3M ESPE

Adper™ Single Bond Plus Adhesive



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Introduction

Product Description

Adper[™] Single Bond *Plus* Adhesive, based on the clinically proven Adper[™] Single Bond Adhesive is a total etch, visible-light activated dental bonding agent incorporating 10 percent by weight of 5nm diameter silica filler. As with the original Adper Single Bond Adhesive, Adper Single Bond *Plus* adhesive is indicated for direct light-cured restorative material as well as for the treatment of cervical sensitivity. Adper Single Bond *Plus* Adhesive may also be used for bonding laboratory fabricated composite or porcelain veneers when used with RelyX[™] Veneer Cement and for bonding amalgam and other indirect applications when used with RelyX[™] ARC adhesive resin cement.

Adper Single Bond *Plus* Adhesive is available in either a vial or unit dose. The vial incorporates a "pinch & flip" cap design that minimizes the messiness associated with typical threaded caps. Unlike the standard black, opaque vial used by manufacturers to shield the photoinitiator from all ambient light, the Adper Single Bond *Plus* vial was designed to shield predominantly the visible light absorbed by the photoinitiator. This design allows for a unique translucent vial that permits visual inspection of the contents.

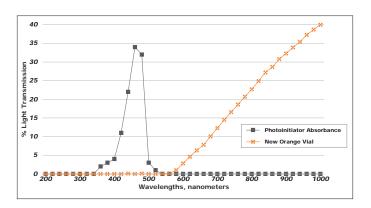




Figure 1. Selective light absorption of Adper Single Bond Plus vial.

Adper Single Bond *Plus* Adhesive is also offered in a convenient and hygienic unit dose delivery system. Simply pressing the single chambered foil package advances adhesive to the self-contained applicator.



Adper Single Bond Plus Adhesive Unit Dose Delivery System

Source: 3M ESPE Laboratory test data

Composition

Adper™ Single Bond *Plus* Adhesive

With the exception of the silica nanofiller, Adper Single Bond *Plus* adhesive contains the same components as the original Adper Single Bond adhesive: BisGMA, HEMA, dimethacrylates, ethanol, water, a novel photoinitiator system and a methacrylate functional copolymer of polyacrylic and polyitaconic acids (see structure in figure 2) first introduced in Vitrebond™ Glass Ionomer liner/base and also utilized in Adper™ Scotchbond™ Multi-Purpose Adhesive, RelyX™ Luting Plus Cement and Vitremer™ Core/Restorative. Incorporation of the polyalkenoic acid into the Adper™ Scotchbond™ Multi-Purpose primer has been shown to aid in resisting the detrimental effect of moisture in an elevated relative humidity environment (Fundingsland et al. 1992). The patented photoinitiator system allows for a fast 10-second light cure. The cure time may be reduced to 5 seconds when using the Elipar™ FreeLight 2 LED Curing Light.

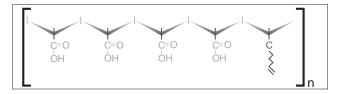


Figure 2. Vitrebond polyalkenoic acid copolymer

Nanotechnology in Adper Single Bond *Plus* Adhesive

Adper Single Bond *Plus* adhesive incorporates 10% by weight of 5 nanometer-diameter spherical silica particles. These silane treated particles are incorporated into the adhesive through a process that prevents agglomeration. As discrete particles, their extremely small size keeps them in colloidal suspension. This means you never have to shake Adper Single Bond *Plus* adhesive prior to using. In contrast, larger filler particles incorporated into some adhesives are at risk of settling out of solution. Such adhesives require routine shaking before use.

Figure 3 demonstrates this difference in suspension stability between the nanoparticles in Adper Single Bond *Plus* adhesive and the much larger particles averaging 0.4 microns in diameter in Optibond Solo Plus[™] adhesive (filled 15% by weight).

Approximately four grams of each adhesive was dispensed into separate glass vials and tightly capped: Optibond Solo Plus adhesive was vigorously shaken for 10 seconds prior to disensing. Within one week of observation, a phase separation in Optibond Solo Plus adhesive became evident. This separation progressed to that shown in Figure 3, which shows Optibond Solo Plus adhesive after storing undisturbed for approximately 4 months. Conversely, the vial containing Adper Single Bond *Plus* adhesive shows no separation after storing undisturbed for approximately 10 months.



Figure 3. (I) Nanofiller in Adper^M Single Bond Plus Adhesive remains in solution; (r) filler in Optibond Solo PlusTM does not.

3M ESPE Scotchbond™ Etchant

Prior to applying Adper Single Bond *Plus* adhesive, enamel and dentin require a separate etch with phosphoric acid. Scotchbond etchant superficially demineralizes the enamel and dentin in preparation for bonding. The etchant is 35% phosphoric acid by weight. Use of an etchant is critical on both enamel and dentinal surfaces. The phosphoric acid etchant has a pH of approximately 0.6. The phosphoric acid gel etchant is thickened to a high viscosity with



fumed silica and a water soluble surfactant. The surfactant enables the etchant to be rinsed away more easily.

3M ESPE RelyX™ Ceramic Primer

RelyX Ceramic Primer is a prehydrolyzed, single-phase silane specifically designed to enhance the bond to ceramic surfaces. Test results have also suggested some benefit of application to metals. Previous testing also suggests that RelyX Ceramic Primer has three years of shelf-life stability. The ceramic primer is required for indirect bonding applications such as porcelain veneers, crown and bridge, inlay/onlays and for porcelain repair.



Indications for Use

3M[™] ESPE[™] Adper[™] Single Bond *Plus* Adhesive is indicated for use in the following types of restorations.

