

INSTRUCTION MANUAL

Components: 66% filler particles (0.900 microns, Dental Glass), bis-GMA and new generation flowable resins.
Packaging: 2 g.

PROFILLER BULK FLOW - FLOW COMPOSITE BULK FILL

1- Description

PROFILLER Bulk Flow Composite Bulk Fill is a low viscosity, visible light activated, radiopaque, flowable material. The low viscosity flowable composite is a semi-translucent material that allows polymerization to a depth of 4 mm. The product is in syringe or capsule form.

PROFILLER Bulk Flow treatment involves a complex surgical procedure. The instructions provided in the user manual included in the box are not sufficient to perform the operation. Such applications should be performed by specialist dentists who have received the necessary training in this field.

Compound; It contains 66% filler particles (0.900 microns, Dental Glass) by weight. PROFILLER Bulk Flow's matrix consists of bis-GMA and new generation flowable resins. Additionally additives, reaction initiators, stabilizers and pigments. PROFILLER Bulk Flow is applied to the tooth following the use of a methacrylate-based dental adhesive that permanently bonds the restoration to the tooth.

Curing of PROFILLER Bulk Flow can be easily achieved using a light curing unit with a wavelength between 400 and 500 nm (highest cure: 470 nm). (The recommended light intensity is 1200 mW/cm², it is recommended to extend the curing time for devices with lower intensity.)

Classification of the product according to Product Type Standard EN ISO 4049:

Type 1 / Class II / Group 1

2- Usage area / Indications

- As pit and fissure sealant
- In minimally invasive cavity restorations (including small, stress-free occlusal restorations)
- Class III and V restorations (tooth neck caries, root erosions, wedge-shaped defects)
- For the purpose of filling out the slips
- Elimination of minor tooth enamel defects
- In the repair of minor defects in aesthetic indirect restorations
- In the repair of resin and acrylic based temporary materials
- For core construction in cases where at least half of the crown tooth structure is present to provide structural support for the crown to be made.
- Restoration of milk teeth
- Posterior region restorations (class I and II, including single cap renewal)
- Reconstructive applications – Covering widened fissures in molars and premolars

3- Usage

a. Cleaning

A cavity that is not properly cleaned can negatively affect bond strength. Clean teeth thoroughly to remove plaque and debris from enamel surfaces and cracks. Therefore, clean the tooth surface thoroughly with a brush and paste if necessary, then wash the teeth thoroughly with air/water spray and rinse with water to remove the abrasive substance.

b. Humidity Control

Remove the rinse water by suction and dry the worn surfaces. To achieve better results as much as possible, avoid saliva or blood contamination of the treatment area, isolate the treated teeth. (Rubber-dam is the preferred isolation method; saliva ejector and cotton rolls can also be used for the same purpose.) The tooth surface should be dried.

c. Color Selection

Teeth are not monochrome, and the color reflected by a restorative material is affected by the thickness of the restorative. Therefore, when choosing a color, the color selection should be made by looking at the part of the scale that is most similar to the restoration thickness.

d. Preparation of the cavity

Prepare the cavity by removing any infected dentin.

e. Protection of the pulp

The exposed pulp and areas close to the pulp should be covered with a fast-setting calcium hydroxide material. There is no need to prime or base with cement. Do not use materials containing eugenol to protect the pulp.

f. Application of matrix tape and wedges

Where necessary, the application of matrix tape and wedges can reduce the amount of material consumed. If preferred, the matrix can be placed after the etching and adhesive process of the tooth enamel.

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75. YIL MAH. KÜÇÜK ORGANİZE SANAYİ 3. CADDE 6A
ODUNPAZARI/ESKİŐEHİR

info@promida.com.tr www.promida.com.tr



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g. Adhesive System

Perform your process with suitable adhesive material.

h. Adjusting Composite Filling

PROFILLER Bulk Flow can be applied directly from the application tip. It is recommended that the patient and staff wear protective glasses when using the application tip.

