

ENGLISH

General Information

3M™ Filtek® Bulk Fill Flowable Restorative, is a low viscosity, visible-light-activated, radiopaque, flowable. This low viscosity flowable material is semi translucent enabling a 4 mm depth of cure. The restorative is packaged in syringes. The shades offered with Filtek Bulk Fill include Universal, A1, A2, and A3. Filtek Bulk Fill flowable contains no glass ionomer, Cements, or compomers. It is a combination of yttrium trifluoride filler with a range of particle sizes from 0.1 to 5 microns and zirconia/silica with a particle size range of 0.01 to 3.5 um. The inorganic loading is approximately 64.5% by weight (42.6% by volume). Filtek Bulk Fill flowable is applied to tooth using a compatible methacrylate-based adhesive, such as manufactured by 3M, which permanently bonds the restoration to the tooth structure.

Indications

• Base under Class I and II direct restorations.

• Liner under direct restorative materials

• Pit and fissure sealants

• Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations)

• Class III and V restorations

• Uniform blockout

• Repair of small enamel defects

• Repair of small defects in esthetic indirect restorations

• Repair of resin and acrylic temporary material

• As a core build-up while at least half the coronal tooth structure is remaining to support the restorative.

Prescription 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 acylate allergies. If prolonged contact with oral soft tissue 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 the product.

Product Safety Information

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 non-augment technique is recommended. Acrylics may penetrate coated surfaces. If product contacts glove, remove glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed.

3M SDSs can be obtained from www.3M.com or through your local subsidiary.

Instructions for Use

Preathy: Teeth should be cleaned with pumice and water to remove surface stains.

2. Shade Selection: Prior to isolation of tooth, select the appropriate shade(s) of Filtek Bulk Fill flowable using a standard VITAPAN® classical shade guide. For sealants or liners, a contrasting shade may be desirable to enhance detection.

Note: As Filtek Bulk Fill flowable is semi translucent, the location of the restoration, underlying tooth color or adjacent restorations may influence the final appearance of the inlay.

3. Isolation: A rubber dam is the preferred method of isolation. Cotton rolls and an evacuator can also be used.

Directions

1. Matrix band: Application of light polymer composite resin to a polished solid-soft-dentin preparation before bonding. When it is necessary to use a thin gingival matrix band, a circumferential soft-dentin band can be used when appropriate. The band should be bonded to ensure a proper proximal contour if Filtek Bulk Fill flowable will not hold its shape.

2. Putty protection: If a pulp exposure has occurred and the situation warrants a direct pulp capping procedure, use a minimum amount of calcium hydroxide on the exposure followed by an application of Vitrebond® or Vitrebond® Plus Light Cure Glass Ionomer Liner/base, manufacture by 3M ESPE, Vitrebond or Vitrebond Plus liner/base may also be used to the area of deep cavity excavation.

3. Adhesive system: To bond Filtek Bulk Fill flowable to tooth structure, use of a 3M ESPE universal adhesive system (example Scotchbond™ Universal adhesive, manufactured by 3M ESPE) is recommended. Refer to the manufacturer's product instructions for full instructions and precautions for the products.

After curing the adhesive, continue to maintain isolation from blood, saliva and other fluids and proceed immediately to placement of Filtek Bulk Fill flowable.

Note: Silane treatment is recommended for repair of ceramic restorations followed by the adhesive application.

4. Warming: Syringe can be warmed up to 70°C for one hour up to 25 times in commercially available composite warmer devices.

5. Dispensing

Syringe delivery: Filtek Bulk Fill flowable can be delivered directly from the dispensing tip.

5.1. Protective eyewear for patients and staff is recommended when using the dispensing tip.

5.2. Prepare the dispensing tip: Remove cap and save. After use, the dispensing tip needs to be discarded and stored until ready for use.

5.3. Two types of dispensing tips are recommended for use: As needed, bend the metal cannula in any direction, up to a 90° angle to access fine prep.

5.4. Holding the tip away from the patient and any dental staff, express a small amount of Filtek Bulk Fill flowable to assure that the delivery system is not plugged.

5.5. If plugged, remove the dispensing tip and express a small amount of Filtek Bulk Fill flowable directly from the syringe. Remove any visible pulp, if present, from the syringe opening. Replace dispensing tip and again express composite. Filtek Bulk Fill flowable may be extruded onto a dispensing pad and applied with an appropriate mixing ratio.

5.6. To avoid contamination of the syringe during treatment, a standard dental protective sleeve should be used. Place the functioning syringe with attached delivery tip into a suitably shaped protective sleeve; pierce end of sleeve with metal cannula, exposing the canula for use. Using a protective sleeve facilitates cleaning and disinfection of the syringe between patients. See the section "Cleaning & Disinfection."

