

ProFil™ Bulk

Dual Cure Bulk Fill Composite

ProFil™ Bulk is a dual cure dental restorative composite designed for direct restorations. It is suitable for bulk fill technique in the posterior region and can be applied in an unlimited layer thickness.

INDICATIONS

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

CONTRAINDICATIONS

ProFil Bulk is contraindicated for patients who have known sensitivity to methacrylate & polymerizable monomers which may cause allergic contact dermatitis in susceptible persons.

ESSENTIAL INGREDIENTS

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

INSTRUCTIONS FOR USE

A. Direct restoration of Class I and II cavities

Tooth preparation:

1. Isolate tooth to prevent contamination of blood and/or saliva. A rubber dam is recommended.
2. Complete conservative cavity preparation with conventional means or with an air abrasive device.
3. Place sectional matrix system to obtain natural interproximal contour, where needed. Ensure good adaptation to minimize clean up.
4. Apply etchant per manufacturer's instructions (Recommend using Silmet's ProEtch).
5. Apply bonding agent per manufacturer's instructions (Recommend using Silmet's ProLink).

Filling:

Important Notice: Before each use, bleed material until both base and catalyst are extruded out.

1. Remove the twist off cap by turning 90° counter-clockwise and turning.
2. Squeeze material and discard until even, homogenous paste flows.
3. Place the mixing tip onto the syringe by aligning the notch on the tip hub with the corresponding notch on the syringe. Turn the mixing tip 90° until it locks into position.
4. Put on the intraoral tip.
5. Place mixing tip in the deepest section of the cavity and stay immersed in the material during application to avoid air pockets. Fill the entire cavity in a single step.
6. Don't disturb ProFil Bulk during its gelatin stage.
7. After use, remove and discard mixing tip and replace cap.

Important: to avoid air pockets, do not shape during the processing period. The surface of the cavity must be completely cured before using rotating instruments.

Note: The dual barrel syringe is designed to prevent material pull-back and cross-contamination of base and catalyst. The syringe plunger disengages as a safety feature.

For cavity filling with no capping

1. Fill entire preparation and sculpt to desired contour as the material self-cures.
2. Allow the material to self-cure for at least 60 seconds until it solidifies.
3. Cure the top layer with a dental curing light. Then proceed to finishing.
4. For cavity filling with capping
5. Place the tip at the deepest part of the preparation and fill being careful not to incorporate air. End filling 0.5-1.0mm from the occlusal surface, or half of the top enamel layer.
6. Allow material to self-cure for at least 60 seconds until it solidifies.
7. Place a universal composite such as Silmet's ProFil and sculpt to desired contour. Then cure the composite according to manufacturer's instructions.

Polymerization:

Curing commences with the first contact between base and catalyst. After 3 min, material is chemically cured.

ProFil Bulk 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 Bulk.

Recommended curing time: 20-30 seconds.

Note: the recommended exposure times should not be exceeded to minimize shrinking stress. It is also recommended to comply with the curing time in the case of very deep cavities to avoid bonding of the material to the matrix.

Finishing:

1. Finish restoration with fine diamonds or finish burs (ProFil Finishing Kit).
2. Polish to a high gloss with discs or composite polishing points. Interproximal finishing is accomplished with fine grit finishing strips.

Cavity Lining

ProFil Bulk can be used as a cavity liner similar to a flowable composite.

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.

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 following website:

<https://ec.europa.eu/tools/eudamed>

Basic UDI-DI: 7290012DMR2X5

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.

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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