

3M™ Filtek™ Bulk Fill
Flowable Restorative

Technical Data Sheet



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Introduction

Our global leadership in restorative dentistry is defined by more than 50 years of innovation.

In 2012, 3M™ Filtek™ Bulk Fill Flowable Restorative was introduced with chemistry that provides a 4mm depth of cure, addressing some of the challenges that placement of higher viscosity material creates for the dentist. The shade choices of bulk fill flowables are limited and they are more translucent than enamel, thereby increasing the ability of light to penetrate the material for a deeper depth of cure. The exhibited shrinkage is at the low end of the flowable category. The low modulus provides one avenue to mitigate shrinkage stress. Marketed as liner/base materials, they require a conventional universal or posterior restorative on the occlusal surface. Dentists have found that these materials address some of the challenges of incremental placement. Their flowable nature adapts easily to the cavosurface with minimum manipulation. The low modulus and low shrinkage result in low shrinkage stress. Fewer increments are required due to the increased depth of cure, resulting in time savings that reduces the risk of contamination during placement. Esthetic and clinical performance concerns are mitigated by the use of a universal or other posterior filling material on the occlusal surface.

Building on dentists' insight and our clinically proven technologies, we designed a new 3M™ Filtek™ Flowable Syringe

Through global customer research, and discussions with general dentists and opinion leaders, it was identified that flowable composites can be prone to bubbles and run-on during dispensing. In response, we have introduced a new ergonomic syringe design.

Improvements

- Bubble and run-on reduction
- Ergonomic syringe design
- Bendable cannula (19 gauge)
- Material volume indicator
- Safe to warm* and injection mold

*Up to 70°C (158°F) for up to 1 hour, up to 25 times.

2012

3M™ Filtek™ Bulk Fill Flowable Restorative

2014

3M™ Filtek™ Bulk Fill Posterior Restorative

2017

3M™ Filtek™ One Restorative

2020

3M™ Filtek™ Flowable Syringe

Product Description

Same trusted product formulation as 3M™ Filtek™ Bulk Fill Flowable Restorative. Intelligent monomer and filler selection produced a restorative that provides a 4mm depth of cure, low shrinkage and low polymerization stress thereby enabling bulk placement. The flow of Filtek Bulk Fill Flowable Restorative allows for easy adaptation in deep posterior restorations with little or no instrumentation. The wear and physical properties are similar to 3M™ Filtek™ Supreme Flowable Restorative; however there are significant differences in the esthetic results.

Indications for Use

3M™ Filtek™ Bulk Fill Flowable Restorative

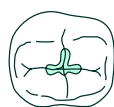
(Incremental up to 4mm)



Base
(Class I – II)



Liner
(Class I – II)



Minimally Invasive
Dentistry (MID)¹



Pit & Fissure
Sealant



Class III



Class V



Repair of Indirect
(small defects)



Repair²



Undercut
Block-out



Core
Build-up³

1. Including small, non stress-bearing occlusal restorations.

2. Repair of acrylic temporary and composite resin.

3. Where at least half the coronal tooth structure is remaining to provide structural support for the crown.

Composition

Filtek Bulk Fill Flowable Restorative is a low viscosity, visible-light activated, radiopaque flowable composite. This low stress flowable material is semi-translucent enabling a 4mm depth of cure. The restorative is packaged in capsules and syringes. Filtek Bulk Fill Flowable Restorative contains BisGMA, UDMA, BisEMA6 and Procrylat resins. The fillers are a combination of zirconia/silica with a particle size range of 0.01 to 3.5µm and ytterbium trifluoride filler with a range of particle sizes from 0.1 to 5.0µm. The total inorganic filler loading is approximately 64.5% by weight (42.5% by volume).

Background Information

Fillers

The fillers used in 3M™ Filtek™ Bulk Fill Flowable Restorative were chosen to maximize strength, wear resistance and radiopacity and to minimize shrinkage while still maintaining good flowable handling. The major filler component is zirconia/silica filler found in 3M™ Filtek™ Z250 Universal Restorative. This filler has a long clinical history of aiding in producing composites that are strong and wear resistant. The zirconia/silica has a particle size range of 0.01 to 3.5µm. The average particle size is 0.6µm. Ytterbium trifluoride (YbF₃) has been added to increase the radiopacity. The ytterbium trifluoride has a particle size range of 0.1 to 5.0µm. The total inorganic filler loading is approximately 64.5% by weight (42.5% by volume).

