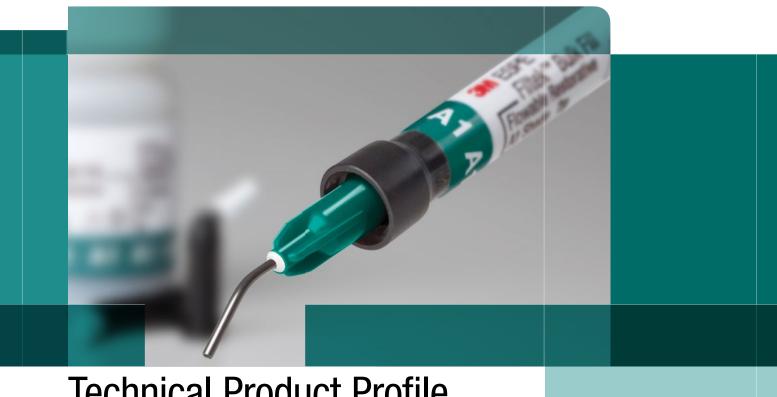
Filtek[™] Bulk Fill

Flowable Restorative



Technical Product Profile



Table of Contents

Introduction	
Product Description	
Product Features	5
Indications for Use	5
Composition	6
Shades	6
Background	
Resin System	
Fillers	8
Physical Properties	
Depth of Cure	
ISO 4049:2009 Depth of Cure	9
Raman Spectroscopy	
Knoop Hardness	
Adhesion	
Volumetric Shrinkage	
Shrinkage Stress	
Flexural Modulus	
Compressive and Diametral Tensile Strength	
In-vitro, 3-Body Wear	
Fracture Toughness	
Flexural Strength	
Radiopacity	
Customer Input	
Questions and Answers	
Technical Data Summary	

Introduction

Since the advent of light curing composites, dentists have had to place them in increments. These composites require light (in the proper wavelength) to initiate the polymerization reaction. Inadequate light penetration leads to poor initiation of this reaction and therefore, under or uncured material. The depth of cure of a composite is compositionally determined by the monomers, the initiators and the shade and opacity of the material. Additionally, the effectiveness of the light is influenced by many factors including the wavelength, the light intensity, the distance from the light source and the exposure time.

Dentists use incremental placement techniques for a variety of reasons besides the cure depth of the composite. Incremental placement is used to manage the shrinkage and corresponding shrinkage stress, resulting from the polymerization reaction. Incremental placement allows for more precise manipulation of the restorative to ensure adaptation, particularly at the cavosurface. It reduces the possibility of voids and aids in forming contacts and sculpting the occlusal surface prior to cure. Managing the shrinkage stress and ensuring proper adaptation may reduce the incidence of post-operative sensitivity. Additionally, incremental placement readily lends itself to creating multi-shade restorations.

On the other hand, incremental placement is considered time consuming and tedious especially in posterior teeth. Increments may increase the potential of voids to form between composite layers. Composites must be placed in a dry field. The risk of contamination leading to a compromised restoration is adversely impacted by the time it takes to place, adapt and cure each increment.

In an effort to provide materials that address the challenges of incremental placement and also provide an alternative material to amalgam, packables were launched in the late 1990s. These materials had a high viscosity and contained a high filler load. Manufacturers claimed the handling was amalgam-like and the material stiffness aided in forming contacts. In addition, many of the packables were reported to have the capability of being bulk placed, i.e., to be placed and cured in 4–5mm increments. However, the high viscosity of these composites made adaptation to the cavosurface more challenging.^{1,2} The actual depth of cure of these materials was found be less than claimed.³ Even if the adequacy of cure was acceptable, the clinical ramifications of shrinkage stress become more prominent with thicker (4–5mm) layers. Studies have shown that many of these materials still had high shrinkage and polymerization stress.⁴

Flowable restoratives can be used to address some of the challenges that placement of higher viscosity (i.e., more highly filled) universal or posterior composites create for the dentist. Inherently, flowable composites flow more than conventional composites. This ability to flow is believed to make adaptation easier with less manipulation of the material. Most dentists using flowables use them as liners in posterior restorations to take advantage of their ease of adaptation on the cavosurface. Flowables have lower filler content resulting in lower physical and wear resistance properties which can limit their use as filling materials for all restorations. Although flowables exhibit higher polymerization shrinkage (than most conventional composites), dentists believe the lower modulus may help to from a stress reducing layer and improve marginal integrity.^{5,6} Research has not supported this theory.^{7,8} Some studies have shown they may reduce the effect of cusp deflection and therefore minimize gap formation which can lead to post-operative sensitivity.^{9,10}

Recently, flowable materials were introduced with chemistry that provides a 4mm depth of cure. The shade choices 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. They also contain similar filler loading to traditional flowable restoratives so their strength and wear resistance can be clinically limiting. 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 2mm increment of 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.

- ¹ Opdam N, Roeters F, Peters M, Burgersdijk R, Teunis M. Cavity wall adaptation and voids in adhesive Class I restorations. *Dent Mater* 1996; 12:230–235
- ² Opdam N, Roeters F, Joosten M, Veeke O. Porosities and voids in Class I restorations by six operators using a packable or syringable composite. *Dent Mater* 2002; 18:58–63.
- ³ Herrero A, Yaman P, Dennison J. Polymerization shrinkage and depth of cure of packable composites. *Quintessence Int* 2005; 36:35–31
- ⁴ Chen H, Manhart J, Hickel R, Kunzelman K. Polymerization contraction stress in light-cured packable composite resins. *Dent Mater* 2001; 17:253–259
- ⁵ Combe EC, Burke FJT. Contemproary resin-based composite materials for direct placement restorations: Packables, flowables and others. Dent Update 2000; 27:326–336
- ⁶ Labella R, Lambrechts P, Van Meerbeek B, Vanherle G. Polymerization shrinkage and elasticity of flowable composites and filled adhesives. *Dent Mater* 1999; 15:128–137
- ⁷ Braga RR, Hilton TJ, Ferracane JL. Contraction stress of flowable composite materials and their efficacy as stress-relieving layers. J Am Dent Assoc 2003; 134:721–728
- 8 Labella R et al.
- ⁹ Ruiz J-L, Mitra S. Using cavity liners with direct posterior composite restorations. *Compendium* 2006; 27: 326-336
- ¹⁰ Prager MC. Using flowable composites in direct posterior restorations. *Dent today* 1997; 16:62–69

Product Description

Filtek[™] Bulk Fill Flowable Restorative is the 3M ESPE choice in the bulk fill flowable category. 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 Filtek[™] Supreme Ultra Flowable Restorative; however there are significant differences in the esthetic results. For this reason, Filtek Supreme Ultra flowable restorative is recommended for use in areas that are visible and demand an esthetic element. Filtek Bulk Fill flowable restorative is more suitable as the first layer in deep posterior preparations that aren't visible and can be covered with at least 2mm of a universal or posterior composite.

