RelyX[™] Veneer

Cement System







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System Features

3M[™] ESPE[™] RelyX[™] Veneer Cement 3M[™] ESPE[™] RelyX[™] Try-In Paste

- Light-cure only system for veneer cementation
- · High efficiency light curing
- Excellent color stability
- Excellent color matching between the try-in pastes and the cured cement
- Simple shading system
 - Translucent
 - B0.5/White
 - White Opaque
 - A1/Light Yellow
 - A3 Opaque/Yellow Opaque
 - A5/Dark
- Excellent handling properties
 - Easy dispensing
 - Easy seating
 - Easy clean-up
- Water soluble try-in pastes

System Description

RelyX Veneer cement system consists of RelyX Veneer cement and RelyX Try-In paste. The system is indicated for the permanent cementation of ceramic or composite veneers. The system is intended to be used in combination with RelyX Ceramic Primer and Single Bond Dental Adhesive System or Scotchbond™ Multi-Purpose Dental Adhesive System.

RelyX Veneer cement is a permanent, light-cure only resin luting material. It must be polymerized by exposure to visible light in the 400-500 nm wavelength range. Most ceramic and composite veneers are thin enough and translucent enough to allow for adequate light penetration through the veneer to completely cure the cement. RelyX veneer cement is very efficient in its light-curing ability. This allows for a simplified bonding technique and also provides for excellent color stability of the cured cement. This feature is vitally important for highly esthetic veneer restorations.

RelyX[™] Veneer Cement is available in 6 shades. The esthetic properties, shading and opacity, were determined through extensive dentist and laboratory input. The shades are described in both a Vita[™] reference and a color reference based on clinician preference for desired shade description. The Vita references are close approximations to standard references. They may vary slightly in opacity due to the unique shading needs for modifying veneers. The available shades are listed below.

- Translucent
- B0.5/White
- White Opaque
- A1/Light Yellow
- A3 Opaque/Yellow Opaque
- A5/Dark

The Translucent shade will be used most often especially when the proper communication has been established between the clinician and the lab. In these cases, the veneer provides for the desired esthetics where color shifting is not necessary. If masking or shade adjustment is required, the remaining 5 shades are available. The white shades are used when adjustments are required to lighten or brighten the final esthetic result. The yellow and dark shades are used when adjustments are required to darken, increase the chroma or change the hue of the final esthetic result. All shades have a 30-second cure time with a standard halogen light except for the A5/Dark shade which requires a 40-second cure. RelyX Veneer cement is packaged in a tapered 3.0 gram syringe that allows for direct placement of the cement onto the veneer.

RelyX Veneer cement offers high physical strength, radiopacity, high wear resistance, high adhesive strengths, low film thickness and complies with the ISO 4049:2000 standard for resin based luting cements.

RelyX Veneer cement provides improved handling properties. RelyX Veneer cement was formulated through clinician input to determine the appropriate viscosity properties that would provide for an easy to dispense, easy to seat (without drift), easy to clean-up and an overall easy to use cement.

RelyX[™] Try-In Pastes are used to guide the dentist in the selection of the shade required for the final cementation with RelyX Veneer cement. The shades of RelyX Try-In paste are specifically formulated to match the final cured shade of RelyX Veneer cement. This is a critical feature to ensure that the expected final desired esthetics are obtained.

Historically, many systems have not provided for adequate shade matching between the tryin pastes and their corresponding cured cement shades which may result in inadequate final results.

RelyX Try-In paste is water soluble for easy clean up and removal from the tooth and veneer surface without residue. The primary component of RelyX Try-In paste is polyethylene glycol resin (PEG). Polyethylene glycol offers complete water solubility and the ability to formulate the handling and shading properties needed in the try-in paste.

RelyX Try-In paste is available in the same 6 shades as the RelyX Veneer cement. RelyX Try-In paste is packaged in a tapered 2.0 gram syringe that allows for easy and direct placement of the paste onto the veneer.

Composition

3M™ ESPE™ RelyX™ Veneer Cement

RelyX Veneer cement is a light-cure, methacrylate resin-based luting material. RelyX Veneer cement is a single component, light-cure material packaged in a single syringe. The resin is composed of bisphenol-A-diglycidylether dimethacrylate (BisGMA) and triethylene glycol dimethacrylate (TEGDMA) polymer. Zirconia/silica and fumed silica fillers are used to impart radiopacity, wear resistance and physical strength. The filler loading is approximately 66% by weight. The average particle size for the filler is approximately 0.6 mm.

