

ProFil™ Flow SE

Light-Cure Self Adhesive Flowable Composite

ProFil™ Flow SE is a light cure self-etching, self-adhesive, radiopaque, flowable composite. Combining 3 in 1 ProFil Flow SE features the benefits of adhesive and restorative technology thus simplifying direct restorative procedures. With this flowable dental composite there is no need to bond separately, reducing steps and saving time. ProFil Flow SE is faster, easier, safer and is the ideal restorative material for pediatric patients.

INDICATIONS

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

CONTRAINDICATIONS

- Do not apply the material to the exposed pulp.
- Do not use the material on etched dentine.
- Do not use where there are known allergies to any of the components or contact allergies.
- Do not use if a sufficiently dry working area or the recommended application technique is not possible.

ESSENTIAL INGREDIENTS

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

INSTRUCTIONS FOR USE

ProFil Flow SE is self-adhesive and therefore does not require etching or bonding prior to placement

1. Determine tooth color and select the appropriate shade.
2. Prepare Cavity. Wash thoroughly with water spray and air dry at maximum air pressure for 5 seconds. Prep the enamel edges if necessary. Protect pulp in deep cavities with appropriate preparations. A moist layer must remain on the surface of the tooth. Note:
 - Cleaning with alcohol may cause over drying of the dentine.
3. Dispense the material to the cavity surface. Use provided brush to massage a thin layer (< 0.5 mm) into the entire surface of the cavity wall and beveled area for 25 seconds. Remove excess material with the brush if necessary.
4. After lining the cavity wall and prep area, layer the material as follows:
 - Small restorations of class I, III and V: Use the material to build the restorations in increments of up to 2 mm layer thickness. Light-cure each layer for 20 sec.
 - Under filling material for class I and II: Use the material to build up one layer with a maximum 1 mm layer thickness and light-cure for 20 sec.

Note: It is not necessary to work in the individual layers once more.
5. Remove excess, contour the filling surface and finish using suitable instruments.
6. Using ProFil Finishig Kit is highly recommended.

When used for Pit and Fissure sealing, it is recommended to etch the enamel for 15 - 30 seconds using a 37% phosphoric acid gel (such as ProEtch™). Rinse for 15 seconds with water and dry with oil-free and water-free air. In doing so, leave the enamel surface moist.

Etching is necessary for cleaning purposes only.

Polymerization:

ProFil Flow SE 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 Flow SE

Disinfection:

The brush holder is reusable after disinfection, although it should be replaced if visible signs of wear appear (such as scratches). Disinfection can be carried out using a commercially available wiping or dipping disinfectant.

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

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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