- Direct light-cured composite/compomer restorations
- · Root surface desensitization
- Porcelain/composite repair
- Porcelain veneers (when used with RelyX™ Veneer Cement)
- Crown & bridge, inlay/onlay, bonding amalgam (when used with RelyX[™] ARC Adhesive Resin Cement)

Background

Modern adhesives for bonding restorative materials to tooth structure encompass a range of strategies. Currently, a popular strategy in adhesive dentistry involves the total etch, single solution adhesive (also known as fifth generation adhesive). The original Single Bond Adhesive, introduced in 1997, offered the dental profession the performance of a multi-bottle system in an easy to use, time saving single bottle system. With the introduction of RelyX™ ARC Resin Cement in 1998, Single Bond adhesive expanded its versatility to include bonding amalgam and cementation of laboratory fabricated restorations. The Single Bond adhesive ease of use philosophy was realized with RelyX ARC resin cement as no additional bottles containing accelerants are needed. In 2001, a complementary cement, RelyX™ Veneer Cement, was introduced specifically for use with Single Bond adhesive, once again, expanding the versatility of this adhesive.

Adper™ Single Bond *Plus* Adhesive offers all the features and benefits of the clinically proven Adper Single Bond adhesive and introduces new nanofiller technology and the convenience of a unique unit dose delivery.

Bonding Mechanism

Current dental adhesives rely on a micromechanical bond for adhesion to enamel and dentin. With total etch adhesives the mineral phase of enamel and dentin (hydroxyapatite) is superficially demineralized by an acidic agent in a separate step prior to application of the adhesive. The acid used is typically a gelled phosphoric acid with a concentration of approximately 35%.

On enamel, acid etching greatly increases the surface area available for bonding. Low viscosity, polymerizable resins penetrate the porosities revealed by the etching procedure forming an interlocking mechanical bond after curing. These interlocking "resin tags" can be seen in Figure 4 which shows a cross-section of the enamel/adhesive bond interface produced with Adper Single Bond *Plus* adhesive.

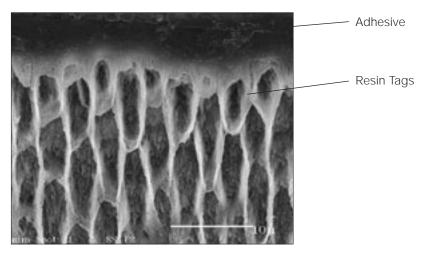


Figure 4. Scanning electron photomicrograph of Adper™ Single Bond Plus Adhesive bond to enamel. Enamel has been partially dissolved during microscopy specimen preparation to reveal "resin tags" penetrating into etched enamel. (image from Patricia N.R. Pereira).

A similar process involving dissolution of the mineral phase and an interlocking adhesive layer occurs when bonding to dentin. A 15 second etch of prepared dentin completely dissolves the smear layer and removes the mineral phase to a depth of around 5 microns. A collagen, or protein phase, resistant to acid dissolution is present at the surface after washing off the etchant. Penetration of the adhesive into this collagenous phase and its subsequent polymerization provides an interlocking layer commonly referred to as the "hybrid layer." The dentinal hybrid layer is revealed in a scanning electron micrograph in Figure 5 for Adper™ Single Bond *Plus* Adhesive.

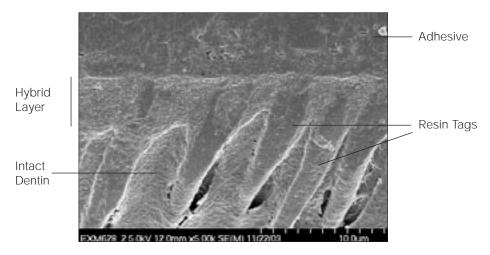


Figure 5. Scanning electron photomicrograph of Adper Single Bond Plus adhesive bond to dentin (image from J. Perdigo & M. Lopes, University of Minnesota).

Role of Inorganic Filler in Single Solution, Total-Etch Adhesives

To ensure optimum penetration of single solution adhesives into the collagen network, the adhesive resins are dissolved in a volatile solvent. After application, the solvent is evaporated with a stream of air leaving the adhesive layer ready for light curing. It has been suggested that the presence of filler in these relatively low viscosity adhesives helps develop a uniform adhesive film and "stabilizes" the hybrid layer (Inoue). This theory may be especially significant in instances where an overly aggressive drying technique is practiced.

The filler density in cured films of adhesives was explored by transmission electron microscopy (TEM) at 3M Laboratories. In these images, the electron dense areas (grey to black shaded areas) represent filler. It is readily observed that the cured film of Adper Single Bond *Plus* Adhesive (Figure 6) exhibits the greatest filler density of the four, total etch, single solution adhesives. Of interest is the relatively low filler density in the cured film of Excite® adhesive (Figure 7) and the lack of homogeneity in both filler density and particle size in Optibond Solo Plus™ adhesive (Figure 9). The bar in each image represents 100nm.

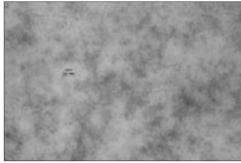


Figure 6. Adper™ Single Bond Plus adhesive.

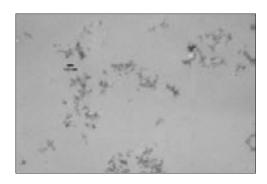


Figure 7. Excite® adhesive

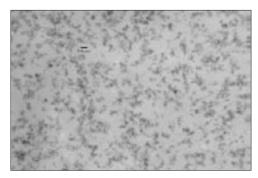


Figure 8. Prime & Bond® NT™ adhesive

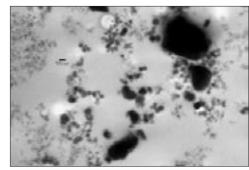


Figure 9. Optibond Solo Plus $^{\text{\tiny TM}}$ adhesive

Figure 10 represents a TEM photomicrograph of 3M[™] ESPE[™] Filtek[™] Flow Flowable Restorative bonded to dentin with Adper Single Bond *Plus* adhesive. The zirconia silica particles of Filtek Flow restorative, are readily observed in the uppermost layer. The homogeneous nanofilled layer of Adper[™] Single Bond *Plus* Adhesive is also observed. Below the adhesive layer is the "hybrid layer" consisting of interlocking collagen fibrils and cured resin. An adhesive resin tag can be seen bisecting the hybrid layer (circled). The resin tag has a similar electron density as the adhesive layer above indicating a continuous nanofiller concentration. At higher magnification, the particulate nanofiller within the resin tag is observed. It is also significant to note that the periphery of the tubules have been "hybridized" and that the hybrid layer extends the full depth of the demineralized zone. In other words, complete adaptation between the tooth and restorative material has been achieved. This result forms the foundation for a pain-free, long lasting restoration.