Product Features

- Packaged in 2 gram syringes and 0.2 gram capsule (unit-dose)
 - 19 gauge syringe tips and syringe plungers
 - Capsules
- 4 shades U (Universal), A1, A2, A3
- 4mm depth of cure for all shades

Indications for Use

- Base under Class I and Class II direct restorations
- Liner under direct restorative materials
- · Pit and fissure sealant

The 4mm depth of cure, strength and easy adaptation lends itself for use:

 As a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown

Because the wear and physical properties of Filtek Bulk Fill flowable restorative are similar, it can be used in the same indications as Filtek Supreme Ultra flowable restorative. However, Filtek Supreme Ultra flowable restorative is a better choice in the following indications because of the esthetic component needed.

- Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations)
- Class III and Class V restorations
- Undercut blockout
- · Repair of small defects in esthetic indirect restorations
- · Repair of resin and acrylic temporary materials

And finally, Filtek Bulk Fill flowable restorative can be used in the following indication:

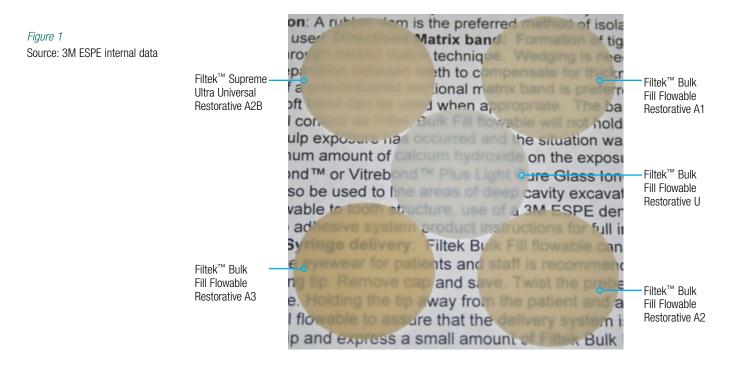
· Repair of small enamel defects

Composition

3M[™] ESPE[™] 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, bisEMA (6) and Procrylat resins. The fillers are a combination of zirconia/silica with a particle size range of 0.01 to 3.5µ and ytterbium trifluoride filler with a range of particle sizes from 0.1 to 5.0µ. The inorganic filler loading is approximately 64.5% by weight (42.5% by volume).

Shades

Filtek Bulk Fill flowable restorative is available in 4 shades: U (Universal), A1, A2, and A3. These shades are more translucent than the body or enamel shades of conventional composites. As opacity was not a component in the appearance of these shades, matching Filtek[™] Supreme Ultra Universal Restorative shades was not possible. Instead, the shades are similar to SureFil[®] SDR[™] Flow.



Background

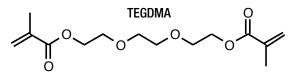
Resin System

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 and shrinkage stress generated while curing a 4mm increment must not exceed clinically successful restoratives placed in 2mm increments.

Frequently, in order to reduce shrinkage in a composite, manufacturers increase filler loading. The lower the viscosity of the resin system, the more filler can be added to the resin before the viscosity becomes too stiff. In the case of flowable restoratives, increasing filler loading is not usually a viable option to reduce shrinkage because the flow properties diminish.

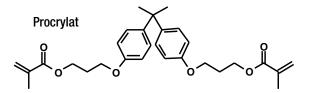
The resin systems in flowable restoratives play an important role in handling, shrinkage and shrinkage stress. Unlike universal composites where the resin component is about 20%, the resin systems in flowables account for closer to 40% of the composition. Therefore, their influence on the handling, wear,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

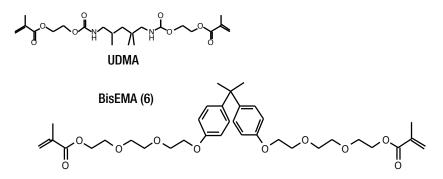


TEGDMA is a low molecular weight, low viscosity monomer which leads to high shrinkage but helps create a hard resin matrix due to the tight crosslink network it enables. TEGDMA is present in Filtek[™] Supreme Ultra Flowable Restorative to keep the viscosity low enough to flow while containing a high enough filler load to impart good strength and wear resistance. To reduce the shrinkage and shrinkage stress to enable a 4mm increment, a substitute for TEGDMA needed to be found.

The resin system of Filtek[™] Bulk Fill Flowable Restorative is a combination of four (4) high molecular weight monomers BisGMA (2,2-bis[4-(2-hydroxy-3-methacryloxypropoxy)phenyl]propane), BisEMA(6) (2,2-Bis[4methacryloxypolyethoxyphenyl)propane], Procrylat (2,2-bis[4-(3-methacryloxypropoxy)phenyl]propane) and UDMA (urethane dimethacrylate). All four of these monomers have been used in clinically successful composites. BisGMA and Procrylat were key components in Filtek Supreme Ultra flowable restorative. BisGMA, BisEMA (6) UDMA were used in Filtek[™] Z250 and Filtek[™] Supreme Ultra Universal Restoratives.



Procrylat is a high molecular weight monomer similar to BisGMA but with a lower viscosity. The difference between BisGMA and Procrylat is the lack of pendant hydroxyl groups. The lack of hydroxyl groups reduces the viscosity of this monomer due to decreased hydrogen bonding potential.



UDMA and BisEMA (6) are relatively low viscosity, high molecular weight monomers. These monomers were used to reduce the viscosity of the resin. In addition, the higher molecular weight effectively reduces the shrinkage while still creating a tough, hard crosslink network.

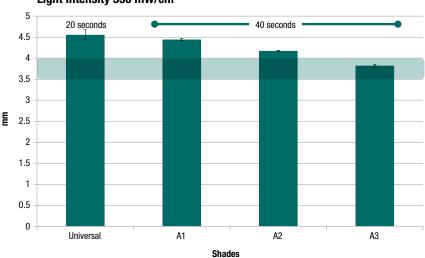
By adjusting the proportions of these high molecular weight monomers a resin system with a viscosity appropriate for a flowable was developed. The resin system also produces low polymerization shrinkage combined with a low modulus that results in low shrinkage stress.

