Packaging:

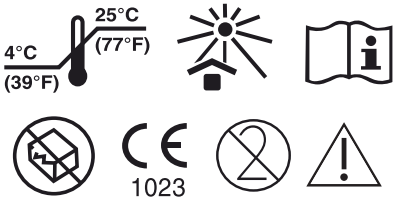
Each pack contains a total of nine blisters of four application doses. The complete packaging contains a total of 36 application doses. Only the size of the application doses differs in the different types of packaging:

Fibrafill® CUBE S – 65 ± 5 mg
Fibrafill® CUBE M – 95 ± 8 mg
Fibrafill® CUBE L – 180 ± 10 mg

Version information of the instructions for use:

Last updated: March 2021

ADM, a.s., 03/2021, FORM: 210304



Manufacturer

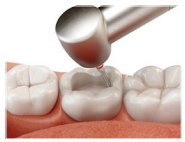
ADM, a.s., U vodárny 2, 616 00 Brno, Czech Republic,
www.dentapreg.com

Fibrafill® CUBE

INSTRUCTIONS FOR USE

DENTAL FILLING COMPOSITE WITH INTEGRATED FIBER REINFORCEMENT IN THE FORM OF DISCRETE APPLICATION DOSES

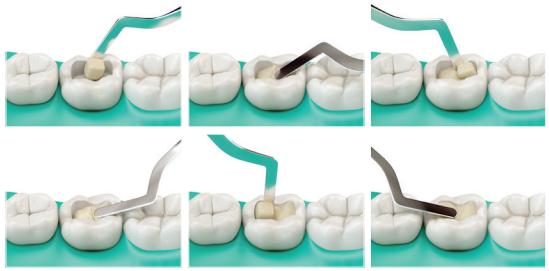
1) Prepare the cavity using standard techniques and following the principles of minimally invasive dentistry. Gently air dry without oil. Ensure a dry working area to prevent contamination. It is recommended to use a rubber dam for insulation. If necessary, use calcium hydroxide to cover the pulp.



2) Perform the adhesive preparation of the surface. Use a standard adhesive system (etching, bonding). Follow the instructions of the adhesive system manufacturer. Clinical tip: To simplify the adaptation of Fibrafill® CUBE, it is recommended to apply a thin layer of flowable composite to the bottom of the cavity.

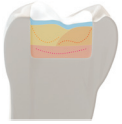
3) Remove the individual application doses from the blister and transfer directly to the cavity using a suitable tool. It is important that the orientation of the application dose of material in the cavity is the same as in the blister.

4) Adapt the individual batches of material to the prepared cavity using a suitable tool with a non-stick surface so that the material is well adapted to the bottom and walls. Apply each dose to the cavity so that its orientation is the same as it was stored in the packaging. The number of applied application doses depends on the dimensions of the prepared cavity. When applying, make sure that there is enough space to cover with an abrasion-resistant and polishable covering composite (layer thickness 1-2 mm from the surface of the occlusion).



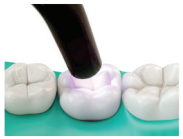
CLINICAL TIPS: In the event of a significant loss of hard dental tissue (cavities with a wall thinner than 2 mm, endodontic treatment of the tooth, insufficient ferrule), it is recommended to additionally treat the tooth with a crown replacement after completion with Fibrafill® CUBE.

For Class II fillings and larger cavities, it is advisable to first convert the cavity to a central cavity (completion of approximate contours and contact points). An example of the arrangement of discrete application doses of Fibrafill® CUBE in a filled cavity.



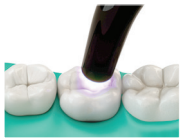
5) Cure the applied material with a curing light. Hold the light-water tip as close to the surface of the adapted composite as possible. For layer thickness of 4 mm, the curing should be performed according to the following type of light source:

- **30 s** when using a halogen or standard LED light (power around 700 mW/cm^2)
- **13 s** when using a high-power LED light (power around 1200 mW/cm^2)
- **10 s** when using a plasma arc light (power around 2000 mW/cm^2).



6) Apply a layer of standard composite to the surface of the cured filling composite, taking into account the aesthetic requirements of the application. This material should form a layer 1-2 mm thick on the surface of the occlusion. Cure the composite according to the instructions of the manufacturer.

7) The final steps are no different from making a classic straight filling. Make articulation adjustments, check the filling/tooth transition, and finally polish the filling using standard techniques.



Basic description:

Fibrafill® CUBE is a dental filling composite material with integrated fiber reinforcement, which is intended for use in restorative dentistry. The medical product is in the form of discrete pad-shaped application doses, which consist of two layers of particulate composite interspersed with an oriented glass fiber reinforcement.

Intended purpose of use:

Fibrafill® CUBE is a medical product intended for creating direct fillings in the event of extensive loss of hard dental tissues, especially in the lateral section of the teeth as a replacement for the dentinal 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 surface layer, it is always necessary to cover with a layer of universal composite.

Safety measures:

- The product is intended exclusively for use by a dentist.
- The method of use is limited to indications related to the intended purpose of use.
- When applying, we recommend using protective gloves and applying with non-contact techniques.
- Avoid contact with eyes, swallowing, skin, and soft tissue contact.
- In the event of contact of uncured material with soft tissue or skin, wipe gently with a cotton swab or gauze and rinse with water. In the event of an allergic reaction (eczema, rash, signs of an inflammatory reaction, swelling or itching), 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 and wear safety goggles when curing the material.
- If the material adheres to the hard dental tissue or prosthetic appliance outside the designated area, remove the material with a suitable tool before starting to cure.
- Inform the patient about the importance of hygiene.
- When grinding and polishing hardened material, use suction and a protective shield to minimize the risk of inhaling or swallowing the griding dust.

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 composite materials. Use any universal composite suitable for use as an enamel replacement (e.g., Tetric EvoCeram®, Filtek-Ultimate and similar).

Important notice:

- Fibrafill® CUBE is intended for use at room temperature. If stored in a 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 - the material may harden prematurely.
- Do not use the product if the protective packaging is damaged in any way.
- Do not continue to use the application doses if the material is contaminated or damaged during transport to the intended place of use.
- Do not use the product after the expiration date.
- Unopened application doses may be further used if the cover foil is not broken, and the packaging is stored in accordance with the prescribed conditions.
- In the event of serious adverse effects, contact the manufacturer and the competent authorities of the EU Member State immediately.
- 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.
- The target group of patients is not limited and corresponds to the prevalence of disability.
- 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..

Storage:

To maintain optimal properties, it is recommended to store at temperatures in the range of 4-25 °C in an intact blister 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. Doses of the material that remain in the intact compartment of a partially opened blister (i.e., the aluminum cover foil has not been torn off) may be used without limitation.

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.