

## ENGLISH

## General Information

**Filetek™ Universal Restorative** is a visible-light-activated restorative composite optimized to create esthetic anterior and posterior restorations. The shades are body like opacity enabling up to a 2 mm depth-of-cure. The pink opaquer can be placed in 1 mm thick increments. The shades are body like opacity enabling up to a 2 mm depth-of-cure. The pink opaquer can be placed in 1 mm thick increments. The shades are body like opacity enabling up to a 2 mm depth-of-cure. The pink opaquer can be placed in 1 mm thick increments. The shades are body like opacity enabling up to a 2 mm depth-of-cure. The pink opaquer can be placed in 1 mm thick increments. The shades are body like opacity enabling up to a 2 mm depth-of-cure. The pink opaquer can be placed in 1 mm thick increments.

The fillers are a combination of a non-agglomerated/non-aggregated 20 nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, an aggregated zirconia/silica composite (composed of 20 nm silica and 4 to 11 nm zirconia), and a fine trilayered trilayered filler consisting of aggregated 100 nm particles. The inorganic filler loading is about 65.6% by weight (58.4% by volume).

Filetek Universal Restorative contains AUDMA, AFM, diurethane-DMA, and 1.12-dodecan-DMA. Filetek Universal Restorative is applied to the tooth structure using a self-curing acrylate-based dental adhesive, such as manufacturer's 3M ESPE. Filetek Universal Restorative is packaged in traditional syringes and single-dose capsules.

## Indications

- Direct anterior and posterior restorations (including occlusal surfaces)
- Core build-ups
- Splints
- 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 acrylic allergies. If prolonged contact with oral soft tissue occurs, seek medical attention as needed. Remove the product if necessary and discontinue future use of the product.

## Precautionary Information for Dental Personnel

Capsules may be warm (Do not warn syringes). 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 products. If skin contact occurs, wash skin with soap and water. Use protective gloves. Acrylicates may irritate the eyes. If product contacts glove, remove and discard glove. If product contacts eye, wash hands immediately with soap and water, and then re-glove. If allergic reaction occurs, seek medical attention as needed.

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

## Instructions for Use

## Preparation

1. Prophy: Teeth should be cleaned with pumice and water to remove surface stains and debris.
2. Shape: After isolating the tooth, select the appropriate shade(s) of restorative material.
3. Isolation: A rubber dam is the preferred method of isolation. However, other isolation systems can be used by following their appropriate instructions for use.

## Direct Restorations

1. Cavity Preparation:

  - Anterior restorations: Use conventional cavity preparations for all Class III, IV, and V restorations.
  - Posterior restorations: Prepare the cavity. Line and point angles should be rounded. No residual amalgam or other base material should 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 paste followed by an application of Vitreobond™ Liner. Use Cavit® GIC liner/bases may also be used to line areas of deep cavity excavation. See the Vitreobond liner/base instructions for details.

## 3. Placement of Matrix:

- 3.1 For Anterior & Posterior restorations: Place the matrix system of choice by following the manufacturer's instructions for use.
- 3.2 Adhesive System: To bond Filetek Universal restorative to tooth structure, use the bonding system of choice (e.g., manufacturer's 3M ESPE® Single Bond® ESPE Universal Adhesive) is recommended. Refer to adhesive system 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 Filetek Universal restorative.

4. Dispensing & Placement (Glossary): In是指ing or discoloration of the tooth structure has occurred, we recommend placing 3M PO.

Because of the higher opacity, it is important to apply the paste in layers with a maximum thickness of 1 mm to ensure complete curing of the material. Follow the dispensing, placement, and light curing instructions below for proper use.

## 5. Dispensing &amp; Cure: Follow the directions corresponding to the procedure in Step 6.

6. 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 ozing of the restorative when dispensing is completed, turn the handle counter-clockwise a half turn to stop dispensing, immediately repeat the syringe cap. If not used immediately, the dispensed restorative material should be protected from light with an appropriate cover.

6.2 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.

## 6.3 Placement &amp; Light Curing: Place in increments and light cure the composite as indicated in Step 8.

## 7. Placement

1. Place and light cure restorative in increments as indicated in Step 7.
2. Contour and shape with appropriate composite instruments.
3. Avoid intense light in the working field.

## 7.4. Posterior planning:

7.4.1 To aid in adaptation, the first 1 mm layer may be placed and adapted to the proximal box.

7.4.2 A condensing instrument (or similar device) can be used to adapt the material to all of the internal cavity aspects.

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

## 9. Contouring: Contour restoration surfaces with fine finishing diamonds, burs or stones. Contour proximal surfaces with Sof-Lex™ Finishing Strips, manufactured for 3M ESPE.

## 10. Adjust Occlusion: Check occlusion with a thin articulating paper. Examine centric and lateral excursive contacts. Carefully adjust occlusion by removing material with a fine finishing diamond or stone.

## 11. Finishing and Polishing: Polishing with the Sof-Lex™ Diamond Polishing System, or Sof-Lex™ Finishing and Polishing System is recommended.

## Indirect Procedure for Inlays, Onlays, or Veneers

## 1. Dental Operatory Procedure

- 1.1 Shade selection: Choose the appropriate shade(s) of Filetek Universal Restorative prior to isolation.

## 1.2 Preparation:

1.3 Impression: 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.

1.4 Digital Scanning Systems: Alternatively, a digital scan may be taken to replace the impressioning step above. Follow the manufacturer's instructions of the scanning system chosen. A scan system, such as one 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.