Photomicrograph of Adper™ Single Bond Plus Adhesive bond to dentin. Images from J. Perdigo & M. Lopes, University of Minnesota

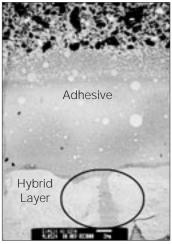


Fig. 10. Transmission electron

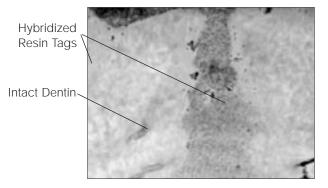


Fig 10b. Magnified area of Figure 10 showing penetration of nanofilled resin into dentinal tubule.

Physical Properties

Bond Strength Measurements

For this report, a number of test methodologies were used to explore the bond strength of Adper $^{\text{TM}}$ Single Bond Plus Adhesive to various dental substrates. Internal laboratory data was generated using two different shear test methodologies. The methods differ primarily in the diameter of the bonded sample and the configuration of the fixture that applies the shear force. The independent laboratory study presented was performed using a microtensile method. Due to differences in sample geometry and the applied force of these methods, different bond strengths are expected for similarly bonded substrates.

Enamel and Dentin Bond Strengths. Notched edge shear test.

The graph below depicts pooled results from a multi-user dentin bond strength test performed using a notched edge shear test. In this test Filtek™ Z250 Restorative buttons with a diameter of 2.38 microns were bonded to bovine dentin with Adper™ Single Bond Adhesive and Adper Single Bond *Plus* adhesive using their respective instructions (with Adper Single Bond *Plus* adhesive, two to three coats of adhesive are applied over 15 seconds; this is modified from Adper Single Bond adhesive which instructed two sequential coats). Each operator bonded 20 samples. Samples were stored in water at 37° C for 24 hours before testing. Three of the four operators obtained statistically higher bond strength with Adper Single Bond *Plus* adhesive, while for the other operator, the bonds strength of the two adhesives were equivalent. The pooled results for all operators revealed a p-value of 0.000.

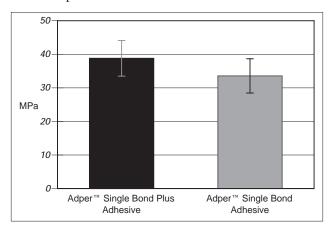


Figure 11. Pooled multi-user dentin bond strength (MPa)

The above results represent enhanced performance of Adper Single Bond *Plus* adhesive due to incorporation of nanofiller and the modified application instructions noted above.

To determine the effect of the incorporation of nanofiller alone under more rigorous conditions, two operators performed a similar study where the two adhesives were applied using the instructions for Adper Single Bond *Plus* adhesive. This study design negates the effect of the application protocol on the results. For this study, each operator bonded ten samples. To challenge the adhesive, an aggressive ten-second air dry of the adhesive was used prior to light-curing. The pooled results, shown in Figure 12, reveal that incorporation of nanofiller has resulted in significantly higher dentin bond strength (p=0.04).

Source: 3M ESPE Laboratory test data

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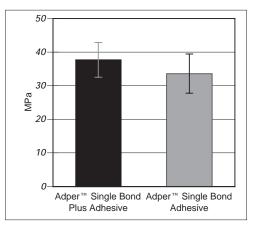


Figure 12. Dentin bond strengths—effect of filler.

Adper™ Single Bond *Plus* Adhesive was also tested for adhesion to various substrates using a wire loop shear method. In this method, an approximate 5mm diameter button is bonded to the substrate and a shear force is applied with a wire loop until failure. For the direct light-cure indications, Filtek™ Z250 Restorative paste is bonded to the substrate of interest—enamel, dentin, cured composite, porcelain or metal. The latter three substrates are relevant for composite or porcelain repair. To simulate indirect restorations, a porcelain or metal button is bonded to enamel or dentin using Adper Single Bond *Plus* adhesive and either RelyX™ ARC Resin Cement or RelyX™ Veneer Cement. In the case of RelyX ARC resin cement, the adhesive was cured prior to cementation as per instructions and the cement was allowed to self-cure. With RelyX veneer cement, the adhesive and cement are light-cured together. Results are shown in Table 1. Comparable bond strengths were found for Adper Single Bond *Plus* adhesive and Adper™ Single Bond Adhesive using this method.

Table 1. Shear bond strengths in MPa for direct and indirect indications (wire loop shear method).

