

ProFil™ Universal Dental Restorative Material

ProFil restorative material is a visible-light activated, radiopaque, restorative composite for use in both anterior and posterior restorations.

ProFil composite resin is the perfect combination of simplicity and exceptional esthetics.

Available in the following Shades*: A1, A2, A3, A3.5, A4, B1, B2, B3, C2, C3, D3, P, BW

Opaque: OA2, OA3, OA3.5, OB2

ProFil is available in syringes and single dose capsules.

* All shades correspond to Vita™ shade guide (Vita is a registered trademark of Vita Zahnfabrik, Germany)

INDICATIONS

Cementation or fixation of restorations or dental, direct restorative materials in the treatment of dental caries and veneering.

CONTRAINDICATIONS

In rare cases the product may cause sensitivity to some persons. If such reactions are experienced, discontinue use of the product and refer to a physician

ESSENTIAL INGREDIENTS

Glass fillers, Amorphous silica, methacrylate resin monomers, Polymerization activators, Pigments.

DIRECTIONS FOR USE

I. Preliminary:

- a. Prophyl: Clean teeth with pumice and water to remove surface stains or extraneous plaque.
- b. Shade selection: Teeth are not monochromatic and the tooth can be divided into 3 color characteristic regions; Gingival, body and incisal areas. When considering shade and restoration depth, it is recommended to choose the shade after mocking up. It is recommended to use rubber dam for isolation.

II. Direct Restorations: Cavity preparation:

1. Cavity preparation:
Anterior: Use the conventional acid etching, prepare cavity for all Class III - V restorations.
Posterior: Prepare the cavity. No residual amalgam or other base material should be left on the internal surfaces of preparation that would interfere with light transmission and therefore, the hardening of the restorative material.
2. Pulp Protection: In deep cavities cover the dentin close to the pulp with a minimum amount of calcium hydroxide liner leaving the rest of cavity surface free for bonding.
 Glass ionomer or other non-eugenol base materials may be used and it is recommended to use ProBase™. (See ProBase™ instructions for use.)
3. Placement of matrix: Use a matrix system, preferably a transparent one, with proper wedging for proximal contacts. Pre-wedging is advisable to achieve slight separation and facilitate optimal proximal contact.
4. Enamel and Dentin treatment: It is recommended to use ProFil™ in combination with an acid etchant and ProLink™ Bonding agent. Follow the instructions for etching, adhesive application and curing.
5. Dispensing the composite
 - Syringe:
 Dispense the necessary amount of restorative material from the syringe onto the mixing pad. Immediately replace syringe cap. If not used immediately the dispensed material should be protected from light. Place composite into the cavity.
 - Single dose capsule:
 Insert capsule into dispenser and rotate to gain the proper angle of entrance into cavity. Extrude restorative material directly into cavity using slow and steady pressure.
6. Placement: Place and light cure restorative in increments of maximum 2.5mm levels. To permit extension of composite beyond cavity margins, overlap the cavity slightly.
 Avoid intense light in the working field.
7. Curing: ProFil will cure only by exposure to a high visible light source.
 Hold the light guide tip as close to the restorative as possible during light exposure.

ProFil is suitable to be cured by all Light-curing units (Halogen, Led & plasma) that have a luminous intensity of min. 550 mW/cm² (with higher intensity curing time can be reduced by half), emit at 400 -515nm, and that their performance is checked regularly.
 Observe the light-curing unit manufacturer's instructions before use with ProFil.

Exposure time and increment thickness is indicated as follows:

Regular shades: Increment of max. 2.5mm & cure time 20 secs.

Opaque shades: Increment less than 2.0mm & cure time 30 secs.

8. Finishing:

After curing, contour restoration surfaces with finishing diamonds, burs or stones immediately.
Adjust occlusion by carefully removing material with burs of fine polishing diamonds or stones.
Recommended: ProFil Finishing Kit.

SHELF LIFE

The lot number & expiry date are indicated on the product. Do not use after expiry date.

PRECAUTIONARY INFORMATION FOR PATIENTS

Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissues occurs, flush with large amounts of water.

PRECAUTIONARY INFORMATION FOR DENTAL PERSONNEL

Use of protective gloves and a no touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed.

Eugenol-containing dental materials should not be used in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material. SDS can be obtained from www.silmetdental.com

STORAGE & DISPOSAL

Store in a cool and dark place / room temperature (5-30°C / 41-86°F) away from direct sunlight. Do not store material in proximity to eugenol containing material.

For optimum freshness, keep refrigerated. If refrigerated, allow the syringe to reach room temperature before use.

See the Safety Data Sheet (available at www.silmetdental.com or through your local subsidiary) for disposal & safety information.

CUSTOMER INFORMATION

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

CAUTION

U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

EU NOTICE

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. Summary of Safety and Clinical Performance (SSCP) is available at <https://ec.europa.eu/tools/eudamed>
Basic UDI-DI: 7290012DMR2X5

WARRANTY

Silmet Ltd. will replace product that is proven to be defective. Silmet Ltd. does not accept liability for any damage or loss, direct or consequential, arising from the use of or inability to use the product described. It is the responsibility of the dentist to determine before use, the suitability of the product for its intended use.

The dentist assumes all risk and liability in connection therewith.

For instructions in additional languages:

- FR Pour des instructions dans d'autres langues:
- DE Die Anleitung in weiteren Sprachen:
- ES Para obtener las instrucciones en otros idiomas:
- IT Per istruzioni in altre lingue:



www.silmetdental.com/downloads/downloads_instruction



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