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Introduction

Product Description

3M ESPE Filtek™ Z350 Universal Restorative is a visible-light activated direct restorative nanocomposite designed for anterior and posterior restorations. Filtek Z350 universal restorative contains the same patented and proprietary nanotechnology used to create Filtek™ Supreme Universal Restorative.

Filtek Z350 universal restorative is available in eight of the most popular shades corresponding to the optimized shades of Filtek™ Supreme XT Universal Restorative. Consequently, Filtek Z350 universal restorative may be used with Filtek Supreme XT universal restorative to expand its versatility in the creation of multi-shade/multi-opacity restorations.

Filtek Z350 universal restorative material properties such as handling, strength, polish retention and polymerization shrinkage are unchanged from the original Filtek Supreme universal restorative. Therefore, much of the data related to these properties as described in the Filtek Supreme universal restorative product profile has been retained as originally presented.

Composition

- The resin system is the same reduced shrinkage resin as found in 3M ESPE’s Filtek™ Z250 Universal Restorative and Filtek™ P60 Posterior Restoratives: BIS-GMA, BIS-EMA (6), UDMA with small amounts of TEGDMA.
- The filler contains a combination of a non-agglomerated/non-aggregated, 20 nm nanosilica filler, and loosely bound agglomerated zirconia/silica nanocluster, consisting of agglomerates of primary zirconia/silica particles with size of 5-20 nm fillers. The cluster particle size range is 0.6 to 1.4 microns. The filler loading is 78.5% by weight. All shades are radiopaque.

Shades

- A1, A2, A3, A3.5, B2, B3, C2, OA3 (Opaque A3)
- Shade selection is accomplished referencing the VITAPAN® classical shade guide, or the accompanying Filtek Z350 universal restorative shade guide.
Indications for Use

3M ESPE Filtek™ Z350 Universal Restorative is indicated for use in the following types of restorations.

- Direct anterior and posterior restorations
- Sandwich technique with glass ionomer resin material
- Cusp buildup
- Core buildup
- Splinting
- Indirect anterior and posterior restorations including inlays, onlays and veneers

Background

Nanotechnology

“Nanotechnology is offering us the ability to design materials with totally new characteristics.”
(Ottilia Saxl, CEO of the The Institute of Nanotechnology) Worldwide government sponsored R&D has been steadily increasing. Expenditures in western Europe, Japan, US and other countries grew almost 3.5 times between 1997 and 2002, the year Filtek™ Supreme Universal Restorative was introduced. In 2005, expenditures in these same countries have increased five times over that spent in '97 with the US leading the way with over a billion dollars budgeted for nanotechnology research by the National Science Foundation for 2005.

A nanomer is 1/1,000,000,000 (one-billionth) of a meter or 1/1000 of a micron. This is about 10 times the diameter of a hydrogen atom or 1/80,000 of a human hair. Frequently, nanotechnology is used to describe research or products where critical component dimensions are in the range of 0.1 to 100 nanomers. In theory, nanotechnology can be used to make products lighter, stronger, cheaper, and more precise. If this type of material was used to make an airplane instead of metal, the airplane could weigh 50 times less but be just as strong.

One of the major initiatives of this technology is in creating value-added products. From scratch-resistant lacquers and UV protective coatings for the automobile industry to stain free clothing, nanotechnology is enhancing the products we use everyday. For 3M ESPE, the goal was to use nanotechnology to create a composite that offers the polish retention of a microfill with the strength of a hybrid composite. The result was the introduction of Filtek Supreme Universal Restorative.

