3M

Filtek™ Z250

Universal Restorative System

Technical Product Profile

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Background

The market for filling materials continues to proceed through an evolutionary process that is fueled by a combination of factors including:

- the desire for new materials by dentists
- the inability of dental materials to provide consistent, esthetic restorations every time
- the efforts of dental manufacturers to optimize the properties most desired by dentists
- the dentist's increased understanding of the choices made by manufacturers to produce the materials
- the changes in the industry, including reimbursement changes and patient demands.

Composite materials have been used in dental practices to restore teeth since 3M first introduced a composite to the dental market in 1964. The early materials were chemically cured. These materials provided better esthetics than amalgam. However much had to be learned about the physical properties that were required to survive in the oral environment. High wear, color changes, and lack of bonding to tooth surfaces were some of the issues associated with these early materials.

Significant advances have been made since these early materials which have improved upon many of the early materials' weaknesses. Adhesive systems have been developed that adhere well not only to enamel (with acid etching), but to moist dentin even when placed in a humid environment. Composites have been made stronger, more wear resistant and more color stable. Both types of materials were made curable on demand with high intensity lights that emit light in the wavelength range of 400-500 nm.

In the 1980's composites were developed that were specific to restoration type, i.e. materials were designed for anterior or posterior use. The main distinction between these materials was the high esthetic requirements for anterior use vs. the high strength requirement for posterior use. One material was not available that offered both. The gap between the two types of materials was very wide.

In the late 1980's composite materials were developed to be used both for anterior and posterior restorations. These materials narrowed the gaps between esthetics and strength. Dentists were now able to use one composite material for all of their composite restorative use. The reduction in inventory (one set of shades) and ease of material selection were additional benefits realized that made the dental practice easier.

3M entered this “universal composite” marketplace in 1992 with 3M™ Z100™ Restorative. Z100 restorative provided dentists with a material that provided very good esthetics, strength and wear resistance. Three clinical studies have documented the clinical success. Two of the studies, conducted at Creighton University and University of Manitoba, examined the overall clinical performance over a 4-year period. The attributes examined include:

- retention
- color match
- anatomic form
- marginal adaptation
- marginal discoloration
- axial contour
- proximal contact
- secondary caries and
- post-operative sensitivity

Both of these studies concluded that Z100 restorative is a viable and clinically acceptable material for use in posterior restorations.

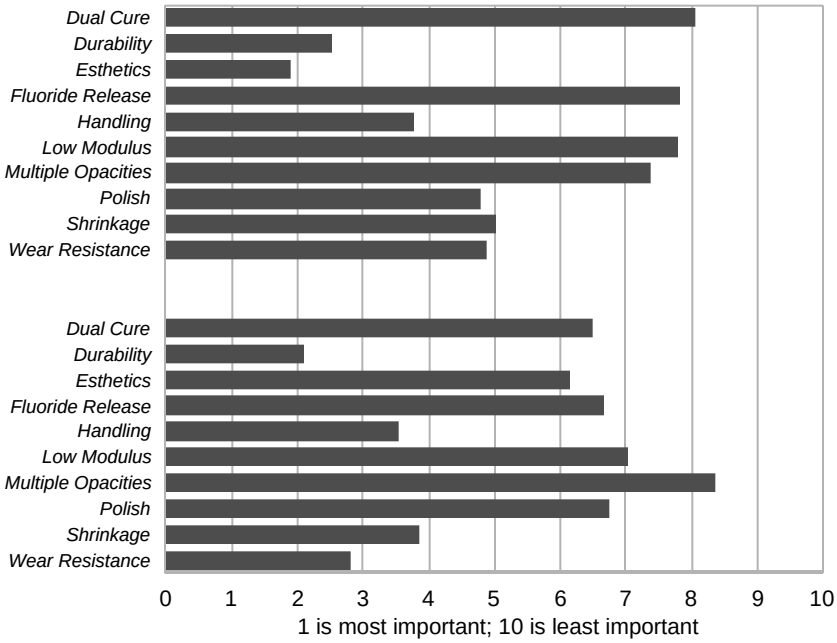
The third study, conducted at Catholic University at Leuven, closely examined the wear of the material using a computerized measuring technique accurate to within 1 micron. The 4-year clinical results of contact-free occlusal areas and occlusal contact areas demonstrated this material has wear similar to amalgam. Additionally, the wear rate of Z100 restorative on enamel in occlusal contact areas is comparable to the occlusal contact wear for enamel on enamel. In an ideal situation, the wear of material from a composite restorative should match that of enamel.

Other studies by independent research organizations (who use a wide variety of practitioners) have confirmed the favorable results of the controlled clinical studies. Anterior 5-year clinical results were also reported on by one of these organizations. Again the results indicated the high level of patient and doctor satisfaction with the performance of Z100 restorative (*The Dental Advisor*, August 1998, Volume 15, No. 6).

The Development Process

Three years ago, a survey was sent to 3M™ Z100™ Restorative users. The participants were asked to rank 10 attributes for a material in the anterior and then in the posterior. The results were not surprising and confirmed that restorative requirements differed between anterior and posterior use.

Figure 1. Importance



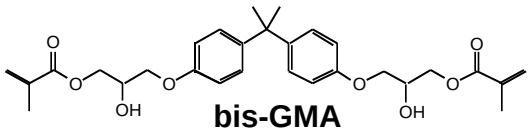
The most important features (of those asked) in anterior applications are esthetics and durability. The next most important group included handling, shrinkage, wear resistance and polish. For posterior applications, the groupings changed slightly. Durability and wear resistance were in the most important group, followed by handling and shrinkage. The other attributes could be grouped in one final category.

A product that is to be used in both anterior and posterior applications would have to maximize the most important attributes for each category. Hence, attention was focused on esthetics, durability, handling, shrinkage and wear resistance.

Dentists using Z100 restorative were asked what improvements could be made to Z100 restorative to enhance the clinical performance. The top four responses were reduce shrinkage, improve initial and sustained polish, improve marginal integrity and reduce post-operative sensitivity.

Chemistry

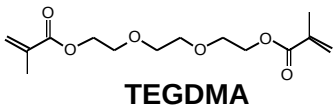
Examination of the Z100 composition established the belief that modifying the resin system could result in enhanced properties. The Z100 resin system consists of BIS-GMA (Bisphenol A diglycidyl ether dimethacrylate) and TEGDMA (tri[ethylene glycol] dimethacrylate).



bis-GMA

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.

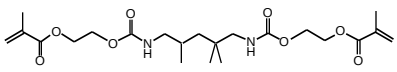


TEGDMA

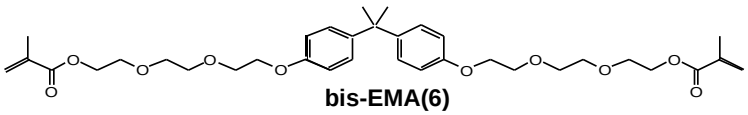
However, the TEGDMA concentration also allows for some opportunities for improvements.

- 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.
- TEGDMA is somewhat hydrophilic. The differences in moisture content of the paste can contribute to thickening or softening of the paste in the capsule depending on the ambient moisture content of the surrounding air under extreme climatic conditions.

The new resin system of 3M™ Filtek™ Z250 Universal Restorative consists of 3 major components. In Filtek Z250 restorative, the majority of TEGDMA has been replaced with a blend of UDMA (urethane dimethacrylate) and Bis-EMA(6)[1] (Bisphenol A polyetheylene glycol diether dimethacrylate). Both of these 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. A typical batch of 3M™ Z100™ Restorative has a viscosity of 30,000 poise, whereas Filtek Z250 universal restorative has a target viscosity of 350,000 poise. Despite this large disparity, dentists may not distinguish any difference in handling viscosity. However, the higher molecular weight of the resin results in less shrinkage, reduced aging and a slightly softer resin matrix. Additionally these resins impart a greater hydrophobicity and are less sensitive to changes in atmospheric moisture.



UDMA



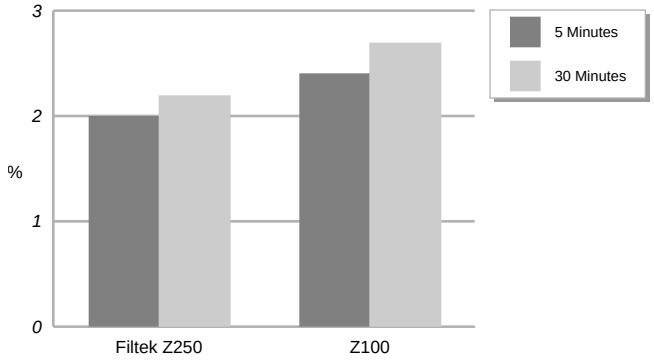
bis-EMA(6)

The final resin composition was determined on the basis of physical properties, including compressive and diametral tensile strengths, shrinkage, wear resistance and customer handling preferences. A Simulated Operatory (handling evaluation in heated typodonts) was conducted to determine which resin system produced the most acceptable handling. By combining the data from all tests, a resin composition which optimized the property combination, was chosen.

