INSTRUCTIONS FOR USE

solafil® N50

Solafil N50 is a light-curing Nano-composite for the adhesive filling technique. It contains an ultrafine,radiopaque glass filler. The composition with ultrafine filler leads to exceptionally homogenous restorations. An optimal adaption of the colour is the result of an optimally adjusted chameleon effect. The guidelines and requirements of DIN EN ISO 4049 apply. Nano Composite should be used in connection with the system components Solaetch and Solabond. Nano Composite is available in syringes and compules. The compules are for single use only. Please do not reuse them, as this makes it impossible to rule out contamination and germ formation.

Composition

Monomer matrix: Diurethane dimethacrylate, butanediol dimethacrylate, isopropylidenebis [2(3) hydroxy-3(2)- (4-phenoxy)- propyl] bismethacrylate [Bis-GMA]

Filler content 83.5 % by weight (66.5 % by volume) inorganic filler (28 nm -15 µm)

Indications

- Direct anterior and posterior tooth restorations in Black's classes I, II, III, IV and V.
- Indirect restorations such as inlays, onlays and veneers
- Extended fissure sealing on molars and premolars
- Building up stumps
- Splinting of loosened teeth
- Corrections of shape and colour to enhance aesthetics

Available colours

Incisal masses: InW (white), InTr (transparent), InBl (bl-each), InU (universal), IR (red)

Dentin masses: A1, A2, A3, A3.5, A4, B1, B2, B3, C2, D3

Opaque dentin: OD A2, OD B2

Selection of colours

The selection of the colours depends on the position and the size of the cavity as well as on the colour of the remaining tooth substance and/ or the colour of the remaining dentition. The colour selection for the cervical sectors should be made among the different darker yellow and red shades. For the dentin sector, select colours from among the yellow, grey or red shades. For the incisal sector, use material in lighter or transparent shades.

Application

Preparation of the natural tooth

Before starting the treatment, clean the hard tissue with fluoride-free polishing paste. Choose the colour with help of the shade guide while the tooth is still moist.

Cavity preparation

Gently prepare the hard tissue according to the rules of the adhesive technique. When working on anterior teeth, bevel all enamel edges. Do not bevel the edges when working on posterior teeth. Avoid featheredged margins. Next, clean the cavity with water spray, remove all residue and dry. Complete drying is necessary. We recommend the use of a rubber dam.

Pulp protection/ liner

When using an enamel-dentin adhesive the liner can be foregone. In case of very deep cavities near thepulp, line with a calcium hydroxide compound accordingly.

Design of approximal contacts

In cavities with approximal sections, set in a transparent matrix and fix.

Adhesive system

Etch (e. g. Solaetch) and bond (e. g. Solabond) according to the manufacturer's instructions.

Application of N50 composite in syringes

Take the required amount of composite out of the application tip. Fill the cavity with the material and shape as needed, using conventional metal instruments. A layer thickness of 2 mm must not be exceeded. Due to the oxygen in the ambient air, a thin dispersion layer will remain on top of each layer. This dispersion layer forms the chemical bond between the layers and must not be touched or contaminated with moisture.

Application of N50 composite in 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 areintended for single use only.

Polymerisation

The polymerisation time is 20 sec. Per layer for colours with a halogen polymerisation system, an LED polymerisation lamp or 2 x 3 sec. With a plasma polymerisation system. Hold the light-guide as close to the surface of the filling as possible. Fillings with several surfaces should be polymerised from the direction of each surface.

Finishing

N50 composite can be finished and polished immediately after polymerisation. Suitable are finishing diamonds, flexible separating discs, silicone polishers and polishing brushes. Check occlusion and functional movements, correct if necessary. Finally, polish with suitable polishing pastes.

Indirect method

Cavity preparation:

A tooth-conserving preparation with only little divergence in the cavity walls should be preferred. All inner edges and angles must be rounded, avoid feathery margins. Design a planar cervical shoulder, do not bevel it. Block out any unavoidable undercuts with glass ionomer cement. For the preparation, use slightly cone-shaped diamond grinders with rounded edges. Cover dentin close to the pulp with a thin layer of a calcium hydroxide compound. Any liner materials that contain eugenol are contraindicated.

Impression and temporary restoration

After taking the impression, a temporary resin restoration is produced. Fix temporaries only with eugenol free cement.