	Adper [™] Single Bond Adper [™] Single	
	Plus Adhesive	Bond Adhesive
Direct indications		
Composite to enamel	29.7 ± 6.0	26.6 ± 3.3
Composite to dentin	28.9 ± 1.8	23.8 ± 5.1
Composite to composite (Z100™ Restorative)	20.5 ± 3.5	23.8 ± 1.7
Composite to porcelain	13.5 ± 5.2	15.6 ± 2.2
Composite to semi-metal	17.0 ± 3.8	21.9 ± 3.1
Indirect indications		
Porcelain to enamel with RelyX Veneer Cement	27.4 ± 8.1	30.9 ± 8.5
Porcelain to dentin with RelyX Veneer Cement	22.4 ± 5.2	22.6 ± 6.1
Porcelain to enamel with RelyX ARC (self-cure mode	e) 25.3 ± 3.9	19.3 ± 3.5
Porcelain to dentin with RelyX ARC (self-cure mode)	9.7 ± 2.1	13.1 ± 2.9
Metal to enamel with RelyX ARC (self-cure mode)	25.3 ± 5.3	25.3 ± 6.0
Metal to dentin with RelyX ARC (self-cure mode)	12.8 ± 3.4	13.4 ± 3.5

Independent Investigations

Microtensile Bond Strength

A microtensile bond strength experiment was performed at the University of Minnesota comparing Adper[™] Single Bond *Plus* Adhesive to Adper[™] Single Bond Adhesive and Optibond Solo Plus[™] adhesive. Twenty-four extracted human third molars were prepared for bonding, 12 each for enamel and dentin. Enamel was prepared by roughening with a diamond bur for five seconds while dentin samples were prepared by cutting the crown off with a diamond saw exposing middle dentin. Filtek[™] Z250 Restorative was bonded to the substrates using the above named adhesives followed by sectioning into rectangular sticks with cross-sectional areas of 0.7mm² for dentin and 1.6mm² for enamel. Each stick was then tested under a tensile load using an Instron testing machine. Figure 13 depicts the results.

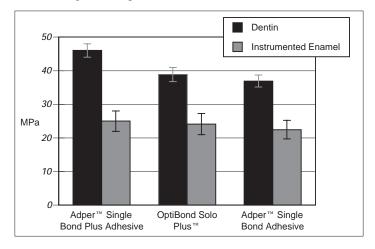


Figure 13. Enamel and Dentin Microtensile Bond Strength (MPa)

While the enamel bond strengths were found to be equivalent for the three adhesives tested, the dentin bond strength for Adper Single Bond *Plus* adhesive was significantly greater than the other two adhesives.

Film Thickness Measurements

As with the original Adper Single Bond adhesive, Adper Single Bond *Plus* adhesive is indicated for indirect restorations. For porcelain veneers, Adper Single Bond *Plus* adhesive is light-cured after cementation with RelyXTM Veneer Cement and, consequently, film thickness is not an issue. For all other indirect restorations, the adhesive is light-cured prior to cementation with RelyXTM ARC Resin Cement. For these restorations, the film thickness of the cured adhesive becomes a significant variable as it could prevent the restoration from seating completely.

The film thickness of Adper Single Bond *Plus* adhesive was determined using scanning electron microscopy. The results, shown below in Table 2, reveal a film thickness, on both enamel and dentin, comparable to the original Adper Single Bond adhesive.

Table 2. Film Thickness

Substrate	Adper™ Single Bond Adhesive	Adper™ Single Bond <i>Plus</i> Adhesive
Enamel adhesive layer(µm)	11.74 (2.00)	6.40 (2.80)
Dentin adhesive layer (µm)	5.94 (0.86)	4.22 (1.25)

Source: Dr. J. Perdigao, University of Minnesota

Source: Dr. Patricia N. R. Pereira

Technique Guides



DISPENSING UNIT DOSE

Adper™ Single Bond Plus Adhesive

- Hold the shaft of the disposable applicator over the opening where the applicator enters the foil package with your thumb and index finger.
 Do not activate the unit dose without a disposable applicator.
- With your thumb and index finger of the other hand, squeeze the large blister to transfer the adhesive into the chamber enclosing the applicator.



• Briefly spin the applicator to fully saturate with adhesive.



Optional

- Prior to dispensing adhesive, the applicator may be bent in the foil package to enhance intra-oral access.
- Carefully depressing the unit dose as shown facilitates rewetting applicator with adhesive.





DISPENSING FROM VIAL

Adper™ Single Bond Plus Adhesive

• Pinch the sides of the cap to release the locking mechanism.



• Flip the cap back to reveal the dispensing tip.



• Squeeze out the exact number of drops desired into the mixing well.



• When finished, flip the cap back until it is secured by its locking mechanism.



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3M ESPE DIRECT LIGHT-CURE RESTORATION

Adper™ Single Bond Plus Adhesive

Etch:

- Apply Scotchbond™ Etchant to enamel and dentin. Wait 15 seconds.
 Rinse for 10 seconds.
- Blot excess water using a cotton pellet or mini-sponge. Do not air dry.
- The surface should appear glistening without pooling of water.



Adhesive:

- **Immediately after blotting**, apply 2-3 consecutive coats of adhesive for 15 seconds with gentle agitation using a fully saturated applicator.
- Gently air thin for 5 seconds to evaporate solvent.



Light-Cure:

• Light-cure for 10 seconds.



Restorative:

• Place restorative according to manufacturer specifications.



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3M ESPE PORCELAIN REPAIR

Adper™ Single Bond Plus Adhesive Filtek™ Restoratives

Preparation:

- Isolate and clean the surface.
- Roughen the alloy surface with a bur, diamond or sandblast
- Remove all loose or weakened porcelain. Bevel the margin. Remove surface glaze 1mm beyond margin.

- Apply Scotchbond™ Etchant to porcelain and alloy. Wait 15 seconds.
- Rinse.
- Dry 2-5 seconds.



Silane Prime:

- Apply RelyX[™] Ceramic Primer to the porcelain and alloy surface.



Adhesive:

- Apply 2 consecutive coats of Adper[™] Single Bond Plus Adhesive to silane primed surfaces.
- Dry gently for 2-5 seconds.Light-cure for 10 seconds.



Mask Metal:

- Mask the metal surface with a thin layer (.25 - .5mm) of the appropriate $3M^{\text{\tiny M}}$ ESPE Masking Agent shade, using a brush.
- Light-cure each layer for 20 seconds.



Place Filtek™ Restorative:

- Place Filtek™ Restorative in increments.
- Light-cure each increment. (Reference Light-Cure chart for thickness and cure time.)