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

The reduction in shrinkage due to the new resin system was demonstrated using a mercury dilatometer. The actual volumetric shrinkage is measured via this method. In this test, a disc of uncured composite is placed on a glass stopper. This assembly is inserted into a mercury-filled chamber and polymerized through a window with a curing light. The curing light intensity is also measured through the window to determine the intensity of light reaching the sample. The volume change is recorded electronically over time. The final volume is measured and then the per cent volumetric shrinkage is calculated.

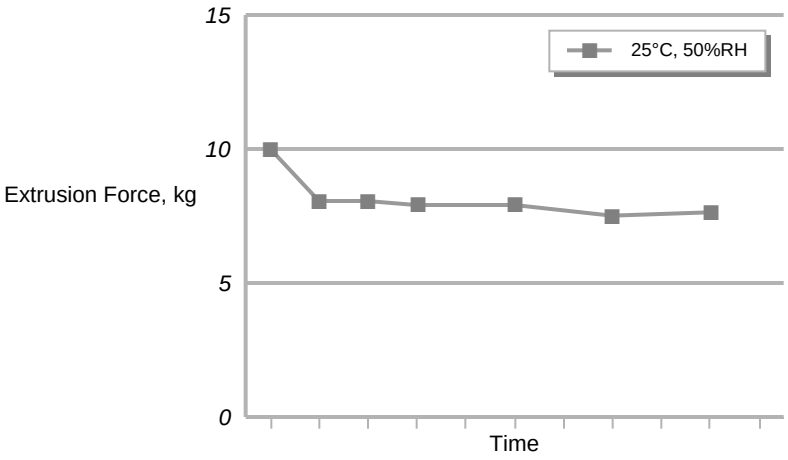
Figure 2. Volumetric Shrinkage



In this example, the samples were exposed for 40 seconds and the light intensity was approximately 400mW/cm^2. 3M™ Filtek™ Z250 Universal Restorative exhibited approximately an 18% reduction of total volumetric shrinkage when compared to 3M™ Z100™ Restorative at both 5 and 30 minutes.

The new resin system has demonstrated reduction in the aging process due to humidity effects and resin sorption into the container walls. As composites age, their viscosity increases. One method of monitoring the viscosity increase is to measure the resultant increase in extrusion force. The chart below traces the extrusion force of the composite system, over time. Note the virtually flat curve for the Filtek Z250 resin system.

Figure 3. Aging

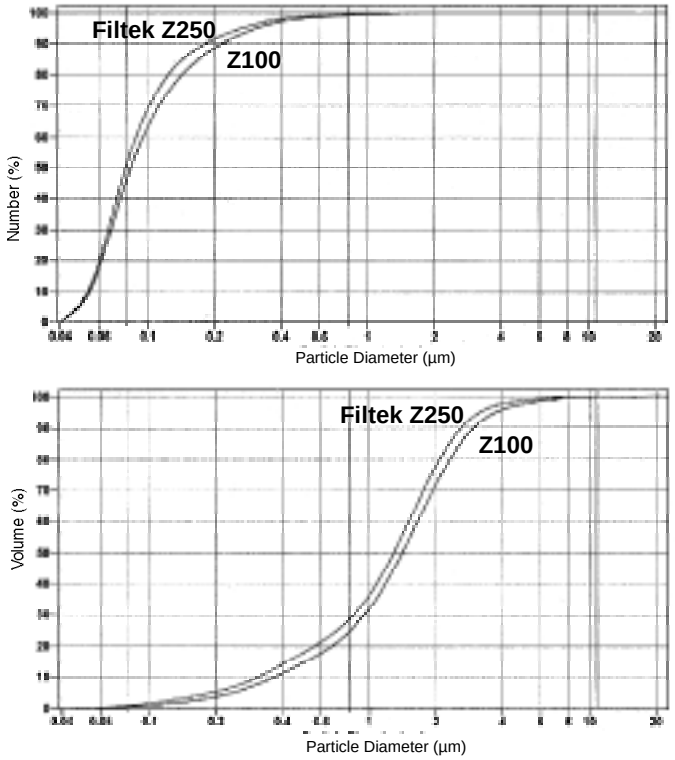


Filler

The filler in 3M™ Filtek™ Z250 Restorative remains essentially the same as the 3M™ Z100™ Restorative filler. There have, however, been significant processing changes to maximize filler consistency. The particle size distribution is 0.01µm to 3.5µm with an average particle size of 0.6µm.

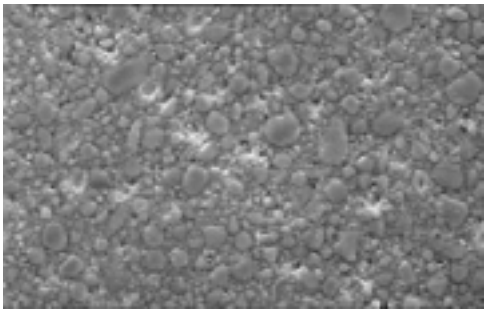
Using a Coulter® LS Particle Size Analyzer, the filler distributions of Z100 Restorative and Filtek Z250 universal restorative were measured. The data was reported based on the number of particles and the volume the particles occupy at each particle diameter. Both provide a different insight into the distribution. The number of particles per diameter indicates the frequency a large particle may be encountered. One large particle can have the same volume of numerous small particles. Both charts report cumulative data, that is, the number or volume of particles at or below a specific diameter.

Figure 4. Cumulative Particle Size Distribution

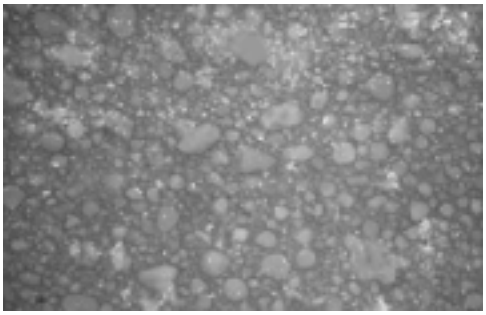


The data shows that the particle size distribution for Filtek Z250 universal restorative contains a larger number of finer particles than found in Z100 restorative. The photos below were generated using scanning electron microscopy. Cured composite samples were photographed at 2500× magnification. However, even at this magnification the very small filler particles cannot be seen. Observation of the photos confirms the similarities between the size and shapes of Filtek Z250 universal restorative and Z100 restoratives.