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 a softener/healer to the preparation, let it dry somewhat, and 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 Restorations (Step 8)**.

2.7 Place and cure additional increments of composite. Allow for the last increment (final) 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. For a temporary, distal, and occlusal contact, add a small mass of restorative and hold under 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 Restorations (Step 8)**.

2.9 With the occlusal contacts already established, begin removing the excess increments of composite until the contact areas.

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. If necessary, and then polish as noted above in **Direct Restorations (Step 9)**.

## 3. Dental Operatory Procedure

- 3.1 Roughen the interfacial 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.

## 4. Cleaning &amp; Disinfection

The multiple-use syringe dispenser is not intended for direct patient contact. Use new, uncontaminated gloves when handling the syringe dispenser. Directions for cleaning and low level disinfection of the syringe dispenser are provided below:

## Step 1 (Cleaning):

Use a CaviWipes™, or equivalent cleaning wipe, and wipe the entire surface of the device thoroughly for at least 30 seconds and until no soil remains on the device.

## Step 2 (Disinfecting):

Use a CaviWipes™, or equivalent alcohol-quaternary ammonium disinfectant wipe, to disinfect the entire surface of the device by keeping wet for the contact time listed on the disinfectant label.

## 5. Storage and Use

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

2. The product is best stored at room temperature. If stored in cooler conditions to reach room temperature prior to use, store at room temperature is 36 months. Store in a cool environment; not higher than 27°C/80°F may reduce shelf life. See outer package for expiration date.

3. Do not store materials in proximity to eugenol containing products.

6. Disposal - See the Safety Data Sheet available at [www.3M.com](http://www.3M.com) or through your local subsidiary.

## 7. Customer Information

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

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

## 9. 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 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 paste followed by an application of Vitreobond™ Liner.

Use Cavit® GIC liner/bases may also be used to line areas of deep cavity excavation. See the Vitreobond liner/base instructions for details.

## 3. Placement of Matrix:

- 3.1 For Anterior & Posterior restorations: Place the matrix system of choice by following the manufacturer's instructions for use.

## 4. Adhesive System:

To bond Filetek Universal restorative to tooth structure, use the bonding system of choice (e.g., manufacturer's 3M ESPE® Single Bond® ESPE Universal Adhesive) is recommended. Refer to adhesive system 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 Filetek Universal restorative.

## 5. Dispensing &amp; Placement (Glossary): In是指ing or discoloration of the tooth structure has occurred, we recommend placing 3M PO.

Because of the higher opacity, it is important to apply the paste in layers with a maximum thickness of 1 mm to ensure complete curing of the material. Follow the dispensing, placement, and light curing instructions below for proper use.

## 6. Dispensing &amp; Cure: Follow the directions corresponding to the procedure in Step 6.

## 7. Placement

1. Place and light cure restorative in increments as indicated in Step 7.

## 7.2 Contour and shape with appropriate composite instruments.

7.3 Avoid intense light in the working field.

## 7.4.1 To aid in adaptation, the first 1 mm layer may be placed and adapted to the proximal box.

7.4.2 A condensing instrument (or similar device) can be used to adapt the material to all of the internal cavity aspects.

## 8. Curing: This product is intended to be cured by exposure to a halogen or LED light with a minimum intensity of 500 mW/cm².

To achieve a high quality, Cure each increment by exposing its entire surface to a high-intensity light source, such as a 3M ESPE curing light. Hold the light guide tip as close to the restorative as possible during light exposure.

## 9. Contouring: Contour restoration surfaces with fine finishing diamonds, burs or stones. Contour proximal surfaces with Sof-Lex™ Finishing Strips, manufactured for 3M ESPE.

## 10. Adjust Occlusion: Check occlusion with a thin articulating paper.

Examine centric and lateral excursive contacts. Carefully adjust occlusion by removing material with a fine finishing diamond or stone.

## 11. Finishing and Polishing: Polishing with the Sof-Lex™ Diamond Polishing System, or Sof-Lex™ Finishing and Polishing System is recommended.

## 12. Direct restorative:

1. Cavity Preparation:

1.3 Impression: 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.

1.4 Digital Scanning Systems: Alternatively, a digital scan may be taken to replace the impressioning step above. Follow the manufacturer's instructions of the scanning system chosen. A scan system, such as one manufactured by 3M ESPE, may be used.

## 2. Laboratory Procedure

2.1 Pour the impression of the preparation with die stone.

2.2 Place pins at the preparation site at this time if a "triple tray" type of impression was used.

2.3 Separate the cast from the impression after 45 to 60 minutes.

2.4 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.

2.5 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.

## 3. Finishing and Polishing:

3.1 Finishing and polishing with the Sof-Lex™ Diamond Polishing System, or Sof-Lex™ Finishing and Polishing System is recommended.

## 4. Placement:

4.1 Placement: Use the appropriate shade(s) of Filetek Universal Restorative prior to isolation.

4.2 Preparation:

4.3 Impression: 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.

4.4 Digital Scanning Systems: Alternatively, a digital scan may be taken to replace the impressioning step above. Follow the manufacturer's instructions of the scanning system chosen. A scan system, such as one manufactured by 3M ESPE, may be used.

## 5. Finishing and Polishing:

5.1 Finishing and polishing with the Sof-Lex™ Diamond Polishing System, or Sof-Lex™ Finishing and Polishing System is recommended.

## 6. Direct restorative:

6.1 Cavity Preparation:

6.2 Impression:

6.3 Finishing and Polishing:

6.4 Placement