Fillers

The fillers used in FiltekTM 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 FiltekTM Z250 Universal Restorative and $3M^{TM}$ ESPETM Z100TM 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 $0.01-3.5\mu$. The average particle size is 0.6μ . Ytterbium trifluoride (YbF3) has been added to increase the radiopacity. The ytterbium trifluoride has a particle size range of $0.1-5.0\mu$. The inorganic filler loading is approximately 64.5% by weight (42.5% by volume).

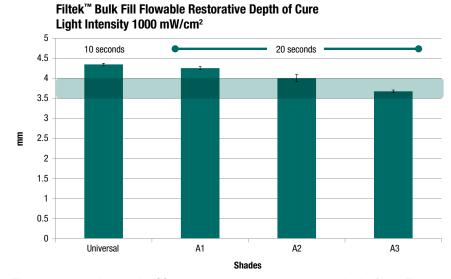
Physical Properties Depth of Cure ISO Test

The ISO 4049:2009 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 4mm in diameter and at least twice as long as the claimed depth of cure. 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.



Filtek[™] Bulk Fill Flowable Restorative Depth of Cure Light Intensity 550 mW/cm²







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.

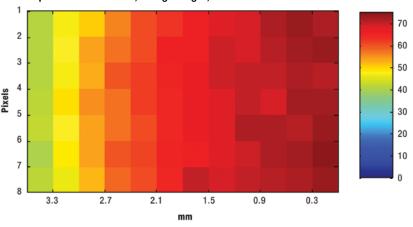
Raman Spectroscopy

Raman spectroscopy was used to measure the degree of methacrylate conversion. Sample preparation was based on the ISO 4049:2009 methodology. The mold was modified to provide a smaller diameter and flat surface for the spectroscopy measurements. A metal hemicylindrical mold was used with a 3mm diameter and a length of 10mm. As in the ISO test, the samples were cured from one end using the curing lights as above. 3M[™] ESPE[™] Filtek[™] Supreme Ultra Flowable Restorative, A2 shade, was used as a control.

Raman spectra were acquired with a Kaiser Optical System's microscope and spectrograph using a 785nm laser, a 2 second exposure time, and a 300 by 300 um pixel size. The peak integration mapping tool with baseline correction was used to prepare two individual images showing intensity of the area of the 1636 and 1608 cm-1 bands. These images were used to create a degree of conversion (DC) mapping using the following equation:

$$DC = 100 - \left[\frac{(Area1636/Area1608)_{\text{polymer}}}{(Area1636/Area1608)_{\text{monomer}}} * 100 \right]$$

The maps generated are color coded to depict the degree of conversion at each depth. The right side of the map depicts the end of the sample where the light guide was positioned during cure. The bar at the right indicates degree of conversion.



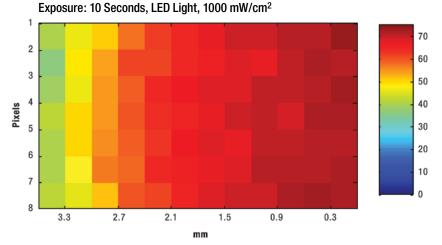


Note the higher conversion, the deeper red color, at the surface of the sample nearest the curing light tip (right side of image). The degree of conversion (DC) decreases the further from the light source.

At 2.1mm from the surface exposed to the light source, the DC of Filtek Supreme Ultra flowable is 92% of maximum conversion. The maximum conversion usually occurs at the top of the sample (the closest to the light guide). This confirms the claimed depth of cure.

Figure 4 Source: 3M ESPE internal data

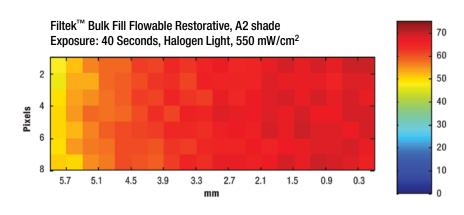
Figure 5 Source: 3M ESPE internal data



Filtek[™] Supreme Ultra Flowable Restorative, A2 shade

Figure 6 Source: 3M ESPE internal data

At 2.1mm from the surface exposed to the light source, the degree of conversion (DC) of Filtek Supreme Ultra flowable restorative is 91% of maximum conversion (usually area closest to the light source). This confirms the claimed depth of cure using a high intensity LED light at half the cure time.



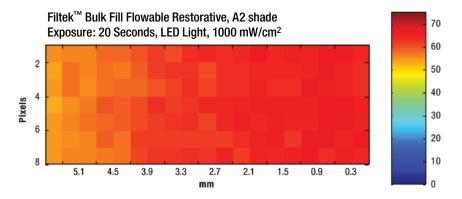
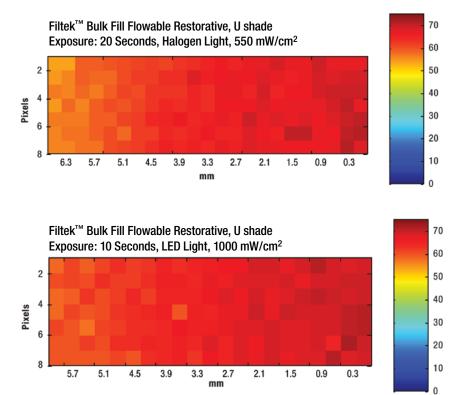




Figure 8 Source: 3M ESPE internal data

The 4mm cure depth was confirmed for the A2 shade of Filtek Bulk Fill flowable restorative. The DC was 91% of the maximum conversion (usually area closest to the light source) at 4.2mm for both sets of curing conditions.







The 4mm cure depth was confirmed for the U shade of Filtek Bulk Fill flowable restorative. The DC was 91% of the maximum conversion (usually area closest to the light source) at 4.2mm for both sets of curing conditions.

The DC values at all depths were converted to percent of maximum conversion values. These were plotted as a function of depths (distance from the light). The DC stays at a high level (>90%) until the stated depth of cure is reached.