Figure 5. SEMs 2500x



Filtek Z250 Restorative

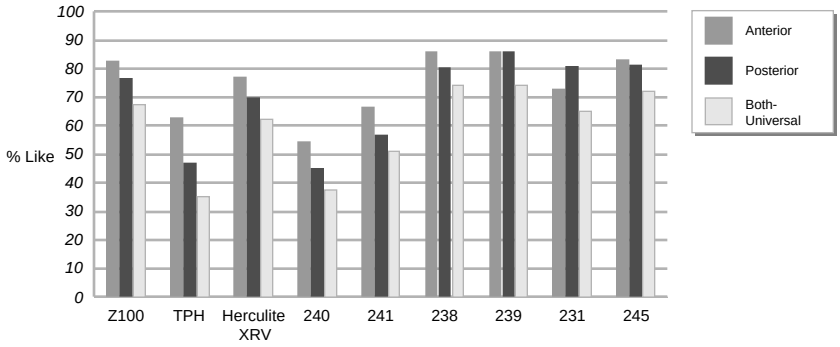


Z100 Restorative

Final Specifications

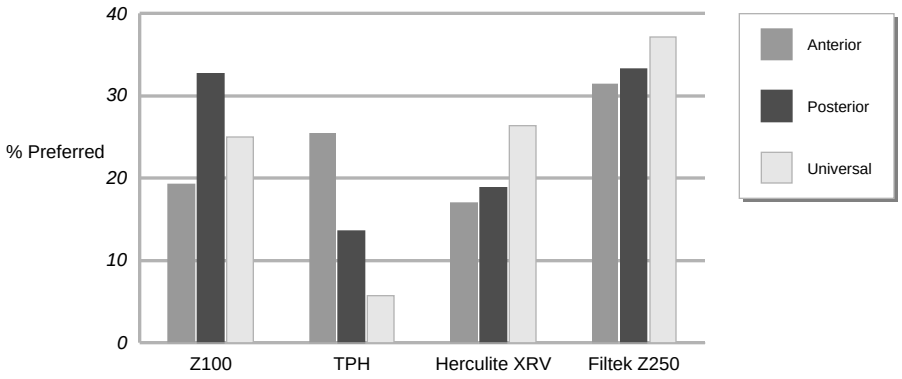
A global Simulated Operatory was conducted to determine final handling specifications for 3M™ Filtek™ Z250 Restorative. One hundred seventeen dentists participated in a blind study that included six experimental pastes, 3M™ Z100™ Restorative, TPH™ Spectrum and Herculite XRV™. The dentists were currently using Z100 restorative, TPH or TPH Spectrum, Herculite XRV, Prodigy™, Tetric®, Tetric Ceram™ or Charisma®. The participants evaluated four of the nine pastes by placing them in an anterior and a posterior restoration (in a mannequin heated to 37° C). Handling acceptance was determined by simply asking the participants if they "liked or disliked" the handling after placing the material. After handling all four materials, dentists were asked which paste they preferred as an anterior, posterior and as a universal restorative material. In the chart below, the experimental product formulations are indicated with the numbers 240, 241, 238, 239, 231 and 245. Progressing from left to right on the chart (within the experimental materials) corresponds to viscosity increases. Lots 238, 239, 231 and 245 show a very high acceptance.

Figure 6. Handling Acceptance



When participants were asked to indicate which materials they prefer (selecting one out of the four pastes handled), the following data was obtained.

Figure 7. Handling Preference

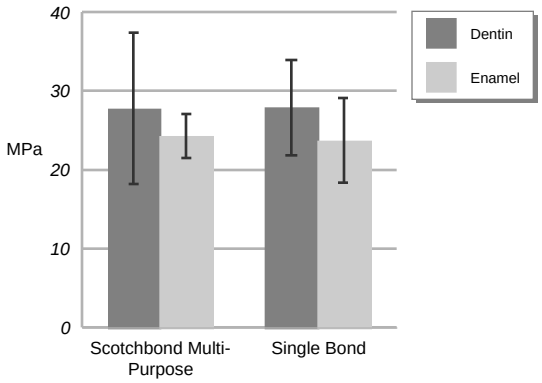


Data for the experimental lots that meet the specification for Filtek Z250 universal restorative were combined and are presented as Filtek Z250 restorative. The handling preference for the new composite as a universal product versus TPH Spectrum, Herculite XRV and Z100 restorative is particularly notable. The handling of Filtek Z250 restorative was preferred more often for anterior restorations than Z100 restorative and Herculite XRV. The handling of Filtek Z250 universal restorative was preferred more often for posterior restorations than TPH Spectrum and Herculite XRV. The overall handling of Filtek Z250 universal restorative was preferred as an anterior and posterior restorative more often than Z100 restorative, TPH Spectrum or Herculite XRV restoratives.

Product Description

3M™ Filtek™ Z250 Universal Restorative is an esthetic, light-cured, radiopaque composite specifically designed for use in both anterior and posterior direct or indirect restorations. Bonding to the tooth structure is accomplished by using a dental adhesive system, such as 3M™ Single Bond Dental Adhesive or 3M™ Scotchbond™ Multi-Purpose Adhesive Systems.

Figure 8. Adhesion



Filtek Z250 universal restorative is packaged in single-dose capsules and bulk syringes. Filtek Z250 universal restorative is available in 15 shades that correspond to the most commonly used shading system:

- A1, A2, A3, A3.5, A4
- B0.5, B1, B2, B3
- C2, C3, C4
- D3
- UD (universal dentin based on A3) and Incisal (more translucent)

The material is incrementally placed and cured in the cavity. The maximum cure depth for an increment is 2.5mm for most shades. Each layer is cured for 20 seconds. The exceptions to this are the B0.5, C4 and UD shades that should be placed in increments of less than 2.0mm. Each layer is then light cured for 30 seconds.

Indications for Use

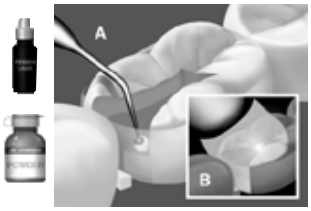
Filtek Z250 universal restorative is indicated for use in the following types of restorations.

- 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

Technique Guides

3M Direct Posterior Restorations

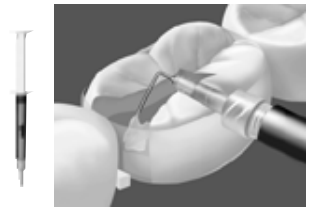
3M™ Vitrebond™ Light Cure Glass Ionomer Liner/Base
3M™ Single Bond Dental Adhesive System
3M™ Filtek™ Z250 Universal Restorative



Prepare tooth and isolate.

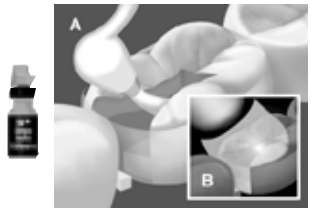
Apply liner/base if desired:

- Mix a level scoop of Vitrebond powder and a drop of Vitrebond liquid on a mixing pad.
- Apply a thin layer of the liner/base to dentin surfaces using a ball applicator.
- Light cure for 30 seconds.



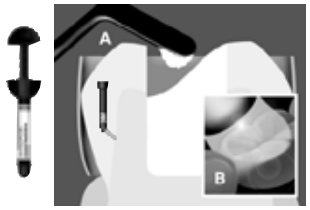
Etch:

- Apply 3M™ Scotchbond™ etchant to enamel and dentin. Wait 15 seconds. Etchant on Vitrebond base is not deleterious.
- Rinse.
- Blot excess water, leaving tooth moist.



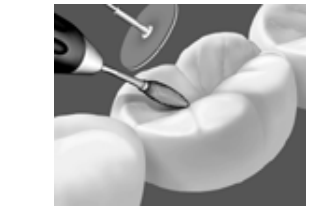
Bond:

- Using a fully saturated brush tip for each coat, apply 2 consecutive coats of 3M Single Bond adhesive to enamel and dentin.
- Dry gently for 2-5 seconds.
- Light cure for 10 seconds.



Place Restorative:

- Place 3M Filtek Z250 restorative in increments less than 2.5mm.
- Light cure each increment for 20 seconds (Increments less than 2.0mm of B0.5, C4 and UD are cured 30 seconds).



Finish and Polish:

- Finish occlusal surface using an appropriate finishing instrument.
- Finish interproximal surfaces with 3M™ Sof-Lex™ Pop-on™ extra-thin discs and Sof-Lex strips.

Check Occlusion:

- Check lateral and centric occlusion.
- Adjust if necessary.

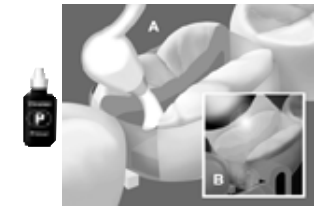
Please refer to instructions for more detailed information as well as precautionary and warranty information.
3M Customer Hotline 1-800-634-2249

3M Glass Ionomer/Composite Laminate/Sandwich

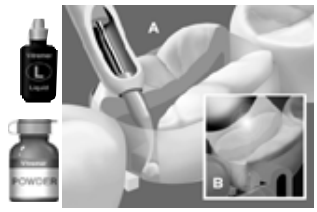
3M™ Single Bond Dental Adhesive System
3M™ Vitremer™ Core Buildup/Restorative
3M™ Filtek™ Z250 Universal Restorative

Indications

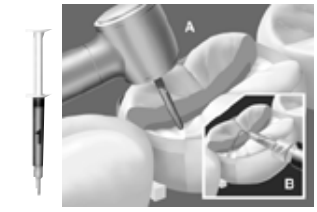
Direct posterior restorations where the benefits of glass ionomers and composites are desired.



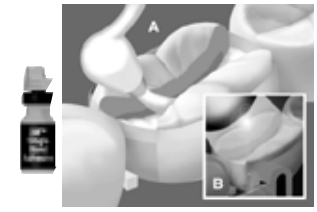
Prepare/Prime:
- Note that this technique is indicated where cavity design allows for a minimum composite restorative thickness of 2mm on the occlusal surface.
- Conservatively prepare the tooth; place matrix bands and wedges.
- Apply Vitremer primer for 30 seconds to all dentin surfaces; air dry.
- Light cure for 20 seconds.



