

ProFil™ Universal Micro Hybrid Composite



Prior to use, carefully read the instructions for use.
For use only by a dental professional in the recommended indications.

ProFil™ restorative material is a visible-light activated, radiopaque, restorative composite and contains BIS-GMA & TEGDMA resins plus silica filler.

Shades*: A1, A2, A3, A3.5, A4, B1, B2, B3, C1, C2, C3, D3, P, BW.

Opaque: OA2, OA3, OA3.5, OB2

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

ProFil™ is available in syringes and single dose capsules.

Features

- Designed for minimal polymerization shrinkage
- Excellent marginal sealing properties & workability.
- Radiopaque & Color stable

Indications

Direct anterior & posterior restorations

Core Build-ups

Splinting/Veneering

Contraindications

1. 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

Main Composition

Barium aluminosilicate (Average Particle size: <math><1\mu\text{m}</math>)

Fumed silica (Average Particle size: <math><0.04\mu\text{m}</math>),

Bis-GMA, Triethyleneglycol dimethacrylate,

Weight of total inorganic filler is 80%

Precautionary information for patients

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. 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. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of this product.

Precautionary information for Dental Personnel

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. 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. SDS can be obtained from www.silmetdental.com.

Directions for use

I. Preliminary:

- a). Prophy: 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. Alternatively, *Vita™ Lumin Vacuum color shade guide may be used. It is recommended to use rubber dam for isolation.

II. Direct Restorations: 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.

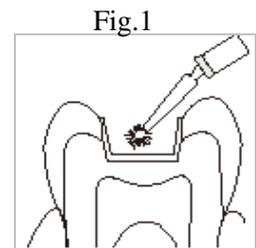
Etching: Dispense the necessary amount of etching agent to both enamel and dentin. After 20 seconds rinse with water spray. Dry with air jet for 2 seconds to remove excess water.

► One-step bonding agent: (Fig. 1)

Apply bonding agent to enamel & dentin 2 times consecutively and wait for 15 seconds.

Dry bonding agent with gentle air stream for 3 seconds.

Light cure for 20 seconds with visible light curing unit.



5. Dispensing the composite

► Syringe:

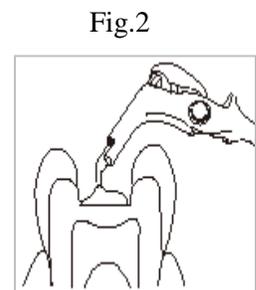
Dispense the necessary amount of restorative material from the syringe onto the mixing pad. Immediately replace syringe cap.

If not used immediately the dispensed material should be protected from light. Place composite into the cavity.

► Single dose capsule: (Fig.2)

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.



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6. Placement:

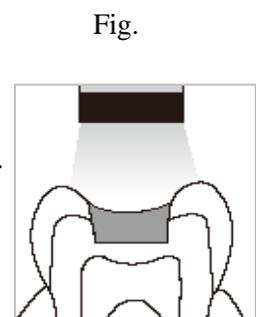
Place and light cure (Fig. 3) restorative in increments of maximum 2.5mm levels.

To permit extension of composite beyond cavity margins, overfill the cavity slightly. Avoid intense light in the working field.

7. Curing: ProFil will cure only by exposure to a high visible light source.

Expose each area of restoration surface according to table 1 below.

Hold the light guide tip as close to the restorative as possible during light exposure.



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

Table 1: Curing time & depth of cure per dental curing unit

Curing Unit	Curing time (sec)	Depth of cure (mm)	
		A1, A2, A3, A3.5, A4, B1, B2, B3, C1, C2, C3, D3, P, BW	Opaque: OA2, OA3, OA3.5, OB2
*Conventional Halogen	20	2.5	2.0
*Fast Halogen	10		
* Plasma arc	6		
*LED	20		

*Dental Curing Unit

Type	Light Source	Wavelength range and intensity
Conventional Halogen	Halogen lamp	Light intensity of 300 - 550mW/cm ² in wavelength range from 400 - 515nm
Fast Halogen	Halogen lamp	Light intensity >550mW/cm ² in wavelength range from 400 -515nm
Plasma arc	Xenon lamp	Light intensity >2000mW/cm ² in wavelength range from 400-515nm and light intensity of more than 450mW/cm ² in wavelength range from 400 - 430nm.
LED	Blue LED	Light intensity >300mW/cm ² in wavelength range from 400 -515nm. Peak of emission spectrum 450 – 480nm

8. Finishing:

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

Shelf life:

Syringes and Capsules: 3 years . Unopened material should be kept at < 24°C.

Caution: US Federal Law restricts this device to sale or use on the order of a dental professional.

Storage and use:

1. Do not store material in proximity to eugenol containing material.
2. ProFil™ is designed for use at room temperature (21-24°C), ambient temperatures higher than this may reduce shelf life. The lot number & expiry date are indicated on the product. Do not use after expiry date.
2. Do not expose restorative materials to elevated temperatures or to intense light.

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

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

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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.



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