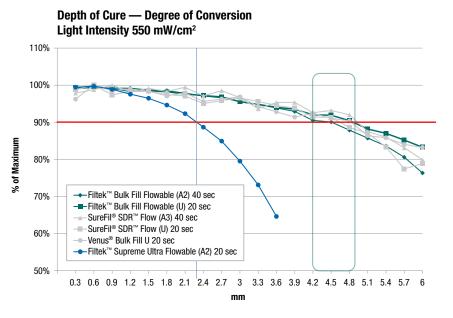
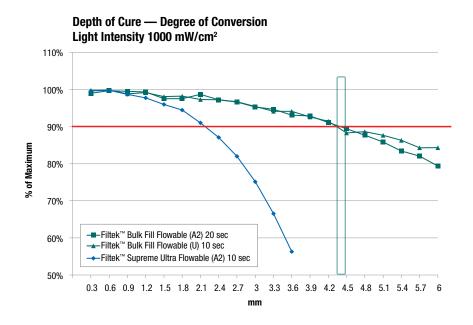


Figure 11 Source: 3M ESPE internal data

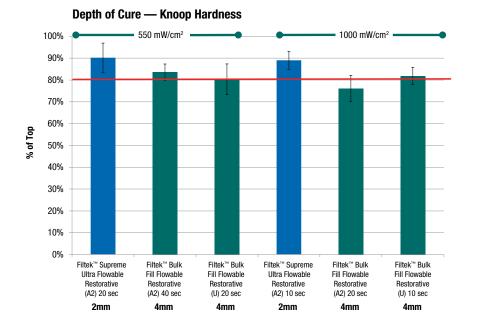
When a LED light source with an intensity of 1000 mW/cm² is used, the cure times can be cut in half and still achieve a similar degree of conversion and, therefore, depth of cure.





Knoop Hardness

Samples for Knoop hardness were prepared using the same method as described above (Raman Spectroscopy). The Knoop hardness clearly shows the material has an acceptable hardness at 4mm when cured following the appropriate conditions.





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 Adper[™] Single Bond Plus Adhesive. Samples were stored at 37°C for 24 hours.

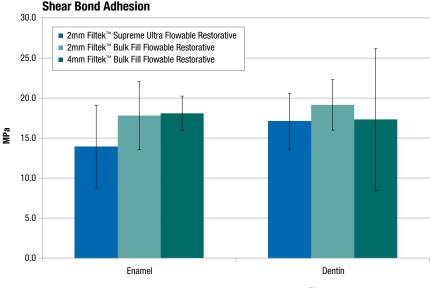


Figure 14 Source: 3M ESPE internal data

The adhesion values for a 2mm and a 4mm increment of Filtek[™] Bulk Fill Flowable Restorative are equivalent to each other and to the adhesion of 2mm of Filtek[™] Supreme Ultra 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 Ultra flowable restorative or Filtek Bulk Fill flowable restorative.

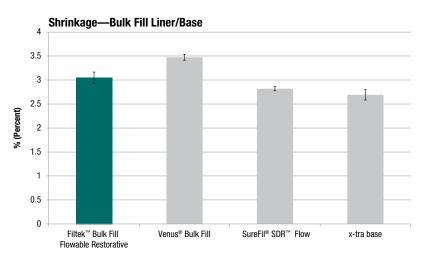
Volumetric Shrinkage

A method for determining polymerization shrinkage was described by Watts and Cash (Meas. Sci. Technol. 2(1991) 788-794). In this method, a disc shaped test specimen and uncured paste is sandwiched between two glass plates and light cured through the lower rigid plate. The flexible upper

Transducer	
Cover Slide \longrightarrow Deflection Glass Slide \longrightarrow Light \longrightarrow	

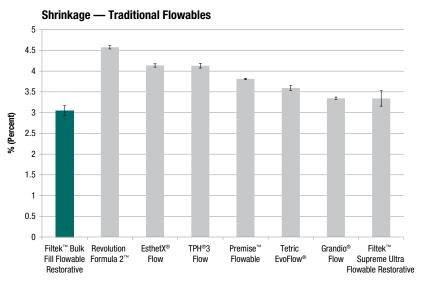
plate is deflected during the polymerization of the test specimen. The amount the flexible plate bends is proportional to the shrinkage. Deflection is measured and recorded as a function of time. Although this process actually measures linear shrinkage, volumetric shrinkage was closely approximated due to the fact that the dimensional changes were limited to the thickness dimension.

In this test, samples were exposed for 60 seconds to a 3M[™] ESPE[™] LED Curing Light (with output of 595 mW/cm²). The final shrinkage was recorded 4 minutes after the end of light exposure.





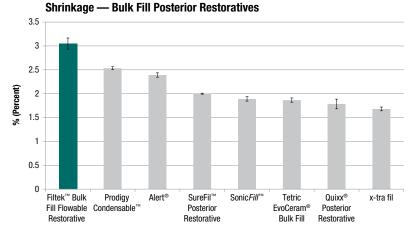
The volumetric shrinkage of Filtek[™] Bulk Fill Flowable Restorative is lower than Venus Bulk Fill Flow and within the range of other commercially available bulk fill liner base products.





Source: 3M ESPE internal data

The shrinkage of Filtek Bulk Fill flowable restorative is significantly less than that of other traditional flowable restoratives.





The shrinkage of Filtek Bulk Fill flowable restorative is higher than the shrinkage of commercially available bulk fill posterior restoratives.

Shrinkage Stress

Cusp Deflection

Shrinkage can cause stress in the tooth, 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) will produce greater stress. Conversely, for materials with similar modulii, the material that exhibits the highest shrinkage will produce greater stress. Cusp deflection is a 3M ESPE test method that was designed to provide a relative estimate of polymerization shrinkage stress resulting from placing and curing a dental composite in a 4x4mm 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 is sandblasted, silane treated and a dental adhesive is applied. A composite is then placed in the aluminum cavity to a final depth of 4mm, either incrementally or bulk filled, and cured with a dental curing light (e.g., one 4mm deep application of bulk fill flowable composite or two 2mm deep increments of traditional flowable composite, each placed and light-cured). A linear variable displacement transducer is 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 literature¹¹.

¹¹Park J, Chang J, Ferracane J, Lee IB: How should composite be layered to reduce shrinkage stress: Incremental or bulk filling?. Dental Materials 2008; 24: 501-1505

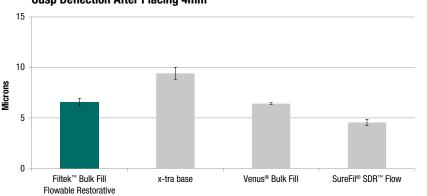




Figure 18 Source: 3M ESPE internal data

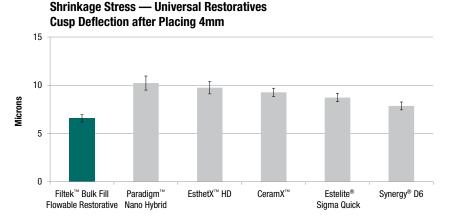
The shrinkage stress generated when placing and curing a 4mm increment of Filtek[™] Bulk Fill Flowable Restorative is less than x-tra base and within the range of other bulk fill flowable liner bases.

