Product Description

Single Bond Universal Adhesive is a unique dental adhesive built on a trusted 3M ESPE bonding legacy. It is the single-bottle solution for all surfaces, and can be used reliably in total-etch, self-etch or selective-etch mode for both direct and indirect restorations. It provides the flexibility for the clinician to choose one adhesive to use independent of their preference of technique. It bonds methacrylate-based restoratives, cement and sealant materials to dentine, enamel, glass ionomer and various indirect restorative substrates (metals, glass ceramics, alumina and zirconia) without an extra primer step. The primary use is with light-cured materials, however, when used in conjunction with a separate activation solution, Single Bond Universal DCA Dual Cure Activator, it has the capability to also bond to self- or dual-cure composite and cement materials that rely on self-cure polymerization.

Single Bond Universal Adhesive has a very unique set of properties that include:
- Combined total-etch and self-etch bonding capability
- Uncompromising and consistent bond strengths
- High moisture tolerance to allow consistent bonding to both moist- and dry-etched dentine
- Virtually no post-op sensitivity in both total-etch and self-etch modes
- Combined primer/adhesive capability to bond to indirect substrates (metals, zirconia, alumina and glass ceramics) without a separate primer
- No refrigeration required – 2-year shelf life
- Dual-cure capability with separate dual-cure activation solution

Single Bond Universal adhesive provides a strong bond to seal the dentine if used in the self-etch or total-etch mode and protects the dentine from open tubules and potential sensitivity, or as a method for reducing sensitivity for patients that are already symptomatic.

Single Bond Universal adhesive is packaged in both a vial for multiple dosing and the L-Pop™ delivery device for unit dose dispensing. The vial incorporates a new “flip-top” cap design which allows the user to open and dispense with one hand.

### Table of Contents

- **Product Description** ............................................................................................................................. 3
- **Indications** ............................................................................................................................................. 4
- **Composition** .......................................................................................................................................... 5–6
  - Single Bond Universal DCA Dual Cure Activator .................................................................................. 7
  - Scotchbond™ Universal Etchant ............................................................................................................. 7
  - Summary of Single Bond Universal Adhesive—Unique Chemistry Powered by “VMS” technology .... 7
- **Mechanism of Adhesion** .......................................................................................................................... 8
  - Total-Etch Systems ............................................................................................................................... 8
  - Self-ETCH Systems ............................................................................................................................... 8
  - Single Bond Universal Adhesive ........................................................................................................... 9–13
- **Virtually No Post-Operative Sensitivity** ................................................................................................ 14
- **Internal and External In-Vivo Studies** ..................................................................................................... 15
  - Adhesion to Dentine and Enamel ........................................................................................................... 15–18
  - Adhesion to Etched Dentine (Moist and Dry Conditions) .................................................................... 19–20
  - Adhesion to Saliva-Contaminated Enamel and Dentine ...................................................................... 21
  - Adhesion to Various Indirect Substrates ............................................................................................... 21–23
  - Marginal Integrity ................................................................................................................................. 24
  - SEM Images – Dentine Sealing .............................................................................................................. 25
  - Bond Strength and Dye Penetration – Veneers ..................................................................................... 26
  - Bond Strength and Dye Penetration – Pit and Fissure Sealsants ............................................................ 27–29
  - Single Bond Universal Adhesive as a Protective Coating/Varnish for Glass Ionomer-based Restorative Materials ......................................................................................................................... 30–31
  - Bonding Self- or Dual-Cure Composite or Cement Materials with the Single Bond Universal DCA Dual Cure Activator ......................................................................................................................... 32–33
- **Customer Feedback** ............................................................................................................................... 34–36
  - Improved Vial Delivery .......................................................................................................................... 34
  - Overall Satisfaction ............................................................................................................................... 36

### Figure 1: Light Absorption of Single Bond Universal Adhesive Vial

![Figure 1: Light Absorption of Single Bond Universal Adhesive Vial](image-url)
Single Bond Universal Adhesive is also offered in a convenient and hygienic unit dose delivery system. The adhesive is advanced into the self-contained reservoir and applicatory by simply pressing the single-chambered foil package.

