3M ESPE

Filtek™ Supreme XT Flowable Restorative

technical product profile

Filtek™

Table of Contents

Introduction

3M™ ESPE™ Filtek™ Supreme XT Flowable Restorative is a low viscosity, visible light-cured, radiopaque flowable restorative indicated for a variety of uses including liner/base, direct restorative for Class III ,V and minimally invasive preparations, pit and fissure sealant and repair of indirect composite, porcelain and temporary acrylic materials.

Filtek Supreme XT flowable restorative blends the strength and beauty of Filtek Supreme XT Universal Restorative with the "flow on demand" handling of 3M™ ESPE™ Filtek™ Flow Flowable Restorative. Using the nanofiller technology of Filtek Supreme XT universal restorative and the rheology modifier of Filtek Flow flowable restorative, 3M ESPE has developed an esthetic flowable restorative with excellent wear and polish properties and handling optimized for a variety of indications.

History

Flowable composites became popular additions to the dentist's armamentarium in the mid to late 1990s. Composition often mimics that of a composite resin with one critical exception – that of a lower filler loading. Rada, in his 1998 article "The Versatility of Flowable Composites," states: "Flowable composites offer an additional alternative in dentists' tooth-colored restorative material selection. Their viscosity, consistency, handling characteristics, and delivery system make flowable resins a very attractive choice in selected cases."

Flowable composites, due to their limited filler loading, typically display lower physical properties than hybrid composites (Bayne 1998, Attar, 2003, Bonilla 2003). Thus, recommended indications have not included use in stress-bearing restorations. Rada considers flowables suitable as liners, Class V restorations, small Class I restorations including preventive resin restorations, small Class III resins, porcelain repairs, and the restoration of marginal defects. Behle (1998) emphasizes the excellent fit of the flowable concept into the trend towards conservative treatment techniques and microdentistry. A similar recommendation is offered by Peters and McLean (2001) who note that flowable composites "are excellently suited for minimally invasive cavities." This includes various occlusal surface preparations (Preventive Resin Restorations involving only contiguous fissures; small "occlusal" preparations involving a significant portion of occlusal fissure pattern; sealants involving the use of dedicated burs) proximal slot and tunnel preparations and cervical preparations.

Flowable composites also typically exhibit higher polymerization shrinkage than conventional composites. However, it is the polymerization stress that is ultimately destructive. Braga et al, (2003) reported that the polymerization stress of flowable composites was measured to be no greater than that measured for conventional composites. It was surmized that the lower elastic modulii (stiffness) of the flowable composites compared to conventional composites compensates for the higher shrinkage. This suggests that the risk of debonding during polymerization of a flowable composite should be no greater than the risk of debonding for a conventional composite.

It has also been suggested that use of a low modulus flowable as a liner may absorb some of the polymerization stress of a conventional composite. Although Braga (2003), measured some stress relief when a flowable was modeled for use as a liner, its magnitude was found to be low and variable depending upon the flowable examined. The authors also note, however, that the lower modulii of the flowable composites may be beneficial in relieving stress at the bonded interface created by mechanical and thermal stimuli. Thus far, this benefit as measured by lower microleakage or reduced gap formation has been found in some laboratory studies (Ferdianakis (1998), Tung et al

(2000), Leevailoj et al (2001), Fruits et al (2002), Yazici (2003)), but not in others (Jain et al (2001), Wibowo et al (2001)).

Although the literature is equivocal on the benefit attributed to flowable materials in reducing microleakage or gaps at the bonded interface, the benefit associated with the reduction of voids or gaps during placement of traditional composite is intuitive. Due to their lower viscosity, it is expected that flowable materials will adapt to the cavosurface more readily than traditional composite especially the highly filled "packable" type. Marginal adaptation under packable resin composites has shown to be improved by the use of a flowable, as reported by Fabianelli et al (2003). Chuang et al (2001), while not finding reduced microleakage when using a flowable liner under Class II restoration, did report significant improvements in the reduction of voids in the restored interface.

Finally, the potential clinical benefits of using flowable composites as a liner under a direct restorative has been noted. Unterbrink et al (1999) reviewed the literature pertaining to flowable composites as potential "filled adhesives," concluding that flowable materials "appears to be one of the keys to achieving clinically acceptable results with single-component adhesives." Christensen (2002) sites flowable resins as one of the techniques for reducing sensitivity when using the total etch bonding technique and surmizes that the flowable provides a buffer between tooth and restorative and potentially obturates any areas of inadequate seal between the bonding agent and the etched dentinal surface.

Product Description

Filtek™ Supreme XT Flowable Restorative is a low viscosity, visible light-cured, radiopaque flowable restorative. Bonding to the tooth structure is accomplished through the use of a dental adhesive system, such as a 3M ESPE Adper™ branded adhesive. Filtek Supreme XT flowable restorative can be used alone, after placing a compatible adhesive or in conjunction with a methacrylate-based restorative such as Filtek™ Z100™ Restorative, Filtek™ Z250 Restorative, Filtek™ P60 Restorative or Filtek™ Supreme XT Universal Restorative.

Product Features

- Packaged in 2, 2g syringes.
- Directly dispensed through pre-bent disposable dispensing tips.
- Available in 12 shades that correspond to the shades offered with Filtek Supreme XT Universal Restorative:
  - A1, A2, A3, A3.5, A4
  - B1, B2
  - C2
  - D2
  - OA3
  - W, XW

Filtek Supreme XT flowable restorative is incrementally placed and cured using a 400-500nm visible curing light. The recommended maximum depth per increment and cure time is 2.0 mm for 20 seconds for all shades except OA3 (2mm for 40 sec). These cure times can be reduced by one-half when using the Elipar™ FreeLight 2 LED Curing Light.

Indications for Use

- Class III and V restorations
- Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations)
- Base/liner under direct restorations
- Repair of small defects in esthetic indirect restorations
- Pit and fissure sealant
- Undercut blockout
- Repair of resin and acrylic temporary materials

Composition

Resin

Filtek™ Supreme XT Flowable Restorative is formulated with the methacrylate resin monomers Bis-GMA, TEGDMA and Bis-EMA. Filtek Supreme XT flowable restorative also contains a dimethacrylate polymer that modifies the rheology of the material and provides a "flow on demand" handling characteristic allowing the material to flow under pressure, yet hold its shape after placement until light cured. A photoinitiator component allows for light-curing when exposed to visible light in the 400-500 nanometer range.