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ROOT SURFACE DESENSITIZATION

Adper™ Single Bond Plus Adhesive

Lightly clean the root surface with flour of pumice. Rinse and blot dry.

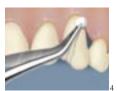
- Apply Scotchbond™ Etchant to the dentin. Wait for 15 seconds.
- Rinse for 10 seconds.
- Blot excess water using a cotton pellet or mini-sponge. The surface should appear glistening without pooling of water.

Adhesive:

- Immediately after blotting, apply 2-3 consecutive coats of adhesive to etched enamel and dentin for 15 seconds with gentle agitation using a fully saturated applicator.
- Gently air thin for 5 seconds to evaporate solvents.
- Light cure for 10 seconds.
- Apply 2 additional coats of adhesive.
 Dry gently for 5 seconds.
 Light cure for 10 seconds.



• Remove the oxygen inhibited layer with a moistened gauze.







Management of Post-operative Sensitivity

Sensitivity following restorative procedures is, in many cases, associated with an incomplete dentinal seal. Often referred to as "dentinal sensitivity", its origin has been associated with movement of dentinal tubular fluid in a coronal direction at a rate that stimulates pulpal pain receptors (Brannstrom). For adhesive restorative procedures, the formation of a fully sealed dentinal hybrid layer will prevent this rapid outward flow of tubule fluid and greatly minimize the risk for post-operative sensitivity if not eliminate it altogether. The following considerations are helpful in achieving this goal with Adper $^{\text{m}}$ Single Bond *Plus* Adhesive.

Isolation with rubber dam is highly recommended.

Contamination of the preparation during adhesive placement of any adhesive may potentially compromise the dentinal seal leading not only to post-operative sensitivity, but also possible margin discoloration and lack of long-term retention.

Use of 3M ESPE Vitrebond™ Liner/Base

The resin-modified glass ionomer, 3M ESPE Vitrebond liner/base, is recommended for the management of post-operative sensitivity.

Vitrebond liner/base can be used routinely to seal the dentin of class I and II restorations since it is with these restorations where post-operative sensitivity often occurs. It is also recommended for dentin bonding in areas of deep cavity excavation where the bond with total etch adhesives may be compromised due to increased dentinal fluid.



Adhesive Application

For optimum penetration of the adhesive into dentin following the etching step, the dentin must remain moist. Dehydration of the etched dentinal surface will cause the collagen fibrils to collapse resulting in a reduction in the porosity of this surface. Consequently, the collagen layer in this state will inhibit the penetration of adhesive throughout this layer and compromise the integrity of the dentinal seal. Following the few simple steps described below will promote complete dentinal sealing and minimize potential for post-operative sensitivity.

- Use of compressed air is not recommended to remove pooled water remaining after the etch step.
- Blot excess moisture from the preparation using a cotton pellet or mini-sponge. The dentinal surface should appear glistening without pooling of water.
- Apply adhesive immediately after blotting. Evacuators may hasten dentinal surface dehydration. If application is delayed, rewet and blot as above.
- Use generous amounts of adhesive. Two to three coats of Adper Single Bond *Plus* adhesive
 are recommended. While two coats should be sufficient in most cases, an additional coat may
 be beneficial in cases where inadvertent pooling of water occur.

Instructions For Use

Adper™ Single Bond Plus Adhesive

General Information

Adper Single Bond *Plus* Adhesive, manufactured by 3M ESPE, is a simple, moist bonding adhesive containing 10%, 5nm colloidal filler.

Adper Single Bond Plus adhesive offers the dental practitioner a wide range of applications. These include bonding to all classes of direct composite restorations as well as procedures involving porcelain, composite, metal repair, set amalgam, root surface desensitization and bonding of porcelain veneers with $RelyX^{m}$ Veneer Cement System and $RelyX^{m}$ Ceramic Primer, manufactured by 3M ESPE.

After light curing Adper Single Bond *Plus* adhesive, it may also be used for amalgam and indirect bonding procedures when combined with RelyX[™] ARC Adhesive Resin Cement, manufactured by 3M ESPE. Compatibility with indirect bonding procedures is due to the low film thickness (approximately 10 μm) of cured Adper Single Bond *Plus* adhesive.

Adper Single Bond *Plus* adhesive is available in two delivery systems, a unit dose delivery and a multi-use vial dispenser.

Use of etchant is critical for both enamel and dentin surfaces.

Recommendations

Use Vitrebond™ Light Cure Glass Ionomer Liner/Base, manufactured by 3M ESPE, in areas of deep cavity excavation such as Class I and II restorations. If pulp exposure has occurred, use a minimum amount of calcium hydroxide followed by an application of Vitrebond liner/base. Adper Single Bond *Plus* adhesive will bond to Vitrebond liner/base whether or not the ionomer was treated with etchant.

Adper Single Bond *Plus* adhesive includes an etch of enamel and dentin as a part of the procedure. It is recommended that the surfaces be left moist after rinsing. Excess surface moisture should be removed by blotting.

Adper Single Bond *Plus* adhesive is cured by exposure to visible light. The light curing times instructed with this product assumes the use of a 3M ESPE light curing unit, manufactured by 3M ESPE, or other dental visible curing light of comparable intensity. Curing lights should be checked often for proper output using a reliable light metering system.

Air used for drying should be free of oil and water contaminants.

Precautions for Dental Personnel and Patients

Scotchbond™ etchant, manufactured by 3M ESPE, contains 35% weight phosphoric acid.

Protective eyewear for patients and dental staff is recommended when using etchants. Avoid contact with oral soft tissue, eyes and skin. If accidental eye contact occurs, flush immediately with large amounts of water. For eye contact consult a physician.