Filler Development

These TEMs show the difference in filler particle size between traditional hybrid composites and the nanofillers used in Filtek Z350 universal restorative. The relatively large filler particle in hybrids allow for high filler loading which increases the strength of the composite. 3M ESPE has developed fillers from a liquid form (sol-gel chemistry) since the zirconia/silica filler was used in 3M ESPE P50 Restorative. The Filtek Z350 universal restorative nanocomposite contains a unique combination of individual nanoparticles and nanoclusters. Nanoparticles are discrete nonagglomerated and nonaggregated particles of 20 nm in size. Nanocluster fillers are loosely bound agglomerates of nano-sized particles. The agglomerates act as a single unit enabling high filler loading and high strength.
Traditional microfills are made from fumed silica with an average particle size of 40 nm. Typically, the primary particles tend to aggregate (the degree of aggregation varies depending on the filler used in the microfill product). Further breakdown of any aggregated particles into smaller entities is difficult if not impossible to achieve. Fumed silica is prepared by a pyrogenic process. The structure of the microfill fillers results in relative low filler loading. Most manufacturers add prepolymerized filled resin particles to increase filler loading. This prepolymerized filler is made by adding the fumed silica filler to resin. The mixture is polymerized, then ground to form small particles. These particles are then added to more resin and silica filler. Even using this process, microfills have a substantially lower filler loading than hybrids resulting in lower strength. Additionally, residual methacrylate groups bind the prepolymerized particles to the resin matrix. The effectiveness of this bond is impacted by the amount of residual double bonds on the surface of these particles. During the polymerization of the prepolymerized filler the reaction is driven to near completion. Hence the bond of the prepolymerized filler particles to the resin is weaker than desired and breakdown frequently occurs at this interface. Microfills containing only silica filler are not radiopaque. These properties have limited the usefulness of microfills, particularly in the posterior area.

Hybrids and microhybrids contain a broad range of particle sizes. A wide range of particle sizes can lead to high filler loading with resultant high strength. While they may contain a small fraction of filler particles in the nanomer particle size range, they also contain a range of substantially larger filler particles which influences the optical properties of these composites and detracts from polish retention. The average particle size of hybrids and microhybrids is typically below 1 micron but above 0.4 microns. The upper particle size range can extend to well over 1 micron as the SEMs reveal below.
These SEMs and graphics reveal the mechanism of abrasion and loss of gloss (polish) for composite products. When hybrids are subjected to abrasion, the resin between and around the particles is lost leading to protruding filler particles (bumps). Eventually the filler particles are plucked from the surface resulting in craters. These bumps and craters create a roughened surface resulting in loss of reflectivity (loss of polish retention) of the composite surface.

Microfills have proven to retain their polish (surface reflectivity) over time. As the surface of a microfill becomes abraded, the primary filler particles (40 nm silica particles) are lost at a similar rate as the surrounding resin. However, since prepolymerized filler particles are only marginally stronger than the matrix resin, the overall composite is not very resistant to fracture.

The graphic (below left) is a composite made using nanoclusters alone. Since the nanocluster filler particles consist of loosely bound agglomerates of nano-sized filler particles, during abrasion, the primary particles, (nanomer-sized) not the clusters themselves, can be worn away. This increases the polish retention of the cured composite when compared to traditional hybrid composites. 3M ESPE Filtek™ Z350 Universal Restorative is formulated using both nanoparticle and nanocluster fillers (below right, courtesy of Dr. J. Perdigao, University of Minnesota). The combination of nanomer sized particles to the nanocluster formulations reduces the interstitial spacing of the filler particles. This provides for increased filler loading, better physical properties and improved polish retention when compared to composites containing only nanoclusters.
Resin System

Examination of the 3M ESPE Z100™ Restorative composition established the belief that modifying the resin system could result in enhanced properties. The Z100 resin system consists of BIS-GMA (Bisphenol A diglycidyl ether dimethacrylate) and TEGDMA (tri[ethylene glycol] dimethacrylate). Many other commercially available composites contain these two components in varying concentrations.

The high concentration of a low molecular weight component, TEGDMA resulted in a system that offered the following advantages:

- The resultant high number of double bonds per unit of weight on a flexible backbone afforded the opportunity to have a high conversion of double bonds during polymerization.
- The low viscosity of the resin permits higher filler loading than with BIS-GMA alone.
- The high degree of crosslinking and compact molecule creates a very hard resin matrix.

However, the TEGDMA concentration also allows for some opportunities for improvements.

- The relatively low molecular weight of TEGDMA contributes to the aging of an uncured composite especially in capsules where there is a high ratio of surface area to volume of paste. This material is labile enough to migrate into the capsule walls leading to a thickening of the composite.
- The low molecular weight and resultant high number of double bonds per unit of weight creates a high degree of crosslinking creating a very rigid, stiff composite with a relatively high amount of shrinkage.