6. Placement

6.1. Avoid intense light in the working field. Exposure of paste to intense light may cause premature polymerization.

6.2. Dispense Filtek Bulk flowable: Start dispensing in the deepest portion of the preparation, holding the tip close to the preparation surface. As material is extruded, gently raise the tip so it is slightly above the dispersed material to minimize a separation between tip and the restorative.

For proximal areas, hold the tip against the matrix to avoid displacement of the proximal box.

6.2.1. Baseline application: Allow for at least 2 mm on the occlusal caries surface for the universal or posterior composite. These occlusal increments provide strength, wear resistance and esthetic qualities needed for posterior restorations.

6.2.2. Core buildups: Syringe material into undercut areas, around pins, around posts and fill the preparation.

6.2.3. Sealant application: Flow material onto the prepared surface.

6.3. Light cure restorations as indicated in Section 7.

7. Curing: This product is intended to be cured by exposure to a halogen or LED light with a minimum intensity of 550 mW/cm² for 400-500 nm range. Cure each increment by exposing its entire surface to a high intensity visible light source, such as a 3M ESPE curing light. Hold the light guide tip as close to the restorative as possible during light exposure.

8. Complete the restoration:

8.1. Basic laboratory application: Place a composite restorative material, such as Filtek® Supreme or Filtek® Bulk Fill flowable Supreme XTE Universal Restorative directly over the Filtek Bulk Fill flowable restorative. Follow the manufacturer's instructions regarding placement, curing, finishing, occlusion, adjustment, and polishing.

8.2. Pit and Sealants: Gently remove the inhibited layer remaining after light curing with slurry of pumice or polishing paste.

8.3. Core build: The bulk fill restorative is compatible with commonly-used impression materials when surface inhibition layer is removed.

8.3.2. The bulk fill restorative should be kept wet with saliva or lubricated to prevent bonding to chemical-cure provisions.

8.3.3. Commonly used temporary luting cements will not bond to the bulk fill restorative.

8.4. Direct Restorative Application

8.4.1. Contra-occlusion: Restoration surfaces with fine finishing diamonds, burs or stones.

8.4.2. Check occlusion with a thin articulating paper. Examine centric and lateral excursion contacts. Carefully adjust occlusion by removing material with a fine polishing diamond or stone.

8.4.3. Polish with Sof-Lex™ Finishing and Polishing System or with white stones, rubber points or polishing paste where discs are not suitable.

Storage and Use

1. This product is designed to be used at room temperature. If desired, the product may be warmed in a commercial composite warmer prior to use (at no higher than 70°C / 158°F for 1 hour), up to 25 times.

2. In stored in cooler areas to product to room temperature prior to use. Shell life after uncapped is 18 months. If uncapped, use within 18 months after opening, higher than 27°C / 80°F may shorten shelf life. See outer packaging for expiration date.

3. Do not expose restorative materials to elevated temperatures, or to intense light.

4. Do not store materials in proximity to expending control products.

5. After use of sleeves syringe, remove delivery tip and sleeve by grasping on the hub of the delivery tip through the sleeve. twist and remove tip along with sleeve. Discard used syringe tip and sleeve in appropriate waste stream, replace with syringe storage cap.

Cleaning & Disinfection

5.1. Reusable protective gloves during all clinical applications for the syringe to reduce the risk of cross-contamination.

2. Place the reusable tip on the syringe and place the protective sleeve over the syringe. Use the metal tip to punch through the end of the protective sleeve.

3. Avoid contact between the reusable parts (e.g., the body of the syringe) and the patient's mouth.

4. After using the syringe in the protective sleeve, remove the sleeve carefully so that there is no contamination of the syringe from the outer surface of the protective sleeve.

5. After removing the protective sleeve and discarding it, wipe the syringe with a ready-to-use cleaning cloth (e.g., CavWiP™) for the recommended contact time on the wipe label.

6. Discard the used protective sleeve along with the syringe tip.

7. Always observe all applicable legal and hygiene regulations for dental offices and/or hospitals during the use and reprocessing of the device.

Note: If the syringe is not visibly clean, i.e., if, contrary to expectations, there is contamination with blood or saliva, for example, discard the syringe immediately. Do not allow the syringe into a disinfection bath or a cleaning-disinfecting device (wash+disinfect).

8. Refer to the Safety Data Sheet (available at www.3M.com or through your local subsidiary) for detailed information.

Customer Information

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

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

Warranty: 3M warrants this product will be free from defects in material and performance for 3 years from the date of purchase.

FTM™ Bulk Fill Flowable Restorative: 3M MAKES NO OTHER WARRANTIES INCLUDING AN IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M's sole obligation shall be replacement or repair of the 3M product.

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