Resin System

The primary objective of this development effort was to design a base that would allow a practitioner to place and cure a 4mm increment. Several factors needed to be considered. The first is a viscosity that would readily adapt to the internal aspects of a preparation with little or no instrumentation. A flowable viscosity was the obvious choice as dentists choose flowables for their ease of use, including adaptation ease. Secondly, the material must be of sufficient strength to support a capping layer of a universal restorative. Third, the material must have a 4mm depth of cure. Finally, the shrinkage stress generated while curing a 4mm increment must not exceed that of clinically successful restoratives placed in 2mm increments.

The resin systems in flowable restoratives play an important role in handling, shrinkage and shrinkage stress. Unlike universal composites where the resin component is about 20% by weight, the resin systems in flowables account for closer to 40% by weight of the composition. Therefore, their influence on the handling, wear, physical properties, etc. is even greater.

Methacrylate composites inherently shrink during polymerization. The amount of shrinkage is impacted by the monomers used. Generally speaking, low viscosity monomers have low molecular weight. Low molecular weight monomers can cause the polymerized resin matrix of the composite system to be harder because the higher number of double bonds per unit of weight enables higher conversion and cross linking. However, it can also lead to higher shrinkage and shrinkage stress. Some of the stress created by polymerization shrinkage can be reduced by a low modulus material.

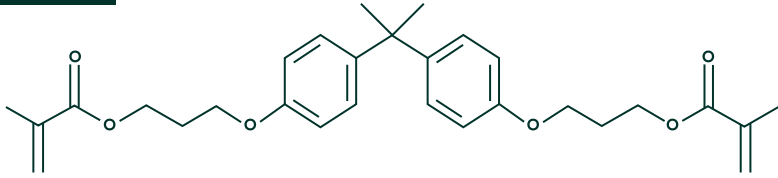
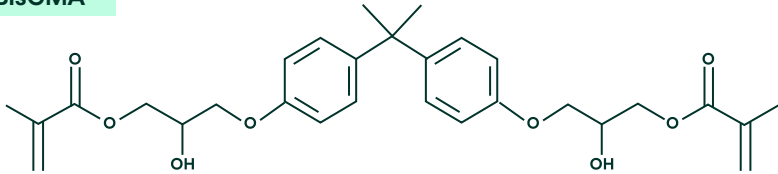
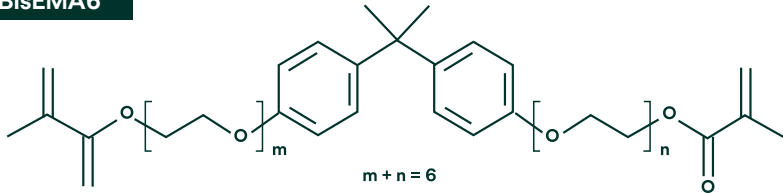
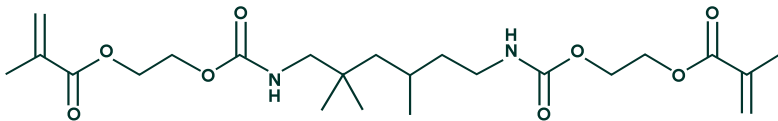
Procrilat**BisGMA****BisEMA6****UDMA**

Table shows monomers used in 3M™ Filtek™ Bulk Fill Flowable Restorative.