25 20 15 Microns 10 5 0 Filtek[™] Bulk Grandio® Filtek^{*} TPH®3 Flow Premise[™] Revolution EsthetX[®] Tetric Supreme Ultra Flowable Fill Flowable Flow Formula 2 Flow **EvoFlow**® Restorative Flowable Restorative

Shrinkage Stress — Traditional Flowables **Cusp Deflection after Placing 4mm**

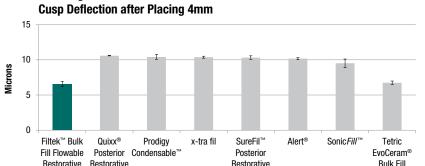


The shrinkage stress generated when placing a 4mm increment of Filtek[™] Bulk Fill Flowable Restorative is substantially less than the shrinkage stress generated when placing and curing two 2mm increments of traditional flowable restoratives.





The shrinkage stress generated when placing a 4mm increment of Filtek Bulk Fill flowable restorative is substantially less than the shrinkage stress generated when placing and curing two 2mm increments of universal restoratives.





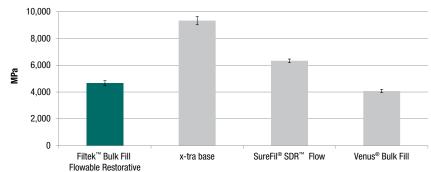


The shrinkage stress generated when placing a 4mm increment of Filtek Bulk Fill flowable restorative is substantially less than the shrinkage stress generated when placing and curing 4mm of bulk fill posterior restoratives.

Flexural Modulus

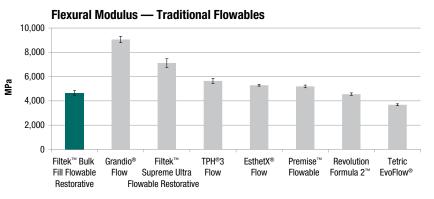
Flexural modulus is a method of defining a material's stiffness. A high modulus indicates a rigid material. The flexural modulus is measured by applying a load to a material specimen that is supported at each end. A low flexural modulus can aid in reducing stress generated during cure.





Flexural Modulus — Bulk Fill Liner/Base

The flexural modulus of Filtek[™] Bulk Fill Flowable Restorative is lower than x-tra base and SureFil[®] SDR[™] Flow and similar to Venus[®] Bulk Fill.



The flexural modulus of Filtek Bulk Fill flowable restorative is in the range of traditional flowable restoratives.

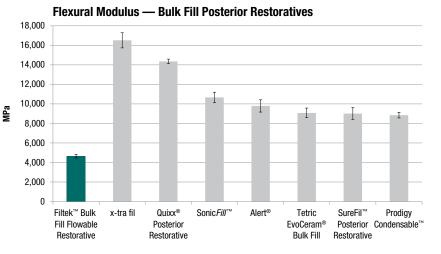


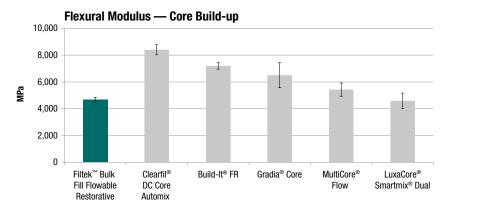
Figure 24 Source: 3M ESPE internal data

Figure 22

Figure 23

Source: 3M ESPE internal data

Source: 3M ESPE internal data

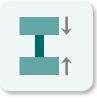


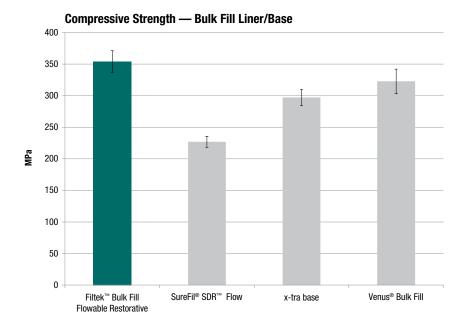


The flexural modulus of Filtek[™] Bulk Fill Flowable Restorative is lower than or equal to conventional 2-paste core build-up materials.

Compressive and Diametral Tensile Strength

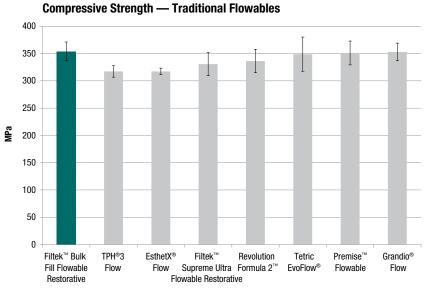
Compressive strength is particularly important because of chewing forces. Rods are made of the material and simultaneous forces are applied to the opposite ends of the sample length. The sample failure is a result of shear and tensile forces.





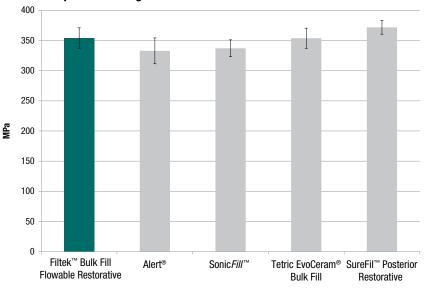


The compressive strength of Filtek Bulk Fill flowable restorative is higher than other bulk fill liner base products.





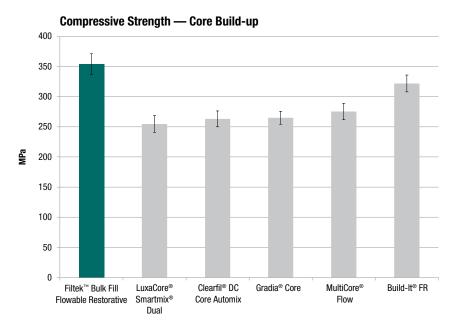
The compressive strength of Filtek[™] Bulk Fill Flowable Restorative is in the range of traditional flowable restoratives.



Compressive Strength — Bulk Fill Posterior Restoratives

The compressive strength of Filtek Bulk Fill flowable restorative is in the range of bulk fill posterior restoratives.