Filler

The filler in Filtek Supreme XT flowable restorative is a combination of:

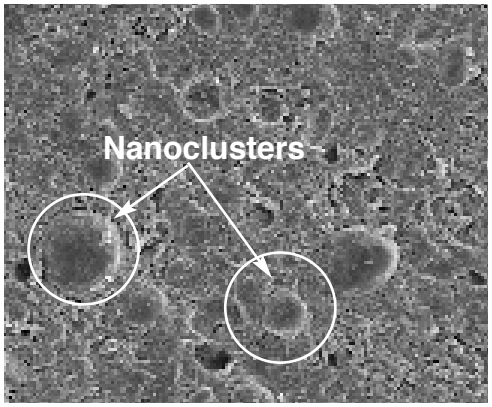
- 75nm diameter non-agglomerated/non-aggregated silica nanofiller
- 5-10nm diameter non-agglomerated/non-aggregated zirconia nanofiller
- loosely bound agglomerated zirconia/silica nanocluster, consisting of agglomerates of 5-20nm primary zirconia/silica particles. The cluster particle size range is 0.6 to 1.4 microns.

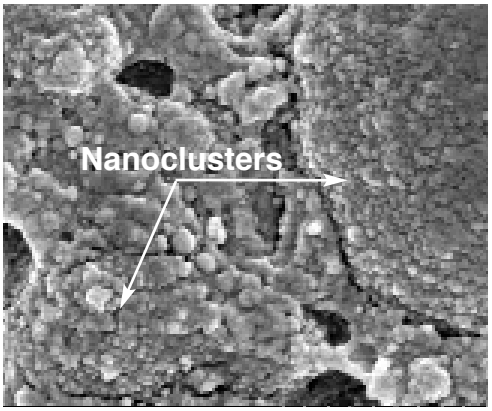
The inorganic filler loading is approximately 65% by weight (55% by volume).

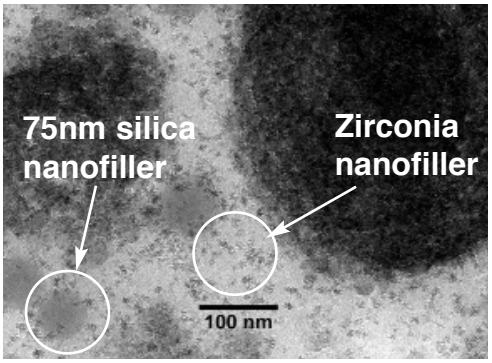
Filtek Supreme XT flowable restorative incorporates fillers based on the patented nanofiller technology of Filtek™ Supreme XT Universal Restorative. For Filtek Supreme XT universal restorative, this technology is critical in achieving the high filler loading necessary to yield a restorative that is highly esthetic and has uncompromized strength. These properties were made possible by formulating the filler with a combination of individual nanoparticles together with clusters of loosly bound nanoparticles. This combination of nanofillers affords optimization of the filler packing architecture to maximize the restoratives mechanical, wear, polish and handling properties.

Filtek Supreme XT flowable restorative uses a similar strategy of combining individual nanoparticles with nanoclusters in an optimum configuration. The nanoclusters used in Filtek Supreme XT flowable restorative (page 8, SEM photomicrographs at 5,000X and 50,000X, courtesy of Dr. J Perdigao – University of Minnesota) are identical to those in the dentin, body and enamel shades of Filtek Supreme XT universal restorative and consist of agglomerates of loosely bound 5-20nm zirconia/silica particles.

Filtek™ Supreme™ XT Flowable Restorative, 5K and 50K magnification. Photos courtesy of Dr. J. Perdigao, University of Minnesota

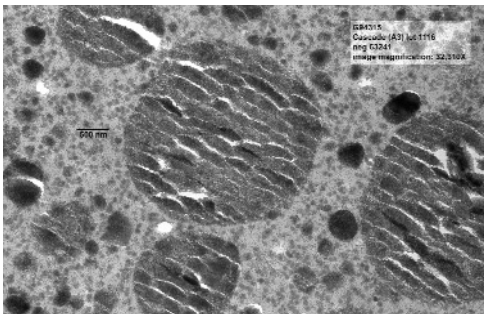


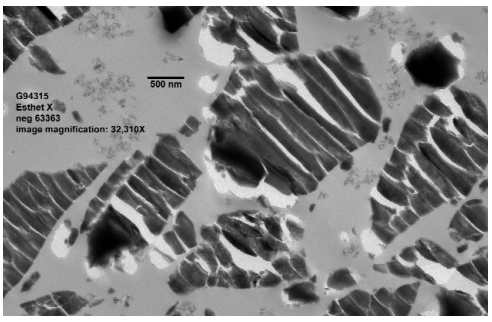




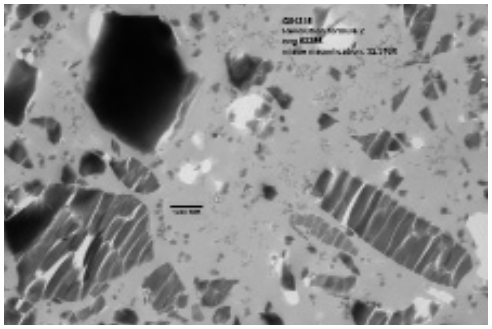
To optimize the filler packing density, Filtek™ Supreme XT flowable restorative contains two additional non-agglomerated/non-aggregated nanofillers (figure at right, TEM photomicrograph at 50,000X). One of these, a 75 nm non-agglomerated/non-aggregated silica nanofiller, is also present in the translucent shades of Filtek Supreme XT universal restorative. The other, a 5-10 nm diameter zirconia particulate, is unique to Filtek Supreme XT flowable restorative and is instrumental in conferring radiopacity comparable to the more highly filled Filtek Supreme XT universal restorative. Together, these two non-agglomerated/non-aggregated nanofillers contribute to more uniform filler density within the resin surrounding the micron and sub-micron nanoclusters than other flowable restoratives. This difference in filler density can be seen in the transmission electron microscopic (TEM) images shown below (in these figures, the scalloped nature of the larger filler particles is due to an artifact of the TEM sample preparation). This optimized "interstitial" filler architecture contributes to the excellent physical, wear and polish properties of Filtek Supreme XT flowable restorative while still allowing for the desirable handling of a flowable restorative.

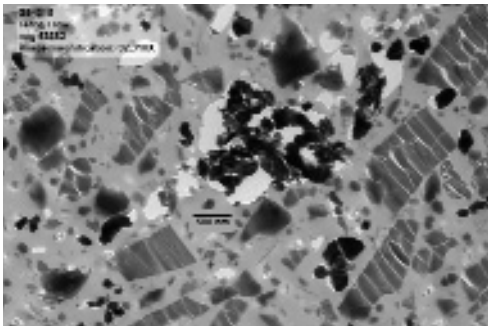
TEM photomicrographs at 32,000X magnification (top row l to r) Filtek Supreme XT Flowable, EsthetX® Flow





(bottom row l to r) Revolution™ Formula 2, Tetric® Flow





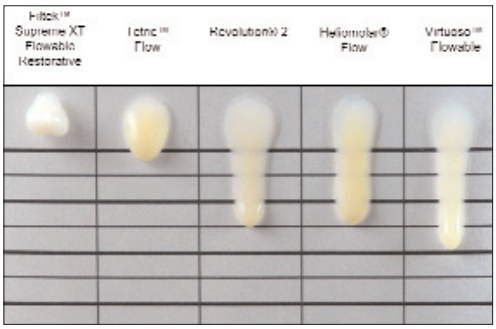
Properties

Filtek™ Supreme XT Flowable Restorative was tested and found to be in compliance with ISO 4049:2000(E), “Dentistry–Polymer-based filling, restorative and luting materials” and ISO/FDIS 6874:2005(E), “Dentistry – Polymer-based Pit and Fissure Sealants.” Additional tests presented below include polish retention, wear resistance, compressive and diametral tensile strengths and flexural modulus. All tests were performed at 3M ESPE Laboratories unless otherwise noted.