RelyX Veneer cement contains a dimethacrylate polymer that modifies the rheology of the material and provides a unique handling characteristic allowing the cement to flow easily under pressure, but hold its shape and stay in place until light-cured.

RelyX Veneer cement also contains pigments and a, high efficiency photoinitiator system. The photoinitiator will allow for light-curing when exposed to visible blue light in the 400-500 nanometer range with a minimum light output of 400mW/cm².

3M™ ESPE™ RelyX™ Try-In Paste

RelyX Try-In paste is a water-soluble material used to guide the dentist in the selection of the shade required for the final cementation with RelyX Veneer cement. RelyX Try-In paste is not polymerizable and cannot be used to cement the final restoration.

RelyX Try-In paste contains polyethylene glycol (PEG), a water-soluble resin which allows for easy water clean-up from the tooth and veneer. Zirconia/silica filler is used at an approximate 10% loading by weight to modify the handling and shading properties. Pigments are also added to allow for proper shading.

3M[™] ESPE[™] Single Bond Dental Adhesive System

Single Bond dental adhesive system consists of Single Bond adhesive and 3M[™] ESPE[™] Scotchbond[™] Etchant. Scotchbond etchant is a 35% by weight phosphoric acid gel with a pH of about 0.6. Its purpose is to etch dentin and enamel and to clean the surface of the veneer prior to applying the ceramic primer.

Single Bond dental adhesive is a one-bottle adhesive containing ethanol, 2-hydroxyethyl methacrylate (HEMA), BisGMA, other dimethacrylate resins, methacrylate-modified polycarboxylic acid copolymer, a small amount of water and a photoinitiator system.

3M™ ESPE™ RelyX™ Ceramic Primer

RelyX Ceramic primer is a stable solution of a prehydrolyzed silane-coupling agent, alcohol and water. RelyX Ceramic primer is specifically designed to enhance the chemical bond to porcelain and ceramics. The primer should be applied to the bonding surfaces of the indirect veneer restorations to be cemented with RelyX Veneer cement.

Property Overview

Shade Matching

It is vitally important that the shades of the try-in paste match the final cured cement shades to ensure that the desired esthetic results are obtained. To determine how well the try-in pastes match the cured cement, samples for each were prepared and analyzed for color. The color analysis was performed on a Hunter UltraScan XE color analyzer. The results for the two materials can then be compared and an overall color difference (Δ E*) determined between the two materials. A color difference or Δ E* of 3 units or less is not considered significant. Therefore samples with a Δ E* of 3 units or less are considered to have a good color match. Samples that have a Δ E* of greater than 3 units will have a noticeable difference.

Discs, one mm thick, of the cement and try-in paste were prepared and the cements lightcured per the manufacturer's recommendations. Color analysis was done immediately with no aging or water storage. The color differences between the try-in paste and cured cement are shown in Figures 1-4 for various veneer bonding systems.

Figure 1. 3M™ ESPE™ RelyX™ Veneer Cement System

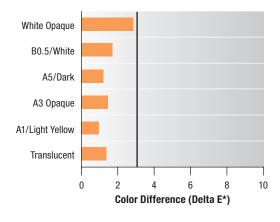
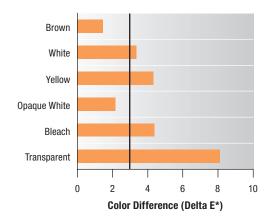


Figure 2. Variolink® II System



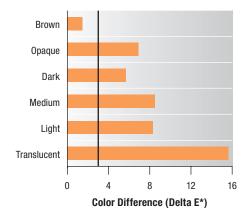


Figure 3. Calibra™ System

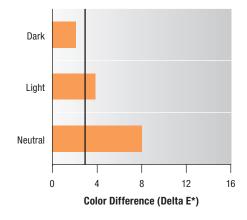


Figure 4. Nexus™ System

Color analysis results show excellent color matching capabilities between the RelyX[™] Veneer Cement and the RelyX[™] Try-In Pastes.

Color Stability

Color stability of the cured cement is necessary to maintain the esthetic results of the veneer restoration. If the cured cement changes color over time after the veneer is seated, it can significantly impact the outward shade of the veneer resulting in an unacceptable restoration. The only course of action is to cut the veneer off of the tooth and start over with the restoration. This is a costly procedure. The light-cure only chemistry of the RelyX Veneer cement will provide for a color stable restoration.