Figure 28 Source: 3M ESPE internal data

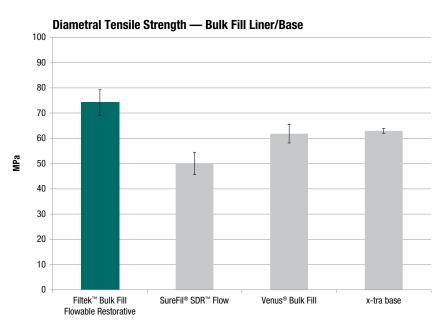




The compressive strength of Filtek[™] Bulk Fill Flowable Restorative is higher than conventional 2-paste core build-up materials.

Diametral tensile strength is measured using a similar apparatus. Compressive forces are applied to the sides of the sample, not the ends, until fracture occurs.







The diametral tensile strength of Filtek Bulk Fill flowable restorative is higher than other bulk fill flowable liner bases.

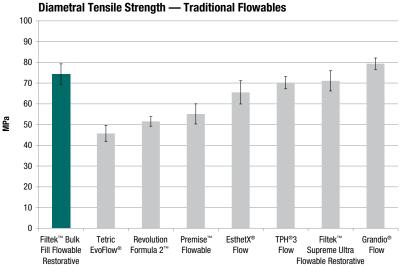


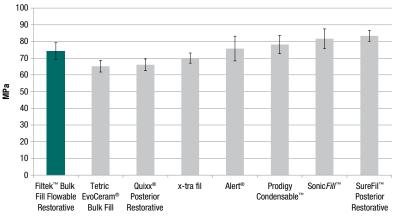


Figure 32

Source: 3M ESPE internal data

The diametral tensile strength of Filtek[™] Bulk Fill Flowable Restorative is similar or higher than traditional flowable restoratives.

Diametral Tensile Strength — Bulk Fill Posterior Restoratives



The diametral tensile strength of Filtek Bulk Fill flowable restorative is within the range of bulk fill posterior restoratives.

80 70 60 50 40 30 20 10 0 Filtek[™] Bulk Clearfil® DC Core LuxaCore® Gradia® Core **MultiCore**[®] Build-It® FR Fill Flowable Smartmix® Dual Flow Automix Restorative

Diametral Tensile Strength — Core Build-up

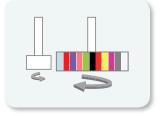
The diametral tensile strength of Filtek Bulk Fill flowable restorative is higher than conventional 2-paste core build-up materials.

Figure 33 Source: 3M ESPE internal data

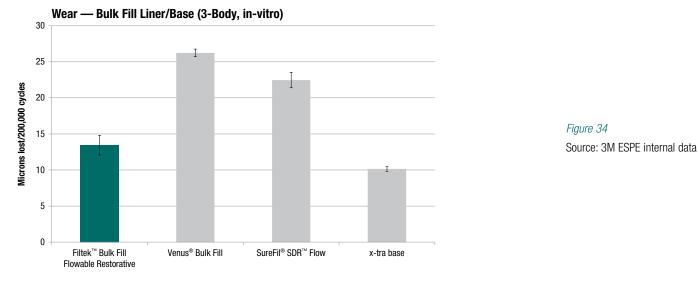
ИРа

In-vitro, 3-Body Wear

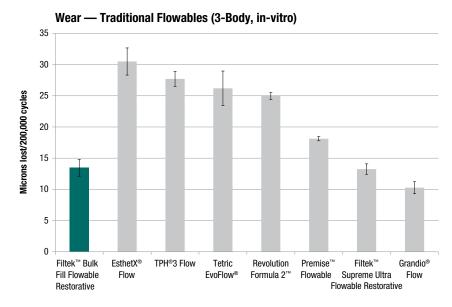
The wear rate was determined using an in-vitro 3-body wear test. In this test, composite (1st body) is loaded onto a wheel, which contacts another wheel, which acts as an "antagonistic cusp" (2nd body). The two wheels counter-rotate against one another dragging abrasive slurry (3rd body)



between them. Dimensional loss during 200,000 cycles is determined by profilometry at regular intervals (i.e., after every 40,000 cycles). As the wear in this method typically follows a linear pattern, the data is plotted using linear regression. The wear rates (i.e., the slope of the lines) are determined. Comparison of the rates reduces some of the variability in the test due to sample preparation, and, can be predictive of anticipated wear beyond the length of the actual test.

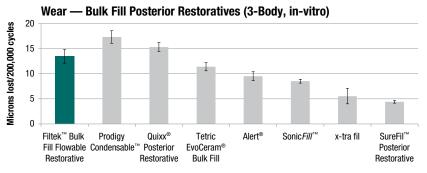


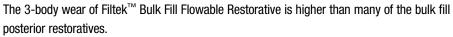
The 3-body wear of Filtek[™] Bulk Fill Flowable Restorative is lower than Venus Bulk Fill and SureFil SDR flow. Wear of proximal surfaces can lead to restoration failure due to open contacts.



The 3-body wear of Filtek Bulk Fill flowable restorative is lower than many traditional flowables and is comparable to Filtek[™] Supreme Ultra Flowable Restorative.

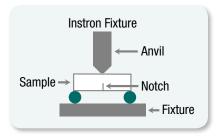
Figure 35 Source: 3M ESPE internal data





Fracture Toughness

The values reported for fracture toughness (K1c) 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.



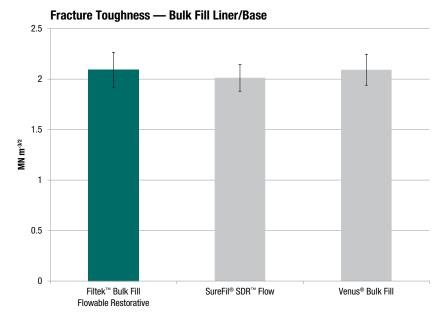
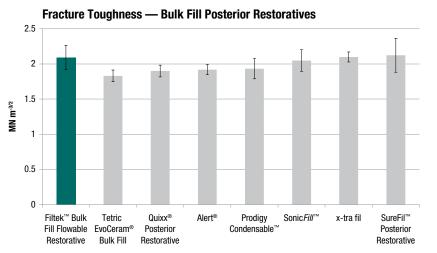




Figure 36

Source: 3M ESPE internal data

The fracture toughness of Filtek Bulk Fill flowable restorative is similar to other bulk fill flowable liner bases.