Handling Properties

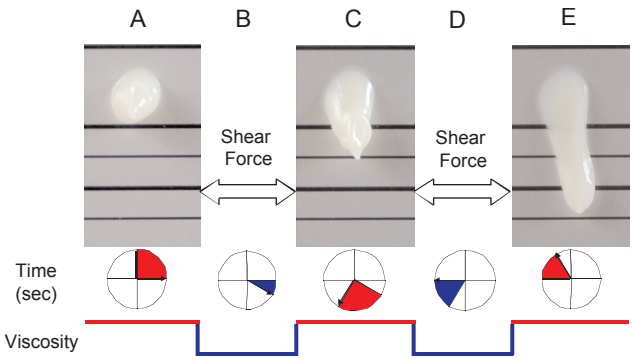
Considering the indications where flowable restoratives are typically used, the ideal flowable would flow readily when manipulated, yet hold its shape once placed. Such properties were realized for flowable restoratives with the introduction of Filtek™ Flow Flowable Restorative in 2000. Building on the chemistry of Filtek Flow flowable restorative, Filtek Supreme XT Flowable Restorative incorporates the same rheological modifier as its predecessor. This additive enables the viscosity of Filtek Supreme XT flowable restorative to change when manipulated offering greater control during placement.

As the photograph at right shows, many flowable composites will run when subjected to gravitational force. This property makes control of the restorative difficult in certain indications such as Class V restorations. As seen in the photograph, Filtek Supreme XT flowable restorative holds its shape under these conditions.

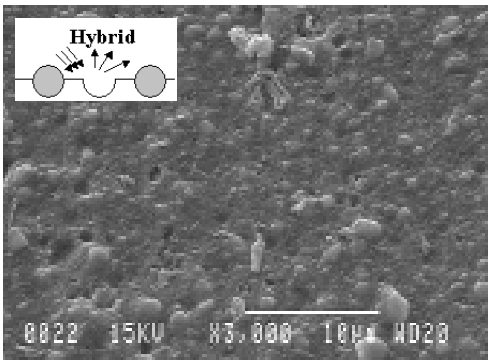


However, when a shear force is applied to Filtek Supreme XT flowable restorative, such as during extrusion through the dispensing tip and manipulation onto the preparation, the viscosity of the restorative decreases. This means Filtek Supreme XT flowable restorative becomes more fluid allowing for easy adaptation to the preparation. Once this shear force is removed, such as when manipulation stops, Filtek Supreme XT flowable restorative returns to its original, non slumping, viscosity.

This property is demonstrated in the photo series below where Filtek Supreme XT flowable restorative was placed on a vertically positioned glass slide and the slide subjected to a shearing force, in this case, by contacting the slide to a laboratory vibrator. In its resting viscosity (A), no flow occurs and Filtek Supreme XT flowable restorative retains its shape. When a shear force is applied (B), the viscocity decreases and flow occurs under the force of gravity. Upon stopping the force (C), Filtek Supreme XT flowable returns to its resting viscosity and flow ceases. Additional flow occurs during a second shear cycle (D) and ceases, once again (E), as the force is stopped.



Polish Retention

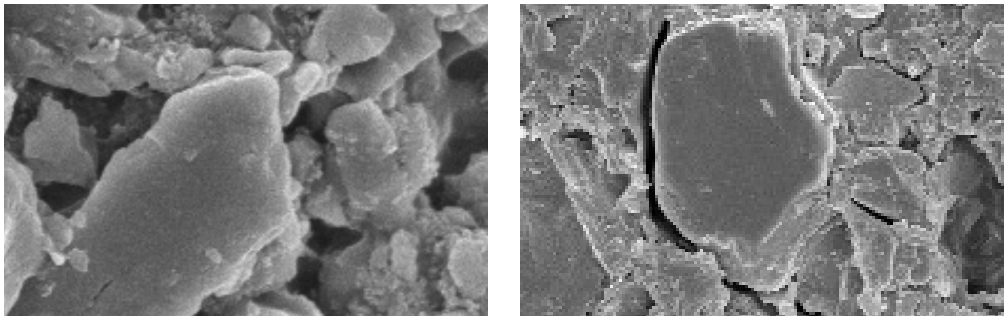


Filler composition has a significant impact on the ability of a resin composite to retain its polish in the oral environment. As resin is lost from the surface of a traditional hybrid and micro-hybrid composite due to abrasive forces, filler particles are exposed and the surface becomes highly irregular. Over time, these particles, some measuring over one micron in diameter, may be lost creating pits or voids at the surface which leads to further irregularity. This roughness causes significant scattering of light (and a reduction in reflectivity) that is observed visually as a loss of polish or gloss.

The filler composition of many flowable restoratives is similar to that used in traditional composite restoratives with mean particle sizes often approaching one micron (Figures below, Dr. J Perdigao – University of Minnesota). It is expected that the surface irregularity and loss of polish with these flowable restoratives will, conservatively, mimic that of the traditional hybrid and micro-hybrid composites when subjected to an abrasive mechanism. Due to their relatively higher resin content, it is more likely, however, that the surface irregularity of these hybrid and micro-hybrid flowable materials will be greater than the more highly filled traditional composites.

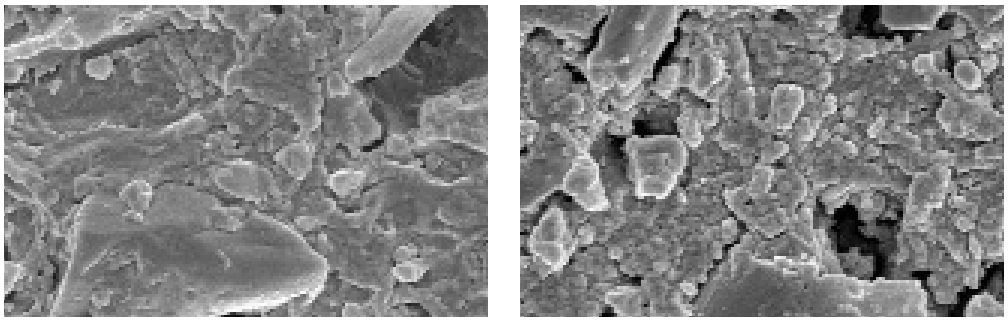
SEM photomicrographs at 30,000X magnificaton