A resin system introduced with 3M ESPE Filtek™ Z250 Universal Restorative is now being used in Filtek™ Z350 universal restorative. The resin consists of three major components. The majority of TEGDMA (in the Z100 restorative system) was replaced with a blend of UDMA (urethane dimethacrylate) and Bis-EMA(6) (Bisphenol A polyethylene glycol diether dimethacrylate). TEGDMA is used in minor amounts to adjust the viscosity. UDMA and Bis-EMA(6) resins are of higher molecular weight and therefore have fewer double bonds per unit of weight. The high molecular weight materials also impact the measurable viscosity. However, the higher molecular weight of the resin results in less shrinkage, reduced aging and a slightly softer resin matrix.

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1 Bis-EMA(6) contains, on average, 6 ethylene oxide groups per Bisphenol A grouping.
Physical Properties

The objective of 3M ESPE in designing composites has always been to deliver both high strength and the best possible esthetic result. Resin and filler technology, however, has limited our ability to deliver both of these requirements in a single product.

Microfills have been known for excellent polish and, perhaps more important, polish retention. While excellent for certain indications, most manufacturers limit the indications for use because the strength characteristics of microfills are not up to the excellent levels achieved by today’s hybrid composites.

Hybrids, on the other hand, have proven track records in all areas of direct restorative dentistry. While the new hybrids display excellent clinical performance, including very low wear, the good initial polish can dull with time in a clinical setting.

3M ESPE chose to take a radically different approach in the design of Filtek™ Z350 Universal Restorative, using novel (and patented!) techniques in nanotechnology to create a composite that displays the polish and polish retention of a microfill while maintaining the strength and wear properties of a modern hybrid.

Polish Retention

Standard Test Method for Specular Gloss (ASTM D 523-89)

A rectangular sample was cured with a Visilux™ 2 unit for 80 seconds followed by additional curing for 90 seconds in a Dentacolor™ XS light box (Kulzer, Inc., Germany). Samples were mounted with double sized adhesive tape (Scotch™ Brand Tape, Core series 2-1300, St. Paul, MN) to a holder. The mounted examples 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, 9mm 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 toothbrushing 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 polish retention of 3M ESPE Filtek™ Z350 Universal Restorative is similar to traditional microfill type products.

The polish retention of Filtek™ Z350 Universal Restorative is improved versus hybrid and micro-hybrid type products (Figures 1, 2).
Surface SEMs After Toothbrush Abrasion

The SEMs below were taken of the sample surfaces after toothbrush abrasion. These SEMs support the gloss retention data reported above.

Filtek™ Z350 Universal Restorative

It is apparent that individual nanoparticles have sheared off of the zirconia/silica nanoclusters. The colored cluster surfaces are still flat. Filler particle “plucking” is not noticeable as there are no craters evident.

Hybrids and Microhybrids (EsthetX™, TPH™ Spectrum, Vitalescence®, Renamel™ Hybrid, Point 4™, Herculite XRV™, Tetric® Ceram)

The surfaces of these composites are markedly different than Filtek Z350 Universal Restorative or microfills. Surfaces are rough. Filler particles are protruding above the resin matrix. Craters are evident as a result of the loss of individual filler particles (plucking). The resin matrix is clearly lost at a different rate than the fillers.
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 plate is deflected during the polymerization of the test specimen. The less the flexible plate bends, the lower 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. The lower the value, the less the shrinkage.

In this test, samples were exposed for 60 seconds to a 3M ESPE Visilux™ 2 Visible Light Curing Unit. The final shrinkage was recorded 4 minutes after the end of light exposure.

The polymerization shrinkage of 3M ESPE Filtek™ Z350 Universal Restorative is statistically lower (less shrinkage) than EsthetX™, Renamel™ Hybrid, Renamel Microfill, Point 4™, Tetric® Ceram, TPH™ Spectrum, Vitalescence®, and Herculite XRV™ (Figure 3).

