

ENGLISH

General Information

3M™ Filtek™ One Bulk Fill Restorative, is a visible-light cured, restorative composite for restorations and veneers that meets or exceeds 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 solution to the prepared surface and then add another thin coat.

This material provides excellent strength and low wear for durability and improved esthetics. The material can be placed and cured up to 5mm deep, enabled by a stress relieving resin system and optimized optical properties.

2.6 Filtek One Bulk Fill Restorative serves to enhance the 3M ESPE line of restorative materials by improving the esthetic properties of a bulk fill material to allow for broader use in both posterior and anterior restorations. Filtek One Bulk Fill Restorative is offered in a range of tooth-colored shades. All shades are radiopaque. The fillers are a combination of a non-agglomerated/non-agglomerated 20 nm silica filler, a non-agglomerated/agglomerated 1 to 10 microns zirconia filler, and a polyfunctional cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles), and a ytterbium trifluoride filler consisting of approximately 100 nm particles.

2.7 Filtek One Bulk Fill Restorative is cured by a light curing process following the cure times in the Direct Restoration section (Step 10).

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 lingually. This will allow the mechanical 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 generating a thick filler layer. Finish the curing process following the cure times in the Direct Restoration section (Step 10).

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 free.

2.11 Using the master die, check the restoration for fit,sh, undercuts, and fit. Adjust as necessary, and then polish as noted above in Direct Restoration steps 11-13.

3. Dental Operatory Procedure

1.3.1 Roughen the interior surfaces of the indirect restoration.

1.3.2 Attach a prosthesis in a wax block using an ultrasonic bath and resin thoroughly. Filtek One Bulk Fill Restorative is used to enhance the 3M ESPE line of restorative materials by improving the esthetic properties of a bulk fill material to allow for broader use in both posterior and anterior restorations. Filtek One Bulk Fill Restorative is offered in a range of tooth-colored shades. All shades are radiopaque. The fillers are a combination of a non-agglomerated/non-agglomerated 20 nm silica filler, a non-agglomerated/agglomerated 1 to 10 microns zirconia filler, and a polyfunctional cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles), and a ytterbium trifluoride filler consisting of approximately 100 nm particles.

1.3.3 Cementation: Cement the prosthesis using a 3M™ ESPE™ resin cement system.

Indications:

Filtek One Bulk Fill Restorative is indicated for use in:

- Direct anterior and posterior restorations (including occlusal surfaces)
- Base/liner under direct restorations
- Core build-ups
- Sublaminar restorations
- Indirect restorations including inlays, onlays and veneers
- Restorations of deciduous teeth
- Extended fissure sealing in molars and premolars
- Repair of defects in porcelain restorations, enamel, and temporaries

Precautionary Information for Patients

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. The preparation 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 soon as possible to 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. The preparation 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 soon as possible to remove the product if necessary and discontinue future use of the product.

Step 1 (Cleaning): Use a Cav/Wipes™, or equivalent cleaning wipe, and wipe the entire surface of the device thoroughly for at least 30 seconds and until no visible soil remains on the device. Step 2 (Disinfecting): Use 70% alcohol or equivalent alcohol/volatile soil remains on the device. Use a new Cav/Wipes, or 30-second alcohol-volatile soil nonionenic disinfectant wipe, to disinfect the entire surface of the device by keeping wet for the contact time listed on the disinfectant label.

Storage and Use
1. This product is designed to be used at room temperature. If stored in cooler conditions, allow product to reach room temperature prior to use. Shelf life at room temperature is 18 months. Ambient temperature higher than 27°C/80°F may reduce shelf life. See outer package for expiration date.

2. Do not use restorative materials to elevated temperatures, or to intense light.
3. Do not store materials in proximity to eugenol containing products.

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

Step 1 (Cleaning): Use a Cav/Wipes™, or equivalent cleaning wipe, and wipe the entire surface of the device thoroughly for at least 30 seconds and until no visible soil remains on the device. Step 2 (Disinfecting): Use 70% alcohol or equivalent alcohol/volatile soil remains on the device. Use a new Cav/Wipes, or 30-second alcohol-volatile soil nonionenic disinfectant wipe, to disinfect the entire surface of the device by keeping wet for the contact time listed on the disinfectant label.

Disposal
See the Safety Data Sheet (available at www.3MESPE.com/dental or through your local supplier) for disposal information.

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

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

Warranty
3M warrants this product will be free from defects in material and manufacture. 3M does not warrant OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the products for user's application. If this product is used for purposes not intended by the manufacturer, 3M shall not be liable for any damage or injury to the product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Limitation of Liability
Except where prohibited by law, 3M 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.