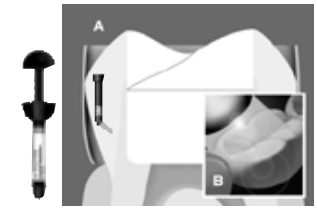
Apply Glass Ionomer:
- Mix Vitremer powder and liquid according to product instructions; back load into delivery tip.
- Syringe Vitremer restorative into the preparation, extending no further than just apical to the proximal contact point.
- Light cure for 40 seconds.



Freshen Preparation Margins/Etch:
- Using a rotary instrument, remove excess Vitremer restorative material from enamel margins and cavity walls that will be bonded.
- Apply 3M™ Scotchbond™ etchant to enamel and exposed dentin; wait 15 seconds, then rinse. Blot excess water, leaving tooth moist.



Bond:
- Using a fully saturated brush tip for each coat, apply 2 consecutive coats of Single Bond adhesive to enamel, dentin and Vitremer restorative base increment.
- Dry gently for 2-5 seconds.
- Light cure for 10 seconds.



Place Restorative:
- Place 3M Filtek Z250 restorative in increments less than 2.5mm.
- Light cure each increment for 20 seconds (Increments less than 2.0mm of B0.5, C4 and UD are cured 30 seconds.)

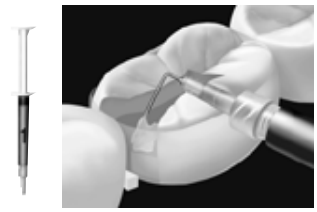
Finish and Polish:
- Finish occlusal surface using an appropriate finishing instrument.
- Finish interproximal surfaces with 3M™ Sof-Lex™ Pop-on™ extra-thin discs and Sof-Lex strips.

Check Occlusion:
- Check lateral and centric occlusion.
- Adjust if necessary.

Please refer to instructions for more detailed information as well as precautionary and warranty information.
3M Customer Hotline 1-800-634-2249

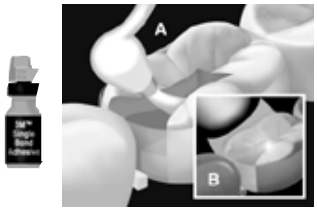
3M™ Single Bond Dental Adhesive System
3M™ F2000 Compomer Restorative
3M™ Filtek™ Z250 Universal Restorative

Indications
Direct posterior restorations where the benefits of a compomer and composite are desired.

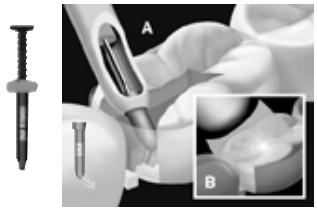


Prepare and Isolate Tooth.

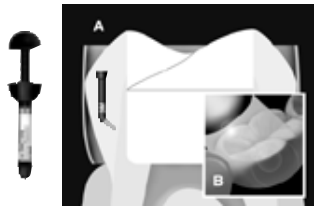
Etch:
- Apply 3M™ Scotchbond™ etchant to enamel and dentin; wait 15 seconds.
- Rinse.
- Blot excess water, leaving tooth moist.



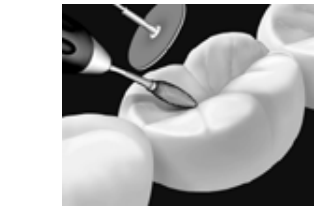
Bond:
- Using a fully saturated brush tip for each coat, apply 2 consecutive coats of Single Bond adhesive to enamel and dentin.
- Dry gently for 2-5 seconds.
- Light cure for 10 seconds.



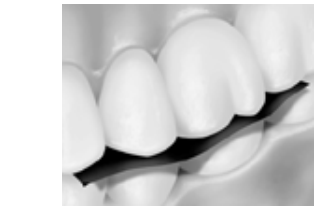
Place Compomer:
- Place F2000 compomer in increments.
- Place F2000 compomer no further than just apical to the proximal contact point.
- Remove any excess compomer inadvertently placed on enamel margins before light curing.
- Light cure each compomer increment for 40 seconds.



Place Composite:
- Place 3M Filtek Z250 in increments less than 2.5mm.
- Light cure each increment for 20 seconds (Increments less than 2.0mm of B0.5, C4 and UD are cured for 30 seconds).



Finish and Polish:
- Finish occlusal surface using an appropriate finishing instrument.
- Finish interproximal surfaces with 3M™ Sof-Lex™ Pop-on™ extra-thin discs and Sof-Lex strips.



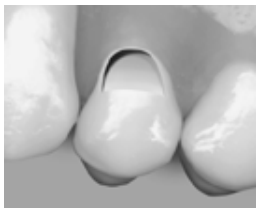
Check Occlusion:
- Check lateral and centric occlusion.
- Adjust if necessary.

Please refer to instructions for more detailed information as well as precautionary and warranty information.
3M Customer Hotline 1-800-634-2249

3M™ Single Bond Dental Adhesive System
3M™ Filtek™ Z250 Universal Restorative

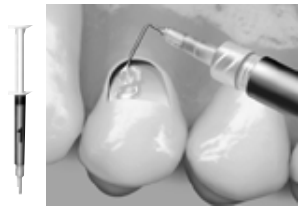
Indications

- Class V cavities and cervical erosion/abrasion lesions and root caries lesion
- Class III cavities



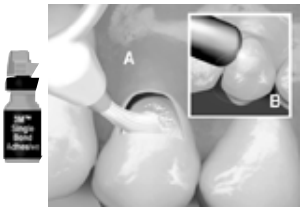
Prepare the Tooth:

- Select shade using the shade guide.
- Isolate the tooth.
- Remove caries.



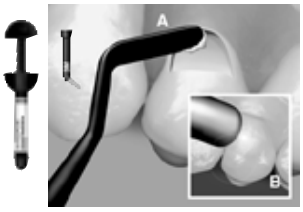
Etch:

- Apply 3M™ Scotchbond™ etchant to enamel and dentin; wait 15 seconds.
- Rinse.
- Blot excess water, leaving tooth moist.



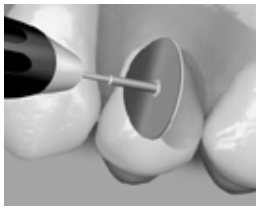
Bond:

- Using a fully saturated brush tip for each coat, apply 2 consecutive coats of Single Bond adhesive to enamel and dentin.
- Dry gently for 2-5 seconds.
- Light cure for 10 seconds.



Place Composite:

- Place Filtek Z250 restorative in layers less than 2.5mm.
- Cure each increment for 20 seconds (Increments less than 2.0mm of B0.5, C4 and UD are cured for 30 seconds).
- For maximum esthetics and surface smoothness a veneer of 3M™ Silux Plus™ Restorative may be placed and cured over Filtek Z250 restorative.

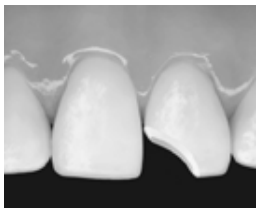


Finish/Polish:

- Use the 3M™ Sof-Lex™ Finishing and Polishing System (discs and strips) for finishing and polishing the restoration.

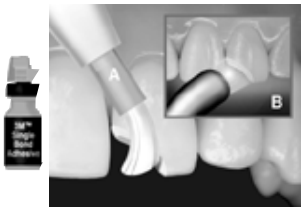
Please refer to instructions for more detailed information as well as precautionary and warranty information.
3M Customer Hotline 1-800-634-2249

3M™ Single Bond Dental Adhesive System
3M™ Filtek™ Z250 Universal Restorative

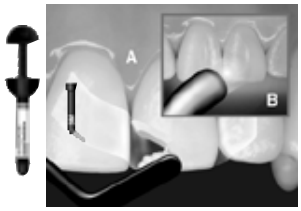


Preparation:
- Select shade.
- Prepare the tooth.
- Bevel enamel margins.

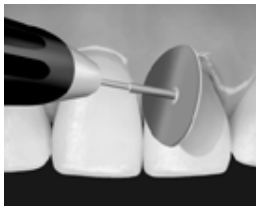
Etch:
- Apply 3M™ Scotchbond™ etchant to enamel and dentin; wait 15 seconds.
- Rinse.
- Blot excess water, leaving tooth moist.



Bond:
- Using a fully saturated brush tip for each coat, apply 2 consecutive coats of Single Bond adhesive to enamel and dentin.
- Dry gently for 2-5 seconds.
- Light cure for 10 seconds.



