ProFil™ Flow  Flowable Restorative Material

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

ProFil™ Flow is a visible-light activated, radiopaque, flowable composite and contains BIS-GMA & TEGDMA resins plus silica filler. ProFil™ Flow offers high compressive and tensile strength for optimal wear resistance based on the advanced Nano technology of ProFil™.

ProFil™ Flow is available in a variety of shades in syringes and will soon be available in single dose capsules

**Shades***: A1, A2, A3, A3.5, B1, B2, B3, C2
* All shades correspond to Vita™ shade guide( Vita is a registered trademark of Vita Zahnfabrik, Germany)

**Features**
* Low viscosity     * Excellent esthetic properties
* Low shrinkage    * No oozing or slumping
* Perfect for minimal invasive restorations

**Indications**
Class III, Class V, Smaller Class IV restorations
Base/liner in Class I & Class II restorations
Repair of resin, porcelain & acrylic temporary materials
Pit & Fissure sealant
Restoration of minimally invasive cavity preparations
Undercut blockout

**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

**Composition**
BisGMA/TEGDMA/UDMA/
Barium glass/Silica.
The weight of total inorganic filler is 60% (mean particle size 0.01 – 2.5μm).

**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
1. Prophy: Clean teeth with pumice and water to remove surface stains or extraneous plaque.
2. Shade selection: Teeth are not monochromatic and the tooth can be divided into three 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.

Instructions
1. Cavity preparation:
   Use the conventional acid etching, prepare cavity for all Class III, Class IV, and Class V restoration. 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™ - Silmet ltd. (See ProBase™ instructions for use.)
3. Enamel and Dentin treatment:
   Follow the manufacturer’s instructions for etching, adhesive application and curing. It is recommended to use ProFil™ Flow in combination with ProLink™ adhesive.
4. Dispensing: (Fig. 1)
   Insert the disposable needle tip onto the syringe after removing the cap. Make sure that the needle of tip is not plugged. If plugged, remove the dispensing tip and express a small amount of resin directly from the syringe. Remove any visible sure that the needle of tip is not plugged. If plugged, remove the dispensing tip and express again. ProFil™ Flow can also be extruded onto a dispensing container and applied using a brush or other appropriate instrument.
5. Placement:
   Place the resin in increments of 2.0mm or less. Pull back on the syringe plugger to prevent oozing.

<table>
<thead>
<tr>
<th>Increment depth</th>
<th>Cure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>All shades</td>
<td>Maximum 2.0mm</td>
</tr>
</tbody>
</table>

6. Curing: (Fig. 2)
   Expose each area of restoration surface to a high visible light source such as shown in table 1 below. Hold the light guide tip as close to the restorative as possible during light exposure. Recommended exposure time is 20sec with a standard light curing unit.
Table 1: Curing time & depth of cure per dental curing unit

<table>
<thead>
<tr>
<th>Curing Unit</th>
<th>Curing time (sec)</th>
<th>Depth of Cure (mm) – all shades</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Conventional Halogen</td>
<td>20</td>
<td>Maximum 2.0</td>
</tr>
<tr>
<td>*Fast Halogen</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>* Plasma arc</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>*LED</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

*Dental Curing Unit

<table>
<thead>
<tr>
<th>Type</th>
<th>Light Source</th>
<th>Wavelength range and intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional Halogen</td>
<td>Halogen lamp</td>
<td>Light intensity of 300 - 550mW/cm² in wavelength range from 400 - 515nm</td>
</tr>
<tr>
<td>Fast Halogen</td>
<td>Halogen lamp</td>
<td>Light intensity of more than 550mW/cm² in wavelength range from 400 - 515nm</td>
</tr>
<tr>
<td>Plasma arc</td>
<td>Xenon lamp</td>
<td>Light intensity of more than 2000mW/cm² in wavelength range from 400-515nm and light intensity of more than 450mW/cm² in wavelength range from 400 - 430nm.</td>
</tr>
<tr>
<td>LED</td>
<td>Blue LED</td>
<td>1) Light intensity of more than 300mW/cm² in wavelength range from 400 - 515nm. Peak of emission spectrum 450 – 480nm</td>
</tr>
</tbody>
</table>

**Shelf life:** 3 years

**Storage:**
Do not store material in proximity to eugenol containing material.
ProFil™ Flow is designed for use at room temperature (21-24°C) and should not be stored at elevated temperatures or under intense light. The lot number & expiry date are indicated on the product. Do not use after expiry date.

**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.

**Caution:** US 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.

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