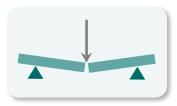


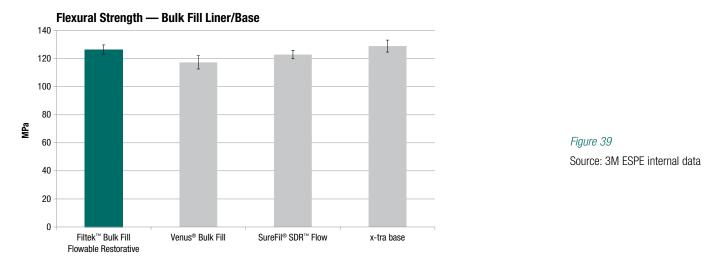


The fracture toughness of Filtek[™] Bulk Fill Flowable Restorative is similar to bulk fill posterior filling materials.

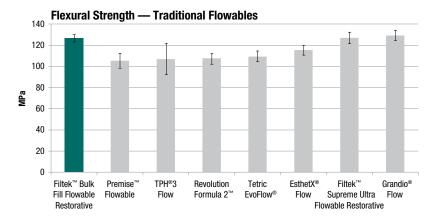
Flexural Strength

Flexural strength is determined in the same test as flexural modulus. Flexural strength is the value obtained when the sample breaks. This test combines the forces found in compression and tension.





The flexural strength of Filtek Bulk Fill flowable restorative is similar to other bulk fill flowable liner bases.



Source: 3M ESPE internal data

Figure 40

The flexural strength of Filtek[™] Bulk Fill Flowable Restorative is similar to Filtek[™] Supreme Ultra Flowable Restorative and higher than many other traditional flowables.

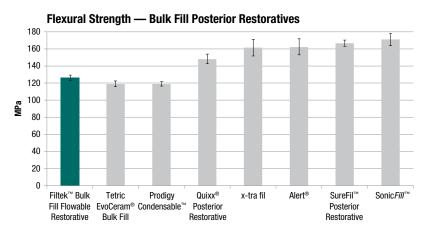
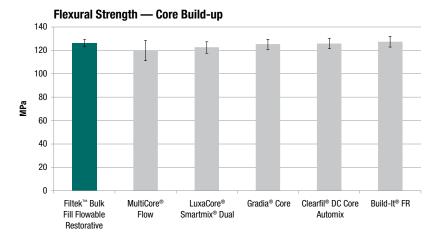


Figure 41 Source: 3M ESPE internal data

The flexural strength of Filtek Bulk Fill flowable restorative is similar to Tetric EvoCeram[®] Bulk Fill and Prodigy Condensable[™].

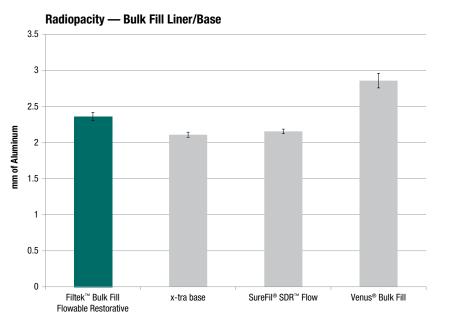


The flexural strength of Filtek Bulk Fill flowable restorative is similar to conventional 2-paste core build-up materials.

Figure 42 Source: 3M ESPE internal data

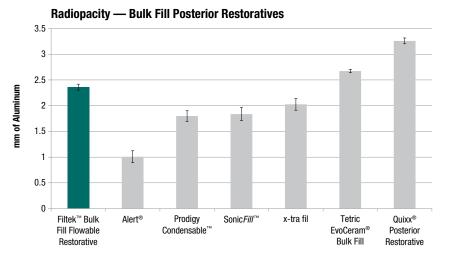
Radiopacity

The radiopacity was measured per ISO 4049:2009(E). In this method, the optical density of a radiograph of the cured material is compared to that of an aluminum step wedge of increasing thicknesses. The radiopacity is reported as the ratio of the optical density of the aluminum sample to that of the test samples. Ratio values greater than 1.0 are considered to be radiopaque.



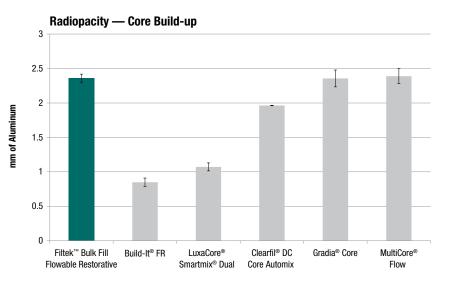


The radiopacity of Filtek[™] Bulk Fill Flowable Restorative is higher than SureFil[®] SDR[™] Flow and x-tra base.





The radiopacity of Filtek Bulk Fill flowable restorative is higher than Alert[®], Prodigy Condensable[™], Sonic*Fill*[™] and x-tra fil.



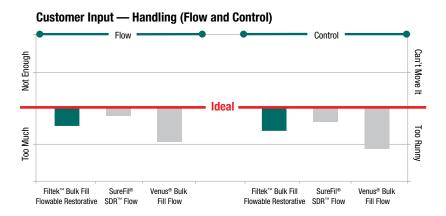


The radiopacity of Filtek[™] Bulk Fill Flowable Restorative is similar to, or higher than, conventional 2-paste core build-up materials.

Customer Input Handling

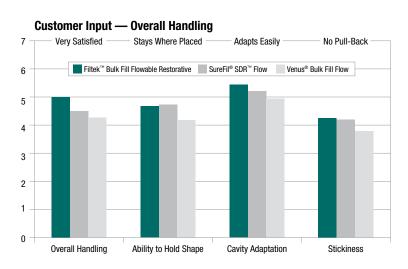
Several simulated operatories were conducted throughout the development. A simulated operatory allows dentists to place several experimental materials on tooth models at mouth temperature (37°C). These studies are double blind with commercially available materials frequently included. The results of these sessions are used to guide the development of the handling. The final study included Venus[®] Bulk Fill Flow and SureFil[®] SDR[™] Flow. Thirty-nine dentists evaluated the materials in tooth models fabricated so that the cured restorations could be removed to evaluate the adaptation.

Over 75% of the participants liked the handling of Filtek[™] Bulk Fill Flowable Restorative. More than 60% preferred the handling when compared to Venus[®] Bulk Fill Flow and SureFil[®] SDR[™] Flow.





The flow and ability to control of Filtek Bulk Fill flowable restorative was rated close to Ideal.





Dentists were satisfied with the overall handling of Filtek Bulk Fill flowable restorative. The ability to hold shape and the stickiness were rated similarly for SureFil SDR flow and Filtek Bulk Fill flowable restorative. The adaptation of all materials was similar.

Questions and Answers

Why would I use this as a sealant?