Place Composite:
- Place Filtek Z250 restorative in layers less than 2.5mm.
- Cure each increment for 20 seconds (Increments less than 2.0mm of B0.5, C4 and UD are cured 30 seconds).
- For maximum esthetics and surface smoothness a veneer of 3M™ Silux Plus™ restorative may be placed and cured over Filtek Z250 restorative.



Finish and Polish:
- Use the 3M™ Sof-Lex™ Finishing and Polishing System (discs and strips) for finishing and polishing the restoration.

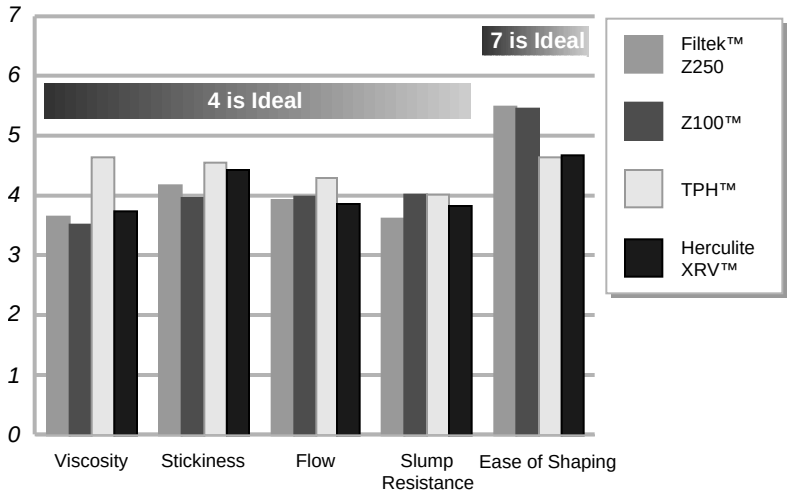
Please refer to instructions for more detailed information as well as precautionary and warranty information.
3M Customer Hotline 1-800-634-2249

Customer Evaluations

Global Simulated Operatory

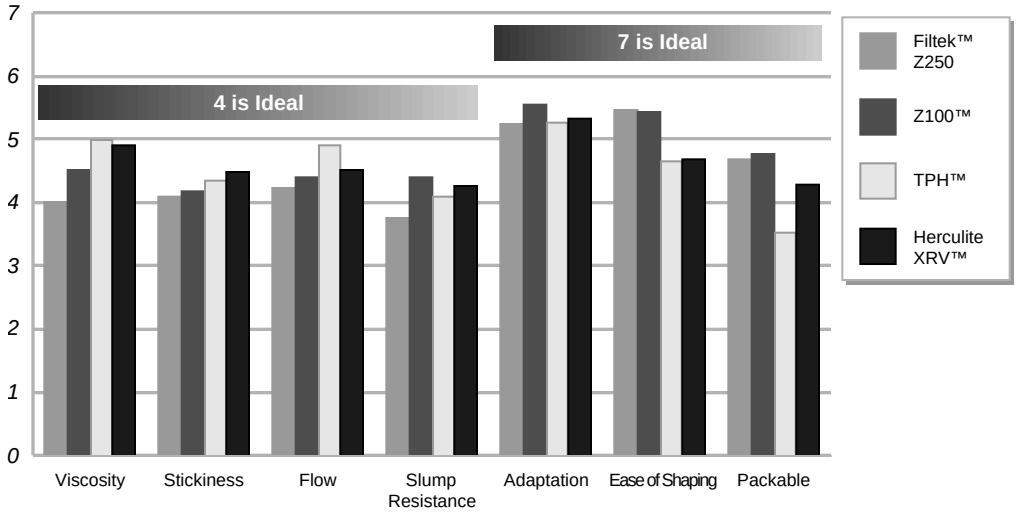
Dentists participating in the Global Simulated Operatory (see Final Specification section) were asked to rate five handling attributes for anterior restorations on a scale of 1 to 7 for each paste. The "ideal" rating for viscosity, stickiness to instrument, flow and resistance to slump was 4. The "ideal" rating for ease of shaping was 7. The results for anterior handling are displayed below. In most cases 3M™ Filtek™ Z250 Universal Restorative and 3M™ Z100™ Restorative are very close to the ideal.

Figure 9. Anterior Handling



Dentists participating in the Global Sim Op were asked to rate seven handling attributes for posterior restorations on a scale of 1 to 7 for each paste. The "ideal" rating for viscosity, stickiness to instrument, flow and resistance to slump was 4. The "ideal" rating for cavity/marginal adaptation, ease of shaping and packability was 7. The results for handling in a posterior restoration are displayed below. As in the anterior handling evaluation, the average values for Filtek Z250 universal restorative and Z100 restorative are closest to the ideal rating than for the other composites included in the study.

Figure 10. Posterior Handling



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Physical Properties

Materials

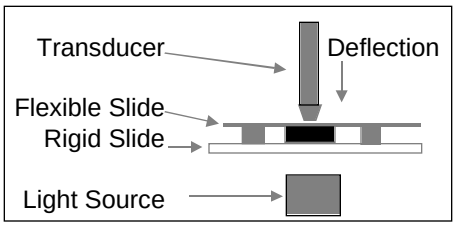
Designation	Product	Manufacturer
Charisma	Charisma®	Heraeus Kulzer
XRV	Herculite XRV™	Kerr
Prodigy	Prodigy™	Kerr
TPH	TPH™ Spectrum	Caulk®/Dentsply®
Tetric Ceram	Tetric Ceram™	Vivadent
Z100	Z100™ Restorative	3M™
Z250	Filtek™ Z250 Universal Restorative	3M™

Shrinkage

Shrinkage of composite is measured in a variety of methods. Some methods measure the total amount of shrinkage volumetrically or linearly. Another method measures a portion of the shrinkage that occurs after the composite has lost the ability to flow (post-gel).

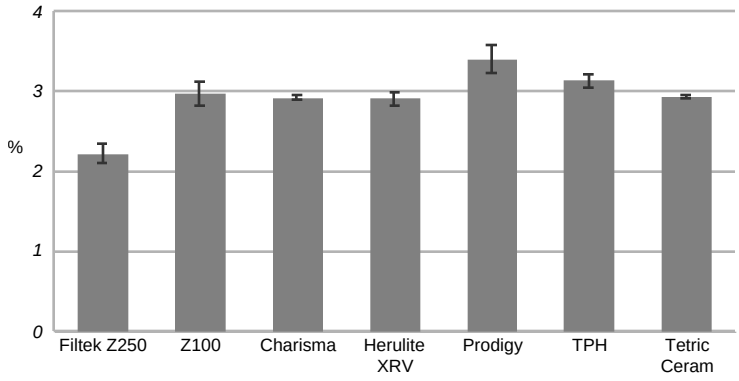
Volumetric Shrinkage

Another 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 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.



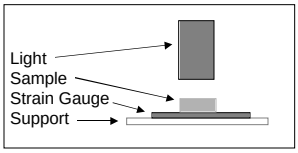
In this test, samples were exposed for 60 seconds to a 3M™ Visilux™ 2 Visible Light Curing Unit. The final shrinkage was recorded 4 minutes after the end of light exposure. As the chart below shows, the value for Filtek Z250 universal restorative is statistically lower than the other materials tested. Charisma, Herculite XRV, TPH Spectrum, Tetric Ceram and Z100 restorative exhibited statistically similar results.

Figure 11. Shrinkage



Post-Gel Shrinkage Strain

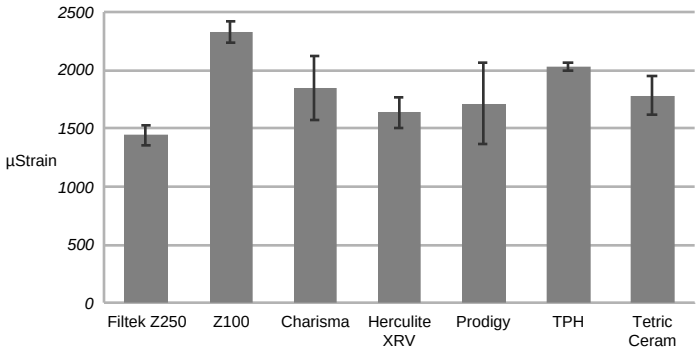
Post-gel shrinkage is reported to be the shrinkage that occurs after the material has gelled, i.e., the material has lost its ability to flow. Shrinkage stresses that occur in the pre-gel phase can be relieved readily by the flow of the material. However, stresses occurring during the post-gel phase cannot be relieved by material flow. These stresses remain built-up in the material and may cause fatigue within the material or at the composite-bond interface over time. Strain gauges have been shown to be an effective method for indicating linear post-gel polymerization shrinkage stress in composites.