Figure 3. Shrinkage
Wear

3-Body (generalized) Wear

The wear rate was determined by 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 an abrasive slurry (3rd body) between them. Dimensional loss during 156,000 cycles is determined by profilometry at regular intervals (i.e., after every 39,000 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. The comparison of 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 in-vitro 3-body wear of 3M ESPE Filtek™ Z350 Universal Restorative is statistically lower (more wear resistant) than 3M ESPE Filtek™ A110 Anterior Restorative, Durafill™ VS, Renamel™ Hybrid, Heliomolar®, Renamel™ Microfill, EsthetX™, TPH™ Spectrum, Tetric® Ceram and Herculite XRV™ (Figure 4).

2-body (localized) Wear

2-body wear estimates were measured at the MDRCBB (University of MN). In this test a stylus (Enamel Cusp) was placed on the restorative material and dragged across the surface. Generally speaking, any volume wear loss less than 0.1mm³ is acceptable. A wear volume at 0.05mm³ would be rated good. A wear of 0.05mm³ for the composite and 0.05mm³ enamel cusp would be considered well balanced. The conclusion drawn by the MDRCBB is that the wear performance appears satisfactory both numerically and microscopically.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Filtek™ Supreme</th>
<th>Enamel Cusp</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Volume loss</td>
<td>Mean depth</td>
</tr>
<tr>
<td></td>
<td>(mm³)</td>
<td>(m)</td>
</tr>
<tr>
<td>Filtek Z350 Universal Restorative</td>
<td>0.068 + .014</td>
<td>32-44</td>
</tr>
</tbody>
</table>

Figure 4

3-body wear
Fracture Toughness

The values reported for fracture toughness \( (K_{1c}) \) are related to the energy required to propagate a crack. In this test a short rod of material is cured. A chevron or notch is cut into the cylinder and the parts on either side of the chevron are pulled apart.

Below are the values for wet fracture toughness. The fracture toughness of 3M ESPE Filtek™ Z350 Universal Restorative is comparable to Filtek™ Z250, EsthetX™, TPH™ Spectrum and Vitalescence®.

The fracture toughness of Filtek Z350 universal restorative is higher than 3M ESPE Filtek™ A110 Anterior Restorative, Durafill™, Heliomolar®, Renamel® Microfill, Point 4™, Tetric® Ceram and Herculite XRV™ (Figure 5).

Flexural Modulus

Flexural modulus is a method of defining a material’s stiffness. A low modulus indicates a flexible material. The flexural modulus is measured by applying a load to a material specimen that is supported at each end.

The flexural modulus of Filtek Z350 Universal Restorative is:

- statistically higher than Filtek A110 Anterior Restorative, Durafill VS, EsthetX, Renamel Hybrid, Heliomolar, Renamel Microfill, Point 4, Vitalescence and Tetric Ceram,
- statistically equivalent to Herculite XRV and TPH,
- statistically lower than Filtek Z250 universal restorative. (Figure 6).
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 3M ESPE Filtek™ Z350 Universal Restorative Dentin, Enamel and Body shades is statistically higher than Filtek A110 anterior restorative, Durafill VS, Renamel Hybrid, Heliomolar, Renamel Microfill, and Tetric Ceram (Figure 7).
Compressive and Diametral Tensile

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 3M ESPE Filtek™ Z350 Universal Restorative is statistically equivalent to all other materials tested (Figure 8).

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 Z350 universal restorative is statistically higher than Filtek A110 anterior restorative, Durafill™ VS, EsthetX™, Heliomolar®, Renamel™ Microfill, and Tetric® Ceram (Figure 9).
Independent Investigations

Polymerization Shrinkage

The polymerization shrinkage of Filtek™ Z350 Universal Restorative was measured in a study conducted at Louisiana State University (LSU), New Orleans. LSU uses the AccuVol technique to measure volumetric shrinkage. A wide variety of products were evaluated, with results given below. Filtek Z350 universal restorative displayed very low shrinkage, averaging 2.09% (Figure 10).

![Figure 10. Volumetric shrinkage (Burgess, JO; Xu, X., Xin, X; LSU)](image)

Wear

The measurement of wear is critical as an indicator of longevity in posterior restorations. While 3M ESPE uses the three-body wear machine for internal measurements, Creighton University uses a device developed by Leinfelder et al that was designed to simulate both generalized and localized wear. Some feel that localized wear from direct contact is a more important contributor to breakdown than generalized wear as generated by a food bolus during mastication.