(top row, l to r) Flow-It® ALC™, EsthetX® Flow

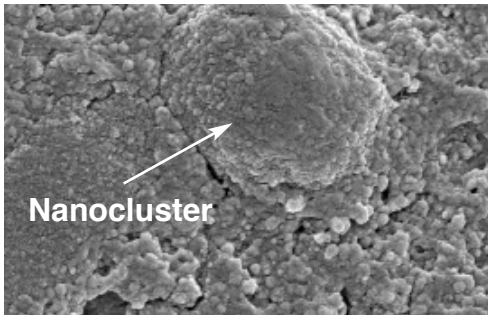


(bottom row, l to r) Tetric® Flow, Revolution® Formula 2

Photos courtesy of Dr. J. Perdigao, University of Minnesota



Filtek Supreme XT Flowable Restorative 30,000X magnification



As previously discussed, the filler composition in Supreme branded restoratives contain primary particles less than 100nm in diameter (Figure at right, Dr. J Perdigao). While the nanocluster particle size can exceed one micron in diameter, during abrasive wear, it is the primary particles that are predominantly lost. With Filtek™ Supreme XT Universal Restorative, the resultant surface irregularity and associated loss of polish has shown to be reduced compared to traditional hybrid and micro-hybrid composites. As shown below, incorporating this nanofiller technology into Filtek™ Supreme XT Flowable Restorative has resulted in a similar benefit.

Tooth Brush Abrasion Test

Cured, rectangular samples of various flowable materials were polished using a Buehler ECOMET 4 Polisher with an AUTOMET 2 Polishing Head. The following sequence of abrasive was used for each sample – 320 grit, 600 grit silicon carbide abrasive, 9 mm diamond polishing paste, 3mm diamond polishing paste and finally a Master Polishing Solution.

A micro-tri-gloss instrument (BYK Gardner, Columbia, MD) was used to collect photoelectric measurements of specularly reflected light from the sample surface after polishing and after tooth brushing. The procedure described in ASTM D 523-89 (Reapproved 1994) Standard Test Method for Specular Gloss, for measurements made at 60A1 geometry was followed. Initial gloss after polishing was measured for initial sample. Gloss readings were recorded after 500 tooth-brushing cycles. Each sample was brushed with an ORAL B™ 40 medium Straight toothbrush (Oral B Laboratories, Belmont, CA.) using CREST™ Regular Flavor (Proctor & Gamble, Cincinnati, OH) toothpaste. The toothbrush and sample were mounted on a device that controlled the stroke length and force on the toothbrush head.

The gloss measured after each 500 stroke cycle is shown above. After 2000 cycles, the measured gloss was statistically higher for Filtek Supreme XT flowable restorative in comparison to the other flowable restoratives shown. Examining the samples using scanning electron microscopy provides a visual comparison of surface irregularity among the materials.

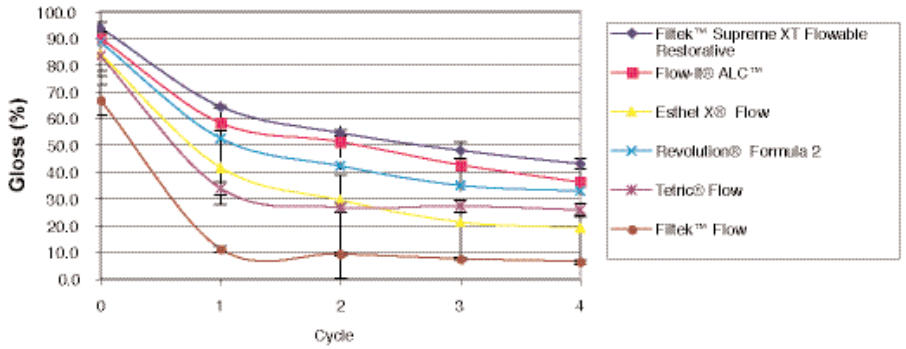
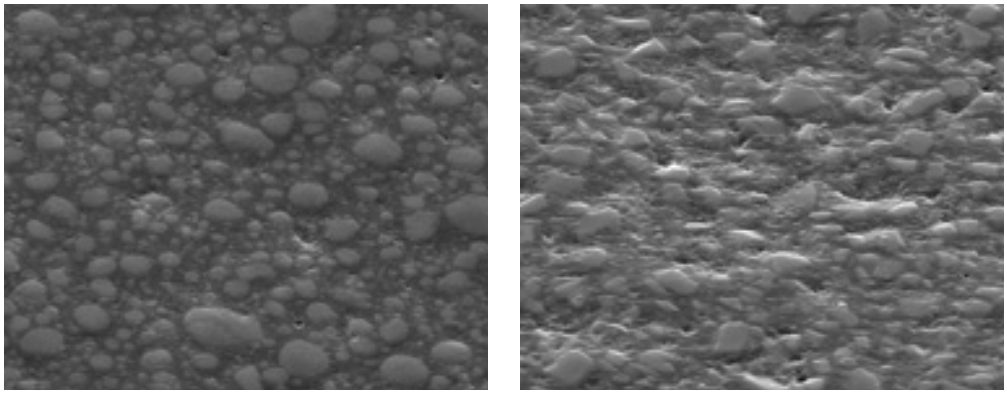


Figure 1.
Tooth Brush Abrasion



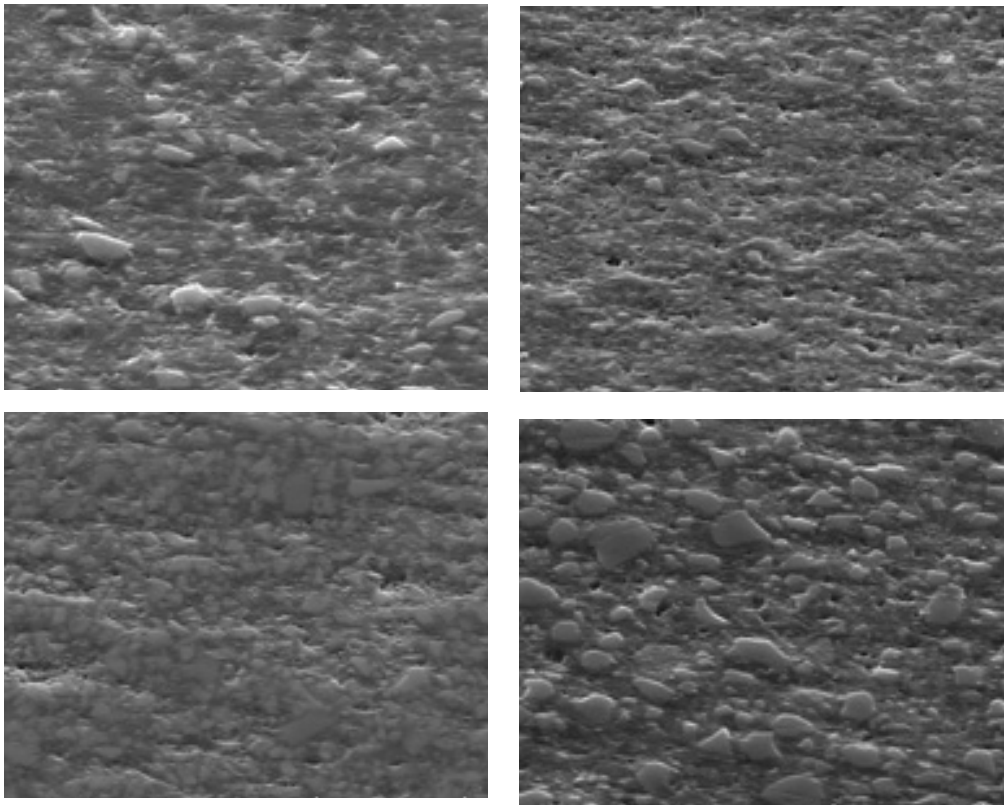
Scanning electron photomicrographs of representative samples from tooth brush abrasion test. 5000X Magnification.