In this method a sample of composite is placed on top of a strain gauge. The composite samples were then light-cured for 60 seconds. The final shrinkage strain (in µStrain), which is the result of dimensional changes in the composite that occurred during polymerization, was recorded 4 minutes after the light was turned off.

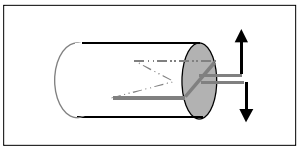
The chart below depicts these final values. 3M™ Filtek™ Z250 Universal Restorative displayed significantly less shrinkage strain than Charisma®, Prodigy™, TPH Spectrum™, Tetric Ceram™ and 3M™ Z100™ Restorative.

Figure 12. Post-Gel Shrinkage Strain



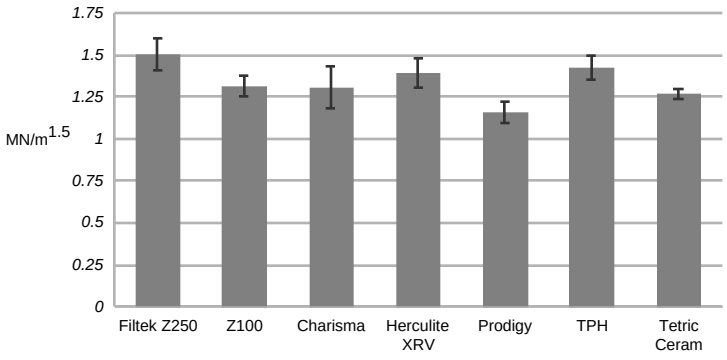
Fracture Toughness

The values reported for fracture toughness (K_{IC}) 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.

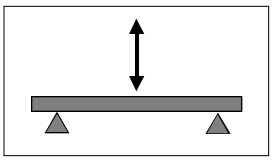


Below are the 24-hour values for wet fracture toughness. The wet fracture toughness for Filtek Z250 universal restorative was determined to be significantly different than Charisma, Prodigy, Tetric Ceram and Z100 restorative.

Fracture 13. Fracture Toughness



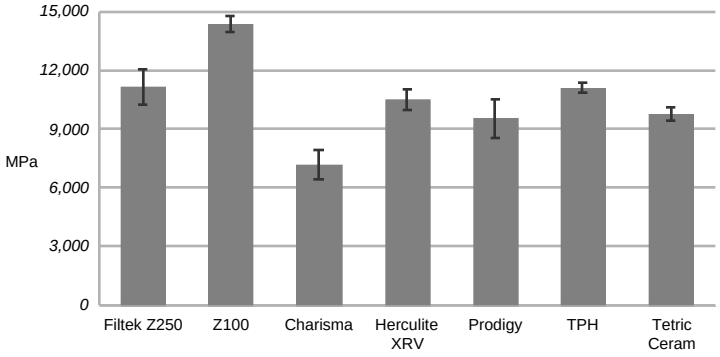
Flexural Modulus



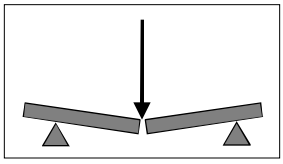
Flexural modulus is a method of defining a material's stiffness. A low modulus indicates a flexible material. The flexural modulus is measured by applying a load to a material specimen that is supported at each end.

The flexural modulus for 3M™ Filtek™ Z250 Universal Restorative is intermediate and comparable to Herculite XRV™ and TPH Spectrum™. Comparatively high flexural modulus materials include 3M™ Z100™ Restorative. Prodigy™ Charisma® and Tetric Ceram™ have a lower modulus than Filtek Z250 universal restorative.

Figure 14. Flexural Modulus

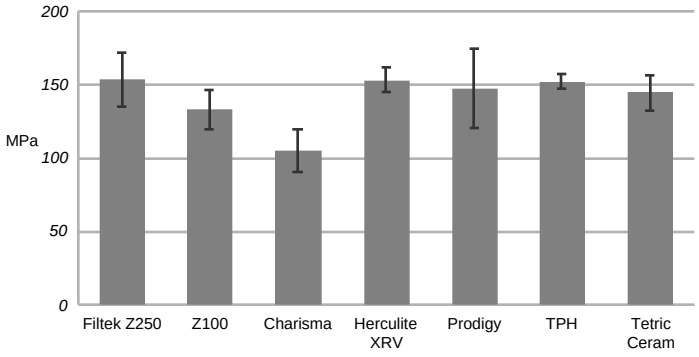


Flexural Strength



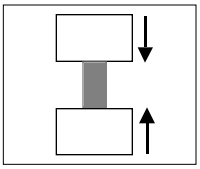
Flexural strength is determined in the same test as flexural modulus. Flexural strength is the value obtained when the sample breaks. This test combines the forces found in compression and tension. As shown in the graph below the flexural strength of Filtek Z250 restorative is statistically higher than Charisma but similar to all other materials tested.

Figure 15. Flexural Strength



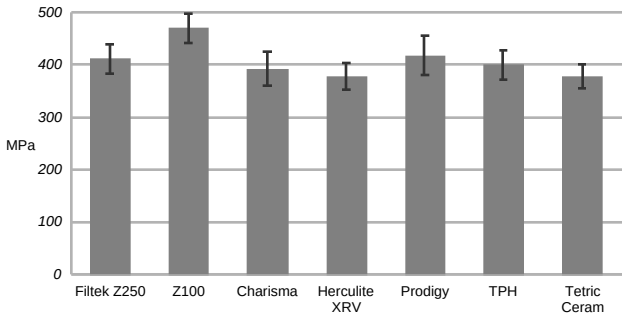
Compressive and Diametral Tensile

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.

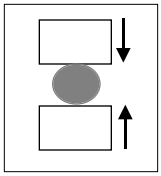


The compressive strengths of various materials are shown below. Filtek Z250 universal restorative was not statistically different from Charisma, Prodigy and TPH Spectrum. However it was significantly higher than Herculite XRV and Tetric Ceram.

Figure 16. Compressive Strength

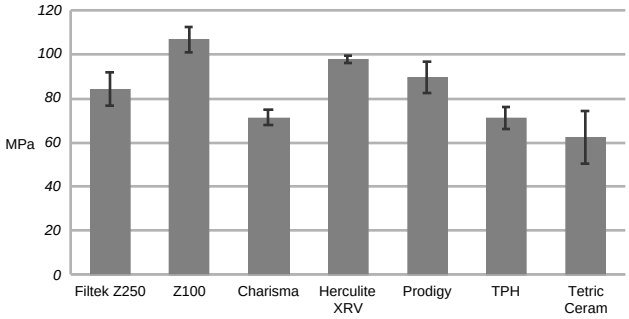


Diametral Tensile strength is measured using a similar apparatus. Compressive forces are applied to the sides of the sample, not the ends, until fracture occurs.



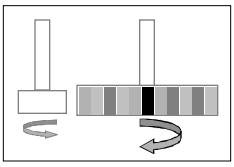
The diametral tensile strength of 3M™ Filtek™ Z250 Universal Restorative was significantly higher than Charisma® and Tetric Ceram™. Filtek Z250 restorative showed similar results to Prodigy™. These data are reported in the chart below.

Figure 17. Diametral Tensile Strength



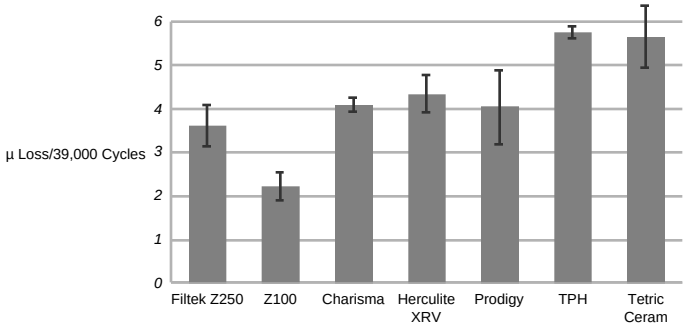
Wear

The wear rate was determined by an in-vitro 3-body wear test. In this test, composite (1st body) is loaded onto a wheel (shaded slots in the diagram) 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 wear rate data shown below indicates the wear rate of Filtek Z250 universal restorative is intermediate between Z100 restorative and other materials tested.