The translucent, clear, neutral or transparent shades of various cement systems were tested for color stability. Studies were done both in the 3M ESPE laboratory in St Paul, MN and at the Houston Biomaterials Research Center, University of Texas-Houston Dental Branch by Dr. R.M. Fay and Dr. J.M. Powers. This study was sponsored by 3M ESPE. The 3M ESPE studies were conducted under the guidelines of the ISO 4049:2000 standard. Discs, one mm thick, of the cement were prepared, cured and analyzed using the Hunter Color Analyzer and recorded as the reference color. The discs were stored in both dry conditions and in water at 37°C. The samples were then tested at various time intervals to determine the level of color change for each sample when compared to the initial reference value. As with the color matching data, the overall color difference between the aged sample and the reference is measured as ΔE^* . Samples with a ΔE^* greater than 3 units will have a noticeable color change. The larger the ΔE^* between samples, the greater the color difference will be. The color change over time for each sample is shown in Figures 5-7.

Figure 5. 3M™ ESPE™ RelyX™ Veneer Cement and Variolink® II

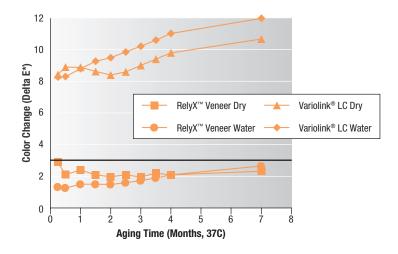


Figure 6. 3M™ ESPE™ RelyX™ Veneer Cement and Calibra™

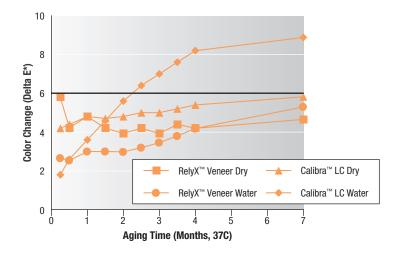
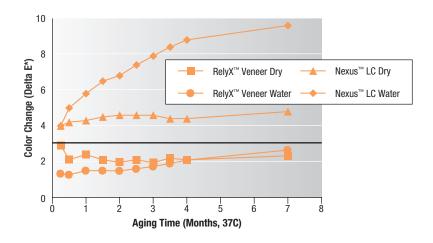


Figure 7. 3M™ ESPE™ RelyX™ Veneer Cement and Nexus™



The study at the University of Texas at Houston[†] varied slightly in methodology from the 3M ESPE study. Discs were prepared, cured and analyzed for reference color in a similar manner. The discs were then split into two groups. The first group was stored in water at 37° C for 1 week. The second group was subjected to accelerated aging conditions by exposing the samples to a light source ($150KJ/m^2$) for 1 week. The samples were then retested for color and the ΔE^* color difference was recorded for each sample and compared to the reference value. The products tested are abbreviated in the graphs as VII (Variolink® II), CB (Calibra[™]), and NX (Nexus[™]). The cements were cured by light exposure (LC) or by self cure (DC). The color change for each sample is shown in Figure 8.

[†]Journal of Dental Research, Vol. 80, January 2001, Abstract #255

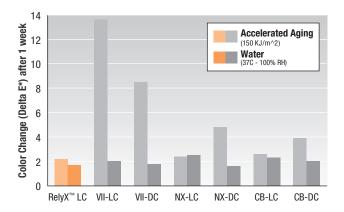


Figure 8. Color Change Accelerated Aging

The results of both color stability studies show that the $RelyX^{TM}$ Veneer Cement has excellent color stability over time and under accelerated aging conditions.

Curing Efficiency

Curing efficiency is important for a veneer cement because curing the cement requires light-curing through the veneer. The light intensity that reaches the cement can be greatly compromised depending on the thickness and shade of the veneer and also depending on the actual light output of the curing light. There are a wide variety of curing lights currently being used by clinicians with varying outputs. To obtain the desired physical properties upon curing, it is recommended that the minimum light output for a curing light is 400 mW/cm² in the wavelength range of 400-500nm.