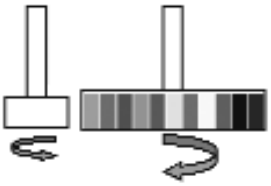
(l to r) Filtek™ Supreme XT Flowable Restorative, EsthetX® Flow

Scanning electron photomicrographs of representative samples from tooth brush abrasion test. 5000X Magnification.

(top row, l to r) Revolution® Formula 2, Tetric® Flow

(bottom row, l to r) Flow-It® ALC™, Filtek™ Flow





Wear

A 3-body wear model is a clinically relevant test for predicting the relative wear between materials intended for non-stress bearing restorations. In this test (ACTA), the sample (1st body) is loaded onto a wheel (see shaded slots in diagram at left) which contacts another wheel acting as an "antagonistic cusp" (2nd body). The two wheels counter-rotate against one another dragging an abrasive slurry (3rd body) between them. Following each cycle set, vertical loss of the test materials was measured using a contact stylus. Wear measurements were made at 39,000 cycle increments for a total of 234,000 cycles. The wear rate for Filtek™ Supreme XT Flowable Restorative was compared to competitive flowable materials, two traditional hybrid composites and the nanocomposite, Filtek™ Supreme XT Universal Restorative. The results are illustrated in Figure 2.

It was determined that the wear for Filtek Supreme XT flowable restorative was statistically less (indicating better wear resistance) than all of the other flowable composites and equivalent to the traditional composite materials TPH[3] and Tetric® Evo Ceram.

The lower filler to resin ratio of flowable composites is the primary contributor to decreased wear resistance in comparison to traditional resin composites. For materials with similar filler loading, other factors, such as filler composition, are expected to contribute to the wear properties. For Filtek Supreme XT flowable restorative, the contribution of the various nanofillers are thought to be instrumental in reducing the wear rate to levels equivalent to the two traditional composites noted above despite having significantly less filler than these materials.

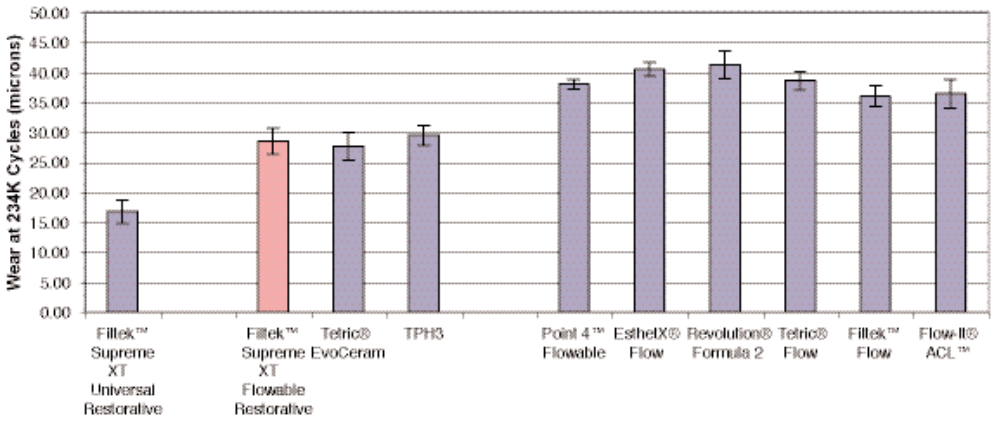
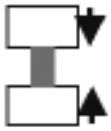


Figure 2.
Wear rate

Mechanical Properties

Compressive and Diametral Tensile Strengths

The ultimate compressive strength involves measuring the compressive force at which the sample fails destructively. Cylindrical samples were made of the test materials and a compressive force applied as indicated in the figure at right. Sample failure is a result of a complex pattern of shear and tensile forces within the sample. The compressive strength of various materials are reported in the chart below.



Filtek™ Supreme XT Flowable Restorative has statistically higher compressive strength in comparison to Dyract Flow® and Esthet X® Flow.

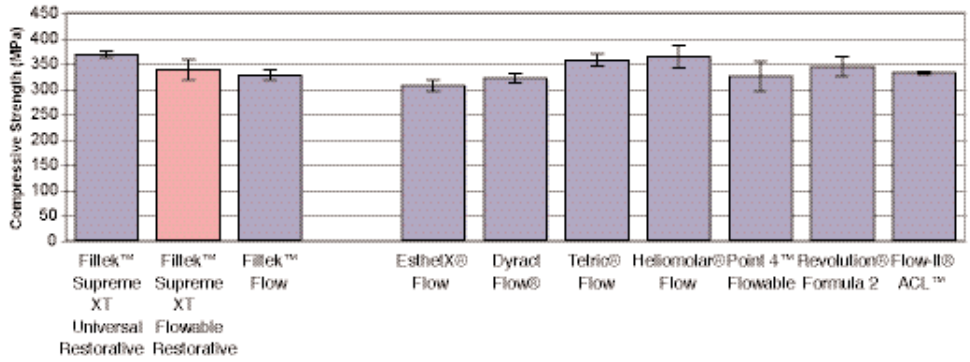


Figure 3.
Compressive Stength

Tensile strength of flowable restoratives were examined using the diametral tensile test. In this test, a compressive force is applied to the sample shaped in the form of a disc. This introduces a tensile stress in the plane parallel to the applied stress as shown in diagram at right. The diametrile tensile strength is determined from the force at which sample failure occurs and the sample geometry. The diametral tensile strengths of various materials are reported in Figure 4.