Figure 18. Wear



Particle Size Distribution

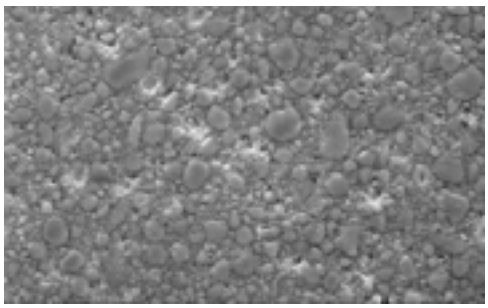
Cross-Section SEM

In this column are SEMs (scanning electron micrographs) of cured universal composites in cross section. Observations of the particle size distributions and shapes can be made by comparing these photos. All samples are magnified at 2500×. However, even at this magnification, the very small filler particles are not visible.

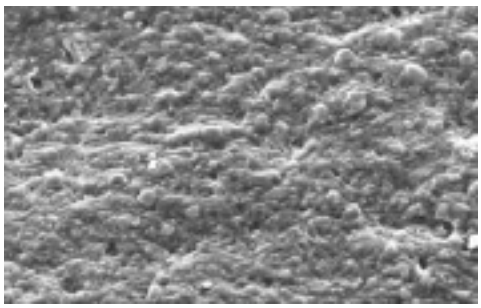
Surface SEM After Wear Wheel Abrasion

In this column are SEMs (2500× magnification) of the surface of a composite sample after 156,000 cycles of a 3-body wear test. See Wear Wheel Section, if desired, for more detailed description of the test methodology. Samples were not obtained from the same wheel. These photos may be indicative of the polish retention of restored occlusal surfaces.

Filtek Z250 Restorative

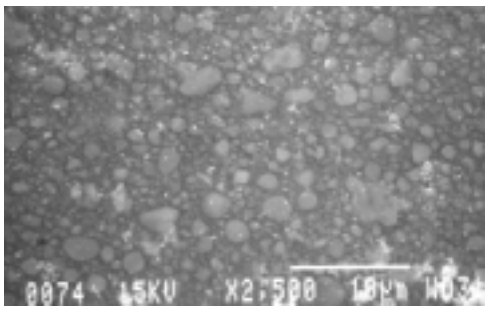


The Filtek 3M™ Z250™ Restorative filler consists of the same proprietary synthetic, rounded zirconia/silica particles as 3M™ Z100™ Restorative. The particle size distribution of Z250 restorative is 0.01 to 3.5 µm. The average particle size is 0.6µm.

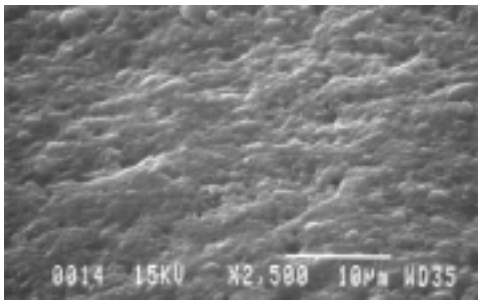


The surface of the Filtek Z250 sample is irregular but not ditched or pitted from filler particle loss.

Z100 Restorative

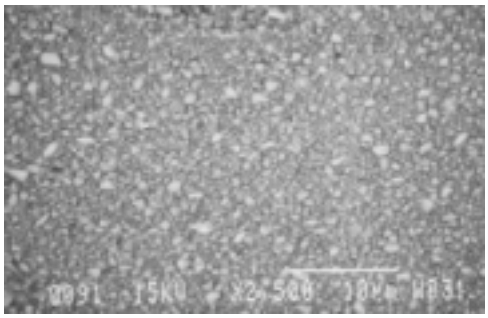


The synthetic proprietary Z100 restorative filler is composed of rounded zirconia/silica particles. The particle size distribution of Z100 restorative is 0.01 to 3.3µm. The white splotches are artifacts of the sample preparation.

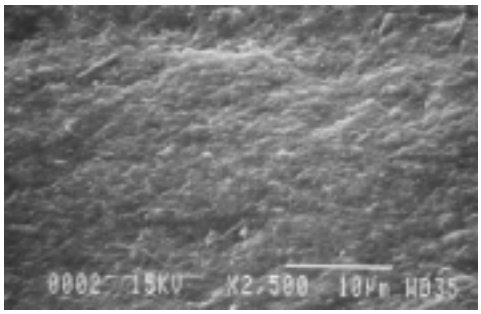


The SEM of the sample surface after wear wheel abrasion of Z100 restorative confirms the similarities in the filler distribution between Z100 restorative and Filtek Z250.

Charisma Restorative

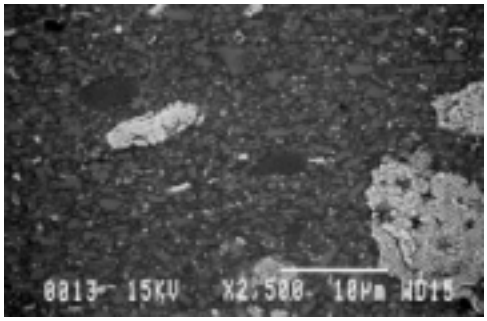


The Charisma® restorative filler consists of jagged barium glass and silica particles (average particle size of 0.4µm). The average particle size is reported to be 0.7µm. It appears that the distribution of particles is more narrow than for Filtek Z250 or Z100 restoratives.

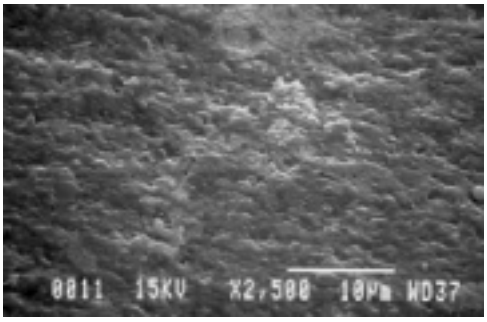


The surface of Charisma after wear abrasion is rough. However there is no evidence of pitting due to large particle loss.

Tetric Ceram

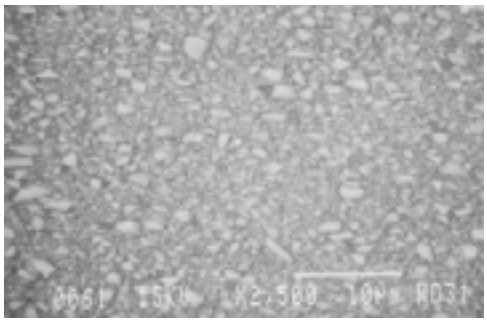


The filler for Tetric Ceram™ is a combination of barium glass, ytterbium trifluoride, barium aluminum fluorosilicate glass, silica, and spheroid mixed oxides. The jagged filler particles in the SEM vary in appearance, shape and sizes. Although the composition of the large blotches is unclear, they are not an artifact of the sample preparation. The product instructions state the average particle size is 0.7µm with range from 0.04-3.0µm.

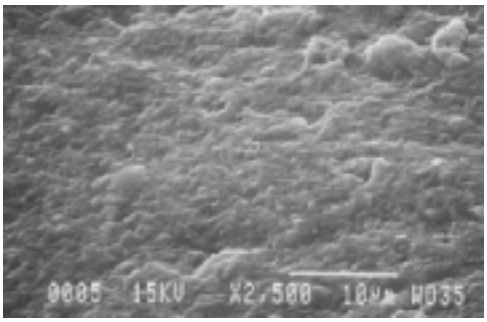


The SEM of the surface of Tetric Ceram after wear abrasion shows evidence of the largest particles. The surface is very rough. There is some evidence of pits (loss of filler particles) and some areas appear as if flaking occurred.

Prodigy

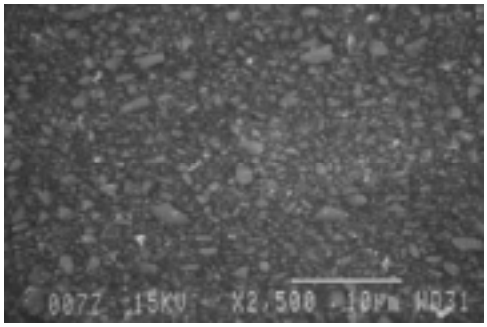


The filler particles in Prodigy™ are irregular and jagged. This is indicative of a ground glass filler. The average particle size is claimed to be 0.6µm.