The light-cure efficiency for various cement systems was measured using the translucent, clear, neutral or transparent shades. Two curing lights were used for the study, a lower power (451 mW/cm²) 3M™ Visilux™ II Curing Light and a high power (>2,000 mW/cm²) DMD™ Apollo™ 95E. The cements were cured at a 1mm thickness directly under the curing light and after filtering through simulated porcelain veneers (1.00 mm thick, Vintage Porcelain Body A2). Cure efficiency was determined by varying the exposure time and then sampling the Barcol hardness of a cement slab. The estimated time to achieve full cure was determined to be the light exposure time necessary to achieve Barcol hardness readings on top and bottom that differ by 1 unit or less. Table 1 shows the required exposure times to achieve full cure of the cement with the two light sources and with either a direct or filtered exposure.

	RelyX™ Veneer Cement	Variolink® II	Calibra™	Nexus™
Visilux II, no Filter	20	20	40	>40
Visilux II, A2 Filter	20	20	60	>50
Apollo 95E, no Filter	3	3	>9	>9
Apollo 95E, A2 Filter	9	9	ND ^{††}	ND ^{††}

Table 1. Required Exposure Times to Fully Cure

^{††}ND – Not determined, did not cure within 9 second test interval

Achieving complete cure of RelyX[™] Veneer Cement and Variolink[®] II cement with the lower output from the Visilux[™] II Curing Light and an A2 filter required only 20 seconds exposure while the Calibra[™] cement required 60 sec exposure and the Nexus[™] cement required >50 seconds. Using the Apollo 95E and direct exposure, the RelyX Veneer and Variolink II cements cured in 3 seconds directly and 9 seconds when filtered, while the Calibra and Nexus cements did not cure under either condition after the 9 second exposure. RelyX Veneer cement has a very efficient cure with a variety of light sources.

Physical Property Testing

RelyX Veneer cement was tested per the ISO 4049:2000 guidelines for resin based luting materials. The results for the testing are shown in Table 2.

	ISO Spec Limits	RelyX Veneer Cement
Film Thickness	50 µm maximum	5-10 μm
Flexural Strength	50 Mpa minimum	123 Mpa
Color Stability	Pass/Fail	Pass
Solubility	7.5 µg/mm³ maximum	0.3 μg/mm³
Water Sorption	40 μg/mm³ maximum	29 μg/mm³
Radiopacity	Pass/Fail	Pass
Sensitivity to Ambient Light	Pass/Fail	Pass
Depth of Cure	1.0 - 1.5 mm minimum	3.0 mm

RelyX Veneer cement meets the requirements per the ISO 4049:2000 standard.

Table 3 shows results for other physical properties such as compressive and diametral tensile strength, shear bond strength to dentin and enamel, wear resistance and film thickness. The bond strength testing was performed with the adhesive systems provided with the cement system.

	RelyX [™] Veneer Cement	Variolink® II	Calibra™	Nexus™
Bond Strength (24 Hour – MI	Pa)			
Ceramco Finesse™ All-Cera	amic Porcelain to enamel			
	28.6 (10.3)	26.8 (4.7)	14.5 (4.3)	11.4 (4.9)
Ceramco Finesse [™] All-Ceramic Porcelain to dentin				
	26.6 (10.4)	21.7 (11.8)	7.9 (5.8)	11.1 (1.7)
Compressive Strength (24 Hour MPa)	345.7 (20.0)	352.4 (13.7)	315.9 (22.1)	279.2 (26.8)
Diametral Tensile Strength (24 Hour MPa)	77.6 (4.0)	54.2 (2.9)	40.4 (4.6)	56.3 (5.1)
Wear Rate (μm/10,000 cycles)	1.0 (0.5)	0.9 (0.2)	1.30 (1.39)	0.97 (0.05)
Film Thickness (µm)	8.7 (1.6)	29.6 (3.8)	12.2 (4.9)	19.7 (3.1)

Table 2. ISO 4049:2000 Testing Results

Table 3.
Physical Properties of 3M™ ESPE™ RelyX™ Veneer Cement

Field Evaluation Results

A field evaluation was conducted in the United States to evaluate the clinical performance of RelyX[™] Veneer Cement and RelyX[™] Try-In Pastes. Dentists were asked to use the system to place veneers and then evaluate and rate the handling, shades, shade matching and overall esthetic results. The results were compiled from responses from 59 dentists with approximately 784 veneers placed.

1. Product use % of evaluators.

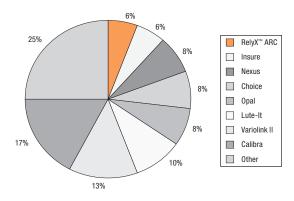


Figure 9.