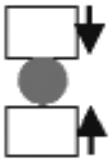
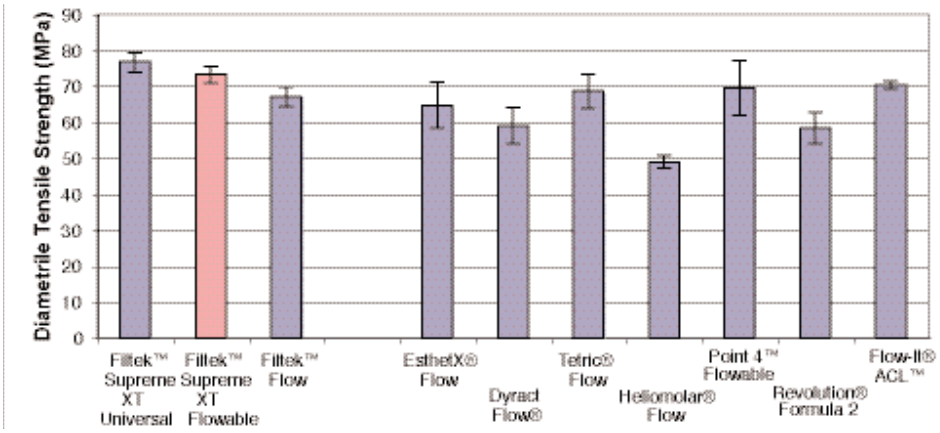
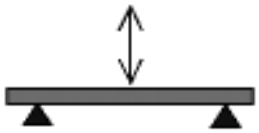


Figure 4.
Diametral Tensile Strength



The diametral strength of Filtek™ Supreme XT Flowable Restorative is statistically greater than that measured for Dyract Flow®, Heliomolar® Flow and Revolution® Formula 2.

Flexural Strength and Flexural Modulus



Flexural strength was determined per ISO 4049:2000(E) Dentistry – Polymer-based filling, restorative and luting materials. A rectangular beam, supported at each end is subjected to a perpendicular force as shown in the diagram at left. The flexural strength is related to the force at which the beam fails and the sample geometry. The flexural modulus is an indication of the stiffness of the beam and is determined by measuring the deformation of the beam as the force is initially applied. The flexural strength and modulii for various flowable materials are shown in Figure 5.

Figure 5.
Flexural Strength

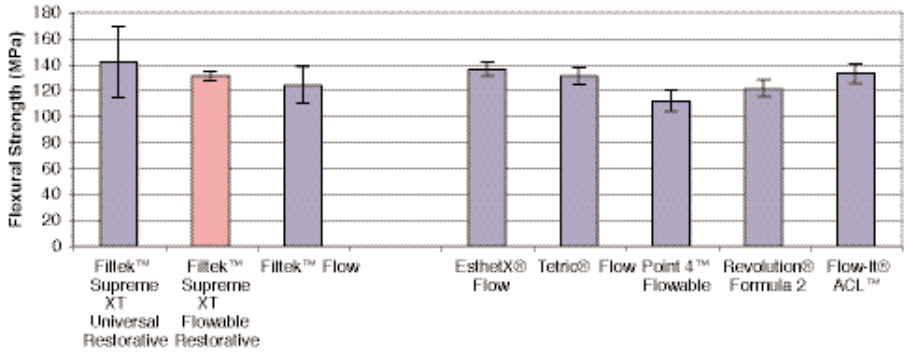
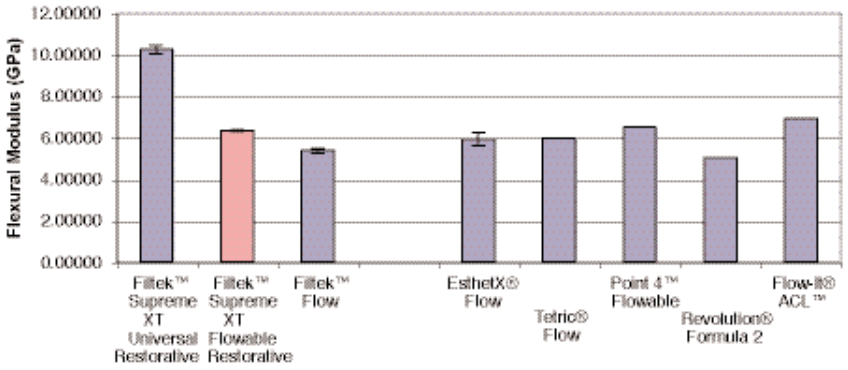


Figure 6.
Flexural Modulus



The flexural strength of Filtek Supreme XT flowable restorative approaches that measured for Filtek™ Supreme XT Universal Restorative. The modulii for the flowable materials are similar and lower than that measured for Filtek Supreme XT universal restorative.

Radiopacity

The zirconia nanofiller and zirconia/silica nanocluster imparts radiopacity to Filtek™ Supreme XT Flowable Restorative. The radiopacity was determined per ISO 4049-2000(E). In this method, the optical density of a radiograph of the cured material is compared to that of an aluminum block of the same thickness. The radiopacity is reported as the ratio of the optical density of the aluminum sample to that of the test sample. Ratio values greater than 1.0 are considered to be radiopaque. Ratio values less than 1.0 are not considered radiopaque by this test standard. The radiopacity value for the Filtek Supreme XT flowable restorative is 1.89 and is therefore radiopaque. Comparison among materials reveals that Filtek Supreme XT flowable restorative is equivalent to that for Filtek™ Supreme Universal Restorative and significantly greater than that for EsthetX® Flow, Revolution® Formula 2, Point 4™ Flowable and Filtek™ Flow Flowable Restorative.

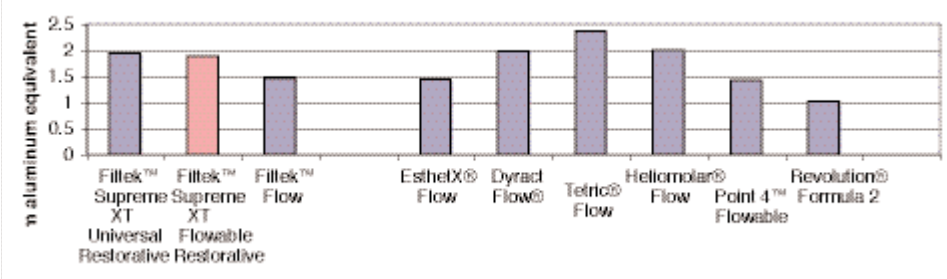


Figure 7. Radiopacity

Polymerization Shrinkage

The method for determining the volumetric shrinkage was described by Watts and Cash (Meas. Sci. Technol. 2(1991) 788-794). In this method, a disc shaped test specimen is sandwiched between two glass plates and light cured through the lower rigid plate (see diagram at right). The flexible upper plate is deflected during polymerization of the test specimen. The less the flexible plate bends, the lower the shrinkage. The vertical deflection measured, under the constraints of the sample geometry, is related to the volumetric shrinkage. The chart below shows that the polymerization shrinkage for Filtek Supreme XT flowable restorative is statistically lower than that for EsthetX Flow, Dyract Flow and Revolution Formula 2.

