Fibrafill® FLOW

INSTRUCTIONS FOR USE

HYBRIDIZED BY A FIBER REINFORCEMENT

Important notice:

- The material is intended for application at room temperature. When storing in the refrigerator, allow the product to reach room temperature for at least 15 minutes before use.
- Do not use in cases where a dry working field cannot be ensured.
- Do not use in combination with materials containing eugenol. Phenols may reduce the curing efficiency of the material.
- Avoid using direct intense light in the working area, as this could lead to premature curing of the material and loss of application properties.
- Do not use the product if the packaging is damaged in any way.
- Do not use the product after the expiration date.
- Before disposing of the product, clearly label or discard the product so that it cannot be used. Arrange for the collection of medical waste by a certified company.
- In the event of an adverse effect, contact the manufacturer and the competent authorities of the EU Member State immediately.
- Familiarize yourself with the composition of the product, safety data sheets are available from the product supplier.
- The lifespan of the filling may be reduced in patients with parafunction, during long-term cyclic loading and in connection with adverse circumstances such as trauma, hard body occlusions, etc.

Compatibility information:

- Adhesive systems: use a light-curable adhesive system for bonding to enamel and/or dentin. We do not recommend the use of single-component adhesives.
- Covering composite layer: the material is compatible with all common light-curable composites. Use any universal composite suitable for replacing enamel.

Storage:

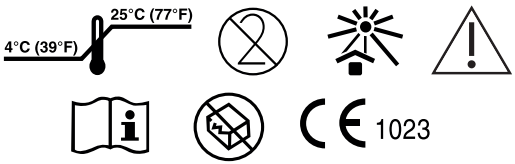
To maintain optimal properties, it is recommended to store for extended periods at temperatures in the range of 4-25 °C in an intact and sealed container (syringe), away from a source of direct intense sunlight. Do not expose to temperatures exceeding 25 °C for extended periods of time. Do not use after the expiry date stated on the packaging.

Additional information:

The product has been developed exclusively for use by a dentist. Always use in accordance with the instructions for use. ADM, a.s. does not accept liability for damage caused by non-compliance with the specified procedure or use outside the specified indication range. The user assumes responsibility for the use of the material for purposes not expressly stated in the instructions for use.

Packaging

Each package contains a total of two syringes with a screw cap. Each syringe contains 1 ml of filler material. The package also contains 15 single-use application cannulas, and instructions for use.



Manufacturer: ADM, a.s., U Vodárny 2, 616 00 Brno,
Czech Republic, www.dentapreg.com

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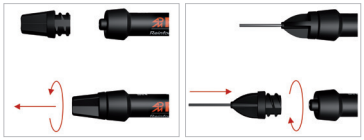
1) Prepare the cavity using standard techniques and following the principles of conservative dentistry. Gently air dry without oil. Ensure a dry working area to prevent contamination. It is recommended to use a rubber dam for insulation. If necessary, use calcium hydroxide to cover the pulp.

2) Perform an adhesive preparation of the surface of the hard dental tissue. Use a standard light-curing adhesive system. Follow the instructions for use of the adhesive system manufacturer.

3) Prepare the syringe for the application of the filling material. Remove the cover by turning it counterclockwise. Then attach the disposable application cannula by turning it clockwise. Make sure the application cannula is securely attached to the syringe. Press the plunger so that the material begins to slowly flow from the end of the cannula.



4) Place the application cannula as close to the bottom of the cavity as possible and slowly extrude the material. After extruding the required amount, refrain from pressing the plunger and pull the syringe in a vertical direction away from the surface of the cavity. When applying the material, make sure that there is enough space to cover with a layer of a suitable covering composite (the layer should be 1-2 mm thick from the surface of the occlusion, see point 6).

Note. Class II fillings and large cavities should be converted to a central cavity. Use a suitable matrix system to create approximate contours and contact points. Missing walls should be bult up using an abrasion-resistant and polishable light-curing composite. Polymerize according to the instructions of the manufacturer

5) Cure the applied material with a curing light. Hold the light-water tip as close to the surface of the filled cavity as possible. For layer thickness of 4 mm, the curing should be performed according to the following type of light source:

• **30** s when using a halogen or standard LED light with power of around 700 mW/cm^2

• **13** s when using a high-power LED light with power of around 1200 mW/cm^2

• **10** s when using a plasma arc (PAC) light with power of around 2000 mW/cm^2

6) Apply a layer of abrasion-resistant and polishable covering composite to the surface of the cured filling. This layer should have a thickness of 1-2 mm on the surface of the occlusion. When choosing a suitable material, take into consideration the aesthetic requirements of the given application. Polymerize according to the instructions of the manufacturer.

7) Make articulation adjustments, check the occlusion, and finally polish the filling using standard techniques.

Basic description:

Fibrafill® FLOW is a flowable filling composite with dispersed fiber reinforcement. The material is intended exclusively for use in dental practice. The target group of patients is not limited and corresponds to the prevalence of disability.

Intended purpose of use:

Fibrafill® FLOW is a medical product intended for creating direct fillings as a replacement for the dentin layer.

Contraindication:

- Do not use to directly cover the pulp.

- Do not use on patients with known allergies to methacrylate monomers and polymers.

- Do not use as a final approximate or occlusive surface layer. The filling must always be covered with a layer of a universal composite.

Safety measures:

- The product is intended exclusively for use by a dentist in dental practice.

- Use is only limited to indications defined by the intended purpose of use.

- Use personal protective equipment such as gloves and face masks when working. Apply non-contact techniques.

- Handle the material only with a clean tool and in clean powder-free disposable gloves. Both the instrument and gloves should be changed in case of any potential contamination.

- In the event of contact of uncured material with the mucous membranes in the mouth or with the skin, immediately wipe gently with a cotton swab or gauze and rinse with water. Be careful not to swallow the material. To prevent contact with the mucous membranes, it is advisable to use a rubber dam to ensure a dry working field.

- In the event of contact with eyes, rinse immediately with water and seek medical advice.

- In the event of an allergic reaction (eczema, rash, swelling, itching, signs of an inflammatory reaction, etc.), seek medical advice and refrain from using the product on the given patient in the future.

- Avoid looking directly into the light of the curing light, use safety goggles when curing.

- In the event of unintentional adhesion of the material to hard dental tissue or a prosthetic apparatus, remove with a suitable tool. Only afterwards start curing

- The application cannulas are for single use only. To prevent cross-contamination, do not use the cannula more than once. The cannulas cannot be sterilized, a new one must always be used.

- When grinding and polishing hardened material, use suction and a protective shield to minimize the risk of inhaling or swallowing the griding dust.

- In the event of contamination when dispensing from the syringe, do not reuse the material.

- Inform the patient about the need to observe hygienic principles.