Many dentists and hygienists want to see the underlying tooth structure. By using a more translucent material as a sealant, caries activity in deep grooves or fissures can be more visually monitored.

Why is this product indicated as a core build-up?

Many dentists use traditional flowables for core build-up. Filtek[™] Bulk Fill Flowable Restorative allows dentists to take advantage of the 4mm depth of cure when placing core build-ups. The physical properties of this product are in the range of current paste-paste composite core build-up materials. Because of this Filtek Bulk Fill flowable restorative can be used as a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown.

	Compressive	essive	Diametral	etral	Flexu	Ira			Fracture	ure			4mm Cusp	usp				
	Strength	igth	Tensile Strength	strength	Strength	ngth	Flexural Modulus	Vodulus	Toughness	ness	Shrinkage	age	Deflection	stion	Radiopacity	acity	3-body wear	
	MPa	StDev	MPa	StDev	MPa	StDev	MPa	StDev	K1c	StDev	%	StDev	Microns	StDev	mm of Al	StDev	microns lost/200k cycles	StDev
Filtek™ Bulk Fill Flowable Restorative	354.2	17.0	74.2	5.1	126.5	3.3	4658.0	188.0	2.1	0.2	3.1	0.1	6.6	0.4	2.4	0.1	13.4	2.1
SureFil® SDR [™] flow	226.9	8.7	50.1	4.4	122.9	3.0	6335.0	131.0	2.0	0.1	2.8	0.0	4.5	0.3	2.2	0.0	22.5	1.1
Venus® Bulk Fill Flow	322.7	19.4	61.8	3.7	117.4	4.7	4080.0	125.0	2.1	0.2	3.5	0.1	6.4	0.1	2.9	0.1	26.2	1.4
x-tra base	297.2	12.6	62.9	1.0	129.0	4.3	9330.0	309.0			2.7	0.1	9.4	0.6	2.1	0.0	10.1	0.3
Build-tt® FR	322.0	14.0	61.3	7.7	127.5	4.5	7201.0	246.0	1.8	0.1	4.2	0.1			0.8	0.1	17.7	1.5
Clearfil® DC Core Automix	263.2	13.2	57.4	5.9	126.2	4.7	8399.0	378.0	1.7	0.1	2.7	0.0			2.0	0.0	12.2	0.7
Gradia [®] Core	265.0	10.7	45.7	11.3	125.3	4.5	6508.0	933.0	1.5	0.1	2.7	0.1			2.4	0.1	31.4	1.7
LuxaCore [®] Smartmix [®] Dual	254.7	13.8	30.0	20.6	122.7	4.9	4590.0	578.0	1.4	0.1	3.7	0.0			÷.	0.1	32.4	2.1
MultiCore [®] Flow	275.5	13.7	50.1	7.2	119.9	8.5	5427.0	493.0	1.8	0.2	3.4	0.0			2.4	0.1	23.5	1.2
EsthetX [®] Flow	317.3	6.0	65.5	5.6	115.5	4.7	5292.0	73.0			4.1	0.0	10.1	0.4			30.5	1.2
Filtek TM Supreme Ultra Flowable Restorative	330.7	21.3	71.1	4.9	127.3	5.4	7119.0	361.0	1.7	0.1	3.3	0.2	13.4	0.5	1.6	0.1	13.2	2.8
Grandio [®] Flow	353.0	16.2	79.4	2.7	129.1	4.7	9066.0	258.0			3.3	0.0	19.9	0.7			10.3	0.6
Premise [™] Flowable	351.1	21.9	55.1	4.9	105.2	7.0	5193.0	112.0			3.8	0.0	10.8	0.3			18.1	0.3
Revolution Formula 2 TM	336.4	21.3	51.5	2.3	107.5	5.2	4554.0	102.0			4.6	0.0	10.1	0.4			25.0	0.8
Tetric EvoFlow [®]	348.9	31.4	45.8	3.9	109.5	5.2	3679.0	78.0			3.6	0.1	7.8	0.4			26.2	1.0
TPH®3 Flow	317.3	10.5	70.2	3.0	107.1	14.9	5642.0	203.0			4.1	0.1	10.9	0.2			27.7	0.5
Alert®	333.0	21.5	75.8	7.4	162.7	9.4	9795.0	626.0	1.9	0.1	2.4	0.0	10.2	0.1	1.0	0.1	9.5	1.3
Prodigy Condensable TM	304.1	26.6	78.2	5.5	119.4	2.8	8848.0	283.0	1.9	0.1	2.5	0.0	10.4	0.3	1.8	0.1	17.3	0.9
$\operatorname{Quixx}^{\circledast}$ Posterior Restorative	279.8	9.3	66.1	3.5	148.4	5.5	14356.0	238.0	1.9	0.1	1.8	0.1	10.6	0.0	3.3	0.1	15.3	0.8
Sonic Fill [™]	337.2	14.0	81.7	5.9	171.1	7.0	10661.0	541.0	2.0	0.2	1.9	0.0	9.5	0.6	1.8	0.1	8.5	0.9
SureFil [™] Posterior Restorative	372.0	11.3	83.4	3.3	166.9	3.6	9019.0	610.0	2.1	0.2	2.0	0.0	10.3	0.2			4.4	0.4
Tetric EvoCeram [®] Bulk Fill	353.8	16.8	65.2	3.5	119.4	3.6	9084.0	496.0	1.8	0.1	1.9	0.0	6.7	0.3	2.7	0.0	11.4	1.5
x-tra fil	316.9	8.2	70.1	3.0	161.6	9.6	16514.0	775.0	2.1	0.1	1.7	0.0	10.4	0.1	2.0	0.1	5.5	0.3

Technical Data Summary

Customer Care Center: 1-800-634-2249 www.3MESPE.com/Filtek



Dental Products

2510 Conway Avenue St. Paul, MN 55144-1000 USA 1-800-634-2249 **3M Canada** Post Office Box 5757 London, Ontario N6A 4T1 Canada 1-888-363-3685

Please recycle. Printed in U.S.A. 70-2013-0518-5

3M, ESPE, Adper, Filtek and Z100 are trademarks of 3M or 3M Deutschland GmbH. Used under license in Canada. © 3M 2014. All rights reserved. Alert, Build-It, CeramX, Clearfil, Condensable, Estelite, EsthetX, EvoCeram, EvoFlow, Formula 2, Gradia, Grandio, LuxaCore, MultiCore, Paradigm, Premise, Quixx, SDR, Smartmix, Sonic*Fill*, SureFil, Synergy, TPH 3 and Venus are not trademarks of 3M.