Placement of Matrix:
1.5.1 Anterior restorations: Mylar strips and crown forms may be used to shape the matrix.

5.2 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 contact and contact area. Seal the band with a light-curing adhesive. Proceed immediately to placement of Filtek One Bulk Fill Restorative.

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

5.3 Pulp Protection: If a pulp exposure has occurred and the situation warrants pulp protection, use a minimum amount of calcium hydroxide cement. Calcium hydroxide on the exposure followed by an application of 3M™ ESPE™ Vitrebond™ or Vitrebond™ Plus Light Cure Glass Ionomer. Vitrebond or Vitrebond™ Plus liner/base may also be used to line areas of deep cavity excavation.

7. Adhesive System: To bond Filtek One Bulk Fill Restorative to tooth structure, use of a 3M™ ESPE™ dental adhesive system (for example 3M ESPE™ Single Bond™ Adhesive System) 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 moisture and proceed immediately to placement of Filtek One Bulk Fill Restorative.

Note: Follow the adhesive system instructions for use for recommended application during repair of ceramic restorations, followed by the adhesive application.

8. Delivery: Dispensing the Composite:

8.1 Syringe: Dispense the necessary amount of restorative material into the syringe onto the mix tray in the handle of the syringe in a clockwise manner. To prevent curing of restorative when dispensing is completed, turn the handle counter-clockwise a half to stop paste flow. Immediately replace syringe cap to seal the syringe area to avoid curing.

8.2 Single-Dose Capsule: Insert capsule into the 3M™ ESPE™ Restorative Dispenser. Refer to separate restorative dispenser instructions for full instructions and precautions. Extrude restorative directly into cavity.

9. Placement:
9.1 Avoid intense light in the working field. Exposure of paste to intense light may cause premature polymerization.

9.2 Capsule: Start dispensing in the deepest portion of the preparation, holding the tip close to the preparation surface. Withdraw the capsule tip slowly as the cavity is filled, and avoid lifting the tip out of the preparation until the white substance, to reduce voids. When dispensing has been completed, drag the capsule tip against the cavity wall while withdrawing from the operative field. For proximal areas, hold the tip against the matrix to prevent flow into the proximal area.

9.3 Slightly overfill the cavity to permit extension of composite beyond axial margins. Contour and shape with appropriate composite finishing instruments.

10. Curing: This product is intended to be cured by exposure to a halogen or LED light with a minimum intensity of 550 mW/cm² in the 400-500 nm range. Cure each increment by exposing its entire surface to light of sufficient intensity to reach the curing depth.

Hold the light guide tip as close to the restorative as possible during light exposure. Use light cure chart to determine appropriate cure times and conditions for all shades.

Indication	Increment Depth	All halogen lights (with output of 550-1000 mW/cm ²)	LED lights (with output of 1000-2000 mW/cm ²)
Core Build-up, Anterior and Direct Restorations	5 mm	20 sec occlusal, 10 sec buccal, 10 sec lingual	10 sec occlusal, 10 sec buccal, 10 sec lingual
All indications listed (except Core Build-up and Deepener Class II Direct Restorations)	4 mm	40 sec	20 sec
Anterior or shallow Class I Restorations	≥ 3mm	20 sec	10 sec

Note: For Class II restorations, remove the matrix band prior to the buccal and lingual curing steps.

11. Contouring: Contour restorations surfaces with fine finishing diamonds, diamond burs, and contour proximal surfaces with 3M™ ESPE™ Sof-Lex™ Finishing Strips.

12. Adjust Occlusion: Check occlusion with a thin articulating paper. Examine occlusal and lateral contacts carefully against occlusion by opposing matrix material with a fine finishing diamond or strip.

13. Finish and Polishing: Polish with the 3M™ ESPE™ Sof-Lex™ Finishing and Polishing System.

Indirect Procedure for Inlays, Onlays or Veneers

1. Dental Operatory Procedure
1.1 Shade Selection: Choose the appropriate shade(s) of Filtek One Bulk Fill Restorative prior to isolation.

1.2 Preparation: Prepare the tooth.

1.3 Impression(s): After preparation is complete, make an impression of the preparation and lateral contacts carefully against occlusion by opposing matrix material with a fine finishing diamond or strip.

1.4 Impression Matrix: The indirect restoration is fabricated using the impressioning material chosen. An impressioning material, such as manufactured by 3M ESPE, may be used.