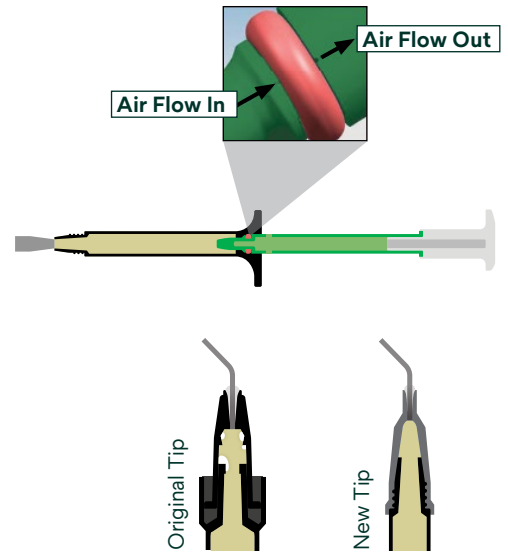
By adjusting the proportions of these high molecular weight monomers, a resin system with a viscosity appropriate for a flowable was developed. The resin system also produces low polymerization shrinkage combined with a low modulus that results in low shrinkage stress.

Delivery

Virtually No Bubbles or Run-on

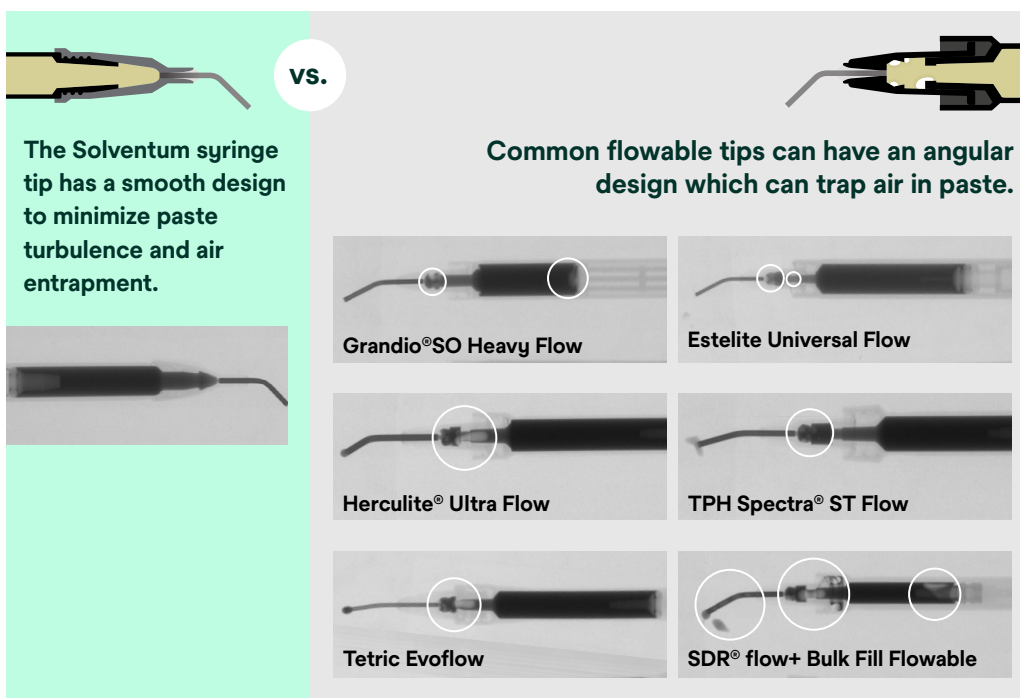
3M™ Filtek™ Bulk Fill Flowable Restorative Syringe was designed to have virtually no bubbles or material “run-on” during dispensing for better control thanks to the inner design which works in two ways:

- 1 Air Entrapment Reduction System: Syringe Design**
 Due to a specially designed channel in the piston, air can escape from the syringe during the filling process at 3M production facilities. This prevents air from becoming trapped in the syringe, which can lead to bubbles and run-on.
- 2 Air Entrapment Reduction System: Tip Design**
 Due to the smooth, tapered, inner-wall of the tip, which corresponds to the tapered angle of the syringe, material is able to flow through the new tip design without trapping air.



Comparison to competitor syringes

Bubbles can be introduced while dispensing flowable composites. Filtek Bulk Fill Flowable Restorative Syringe was designed to avoid this due to a smooth design to minimize paste turbulence and air entrapment.



Source: Solventum internal data. Grandio®SO Heavy Flow Lot # 1846460; TPH Spectra® Flow Lot # 1910000745; Estelite Universal Flow Lot # 012E99; Tetric Evoflow Lot # Y39462; Herculite™ Ultra Flow Lot # 7331880; SDR® flow + Bulk Fill Flowable Lot # 1603291; 3M™ Filtek™ Supreme Flowable Restorative Lot # NA63058.