Adper™ Single Bond *Plus* Adhesive contains acrylates including HEMA (2-hydroxyethyl-methacrylate). 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 resins. 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 adhesive 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. See Material Safety Data Sheet (MSDS) for additional cautionary information. You may obtain the current MSDS by visiting the website: http://www.3M.com/MSDS or contacting your 3M ESPE Dental Products representative.

Sensitivity

Some patients may experience transitory postoperative sensitivity. The risk of sensitivity can be minimized by the following measures:

Tooth Preparation

Remove minimal tooth structure.

Use proper isolation. Use of a rubber dam is highly recommended. Use adequate pulp protection. Use a glass ionomer or resin-modified glass ionomer liner/base (3M ESPE Vitrebond™ Light Cure Glass Ionomer Liner/Base) in areas of deep excavation.

Adhesive Application

Use of compressed air is not recommended to remove pooled water remaining after the etch step—blot excess moisture from the preparation using a cotton pellet or mini-sponge.

Apply adhesive immediately after blotting.

Restorative

Place restorative material in increments, curing each increment separately.

Adequately cure restorative according to instructions for shade and thickness of restorative and light exposure time.

Adjust occlusion carefully. Check for hyperocclusion, particularly in lateral excursion contacts.

Etchant Syringe Assembly

- 1. Protective eyewear for patients and staff is recommended when using the delivery syste
- 2. Prepare the delivery system: Remove cap from etchant syringe and SAVE. Twist a blue disposable tip securely onto the syringe. Holding the syringe with the tip pointed away from the patient and any dental staff, express a small amount of etchant onto a dispensing pad or a 2 × 2 gauze to assure that the delivery system is not clogged.

If clogged, remove the dispensing tip and express a small amount of etchant directly from the syringe. Remove any visible plug, if present, from the syringe opening. Replace dispensing tip and again express etchant. If clog remains, discard dispensing tip and replace with a new

- one. Bend the dispensing tip to a desired angle. Place bend midway along tip. Do not bend dispensing tip at its hub as this may cause the tip to break free.
- 3. Delivery system storage: Remove used dispensing tip and discard. Twist on storage cap. Storage of the delivery syringe with a used dispensing tip or without storage cap will allow drying of the etchant and consequent clogging of the system. Replace storage cap with a new dispensing tip at next use.
- 4. If desired, the etchant may be extruded onto a dispensing pad and applied with a brush or other appropriate instrument.
- 5. If a liquid etchant is desired, the etchant may be dispensed into a dappen dish and stirred to increase its fluidity.
- 6. Disinfection: Discard used dispensing tip. Replace syringe cap. Disinfect the capped syringe in the same manner as nonimmersible handpieces, air/water syringe and ultrasonic scalers following American Dental Association (ADA) and Centers for Disease Control (CDC) recommendations. (Council on Dental Materials, Instruments and Equipment and Council on Dental Therapeutics. Infection control recommendations for the dental office and the dental laboratory. JADA 116(2):241-248, 1988.)

Dispensing Adper™ Single Bond Plus Adhesive

Unit Dose:

Attention: To minimize risk of accidental contact with eyes and skin, hold the shaft of the disposable applicator over the opening where the applicator enters the foil package with your thumb and index finger. Do not activate the unit dose without a disposable applicator. With your thumb and index finger of the other hand, squeeze the large blister to transfer the adhesive into the chamber enclosing the applicator. Briefly spin the applicator to fully saturate with adhesive.

Vial:

Pinch the sides of the cap to release the locking mechanism and flip the cap back to reveal the dispensing tip. Squeeze out the exact number of drops you need into the disposable mixing well. When finished, flip the cap back until it is secured by its locking mechanism.

Instructions for Direct Light Cure Restorations in Enamel and Dentin:

- 1. Isolation: Rubber dam is the preferred method of isolation.
- 2. Cavity preparation: Prepare cavity with minimal tooth reduction. Bevel cavosurface enamel margins.
- 3. Etching: Apply Scotchbond™ Etchant to enamel and dentin. Wait 15 seconds. Rinse for 10 seconds. Blot excess water using a cotton pellet or mini-sponge. The surface should appear glistening without pooling of water.
- 4. Adhesive: Immediately after blotting, apply 2-3 consecutive coats of adhesive to etched enamel and dentin for 15 seconds with gentle agitation using a fully saturated applicator. Gently air thin for five seconds to evaporate solvents. Light cure for 10 seconds.
- 5. Restorative placement, cure and finishing: Refer to manufacturer's instructions for placement, cure and finishing of restorative materials.

Instructions for Bonding Porcelain Veneers:

- 1. Silane treatment: Porcelain bonding surfaces should have been etched using hydrofluoric acid by the dental laboratory. Apply RelyX™ Ceramic Primer (No. 2721) to the bonding surface of the veneer. Dry for 5 seconds.
- 2. Clean the prepared teeth in preparation for seating and bonding using a plain flour of pumice slurry. Rinse thoroughly and dry.
- 3. Try in veneer with RelyX™ Try-In Paste, manufactured by 3M ESPE. After try in, isolate from adjacent teeth with clear matrix strip.
- 4. Etching: Apply Scotchbond™ Etchant to both enamel and dentin. Wait 15 seconds. Rinse for 10 seconds. Blot excess water using a cotton pellet or mini-sponge. The surface should appear glistening without pooling of water. An additional 15 second etch time may be appropriate for teeth that were not prepared using a diamond or bur. Residual organic matter can also require additional etch time.
- 5. Adhesive: Immediately after blotting, apply 2-3 consecutive coats of adhesive to etched enamel and dentin for 15 seconds with gentle agitation using a fully saturated applicator. Gently air thin for five seconds to evaporate solvents. **Do not light cure**.
- 6. Adhesive application to veneer: Apply 1 coat of adhesive to the acid etched, silane treated veneer. Dry thoroughly. Do not light cure.
- 7. Luting material application to veneer: Apply RelyX™ Veneer Cement to the bonding surface of veneer.
- 8. Seating and curing: Carefully seat the veneer. Clean excess luting cement from the veneer margins. Cure each area of the veneer for times recommended by the luting cement manufacturer. We recommend curing the gingival margin first, followed by the body and the incisal margin. Avoid direct contact with the light-guide during initial curing.