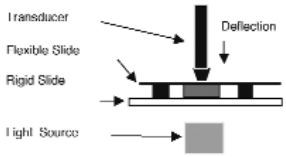
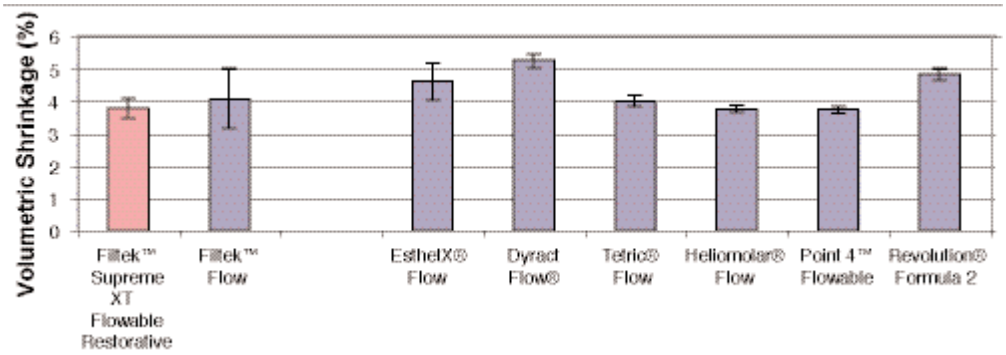


Figure 8. Volumetric Shrinkage



Independent verification of the extent of polymerization shrinkage was provided by Louisiana State University (LSU) in New Orleans. Shrinkage value reported was obtained ten minutes post light curing using the Acuvol method. The results are in good agreement with the those reported above.

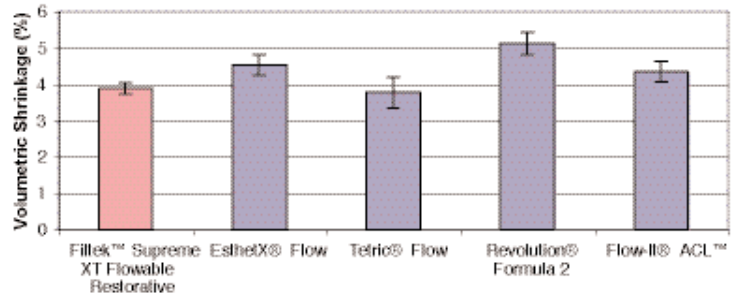


Figure 9. Volumetric Shrinkage

Instructions for Use

Filtek™ Supreme XT Flowable Restorative

General

Filtek Supreme XT Flowable Restorative, manufactured by 3M ESPE, is a low viscosity, visible-light activated, radiopaque, flowable nanocomposite based on 3M™ ESPE™ Filtek™ Supreme XT Universal Restorative. The restorative is packaged in syringes and available in a variety of tooth-colored shades. The shades offered with Filtek Supreme XT flowable restorative were designed to coordinate with shades offered with Filtek Supreme XT Universal Restorative. Filtek Supreme XT flowable restorative contains bisGMA, TEGDMA and bis-EMA resins. The filler in Filtek Supreme XT flowable restorative is a combination of non-agglomerated/non-aggregated, 75nm silica nanofiller; non-agglomerated/non-aggregated, 15-20nm zirconia nanofiller and loosely bound agglomerated zirconia/silica nanocluster, consisting of agglomerates of 5-20nm primary zirconia/silica particles. The cluster particle size range is 0.6 to 1.4 microns. The inorganic filler loading is approximately 65% by weight (55% by volume).

Indications

- Restoration of minimally invasive cavity preparations (including Class III and V restorations and occlusal pits and fissures)
- Base/liner under direct restorations
- Repair of small defects in esthetic indirect restorations
- Pit and fissure sealant
- Undercut blockout
- Repair of resin and acrylic temporary materials

Precautions for Patients and Dental Personnel

Precautionary Information for Patients:

Avoid use of this product in patients with known acrylate allergies. This product contains substances that may cause an allergic reaction by skin contact in certain individuals. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product.

Precautionary Information for Dental Personnel:

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed. Protective eyewear for patients and staff is recommended when using dispensing tip.

Instructions for Use

I) Preliminary

A. Prophy: Teeth should be cleaned with pumice and water to remove surface stains.

B. Shade Selection: Prior to isolation of tooth, select the appropriate shade(s) of Filtek Supreme XT flowable restorative using a standard VitaPan® Classic shade guide. Shade selection accuracy may be enhanced via a mock-up: place the chosen shade of the restorative material on the unetched tooth. Manipulate the material to approximate the thickness and site of the restoration. Cure. Evaluate the shade match under different lighting sources. Remove the restorative material from the unetched tooth with an explorer. Repeat process until an acceptable shade match is achieved.

For sealants, a contrasting shade may be desirable to enhance detection.

C. Isolation: A rubber dam is the preferred method of isolation. Cotton rolls and an evacuator can also be used.

II) Directions

A. Isolate and dry the preparation.

B. Pulp protection: If a pulp exposure has occurred and the situation warrants a direct pulp capping procedure, use a minimum amount of calcium hydroxide on the exposure followed by an application of Vitrebond™ Light Cure Glass Ionomer, manufactured by 3M ESPE. Vitrebond may also be used to line areas of deep cavity excavation.

C. Adhesive System: Follow manufacturer's instructions regarding placement.

Note: Silane treatment is recommended for repair of ceramic restorations followed by the adhesive application.

D. Dispensing: Filtek Supreme XT flowable restorative can be delivered directly from the dispensing tip.

1. Protective eyewear for patients and staff is recommended when using the dispensing tip.
2. Prepare the dispensing tip: Remove cap and SAVE. Twist the prebent disposable dispensing tip securely onto the syringe. Holding the tip away from the patient and any dental staff, express a small amount of Filtek Supreme XT flowable restorative to assure that the delivery system is not plugged.
3. If plugged, remove the dispensing tip and express a small amount of Filtek Supreme XT flowable restorative directly from the syringe. Remove any visible plug, if present, from the syringe opening. Replace dispensing tip and again express composite. Filtek Supreme XT flowable restorative may be extruded onto a dispensing pad and applied with a brush or other appropriate instrument.

E. Placement:

1. Place and light cure restorative in increments as indicated in Section F.
2. Avoid intense light in the working field.
3. To prevent oozing of paste from the syringe tip after placement, pull back on syringe plunger.

F. Curing: Filtek™ Supreme XT Flowable Restorative will cure only by exposure to light. Cure each increment by exposing its entire surface to a high intensity visible light source, such as a

3M ESPE curing light. Hold the light guide tip as close to the restorative as possible during light exposure.