Ergonomic Design

Easy to hold and extrude

A triangular finger plate and plunger make it quick and easy to personalize your grip. The “No Roll” design with triangular finger plate ensures the syringe stays where placed on a flat surface.

Reduced hand pressure offers increased comfort

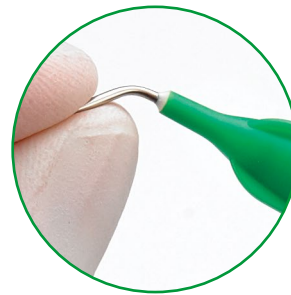
With the increased surface area of the plunger the required pressure on the hand/thumb when extruding the paste can be reduced up to 58%.¹



Bendable Cannula

Easy-to-bend without kinking for better access

Designed to improve access to hard to reach preparations with an easy-to-bend cannula allowing for precise material placement. Then bend, the tip resists kinking, and the material can still be dispensed.



Material Volume Indicator

No more guessing

The green syringe barrel indicates the remaining material volume. When your syringe is empty, only the white plunger shows. The inner cannula design is 19 gauge and can be exchanged with the 3M™ Filtek™ Supreme Flowable Restorative tips (20 gauge).²



Full Syringe



Half Full



Empty

1. Source: Solventum internal data

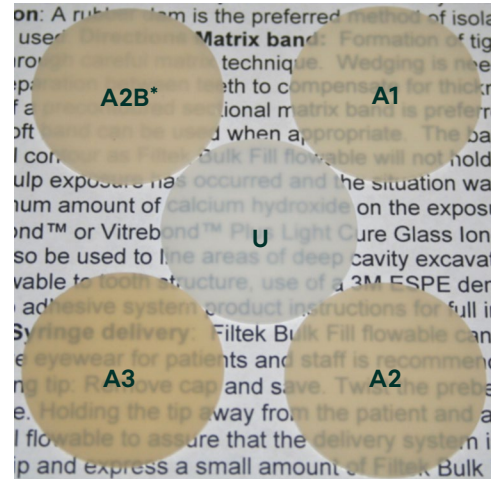
2. Resulting in slightly higher extrusion force due to its smaller inner diameter.

Material Properties

Shades/Shade Match

3M™ Filtek™ Bulk Fill Flowable Restorative is available in 4 shades:

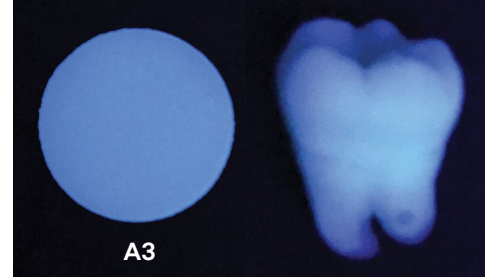
- U (Universal)
- A1, A2, A3



*3M™ Filtek™ Supreme Ultra Universal Restorative A2B

Fluorescence

One additional esthetic property of natural dentition is fluorescence. It is thought that this property contributes to the vitality and lifelike appearance of dentition. Fluorescence in teeth occurs when light energy is absorbed and emitted at a longer wavelength, giving the tooth structure a blue-white appearance. Filtek Bulk Fill Flowable Restorative has fluorescent pigments added to help match natural dentition.