2. Laboratory Procedure

2.1 Prepare the impression of the preparation with the 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, then 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.

После полимеризации адгезива сохраните матрицу от крови, слюны и других жидкостей и сразу же налейте эмалевый реставрационный материал Filtek One Bulk Fill.

Примечание. Следуйте инструкции по использованию адгезивной системы, чтобы полностью полимеризовать адгезив и затем нанести эмаль в промежутки керамических реставраций с последующим применением адгезива.

8. Внесение.

Дозирование композита.

8.1. Дозатор. Извлеките необходимое количество реставрационного материала на блонок для замешивания, медленно поворачивая ручку дозатора по часовой стрелке. Для предотвращения вытекания реставрационного материала после того, как его необходимо количество извлекено, выньте ручку дозатора и направьте дозатор против часовой стрелки и выдвигание прекратится. Сразу же закройте дозатор колпачком. Если материал не используется немедленно, необходимо защитить его от света.

8.2. Одноразовая капсула. Вставьте капсулу в диспенсер 3M™ ESPE™ Restorative Dispenser. Следуйте инструкции и мер предосторожний см. в инструкциях к конкретному дозатору реставрационного материала. Выдвигайте материал из капсулы при помощи окклюзивной пластины.

9. Нанесение.

9.1. Избегайте попадания интенсивного света на рабочее поле. Попадания интенсивных солнечных лучей на пасту могут привести к преждевременной полимеризации.

9.2. Капсула. Наните распределение в самом глубоком участке подготовленной полости, удерживая накончик близко к поверхности полости. Медленно выдвигайте накончик капсулы по мере заполнения полости, пока количество извлекенного материала при выдвигании, чтобы снизить образование пустот. После завершения выдвигания отведите кончик капсулы к ствечной полости, вынимая его из рабочей области. Для обработки проксимальных областей используйте стрипы и матрицы для получения матрицы в проксимальном контуре.

9.3. Плотность должна быть немного переполнена, чтобы композит перенёсся в 40-60 минутах. Ambient temperature higher than 27°C/80°F may reduce shelf life. See outer package for expiration date.

2. Do not use restorative materials to elevated temperatures, or to intense light.
3. Do not store materials in proximity to eugenol containing products.

10. Полимеризация. Полимеризация данного продукта предусмотрена под воздействием света от галогеновой или светодиодной лампы с минимальной интенсивностью 550 мВт/см² в диапазоне 400–500 нм. Полимеризуйте каждый слой, облучая всю его поверхность высокочастотным видимым светом. Для нанесения матрицы используйте матрицу Filtek One Bulk Fill Restorative. При нанесении матрицы используйте стрипы и матрицы для получения матрицы в проксимальном контуре. При нанесении матрицы используйте стрипы и матрицы для получения матрицы в проксимальном контуре.

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

5.3 Pulp Protection: If a pulp exposure has occurred and the situation warrants pulp protection, use a minimum amount of calcium hydroxide cement. Calcium hydroxide on the exposure followed by an application of 3M™ ESPE™ Vitrebond™ or Vitrebond™ Plus Light Cure Glass Ionomer. Vitrebond or Vitrebond™ Plus liner/base may also be used to line areas of deep cavity excavation.

7. Adhesive System: To bond Filtek One Bulk Fill Restorative to tooth structure, use of a 3M™ ESPE™ dental adhesive system (for example 3M ESPE™ Single Bond™ Adhesive System) 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 moisture and proceed immediately to placement of Filtek One Bulk Fill Restorative.

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8. Delivery: Dispensing the Composite:

8.1 Syringe: Dispense the necessary amount of restorative material into the syringe onto the mix tray in the handle of the syringe in a clockwise manner. To prevent curing of restorative when dispensing is completed, turn the handle counter-clockwise a half to stop paste flow. Immediately replace syringe cap to seal the syringe area to avoid curing.

8.2 Single-Dose Capsule: Insert capsule into the 3M™ ESPE™ Restorative Dispenser. Refer to separate restorative dispenser instructions for full instructions and precautions. Extrude restorative directly into cavity.

9. Placement:
9.1 Avoid intense light in the working field. Exposure of paste to intense light may cause premature polymerization.

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9.3 Slightly overfill the cavity to permit extension of composite beyond axial margins. Contour and shape with appropriate composite finishing instruments.

10. Curing: This product is intended to be cured by exposure to a halogen or LED light with a minimum intensity of 550 mW/cm² in the 400-500 nm range. Cure each increment by exposing its entire surface to light of sufficient intensity to reach the curing depth.