Shade Increment	depth	Cure time
Opaque A3	2.0mm	40 sec
All other shades -	2.0mm	20 sec

G. Complete the restoration:

1. Base/Liner application: place a composite restorative material, such as Filtek™ Supreme XT Universal Restorative, manufactured by 3M ESPE, directly over the cured Filtek Supreme XT flowable restorative. Follow the manufacturer's instructions regarding placement, curing, finishing, occlusal adjustment, and polishing.
2. Direct Restorative Application:

   a) Contour restoration surfaces with fine finishing diamonds, burs or stones.

   b) Check occlusion with a thin articulating paper. Examine centric and lateral excursion contacts. Carefully adjust occlusion by removing material with a fine polishing diamond or stone.

   c) Polish with Sof-Lex™ Finishing and Polishing System, manufactured by 3M ESPE, or with white stones, rubber points or polishing paste where discs are not suitable.
3. Pit and Fissure Sealants: gently remove the inhibited layer remaining after light-curing with a slurry of pumice or polishing paste.

III) Storage and Use:

A. Filtek Supreme XT flowable restorative is designed for use at room temperature of approximately 21-24°C or 70-75°F. Shelf life at room temperature is 2 years. See outer package for expiry date.

B. Do not expose restorative materials to elevated temperatures or intense light.

C. Storage in refrigerator ensures longest possible shelf life. Allow to reach room temperature prior to use.

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

E. Disinfection: Discard used syringe tip and replace with syringe storage cap. Disinfect the capped syringe using an intermediate level disinfection process (liquid contact) as recommended by the CDC and endorsed by the ADA. Guidelines for Infection Control in Dental Health-Care Settings – 2003 (Vol.52; No. RR-17), Centers for Disease Control and Prevention.

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

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

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

References

Attar N, Tam LE, McComb D. Flow, strength, stiffness and radiopacity of flowable resin composites. J Can Dent Assoc. 2003;69(8):516-21.

Bayne SC, Thompson JY, Swift EJ Jr, Stamatiades P, Wilkerson M. A characterization of first generation flowable composites. J Am Dent Assoc. 1998;129(5):567-77.

Behle C. Pract Periodontics. Flowable composites: properties and applications. Aesthet Dent. 1998;10(3):347, 350-1. Bonilla ED, Yashar M, Caputo AA. Fracture toughness of nine flowable resin composites. J Prosthet Dent. 2003 Mar;89(3):261-7.

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.

Chuang SF, Liu JK, Chao CC, Liao FP, Chen YH. Effects of flowable composite lining and operator experience on microleakage and internal voids in class II composite restorations. J Prosthet Dent. 2001 Feb;85(2):177-83.

Christensen GJ. Preventing postoperative tooth sensitivity in Class I, II and V restorations. J Am Dent Assoc. 2002 Feb;133(2):229-31.

Fabianelli A, Goracci C, Ferrari M.J Sealing ability of packable resin composites in class II restorations. Adhes Dent. 2003;5(3):217-23.

Ferdianakas K. Microleakage reduction from newer esthetic restorative materials in permanent molars. J Clin Pediatr Dent 1998, 23:221-9.

Fruits TJ, VanBrunt CL, Khajotia SS, Duncanson Jr. MG. Effect of cyclical lateral forces on microleakage in cervical resin composite restorations. Quintessence Int 2002;33:205-12.

Jain P, Belcher M. Microleakage of class II resin-based composite restorations with flowable composite in the proximal box. Am J Dent. 2000;13:235-8.

Peters MC, McLean ME. Minimally invasive operative care, II. Contemporary techniques and materials: An overview. J Adhes Dent. 2001 3(1), 17-31.

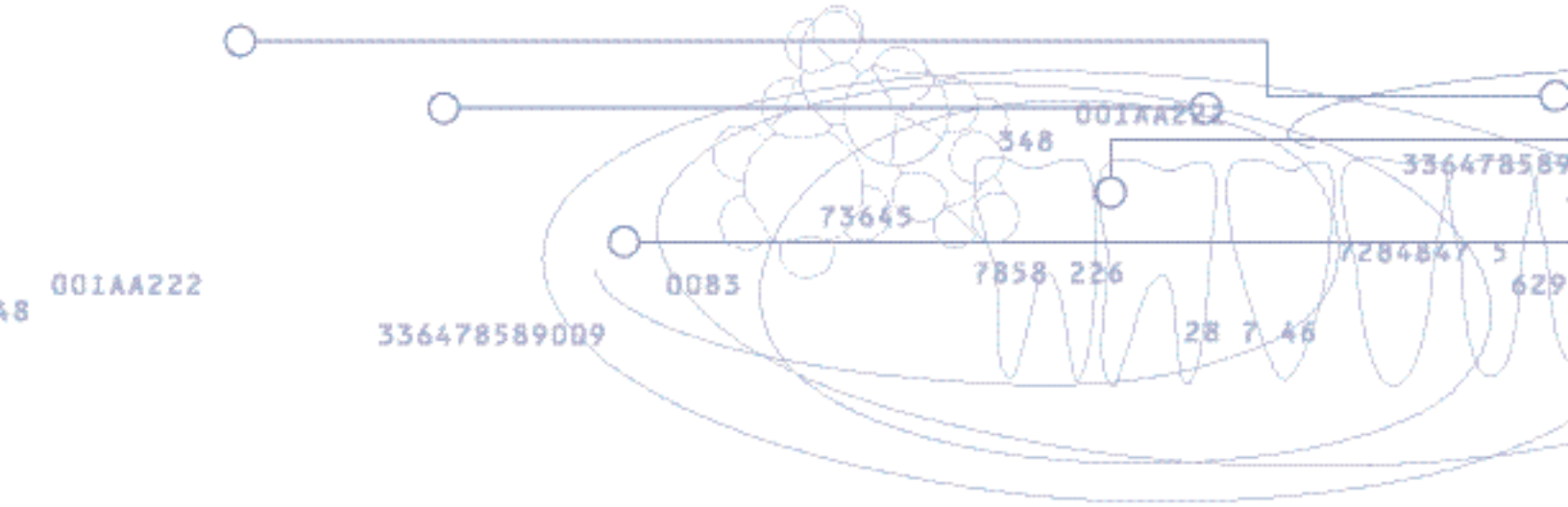
Rada RE. The versatility of flowable composites. Dent Today. 1998;17(4):78-83.

Tung FF, Hsieh WW, Estafan D. In vitro microleakage study of a condensable and flowable composite resin. Gen Dent. 2000;48(6):711-5.

Unterbrink GL, Liebenberg WH. Flowable resin composites as “filled adhesives”: literature review and clinical recommendations.Quintessence Int. 1999;30(4):249-57.

Wibowo G, Stockton L, Microleakage of class II composite restorations. Am J Dent 2001;14:177-85.

Yazici AR, Baseren M, Dayangac B. The effect of flowable resin composite on microleakage in class V cavities. Oper Dent. 2003 Jan-Feb;28(1):42-6.



3M ESPE

Dental Products

3M Center
Building 275-2SE-03
St. Paul, MN 55144-1000
USA

3M Canada

Post Office Box 5757
London, Ontario N6A 4T1
Canada
1-800-265-1840 ext. 6229

10% post-consumer waste paper

Printed in USA

70-2009-3752-5