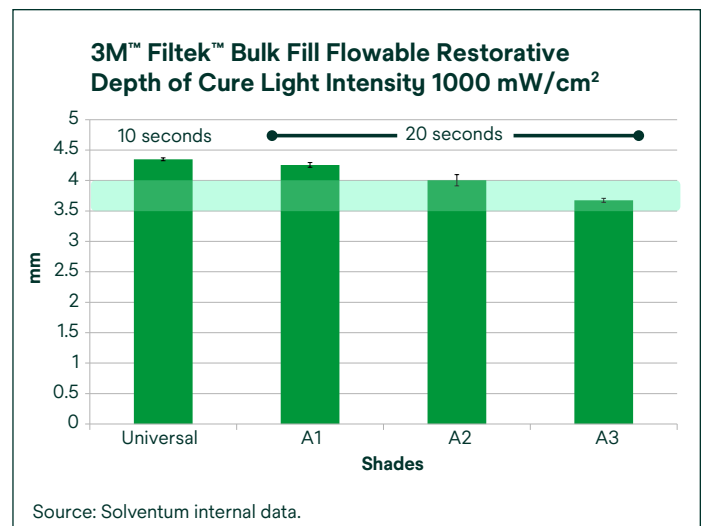
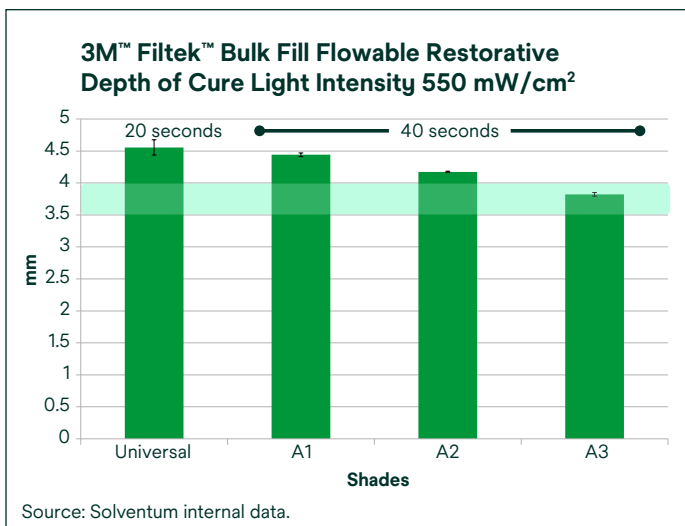
Fluorescence determined with light sources simulating natural UV light.

Source: Solventum internal data.

Technical Data

Depth of cure

The ISO 4049:2019 standard has identified a method for measuring depth of cure for polymer based restorative materials. A metal mold is used to prepare a cylindrical sample. The mold is filled with the composite. The sample is cured from one end of the mold for the recommended cure time. A halogen light with measured output of 550 mW/cm² or an LED light with measured output of 1000 mW/cm² is used to cure the composite. Immediately after exposure, the composite cylinder is removed from the mold and a plastic spatula is used to remove uncured material. The length of the remaining cylinder is measured with a micrometer. Manufacturers may report a depth of cure up to 0.5mm more than one-half the measured cylinder length.



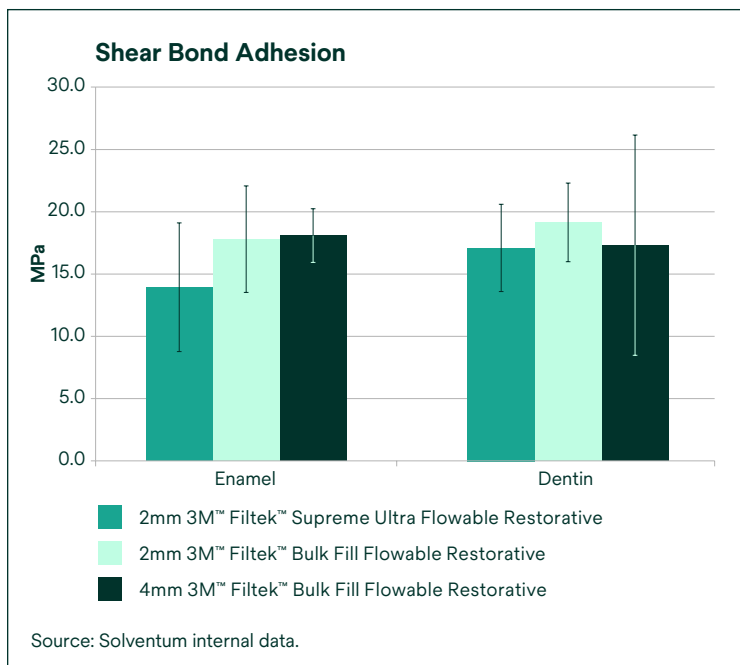
The values determined by the ISO 4049:2009 method support a 4mm depth of cure. The cure time required for the Universal shade is 20 seconds and the A1, A2 and A3 must be cured for 40 seconds with a minimum light intensity of 550 mW/cm². If a high intensity LED light (minimum of 1000 mW/cm²) is used, the cure time of all shades can be cut in half.

