

Prior to use, carefully read the instructions for use

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

Direct restorations of Class I and II cavities
Cavity Liner

Contraindications:

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

Application

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).

Mixing and 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.

For cavity filling with capping

4. 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.
5. Allow material to self-cure for at least 60 seconds until it solidifies.
6. Place a universal composite such as Silmet's ProFil and sculpt to desired contour. Then cure the composite according to manufacturer's instructions.

Polymerisation:

Curing commences with the first contact between base and catalyst. After 3 min, ProFil Bulk is chemically cured. To accelerate the curing process and obtaining a surface suitable for grinding, curing by light can be performed as follows:

Curing Unit	Curing time (sec)	Light Intensity
Conventional halogen	20	Light intensity of 300 - 550mW/cm ²
Plasma arc	6	Light intensity >2000mW/cm ²
LED	20	Light intensity >300mW/cm ²

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.
2. Polish to a high gloss with discs or composite polishing points. Interproximal finishing is accomplished with fine grit finishing strips.

B. Cavity lining

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

Caution:

Federal law restricts this device to sale by or on the order of a dentist.

Precaution:

For Dental use only.

Do not use in presence of eugenol based materials.

A calcium hydroxide or glass ionomer liner may be used to isolate ProFil Bulk from eugenol sources.

If refrigerated, allow to return to room temperature before use. Refrigeration will increase viscosity, making syringing more difficult, and will retard setting time.

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.

Storage:

ProFil Bulk is designed for use at room temperature (21°-24°C / 70°-75°F) and should not be stored at elevated temperatures or under intense light.

Shelf Life:

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



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