Remove and retain the syringe cap. Attach the pre-bent disposable administration tip securely to the syringe. Keeping the tip away from the patient, check whether the tip is clogged to apply some PROFILLER Bulk Flow. If there is a blockage, remove the application tip and apply a small amount of PROFILLER Bulk Flow directly from the syringe. Clean any debris from the mouth of the syringe, if present. Reinsert the application tip and reapply composite. PROFILLER Bulk Flow can also be applied with a suitable tool by squeezing it onto an application pad. Recap the syringe immediately after squeezing.

i. curing

You can apply the cure for approximately 20 seconds by shining a light on the product in the applied area from a distance of 2 mm, as recommended in Table 01. (You can perform the process using a blue light source (ISO 4049) in the 400-500 nm range.)

| Model | Curing Thickness | Light Application Time |
|-----------------|------------------|------------------------|
| A1, A2, A3, B1, | 4,0 mm | 20 seconds |

NOTE: The recommended light intensity is 1200 mW/cm², it is recommended to extend the curing time in devices with lower intensity.

After the curing process is completed, shape the restoration surfaces with thin diamond finishing burs or stones. Ensure and check occlusion with a fine polishing bur or stone.

j. Polishing

Polish with a polishing system and with white stones or rubber tips in areas where the discs are not suitable for use.

4- Contraindications

- If a sufficiently dry working area cannot be provided or the required application technique cannot be applied,
- If the patient is known to be allergic to any of the ingredients: application of the above materials is not appropriate. If an allergic reaction occurs, seek medical attention as appropriate, remove the product if necessary, and do not use this product on this patient in the future.

5- Side effects

Do not use in patients with hypersensitivity to its ingredients.

6- Warning

- Protect the product from light. Exposure to the clinic room may cause discoloration and curing.
- To avoid incomplete curing or entrapment of bubbles, do not apply Bulk Fill with other resin composites or shadows.
- Do not use PROFILLER Bulk Flow for any purpose other than those stated in the instructions for use.
- Check the expiration date and working condition of the product and packaging. Do not use products whose packaging has been opened, damaged and/or expired.
- If PROFILLER Bulk Flow causes an allergic reaction, a hypersensitive reaction such as dermatitis or hypersensitivity on the skin, consult your physician.
- To avoid the possibility of allergic reactions caused by methacrylic monomers, always use examination gloves (plastic, vinyl or latex) when handling PROFILLER Bulk Flow.
- Avoid contact of the product with eyes, mucosal membranes, skin and clothing as it may cause an allergenic reaction.
- PROFILLER Bulk Flow should not be swallowed or inhaled.
- Check the condition of any syringe flow before applying it to the oral cavity. If you feel resistance, replace the tip and check again.
- Keep the product out of reach of children.
- Avoid looking into the curing light when using the light curing unit, use protective eye shields, goggles or large type glasses.
- PROFILLER Bulk Flow is supplied as a 2 g syringe. Products that are opened and left open may damage the material and design characteristics.
- PROMİDA DİŞ MALZEMELERİ SAN. TİC. LTD. ŞTİ. will not accept any liability for any injuries/discomforts resulting from misuse of the product. Returns of products with damaged original packaging will not be accepted.
- To safely dispose of PROFILLER Bulk Flow, squeeze the unused portion of the syringe and light cure before discarding.
- Please use personal protective equipment such as mask, glasses and apron during the procedures.

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ODUNPAZARI/ESKİŞEHİR

info@promida.com.tr www.promida.com.tr



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- The color coding of the products is made in accordance with the VITA Zahnfabrik color grading.

7- Storage conditions












Store PROFILLER Bulk Flow at a temperature between 2-27°C. Shelf life at the specified temperatures is 36 months (3 years) from the date of production. AVOID direct light and heat contact.

NOTE:

Our products are produced for use in dentistry. It is not suitable for use other than professional dentists. Since the use of the products is under the control of the user other than us, the user is completely responsible for the applications. We recommend using it in accordance with the information and warnings given in the instructions.

**** Disposal:** Products should be treated according to their biological hazards and disposed of in accordance with the country's legal regulations and hospital policies.

8- Symbols and Meanings:

| | | | |
|--|--|--|------------------------------------|
|  | Lot number |  | Manufacturing Date |
|  | Catalog Number |  | Manufacturer |
|  | Use on time |  | Keep away from sunlight |
|  | Warning, Consult the accompanying documents. |  | Refer to the Instructions for Use. |
|  | Storage temperature range |  | Notified body |
|  | Store in dry place. | | |

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