

# Filtek™ Supreme Ultra Universal Restorative

## ENGLISH

### General Information

3M™ ESPE™ Filtek™ Supreme Ultra Universal Restorative material, is a visible-light activated, restorative composite designed for use in anterior and posterior restorations. All shades are radiopaque. The fillers are a combination of a non-agglomerated/non-aggregated 20nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler and an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles). The Dentin, Enamel and Body shades have an average cluster particle size of 0.6 to 10 microns. The Translucent shades have an average cluster particle size of 0.6 to 20 microns. The inorganic filler loading is about and 72.5% by wt (55.6% by volume) for the translucent shades and 78.5% by wt (63.3% by volume) for all other shades. Filtek Supreme Ultra universal contains bis-GMA, UDMA, TEGDMA, PEGDMA and bis-EMA resins. A dental adhesive, such as manufactured by 3M ESPE, is used to permanently bond the restoration to the tooth structure. The restorative is available in a wide variety of dentin, body, enamel and translucent shades. It is packaged in traditional syringes and single-dose capsules.

### Indications

Filtek Supreme Ultra universal restorative is indicated for use in:

- Direct anterior and posterior restorations (including occlusal surfaces)
- Core Build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers

### 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 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.

### 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.

3M ESPE MSDSs can be obtained from [www.3MESPE.com](http://www.3MESPE.com) or contact your local subsidiary.

### Instructions for Use

#### Preparation

- 1. Prophylaxis:** Teeth should be cleaned with pumice and water to remove surface stains.
- 2. Shade Selection:** Before isolating the tooth, select the appropriate shade(s) of restorative material using a standard VITAPAN® Classic shade guide. Shade selection accuracy can be enhanced by the following hints.
  - 2.1 Shade:** Teeth are not monochromatic. The tooth can be divided into three regions, each with a characteristic color.
    - a) Gingival area:** Restorations in the gingival area of the tooth will have various amounts of yellow.
    - b) Body area:** Restorations in the body of the tooth may consist of shades of gray, yellow or brown.
    - c) Incisal area:** The incisal edges may contain a blue or gray color. Additionally, the translucency of this area and the extent of the translucent portion of the tooth to be restored and neighboring teeth should be matched.
  - 2.2 Restoration depth:** The amount of color a restorative material exhibits is affected by its thickness. Shade matches should be taken from the portion of the shade guide most similar to the thickness of the restoration.
  - 2.3 Mock-up:** Place the chosen shade of the restorative material on the unetched tooth. Manipulate the material to approximate the thickness and site of the restoration. Cure. Evaluate the shade match under different lighting sources. Remove the restorative material from the unetched tooth with an explorer. Repeat process until an acceptable shade match is achieved.

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

#### Direct Restorations

##### 1. Cavity Preparation:

- 1.1 Anterior restorations:** Use conventional cavity preparations for all Class III, IV and V restorations.
- 1.2 Posterior restorations:** Prepare the cavity. Line and point angles should be rounded. No residual amalgam or other base material should be left in the internal form of the preparation that would interfere with light transmission and therefore, the hardening of the restorative material.

- 2. Pulp Protection:** If a pulp exposure has occurred and if 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, manufactured by 3M ESPE. Vitrebond liner/bases may also be used to line areas of deep cavity excavation. See the Vitrebond liner/base instructions for details.

##### 3. Placement of Matrix:

- 3.1 Anterior restorations:** Mylar strips and crown forms may be used to minimize the amount of material used.
- 3.2 Posterior restorations:** Place a thin dead-soft metal, or a pre-contoured-mylar or a pre-contoured-metal matrix band and insert wedges firmly. Burnish the matrix band to establish proximal contour and contact area. Adapt the band to seal the gingival area to avoid overhangs.
 

**Note:** The matrix may be placed following the enamel etching and adhesive application steps if preferred.

- 4. Adhesive System:** Follow the manufacturer's instructions regarding etching, priming, adhesive application, and curing, for example 3M ESPE adhesives.

##### 5. Dispensing the Composite: Follow the directions corresponding to the dispensing system chosen.

- 5.1 Syringe:** Dispense the necessary amount of restorative material from the syringe onto the mix pad by turning the handle slowly in a clockwise manner. To prevent oozing of the restorative when dispensing is completed, turn the handle counterclockwise a half turn to stop paste flow. Immediately replace syringe cap. If not used immediately, the dispensed material should be protected from light.
- 5.2 Single-Dose Capsule:** Insert capsule into 3M ESPE Restorative Dispenser, manufactured for 3M ESPE. Refer to separate restorative dispenser instructions for full instructions and precautions. Extrude restorative directly into cavity.