Composites are placed incrementally into 6mm diameter, 3mm deep cavities in acrylic fixtures. After curing, composites were polished using a sequence of SiC paper and finally a 0.05 micron polishing paste. Samples are held in a cylinder containing a slurry of PMMA beads. A conical stainless steel stylus, mounted on a spring-loaded piston, produces the localized wear. Both volumetric loss and maximum depth were determined using a profilometry technique. Results are presented in Figures 11 and 12.

![Figure 11. Localized wear: volume loss (Barkmeier, WW; Latta, MA)](image)

![Figure 12. Localized wear: maximum depth (Barkmeier, WW; Latta, MA)](image)
Instructions For Use

General

Filtek™ Z350 Universal Restorative material, manufactured by 3M ESPE, is a visible-light activated, radiopaque restorative composite designed for use in anterior and posterior restorations. The fillers are a combination of aggregated zirconia/silica cluster filler with an average cluster particle size of 0.6 to 1.4 microns with primary particle size of 5-20 nm and a non-agglomerated/non-aggregated 20 nm silica filler. The inorganic filler loading is about 78.5% by wt (59.5% by volume). Filtek Z350 universal restorative contains bis-GMA, UDMA, TEGDMA, and bis-EMA resins. A 3M ESPE dental adhesive is used to permanently bond the restoration to the tooth structure.

Indications

Filtek Z350 universal restorative is indicated for use in:

- Direct anterior and posterior restorations (including occlusal surfaces)
- Core Build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers

Precautions for Patients and Dental Personnel

Composite Paste Precaution: Filtek Z350 universal restorative contains acrylate resins. Avoid use of this product on patients with known acrylate allergies. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured resin. Use of protective gloves and a no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly used gloves. If restorative material contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If accidental contact with eyes or prolonged contact with oral soft tissue occurs, flush with large amounts of water. If irritation persists, consult a physician.

Instructions for Use

I. Preliminary

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

B. Shade Selection: Before isolating the tooth, select the appropriate shade(s) of restorative material using a standard VitaPan Classic shade guide. Filtek Z350 universal restorative may be used in combination with 3M™ ESPE™ Filtek™ Supreme XT Universal Restorative if additional shades and opacities are desired. Shade selection accuracy can be enhanced by the following hints.

1. Shade: Teeth are not monochromatic. The tooth can be divided into three regions, each with a characteristic color.
   a) Gingival area: Restorations in the gingival area of the tooth will have various amounts of yellow.
   b) Body area: Restorations in the body of the tooth may consist of shades of gray, yellow or brown.
c) Incisal area: The incisal edges may contain a blue or gray color. Additionally, the translucency of this area and the extent of the translucent portion of the tooth to be restored and neighboring teeth should be matched.

2. Restoration depth: The amount of color a restorative material exhibits is affected by its thickness. Shade matches should be taken from the portion of the shade guide most similar to the thickness of the restoration.

3. 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.

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

II. Direct Restorations

A. Cavity Preparation:
   1. Anterior restorations: Use conventional cavity preparations for all Class III, IV and V restorations.
   2. Posterior restorations: Prepare the cavity. Line and point angles should be rounded. No residual amalgam or other base material should be left in the internal form of the preparation that would interfere with light transmission and therefore, the hardening of the restorative material.

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

C. Placement of Matrix:
   1. Anterior restorations: Mylar strips and crown forms may be used to minimize the amount of material used.
   2. Posterior restorations: Place a thin dead-soft metal, or a precontoured-mylar or a precontoured-metal matrix band and insert wedges firmly. Burnish the matrix band to establish proximal contour and contact area. Adapt the band to seal the gingival area to avoid overhangs.

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

D. Adhesive System: Follow the manufacturer’s instructions regarding adhesive application.

E. Dispensing the Composite: Dispense the necessary amount of restorative material from the syringe onto the mix pad by turning the handle slowly in a clockwise manner. To prevent oozing of the restorative when dispensing is completed, turn the handle counterclockwise a half turn to stop paste flow. Immediately replace syringe cap. If not used immediately, the dispensed material should be protected from light.