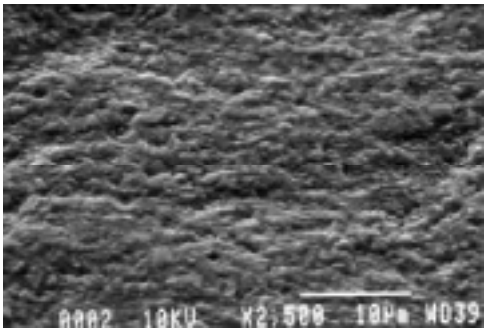


The surface of Prodigy after wear wheel abrasion appears rough. Although it does appear somewhat smoother than the Z100 restorative sample.

Herculite XRV

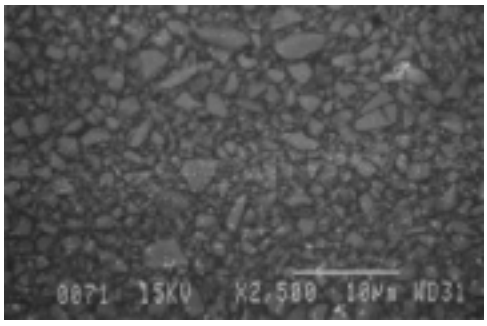


The filler particles in Herculite XRV™ appear very similar to Prodigy in both shape and size. The average particle size is claimed to be 0.6µm also.

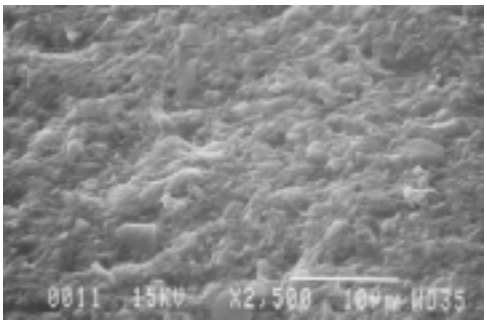


It is apparent in this SEM of Herculite XRV that the resin system can contribute to the surface smoothness after abrasive wear. The surface of Herculite XRV is very rough and irregular.

TPH Spectrum



The filler in TPH™ and TPH Spectrum™ contains some relatively large particles. The jagged and irregular shapes indicate the filler is simply ground glass. Many of the particles are 5µm.



The SEM of TPH Spectrum after abrasive wear demonstrates one of the effects of the large particles in a composite. The rough surface exhibits pits and craters which could be caused by loss of large particles.

Technique Comparison

A comparison of the time to cure an increment for each material is provided below.

Material	Shades	Increment Depth (mm)	Cure Time (sec)
3M™ Filtek™ Z250 Restorative	A1, A2, A3, A3.5, A4 B1, B2, B3, C2, C3 D3, I	2.5	20
	B0.5, C4, UD	2.0	30
3M™ Z100™ Restorative	A1, A2, A3, A3.5 B2, B3, C2, C4, D3, P, I	2.5	40
	A4, CY, CG, UD	2.0	40
Charisma®	A10, A20, A30, A35, B20, B30, C20, BO, YO, I	2.0 [1]	20
Herculite XRV™	All Shades	2.0 3.0	20 30
Prodigy™	A1, A2, A3, B1, B2, C2, D2, D3, I, UO	2.0	40
TPH Spectrum™	A2, A3, A3.5, B2, B3, C2	3.0 [2] 4.0	20 40
	B1	3.5 5.5	20 40
	C4	2.5 3.5	20 40
Tetric Ceram™	A1, A2, A3, A3.5, A4, B2, B3, C3, D3, T 105, 540	2.0	40
	B2 Opaque, A3.5 Opaque, A4 Opaque	1.5	40

[1] The product instructions state “It is general not recommended to cure Charisma beyond 2 mm layer thickness despite the fact that the syringe labels allow by far more curing depth.”

[2] Product instructions also provide cure times when curing through 1mm of enamel. Additionally, the instructions state to place the composite in increments 2mm or less in posterior Class I and II restoration.

The time to cure a 5mm depth (in numerous increments) can vary from 40 seconds (2 increments of many of the materials) to 160 seconds (Tetric Ceram, opaque or dentin shades, 4 increments).

Material	Shades	Number of Increments to Cure 5mm of Composite	Approximate Time to Cure 5mm of Composite
3M™ Filtek™ Z250 Restorative	A1, A2, A3, A3.5, A4 B1, B2, B3, C2, C3 D3, I	2	40
	B0.5, C4, UD	3	90
3M™ Z100™ Restorative	A1, A2, A3, A3.5 B2, B3, C2, C4, D3, P, I	2	80
	A4, CY, CG, UD	3	120
Charisma®	A10, A20, A30, A35, B20, B30, C20, BO, YO, I	3	60
Herculite XRV™	All shades	2	60
Prodigy™	A1, A2, A3, B1, B2, C2, D2, D3, I, UO	3	120
TPH Spectrum™	A2, A3, A3.5,B2, B3, C2 B1, C4	3[1]	60
Tetric Ceram™	A1, A2, A3, A3.5, A4, B2, B3, C3, D3, T 105, 540	3	120
	B2 Opaque, A3.5 Opaque, A4 Opaque	4	160

[1] As more posterior than anterior restorations could be 5mm deep, the instructions for posterior restorations were used.

Questions and Answers

Does the shorter cure time for 3M™ Filtek™ Z250 Restorative affect the operatory light stability?

No. As with any composite, care must be taken to minimize exposure to operatory light during placement.

How is it that 2.5mm increments (for most shades) of Filtek Z250 restorative can be cured in 20 seconds instead of 40 seconds like with 3M™ Z100™ Restorative?

The new resin system with the higher molecular weight materials yield fewer double bonds to crosslink so the resin cures more efficiently. In addition, the cure depths and times for Z100 restorative were conservative.

Instructions For Use

3M™ Filtek™ Z250 Restorative

General

3M™ Filtek™ Z250 restorative material is a visible-light activated, radiopaque, restorative composite. It is designed for use in both anterior and posterior restorations. The filler in Filtek Z250 restorative is zirconia/silica. The inorganic filler loading is 60% by volume (without silane treatment) with a particle size range of 0.01 to 3.5 microns. Filtek Z250 restorative contains BIS-GMA, UDMA and BIS-EMA resins. A 3M dental adhesive is used to permanently bond the restoration to the tooth structure. The restorative is available in a variety of shades. It is packaged in traditional syringes and single-dose capsules.

Indications

Filtek Z250 restorative is indicated for use in:

Direct anterior and posterior restorations

Core Build-ups

Splinting

Indirect restorations including inlays, onlays and veneers

Precautions

Filtek Z250 restorative contains methacrylates A small percentage of the population is known to have an allergic response to acrylate resins. To reduce the risk of allergic response, minimize exposure to these materials. In particular, exposure to uncured resin should be avoided. **Use of protective gloves and a no-touch technique is recommended.** If restorative material contacts skin, wash immediately with soap and water. Acrylates may penetrate commonly used gloves. If restorative contacts glove, remove and discard glove, wash hands immediately with soap and water and then reglove. If accidental contact with eyes or prolonged contact with oral soft tissues occurs, flush immediately with large amounts of water.

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. 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 effected 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 Class 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 3M™ Vitrebond™ Light Cure Glass Ionomer Liner/Base. 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 etching, priming, adhesive application and curing.

E. Dispensing the Composite: Follow the directions corresponding to the dispensing system chosen.

1. Syringe:

   a) 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.

   b) Place restorative into the cavity using a nonmetallic placement instrument.

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

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: 3M™ Filtek™ Z250 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 curing light. Hold the light guide tip as close to the restorative as possible during light exposure. The recommended exposure time and maximum increment thickness for each shade is shown below.

Shade	Thickness	Exposure Time
A1, A2, A3, A3.5, A4, B1, B2, B3 C2, C3 D3, I	2.5mm	20 seconds
B0.5, C4, UD	2.0mm	30 seconds

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

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. Polishing: Polish with 3M Sof-Lex Finishing and Polishing System and with white stones or rubber points where discs are not suitable.

III. Indirect Procedure For Inlays, Onlays Or Veneers

A. Dental Operatory Procedure

1. Shade selection: Choose the appropriate shade(s) of Filtek Z250 restorative prior to isolation. If the restoration is of sufficient depth, use of an opaque shade is recommended. Use of an Incisal shade on the occlusal surface will help to achieve esthetic appearance.
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 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 to 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 being used.*
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 incisal 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 incisal 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, then polish.

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 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.

V. Warranty

3M will replace product that is proven to be defective**. 3M does not accept liability for any loss or damage, direct or consequential, arising out of the use or the inability to use these products.** Before using, the user shall determine the suitability of the product for its intended use and user assumes all risk and liability whatsoever in connection therewith.

Trademarks Cited

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