Hold the light guide tip as close to the restorative as possible during light exposure. Use light cure chart to determine appropriate cure times and conditions for all shades.

11. Contouring: Contour restorations surfaces with fine finishing diamonds, diamond burs, and contour proximal surfaces with 3M™ ESPE™ Sof-Lex™ Finishing Strips.

12. Adjust Occlusion: Check occlusion with a thin articulating paper. Examine occlusal and lateral contacts carefully against occlusion by opposing matrix material with a fine finishing diamond or strip.

13. Finish and Polishing: Polish with the 3M™ ESPE™ Sof-Lex™ Finishing and Polishing System.

Indirect Procedure for Inlays, Onlays or Veneers

1. Dental Operatory Procedure
1.1 Shade Selection: Choose the appropriate shade(s) of Filtek One Bulk Fill Restorative prior to isolation.

1.2 Preparation: Prepare the tooth.

1.3 Impression(s): After preparation is complete, make an impression of the preparation and lateral contacts carefully against occlusion by opposing matrix material with a fine finishing diamond or strip.

1.4 Impression Matrix: The indirect restoration is fabricated using the impressioning material chosen. An impressioning material, such as manufactured by 3M ESPE, may be used.

2. Laboratory Procedure
2.1 Prepare the impression of the preparation with the 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, then 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.

Показание	Длина блока на слои	Высота заложеной пасты (с интенсивностью 1000 – 1000 mW/cm ²)	(LED светлыми с интенсивностью 1000 – 2000 mW/cm ²)
Израженные на гнечата и директно выдвигавания от	5 mm	20 sec оклузально, 20 sec бугально, 20 sec лингвално	10 sec оклузально, 10 sec бугально, 10 sec лингвално
Всички избрени показания (с изключением на гнечата на гнечата по дълбочи директно выдвигавания от клас II)	4 mm	40 sec	20 sec

Преди или глгичи издвигавания от клас I

3mm 20 sec 10 sec

Забелжител: За възстановяване от клас II отстранете матричната лентя преди бугално полимеризация.

1. Оформяне на контура: Контурирайте повърхностите на възстановяването с финирираци ленти. Борер или камък. Агрессивността повърхности се контролира с абразивни ленти 3M™ ESPE™ Sof-Lex™.

2. Активране на оклузията: Проверете оклузията с тънна артикулационна скалка. Проверете за центрична и вентрална оклузията. Внимателно аксрируйте оклузията, като отстраните материала с фини полираш диамант или камък.

3. Финирира и полиране: Полирайте със система за финирира и полиране 3M™ ESPE™ Sof-Lex™.

Индиректни процедури за инлей, онлей или фасети

1. Дентална оперативна процедура

1.1. Избор на цвят: Преди измояване избереите подходящия цвят или цветовете на матрицата за възстановяване на зъби с една стъпка Filtek One Bulk Fill Restorative.

1.2. Подготовка: Препарирайте зъба.

1.3. Внесване на отпечатък: След завършване на подготовката вземете отпечатък на матрицата за възстановяване на зъба с една стъпка Filtek One Bulk Fill Restorative. При нанесении матрицы используйте стрипы и матрицы для получения матрицы в проксимальном контуре.

1.4. Полировка и полирование: Полирайте със система за финирира и полиране 3M™ ESPE™ Sof-Lex™.

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1.2. Подготовка: Препарирайте зъба.

1.3. Внесване на отпечатък: След завършване на подготовката вземете отпечатък на матрицата за възстановяване на зъба с одна стъпка Filtek One Bulk Fill Restorative. При нанесении матрицы используйте стрипы и матрицы для получения матрицы в проксимальном контуре.

1.4. Полировка и полирование: Полирайте със система за финирира и полиране 3M™ ESPE™ Sof-Lex™.

Индиректни процедури за инлей, онлей или фасети

1. Дентална оперативна процедура

1.1. Избор на цвят: Преди измояване избереите подходящия цвят или цветовете на матрицата за възстановяване на зъби с одна стъпка Filtek One Bulk Fill Restorative.

1.2. Подготовка: Препарирайте зъба.

1.3. Внесване на отпечатък: След завършване на подготовката вземете отпечатък на матрицата за възстановяване на зъба с одна стъпка Filtek One Bulk Fill Restorative. При нанесении матрицы используйте стрипы и матрицы для получения матрицы в проксимальном контуре.

1.4. Полировка и полирование: Полирайте със система за финирира и полиране 3M™ ESPE™ Sof-Lex™.

Индиректни процедури за инлей, онлей или фасети

