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 light-curing 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 manufacturer of the polymerisation lamp. Recommended wavelength range: 350 - 500 nm
Composite in the syringe is sticky and soft; colorless liquid separates in the syringe	Material was stored for a longer period of time at temperatures > 25°C	Observe storage temperature; store at 10 - 25°C
	Material was kept too long in a syringe warmer	Never store syringes in a syringe warmer for more than one hour per application
Composite appears too hard and solid in the syringe	Material stored for a longer period of time at temperatures < 10°C	Allow the composite to warm up to room temperature before use; use syringe warmer, if applicable
	Syringe not closed correctly, composite polymerised	Close the syringe correctly with the cap each time after removing composite
Inlay/onlay is not retained after fitting	The restoration is too opaque to secure it with purely light-curing composite	Use dual-curing luting composite
Composite does not correctly cure(dark or opaque shades)	Composite layer too thick per curing cycle	Max. Maintain layer thickness of 2.0 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 screw syringes tightly immediately after use. The material should be at room temperature before use. Turn the syringe spindle back slightly after use to prevent the discharge opening from becoming clogged. For dental use only. This product was specially developed for the field of application outlined. It should be processed according to the information stipulated in the instructions. The manufacturer is not liable for damage resulting from improper handling or processing.

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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