Curing protocol

3M™ Filtek™ Bulk Fill Flowable Restorative	Increment depth	All halogen lights (with output 550 – 1000 mW/cm ²)	3M™ Elipar™ LED Lights (with output 1000 – 2000 mW/cm ²)
U	4mm	20 sec.	10 sec.
A1, A2, A3	4mm	40 sec.	20 sec.

Adhesion

Adhesion can be used to indicate adequate cure. Under-cured material is most likely to occur at the bottom of an increment. Under-cured material is not as strong which may affect the adhesion values. If the light does not adequately penetrate the composite thickness to the adhesive, the cross linking (therefore bond) between the composite and the adhesive may be compromised. Shear bond adhesion testing was conducted using the wire loop method on bovine enamel and dentin. Specimens were prepared by bonding the test material of the desired thickness to polished enamel or dentin by following the instructions for 3M™ Adper™ Single Bond Plus Adhesive. Samples were stored in DI water at 37°C for 24 hours before testing.



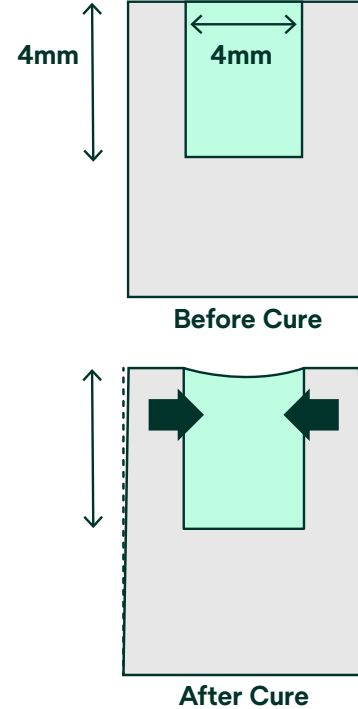
The adhesion values for a 2mm and a 4mm increment of 3M™ Filtek™ Bulk Fill Flowable Restorative are equivalent to each other and to the adhesion of 2mm of 3M™ Filtek™ Supreme Flowable Restorative to both dentin and enamel. This indicates the cure at the bottom of a 4mm increment of Filtek Bulk Fill Flowable Restorative is similar to a 2mm increment of either Filtek Supreme Flowable Restorative or 3M Filtek Bulk Fill Flowable Restorative.

Summary of additional technical data

Property	Unit of measure	3M™ Filtek™ Bulk Fill Flowable Restorative
Cusp Deflection	µm	7.3
Fracture Toughness	MPa m^{1/2}	1.8
Radiopacity	mmAl	2.7

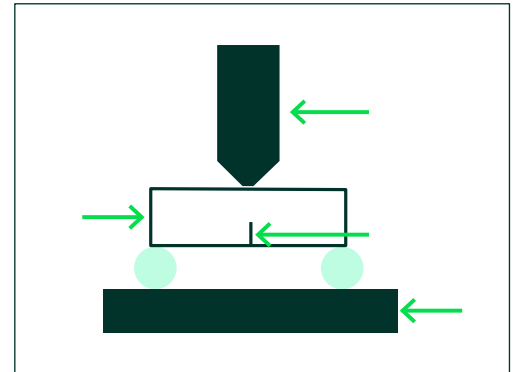
Cusp Deflection (shrinkage-stress) test method

Shrinkage can cause stress in the tooth, in the bonding layer and within the composite. Stress can be a result of the combination of shrinkage and modulus. For materials with similar shrinkage, the material with the higher modulus (or stiffness) usually will produce greater stress. Conversely, for materials with similar moduli, the material that exhibits the highest shrinkage will usually produce greater stress. Cusp deflection is a test method that was designed to provide a relative estimate of polymerization shrinkage stress resulting from placing and curing a dental composite in a 4 x 4mm, open-ended cavity. The cavity dimension roughly simulates a large cavity preparation (e.g., mesial-occlusal-distal (MOD) preparation). The surface of the aluminum cavity was sandblasted and silane-treated, and a dental adhesive was applied. The composite was then placed in the aluminum cavity to a final depth of 4mm and cured with a dental curing light. A linear variable displacement transducer was used to measure the displacement of the aluminum cavity wall due to polymerization shrinkage stress. Aluminum was selected as the block material because it has a modulus similar to human enamel. A similar cusp deflection method using an aluminum block has been described in the literature.¹