Production of inlays, onlays and veneers

At the lab, pour an extra-hard plaster into the impression. Once the die has hardened, remove the impression from the die. Block out undercuts

turn over▶

and insulate the die with an oil-free insulator. Build up the inlay on the die layer by layer. First, build up approximal and deep occlusal areas. Each layer should have a maximum thickness of 2 mm. Polymerise with a commercial polymerisation system (e.g. HiLite Power, Heraeus Kulzer, intermediate polymerisation 90 sec., final polymerisation 180 sec.). Lift off the completed restoration from the die, finish and polish to a high gloss. Clean the restoration thoroughly with water and soap. Rinse with air/ water spray and dry.

Inserting inlays, onlays and veneers

Remove the temporary restoration and clean the cavity. Set in a dental dam, then clean and dry the surface of the tooth. Check the restoration's fit with slight pressure. Avoid rough handling. If necessary, improve the fit by grinding the inside surface. Do not check the occlusion in this first fitting, as the restoration could break. Etch (e. g. Solaetch) and bond (e. g. Solabond) according to 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 instructions

- The working range under a surgical light is 2 min.
- 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.
- Use a light cure system with an emission range of 350-500 nm to cure the material. The required physical properties are only reached if the curing 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/cm²**
Wavelength for curing	**350-500 nm**
Curing time	**40 sec**

Contains teramethylene

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.

Side-effects:

With proper use of this medical device, unwanted side-effects are extremely rare. Reactions of the immune system (e. g. 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 order to avoid a possible pulp reaction, always prepare a liner in cases with exposed dentin (e. g. compound containing calcium hydroxide).

Contraindications/ interactions:

If a patient has known allergies against or hyper sensitivities towards a component of this product, we recommend not to use it or to do so only under strict medical supervision. In such cases, we will supply the composition of our medical device upon request. 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. Phenolic substances (e.g. eugenol) inhibit. Therefore, these materials (e. g. zinc oxide eugenol cements) must not be used a liners.

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). Only for use in dentistry. Keep out of children's reach. This product has been developed for the specific use illustrated above. The 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. We recommend to forego the use of syringe heaters. Solafil N50 Nano Composite compules: 20 x 0.3 g, available in 6 different shades.

* Vita is a registered trademark of Vita Zahnfabrik H. Rauter GmbH & Co. KG, Bad Säckingen.

Trouble shooting

Problem	Cause	Remedy
Composite does not cure.	Light output of the polymerisation lamp is insufficient.	Check the light output and, if necessary, replace the light source.
	Emitted wavelength range of the polymerisation lamp is insufficient.	Consult the manufacturer of the polymerisation lamp. Recommend wavelength range 350-500 nm.
Consult the manufacturer of the polymerisation lamp. Recommend wavelength range 350-500nm.	Material was stored at temperatures >25 °C (>77 °F) for a longer period of time.	Please note the storage temperatures: Store at temperatures between 10 °C (50 °F) and 25 °C (77 °F). Short-duration storage in a refridgerator.
	Material was stored in the syringe heater for too long.	Never leave a syringe longer than one hour per use in a syringe heater.
Composite appears to be too compact and hard inside the syringe.	Material was stored at temperatures <10 °C (< 50 °F) for a longer period of time.	Let composite reach room temperature before use; optionally use a syringe heater for a brief time.
	Syringe was not closed correctly, composite has started to polymerise.	Each time after removing material from the syringe, correctly cap and close the syringe.
Inlay/ onlay does not stay in place after insertion.	Restoration appears too opaque to be fixed with a purely light- polymerising composite.	Use dual-polymerising fixing composite.
Composite does not cure all the way through (dark or opaque colors).	Layers per polymerisation cycle were too thick.	Do not exceed max. layer thickness of 2.0 mm per layer.
Restoration has a yellowish tint when compared to the color reference.	Insufficient polymerisation of the composite layers.	Repeat polymerisation cycle several times; at least 40 sec.

* 10°C and 25°C (50°F and 77°F)

TRENT DENT PRODUCTS LIMITED
UNIT 3C, 88 PETERBOROUGH ROAD
LONDON SW6 3HH, UNITED KINGDOM

EC REP
EU REPRESENTATIVE TRENT DENT
DENMARK, AUTOMATIKVEJ 1,3. &
4.SAL COPENHAGEN 2860, DENMARK

Date of issue: Dec 2021
Rev no: 03