2. Rate your level of satisfaction for the RelyX Veneer cement handling properties.

70-83% were satisfied to very satisfied with the handling properties.

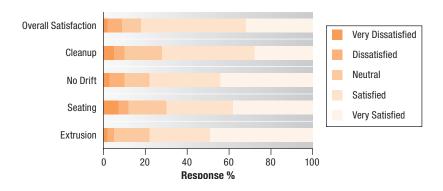


Figure 10.

3. Compare the handling properties of the RelyX Veneer cement to those of your existing product.

68-75% rated the properties as better-much better when compared to their current system.

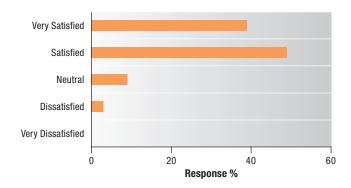
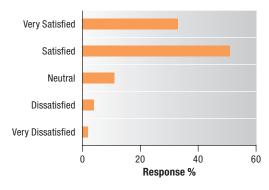


Figure 11.

4. Rate the translucent shade of RelyX™ Veneer Cement.

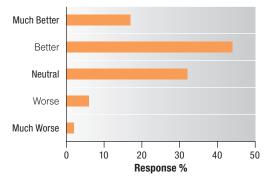
Figure 12.



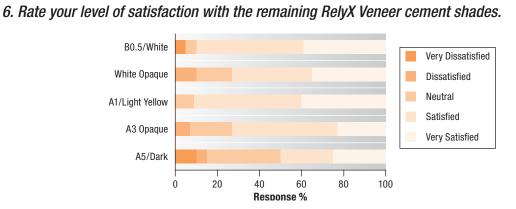
84% were satisfied-very satisfied with the translucent shade of the cement.

5. Compare the translucent shade of RelyX Veneer cement to that of your existing product.

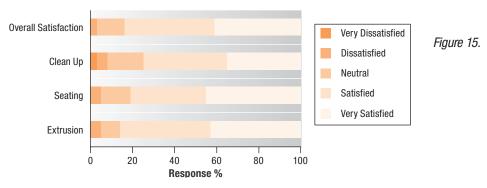
Figure 13.



61% rated the translucent shade as better-much better compared to their current cement.

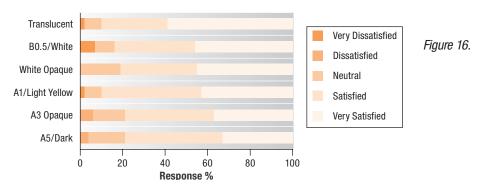


7. Rate your level of satisfaction for the following RelyX™ Try-In Paste handling properties.



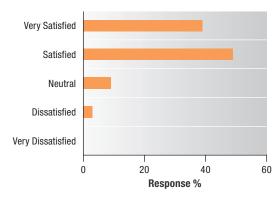
75-85% were satisfied-very satisfied with the try-in paste handling properties.

8. Rate your level of satisfaction with the color matching of the RelyX Try-In pastes to the cured cement.



80-90% were satisfied-very satisfied with the color matching properties of the system.

9. Rate how satisfied you are with the overall esthetic results of the RelyX system.

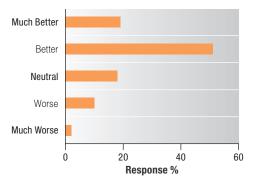


88% were satisfied-very satisfied with the overall esthetics of the system.

Figure 17.

10. Rate how the overall RelyX™ Veneer Cement System compares to your current cement system.

Figure 18.



70% rated the overall cement system as better-much better when compared to their current system.

Questions and Answers

Q Can the Single Bond Dental Adhesive be cured on the tooth surface prior to seating the veneer?

Yes, Single Bond dental adhesive has a low cured film thickness of approximately 10-15 microns and therefore can be placed and cured on the tooth without interfering with the proper seating of the veneer. This is how the Single Bond dental adhesive is recommended to be used with RelyX™ ARC Adhesive Resin Cement. However, it is not necessary to cure the Single Bond adhesive if the clinician is concerned with a potential fit problem. The adhesion studies were performed without curing the Single Bond adhesive layer on the tooth with very good results to both enamel and dentin. If the Single Bond adhesive layer is cured prior to seating, care should be taken to avoid any pooling of the adhesive prior to light curing.

Does RelyX Veneer cement have a catalyst to allow it to self-cure?