F. Placement:
   1. Place and light cure restorative in increments as indicated in Section G.
2. Slightly overfill the cavity to permit extension of composite beyond cavity margins. Contour and shape with appropriate composite instruments.

3. Avoid intense light in the working field.

4. Posterior placement hints:
   a) To aid in adaptation, the first 1mm layer may be placed and adapted to the proximal box.
   b) A condensing instrument (or similar device) can be used to adapt the material to all of the internal cavity aspects.

G. Curing: Filtek™ Z350 universal 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, manufactured by 3M ESPE. Hold the light guide tip as close to the restorative as possible during light exposure.

<table>
<thead>
<tr>
<th>Shade</th>
<th>Increment depth</th>
<th>Cure time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opaque A3 shade (OA3)</td>
<td>1.5mm</td>
<td>40 sec</td>
</tr>
<tr>
<td>All other shades</td>
<td>2.0mm</td>
<td>20 sec</td>
</tr>
</tbody>
</table>

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

I. Adjust Occlusion: 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.

J. Finish and Polishing: Polish with the Sof-Lex Finishing and Polishing System.

III. Indirect Procedure For Inlays, Onlays Or Veneers

A. Dental Operatory Procedure

1. Shade selection: Choose the appropriate shade(s) of Filtek Z350 universal restorative prior to isolation. Filtek Z350 universal restorative may be used in combination with Filtek™ Supreme XT universal restorative if additional shades and opacities are desired.

2. Preparation: Prepare the tooth.

3. Impressioning: After preparation is complete, make an impression of the prepared tooth by following the manufacturer’s instructions of the impressioning material chosen. A 3M ESPE impressioning material may be used.

B. Laboratory Procedure

1. Pour the impression of the preparation with die stone. Place pins at the preparation site at this time if a “triple tray” type of impression was used.

2. Separate the cast from the impression after 45 to 60 minutes. Place pins in die and base the cast as for a typical crown and bridge procedure. Mount or articulate the cast to its counter model on an adequate articulator.

3. If a second impression was not sent, pour a second cast using the same impression registration. This is to be used as a working cast.

4. Section out the preparation with a laboratory saw and trim away excess or, expose the margins so they can be easily worked. Mark the margins with a red pencil if needed.
Add a spacer at this time if one is required.

5. Soak the die in water, then with a brush, apply a very thin coat of separating medium to the preparation, let it dry somewhat, then add another thin layer.

6. Add the first third of composite to the floor of the preparation, stay short of the margins, light cure for 20 seconds.

7. Add second third of composite. Allow for the last third (incisal) to include the contact areas, light cure for 20 seconds.

8. Place the die back into the articulated arch add the last third of translucent composite to the occlusal surface. Overfill very slightly mesially, distally, and occlusally. This will allow for the mesiodistal contacts and the proper occlusal contact when the opposing arch is brought into occlusion with the uncured translucent increment. Light cure for only ten seconds, then remove the die to prevent adhering to adjacent surfaces. Finish the curing process.

9. With the occlusal contacts already established, begin removing the excess composite from around the points of contact. Develop the inclines and ridges as per remaining occlusal anatomy.

10. Care must be taken when removing the prosthesis from the die. Break off small amounts of the die from around the restoration, the die stone should break away cleanly from the cured restoration, until all of the restoration is recovered.

11. Using the master die, check the restoration for flash, undercuts, and fit. Adjust as necessary, and then polish as noted above in Section II, steps H through J.

C. Dental Operatory Procedure

1. Roughen the interior surfaces of the indirect restoration.

2. Clean the prosthesis in a soap solution in an ultrasonic bath and rinse thoroughly.

3. Cementation: Cement the prosthesis using a 3M ESPE resin cement system by following manufacturer’s instructions.

IV. Storage and Use:

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

B. Unopened kits should be refrigerated (40°F or 4°C) to extend shelf life. Allow to come to room temperature for use.

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

D. The composite pastes are designed for use at room temperature of approximately 21-24°C or 70 -75°F. Shelf life at room temperature is 3 years. See outer package for expiry date.

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.