##### 6. Placement:

- 6.1** Place and light cure restorative in increments as indicated in Section 7.
- 6.2** Slightly overfill the cavity to permit extension of composite beyond cavity margins. Contour and shape with appropriate composite instruments.
- 6.3** Avoid intense light in the working field.
- 6.4** Posterior placement hints:
  - a)** To aid in adaptation, the first 1mm layer may be placed and adapted to the proximal box.
  - b)** A condensing instrument (or similar device) can be used to adapt the material to all of the internal cavity aspects.

- 7. Curing:** This product is intended to be cured by exposure to a halogen or LED light with a minimum intensity of 400mW/cm<sup>2</sup> in the 400-500nm 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.

Shades	Incremental depth	Cure time
Body, Enamel, Translucent	2.0mm	20 sec.
Dentin, A6B and B5B	1.5mm	40 sec.

- 8. Contouring:** Contour restoration surfaces with fine finishing diamonds, burs or stones. Contour proximal surfaces with Sof-Lex™ Finishing Strips, manufactured for 3M ESPE.
- 9. Adjust Occlusion:** 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.
- 10. Finish and Polishing:** Polish with the Sof-Lex™ Finishing and Polishing System.

#### Indirect Procedure for Inlays, Onlays or Veneers

##### 1. Dental Operator Procedure

- 1.1 Shade selection:** Choose the appropriate shade(s) of Filtek Supreme Ultra universal restorative prior to isolation. If the restoration is of sufficient depth, use of a dentin shade is recommended. Use of a translucent shade on the occlusal surface will help to achieve esthetic appearance.

**1.2 Preparation:** Prepare the tooth.

**1.3 Impressioning:** After preparation is complete, make an impression of the prepared tooth by following the manufacturer's instructions of the impressioning material chosen. An impressioning material, such as manufactured by 3M ESPE, may be used.

## **2. Laboratory Procedure**

- 2.1** Pour the impression of the preparation with die stone. Place pins at the preparation site at this time if a "triple tray" type of impression was used.
- 2.2** Separate the cast from the impression after 45 to 60 minutes. Place pins in die and base the cast as for a typical crown and bridge procedure. Mount or articulate the cast to its counter model on an adequate articulator.
- 2.3** If a second impression was not sent, pour a second cast using the same impression registration. This is to be used as a working cast.
- 2.4** Section out the preparation with a laboratory saw and trim away excess or, expose the margins so they can be easily worked. Mark the margins with a red pencil if needed. *Add a spacer at this time if one is required.*
- 2.5** Soak the die in water, then with a brush, apply a very thin coat of separating medium to the preparation, let it dry somewhat, then add another thin layer.
- 2.6** Add the first increment of composite to the floor of the preparation, stay short of the margins, and follow the cure recommendations described in the Direct Restoration section (Step 7).
- 2.7** Place and cure additional increments of composite. Allow for the last increment (incisal) to include the contact areas.
- 2.8** Place the die back into the articulated arch. Add the last increment of composite to the occlusal surface. Overfill very slightly mesially, distally, and occlusally. This will allow for the mesiodistal contacts and the proper occlusal contact when the opposing arch is brought into occlusion with the uncured increment. Light cure for only ten seconds, then remove the die to prevent adhering to adjacent surfaces. Finish the curing process following the cure times in the Direct Restoration section (Step 7).
- 2.9** With the occlusal contacts already established, begin removing the excess composite from around the points of contact. Develop the inclines and ridges as per remaining occlusal anatomy.
- 2.10** Care must be taken when removing the prosthesis from the die. Break off small amounts of the die from around the restoration, the die stone should break away cleanly from the cured restoration, until all of the restoration is recovered.
- 2.11** Using the master die, check the restoration for flash, undercuts, and fit. Adjust as necessary, and then polish as noted above in Direct Restorative steps 8-10.

## **3. Dental Operatory Procedure**

- 3.1** Roughen the interior surfaces of the indirect restoration.
- 3.2** Clean the prosthesis in a soap solution in an ultrasonic bath and rinse thoroughly.
- 3.3** Cementation: Cement the prosthesis using a 3M ESPE resin cement system, manufactured by 3M ESPE following manufacturer's instructions.

## **Storage and Use**

1. This product is designed to be used at room temperature. If stored in cooler allow product to reach room temperature prior to use. Shelf life at room temperature is 36 months. Ambient temperatures routinely higher than 27° C/80° F may reduce shelf life. See outer package for expiration date.
2. Do not expose restorative materials to elevated temperatures, or to intense light.
3. Do not store materials in proximity to eugenol containing products.

Disinfect this product using an intermediate level disinfection process (liquid contact) as recommended by the Centers for Disease Control and endorsed by the American Dental Association. Guidelines for Infection Control in Dental Health-Care Settings - 2003 (Vol.52; No. RR-17), Centers for Disease Control and Prevention.

**Disposal** – See the Material Safety Data Sheet (available at [www.3MESPE.com](http://www.3MESPE.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**

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY 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 ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

## **Limitation of Liability**

Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

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**3M ESPE Customer Care/MSDS Information 1-800-634-2249.**

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