Instructions for Bonding to Composite and Set Amalgam

- 1. Isolation: Rubber dam is the preferred method of isolation.
- 2. Roughen the existing material: Roughen the surface of existing amalgam or composite using either a bur, diamond or a sandblast technique.
- 3. Etching: Apply Scotchbond etchant to enamel, dentin and existing restorative material. Wait 15 seconds. Rinse for 10 seconds. Blot excess water using a cotton pellet or mini-sponge. The surface should appear glistening without pooling of water.
- 4. Adhesive: Immediately after blotting, apply 2-3 consecutive coats of adhesive to etched enamel, dentin and existing restorative material for 15 seconds with gentle agitation using a fully saturated applicator. Gently air thin for five seconds to evaporate solvents. Light cure for 10 seconds.
- 5. Masking: In the case of set amalgam, mask the metal surface with a thin layer (0.25 0.5mm) of the appropriate Masking Agent shade, manufactured by 3M ESPE, with a brush. Light cure each layer for 20 seconds.
- 6. Restorative placement: Refer to manufacturer's instructions for placement, cure and finishing of restorative material.

Instructions for Porcelain Repair

- 1. Isolation: Rubber dam is the preferred method of isolation.
- 2. Preparation: Clean the surface to be repaired with a slurry of plain flour of pumice. Rinse and dry thoroughly. Roughen the surface of existing metal or porcelain using either a bur, diamond or a sandblast technique. Be careful to remove all loose porcelain and bevel the margin. Remove surface glaze 1mm beyond the margin.
- 3. Etching: Apply Scotchbond™ Etchant to all substrates. Wait for 15 seconds. Rinse for 10 seconds. Dry 5 seconds.
- 4. Silane treatment for porcelain and metal: Apply RelyX™ Ceramic Primer (No. 2721) to the etched surface and dry.
- 5. Adhesive: Apply 2 consecutive coats of Adper™ Single Bond *Plus* Adhesive to silane treated porcelain or metal. Dry gently for 5 seconds. Light cure for 10 seconds.
- 6. Masking: To opacify the metal before the final composite placement, mask the metal surface with a thin layer (0.25 -0.5mm) of the appropriate Masking Agent shade using a brush. Light cure each layer for 20 seconds.
- 7. Restorative placement, cure and finishing: Refer to manufacturer's instructions for placement, cure and finishing of restorative material.

Instructions for Root Surface Desensitization

- 1. Lightly clean the root surface with flour of pumice. Rinse and blot dry.
- Etching: Apply Scotchbond etchant to the etched dentin. Wait for 15 seconds. Rinse for 10 seconds. Blot excess water using a cotton pellet or mini-sponge. The surface should appear glistening without pooling of water.
- 3. Adhesive: Immediately after blotting, apply 2-3 consecutive coats of adhesive to etched enamel and dentin for 15 seconds with gentle agitation using a fully saturated applicator. Gently air thin for five seconds to evaporate solvents. Light cure for 10 seconds. Apply 2 additional coats of adhesive. Dry gently for 5 seconds. Light cure for 10 seconds.
- 4. Remove the oxygen inhibited layer with a moistened gauze.

Instructions for Amalgam and Indirect Bonding Procedures (using RelyX[™] ARC Adhesive Resin Cement)

Physical properties of today's esthetic indirect restorations require that they be bonded into place to maximize the strength of the restoration as well as the tooth. A general perception may exist that light cured adhesives cannot be used for indirect restorations. It's true that many conventional light cured adhesives have a higher film thickness and can not be used under a fixed prosthesis. However, Adper Single Bond *Plus* adhesive is ethanol/water based, has a low film thickness (approximately 10µm) and should not interfere with the seating of indirect restorations.

Note: Care is required with any bonding agent used beneath precision castings because added film thickness may preclude accurate seating. **Avoid adhesive pooling in areas of the preparation that would effect the fit of any prosthetic device.**

Instructions for Bonding Crowns, Bridges (including resin-bonded bridges), Inlays and Onlays

- 1. Remove temporary restoration. Trial-fit the final restoration with light finger pressure to evaluate the fit, shade and marginal integrity. Adjust if necessary.
- 2. Prepare the bonding surface of the indirect restoration and the core build up, if applicable. Porcelain bonding surfaces should have been etched with hydrofluoric acid by the dental laboratory. Metal and amalgam bonding surfaces should be roughened, preferably using an air abrasion system, diamond or bur. Any composite surfaces should be roughened with a diamond, bur or air abrasion system. Glass ionomer build-ups should be pumiced with a slurry of plain flour of pumice.
- 3. Silane treatment (porcelain or porcelain/metal indirect restorations): Apply RelyX™ Ceramic Primer to the bonding surface of the indirect restoration. Dry for 5 seconds.
- 4. Clean the prepared teeth in preparation for seating and bonding using a plain flour of pumice slurry. Rinse and dry thoroughly, isolate from moisture and adjacent teeth.
- 5. Etching: Apply Scotchbond™ Etchant to both enamel and dentin. Wait 15 seconds. Rinse for 10 seconds. Blot excess water using a cotton pellet or mini-sponge. The surface should appear glistening without pooling of water.
- 6. Adhesive: Immediately after blotting, apply 2-3 consecutive coats of adhesive to etched enamel and dentin for 15 seconds with gentle agitation using a fully saturated applicator. Gently air thin for five seconds to evaporate solvents being careful to avoid excess adhesive on all prepared surfaces.
- 7. Light cure preparation for 10 seconds per bonding surface.
- 8. Dispense the appropriate amount of cement onto a mixing pad and mix for 10 seconds.
- 9. Apply and evenly distribute a thin layer of cement to the bonding surface of the indirect restoration.
- 10. Slowly seat and hold restoration in proper occlusion. Begin clean-up of excess cement approximately 3-5 minutes after seating. Optional: if excess cement is removed immediately after seating, each cement surface/margin must be light cured for 40 seconds.
- 11. Once the restoration is seated, each cement surface/margin may be light cured for 40 seconds or allowed to self cure for 10 minutes. Note: for porcelain and pre-cured composite restorations, each cement surface/margin must be light cured for 40 seconds.
- 12. Instruct patient to avoid applying any pressure for 10-15 minutes.