No, RelyX Veneer cement is a light-cure only system. It cannot be mixed with a separate catalyst to allow it to self cure.

Ocan RelyX Veneer cement be cured with high powered lights?

Yes, RelyX Veneer cement is very efficient in its curing ability with a variety of light sources.

If a high intensity light such as the DMD™ Apollo™ 95E light be used, it is recommended to use a 9 second exposure per area of cure. The light must have the correct output in the 400-500nm wavelength range. Please check with the manufacture for the specific details when using other curing lights.

Do the shades of RelyX[™] Veneer Cement correlate to the existing 3M[™] Opal[™] Luting Composite shades?

The shades of the RelyX Veneer cement are modified versions of the Opal luting composite shades. Although there is not a direct correlation there is a close approximation.

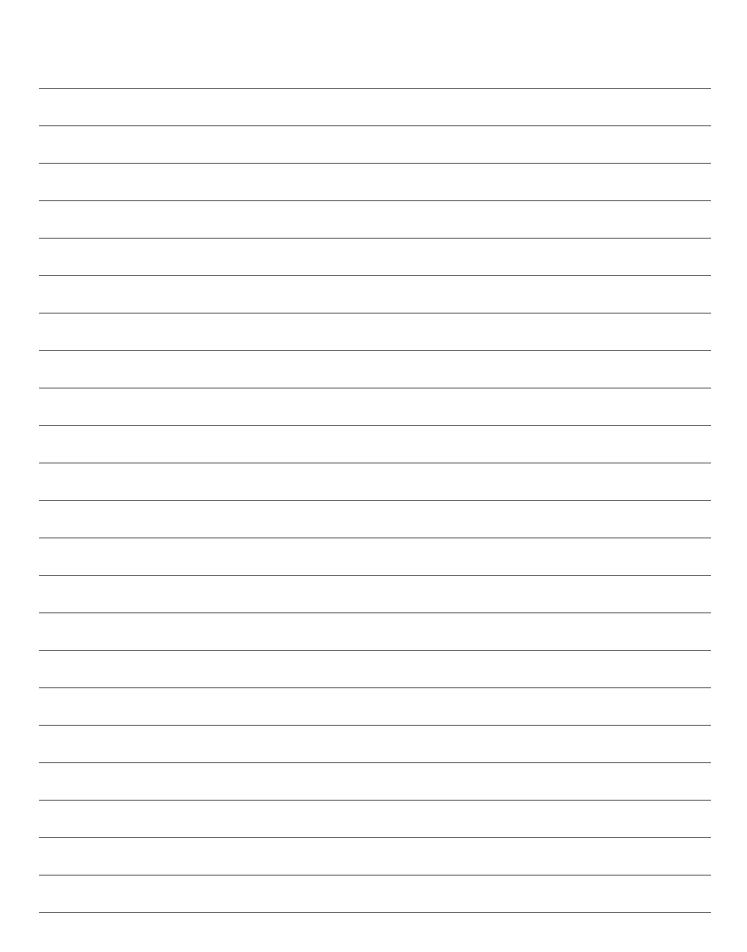
RelyX™ Veneer Cement	Opal Luting Composite
Translucent	Clear
B0.5/White	Similar to Low Opacity-Cool
White Opaque	Similar to a Medium-High Opacity Cool
A1/Light Yellow	Similar to Low Opacity-Warm
A3 Opaque/Yellow Opaque	Similar to Medium-High Opacity-Warm

Does the viscosity of RelyX Veneer cement differ substantially to the Opal Luting composite?

Yes, Opal luting composite is substantially thicker than RelyX Veneer cement. RelyX Veneer cement was specifically formulated to allow for easy dispensing and seating of the veneer without the risk of fracture and to allow the veneer to be seated completely to the margins. The unique "non-slumping" nature of RelyX Veneer cement allows the veneers to be placed easily but without concern about the veneers drifting or slumping. The non-slump feature of the high viscosity Opal luting composite was a desired property.

Can the RelyX Veneer cement be used with Prompt™ L-Pop™ Adhesive?

No, at this time Prompt L-Pop adhesive is not indicated for use to cement indirect restorations.





Dental Products

3M Center Building 275-2SE-03 St. Paul, MN 55144-1000 U.S.A. 1-800-634-2249

3M Canada

Post Office Box 5757 London, Ontario N6A 4T1 Canada 1-888-363-3685

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