Fracture Toughness (strength) test method

The values reported for fracture toughness are related to the energy required to propagate a crack. In this test, a short bar of material is cured. A notch is cut into it. The bar is placed on a fixture that supports either end, and an anvil is positioned above the notch. The anvil presses down until the bar breaks. Higher values mean the material is more resistant to fracturing and have been correlated with better resistance to fracture in clinical use.²



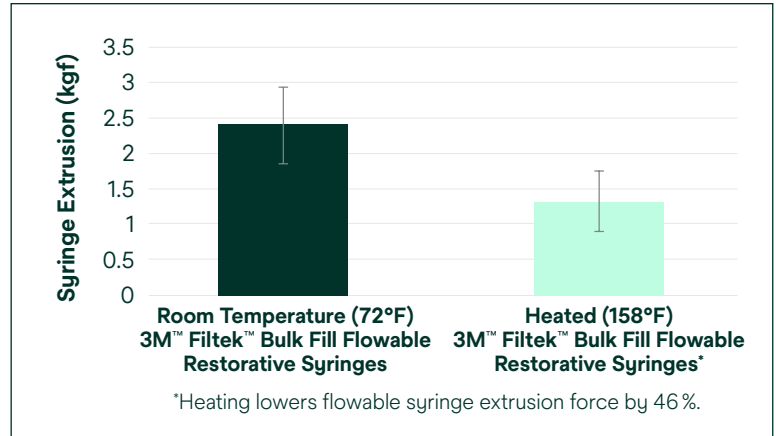
1. C. Thalacker et al., CED-IADR 2007, #0289.

2. N. Ilie, T. J. Hilton, S. D. Heintze, R. Hickel, D. C. Watts, N. Silikas, J. W. Stansbury, M. Cadenaro, and J. L. Ferracane. Academy of Dental Materials guidance—Resin composites: Part I—Mechanical properties. Dental Materials 33 (8):880–894, 2017.

Warming

Reasons to warm

- Warmed composites are more fluid, for easier handling
- Warming improves adaptation of Filtek composite to tooth structure¹
- Warming lowers extrusion force²



The science of safety

We have performed rigorous testing to ensure the safety of pre-warmed 3M™ Filtek™ Bulk Fill Flowable Restorative for both clinicians and patients. Toxicology testing has been completed for all recommended 3M products. Extensive literature search and 3M pulp temperature testing confirm minimal heat transfer to the pulp.

We are the first to offer a dental composite cleared by the FDA for warming.³



Biocompatible
according to
ISO-10993-1:2018
based on a review
by a board-certified
toxicologist.



Minimal heat transfer
to the pulp.^{2,4}

Unchanged physical properties¹

- Diametral tensile strength
- Flexural strength
- Depth of cure
- Flexural modulus
- Color stability

1. Solventum internal data.

2. When warmed according to our IFU (up to 70°C or 158°F for up to 1 hour).

3. 3M™ Filtek™ Universal Restorative capsule.

4. Daronch M, Rueggeberg FA, De Goes MF, Giudici R. Polymerization kinetics of pre-heated composite. J Dent Res. 2006 Jan;85(1):38–43.

Tips for Success

You can safely warm 3M™ Filtek™ Bulk Fill Flowable Restoratives in as little as 5 minutes! Follow these general guidelines and refer to the instructions for use for more information.

DO



DO heat flowable syringes to up to 70°C (158°F) for up to 1 hour, up to 25 times.



DO heat capsules to 70°C (158°F) for up to 1 hour.



DO remove your composite from the heater if it won't be used immediately.



DO consult the Instructions for Use for more information.

DON'T



Do **NOT** use heat from a light bulb, microwave, mug warmer or other unapproved heating devices. Only approved devices have been tested for safety and efficacy when warming select Filtek composites. Consult the Instructions for Use for more information.



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