Instructions for Bonding Endodontic Posts

- 1. Prepare the endodontically treated tooth to receive the post (a root apex sealer and gutta percha filling approximately one third of the root canal are recommended). **Trial fit and adjust post as needed**. Bond to cast posts can be enhanced by using an air abrasion system and then applying RelyX ceramic primer. Dry for 5 seconds.
- 2. Etching: Apply Scotchbond etchant to the prepared tooth. Wait 15 seconds. Rinse for 10 seconds. Dry for 2 seconds. Remove excess moisture with an absorbent paper point.
- 3. Adhesive: Apply a uniform coat to etched enamel and dentin. Remove excess pooled adhesive with absorbent paper point. Air thin for five seconds to evaporate solvents.

- 4. Light cure for 10 seconds. (A light transmitting post of appropriate size may be used for additional curing).
- 5. Dispense the appropriate amount of cement onto a mixing pad and mix for 10 seconds.
- 6. Apply cement to the bonding surface of the preparation (in and around canal using a periodontal probe). Place a thin layer of mixed cement on post.
- 7. Seat the post. While holding in place remove excess cement. Light cure for 40 seconds from the occlusal surface to allow immediate placement of core build-up material

Instructions for Bonding Amalgam to Tooth Structure

- 1. Isolation: Rubber dam is the recommended method of isolation.
- 2. Cavity preparation: Prepare a standard amalgam cavity preparation. Roughen residual restorative materials with an air abrasion system or a bur.
- 3. Matrix application: Lightly lubricate the inner surface of the matrix band with hard wax or petroleum jelly before placement.
- 4. Etching: Apply Scotchbond™ Etchant to enamel, dentin and any residual restorative. Wait for 15 seconds. Rinse for 10 seconds. Blot excess water using a cotton pellet or mini-sponge. The surface should appear glistening without pooling of water.
- 5. Adhesive: Immediately after blotting, apply 2-3 consecutive coats of adhesive to etched enamel, dentin and any residual restorative material for 15 seconds with gentle agitation using a fully saturated applicator. Gently air thin for five seconds to evaporate solvents.
- 6. Light cure for 10 seconds.
- 7. Dispense the appropriate amount of cement onto a mixing pad and mix for 10 seconds.
- 8. Use a brush or appropriate applicator to place cement in adhesive-sealed preparation. **Triturate amalgam during placement of cement.**
- 9. Condense and burnish amalgam in the usual way.
- 10. Instruct patient to avoid applying any pressure for 10-15 minutes.

Additional Notes

 Brush handles can be disinfected in the same manner as nonimmersible handpieces, air/water syringe and ultrasonic scalers following American Dental Association (ADA) and Center for Disease Control (CDC) recommendations. (Council on Dental Materials, Instruments and Equipment and Council on Dental Therapeutics. Infection control recommendations for the dental office and the dental laboratory. JADA 116(2):241-248, 1988.)

Storage and Use

- 1. Adper™ Single Bond *Plus* System can be stored at room temperature.
- 2. Adper Single Bond *Plus* adhesive should be capped immediately after use to minimize evaporation.
- 3. Do not expose materials to elevated temperature or intense light.
- 4. Do not store products in proximity to eugenol containing products.
- 5. This system is designed to be used at room temperature of approximately $21-24^{\circ}$ C or $70-75^{\circ}$ F.

- 6. Shelf life of the unit dose is 24 months at room temperature. Shelf life of the vial delivery is 36 months at room temperature. See outer package for expiry date.
- 7. For cleanup, Scotchbond™ Etchant can be removed with water, while the uncured **adhesive** can be removed with alcohol.

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.

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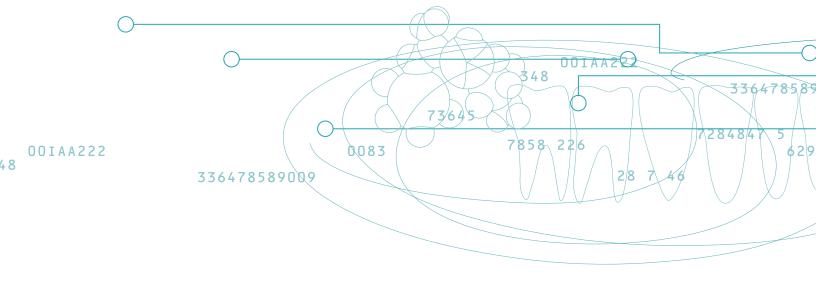
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References

Brannstrom M. (1986). The hydrodynamic theory of dentinal pain. Sensation in preparations, caries, and the dentinal crack syndrome. J Endodontics, 12(10).

Fundingsland JW, Aasen SM, Bodger PD, Cernhous JJ(1992). The effect of high humidity on adhesion to dentin. J Dent Res Special Issue; 71 (abstr1199).

Inoue S, Mechanism of Self-Etching Adhesives in: Tagami J, Tokdano M, Prati L editors, Proceedings of Conference on Advanced Adhesive Dentistry, Third Int. Kuraray Symposium, Dec. 3-4, 1999, Grenada Spain, Cirimido Italy: Grafiche Erredue, 2000.



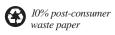


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