The Single Bond Universal Adhesive system offers the Single Bond Universal DCA Dual Cure Activator solution as an accessory item. The adhesive can be combined with Single Bond Universal DCA to allow the capability to bond with self- or dual-cure composite, build-up and cement materials that rely on the self-cure mechanism to polymerize the material.

Single Bond Universal adhesive is compatible with conventional phosphoric acid etchants when utilizing the selective-etch or the total-etch bonding mechanism. However, 3M ESPE is introducing a new etchant, Scotchbond Universal Etchant, which can be used when etching dentine or enamel. Scotchbond Universal Etchant is a 34% phosphoric acid by weight and provides enhanced handling and use features. The viscosity and distinct blue colour allow for easy, consistent and controlled placement of the etchant out of the delivery syringe. The blue colour also aids in confirmation of complete rinsing of the etchant from the tooth surface.

Indications

- All classes of fillings (according to Black) with composite or compomer
- Cementation of veneers when combined with RelyX Veneer Cement
- Root surface desensitization
- Sealing of cavities prior to cementation of amalgam restorations
- Sealing of cavities and preparations of tooth stumps prior to temporary cementation of indirect restorations
- Protective varnish for glass ionomer fillings
- Bonding of pit and fissure sealants
- Intraradical repair of existing composite, porcelain fused to metal, and all ceramic restorations w/o extra primer
- Bonding of dual cure and chemical cure cements, core build-up materials and composites (w/ activator)
- Bonding of core build-ups made of composite or core build-up materials
- Repair of composite or compomer fillings
- Primer for zirconia, alumina, metal or glass ceramic restorations.

Composition

The development of Single Bond Universal adhesive is based on trusted existing technologies currently available in Adper Scotchbond Multi-Purpose Adhesive, Adper Single Bond 2 Adhesive and Adper Easy One Self-Etch Adhesive. The table below (Figure 2) shows a comparison of the compositions for Adper Single Bond 2, Adper Easy One and Single Bond Universal adhesives.

<table>
<thead>
<tr>
<th>Adper® Single Bond 2 Adhesive</th>
<th>Adper® Easy One Self-Etch Adhesive</th>
<th>Single Bond Universal Adhesive</th>
</tr>
</thead>
<tbody>
<tr>
<td>MHP Phosphate Monomer</td>
<td>MDP Phosphate Monomer</td>
<td></td>
</tr>
<tr>
<td>Dimethacrylate resins</td>
<td>Dimethacrylate resins</td>
<td>Dimethacrylate resins</td>
</tr>
<tr>
<td>HEMA</td>
<td>HEMA</td>
<td>HEMA</td>
</tr>
<tr>
<td>Vitreobond™ Copolymer</td>
<td>Vitreobond™ Copolymer</td>
<td>Vitreobond™ Copolymer</td>
</tr>
<tr>
<td>Filler</td>
<td>Filler</td>
<td>Filler</td>
</tr>
<tr>
<td>Ethanol</td>
<td>Ethanol</td>
<td>Ethanol</td>
</tr>
<tr>
<td>Water</td>
<td>Water</td>
<td>Water</td>
</tr>
<tr>
<td>Initiators</td>
<td>Initiators</td>
<td>Initiators</td>
</tr>
<tr>
<td></td>
<td>Silane</td>
<td></td>
</tr>
</tbody>
</table>

Adper Single Bond 2, Adper Easy One and Single Bond Universal adhesives contain Vitreobond™ Copolymer. Vitreobond copolymer was first introduced with Single Bond Multi-Purpose adhesive. During the development of the Single Bond Multi-Purpose adhesive system, it was noted that the bond strengths of other dental adhesive systems tended to decrease when under varying humidity conditions. Also during this period, it was noted that Vitreobond™ Light Cure Glass Ionomer Liner/Base bond strengths did not seem to vary to the same degree. It was determined that by incorporating the proprietary copolymer used in Vitreobond liner/base (now termed the Vitreobond Copolymer) into the Scotchbond™ Multi-Purpose Primer yielded a system that was very resistant to the detrimental effects of varying humidity (Fundingsland et al. 1992). Since then, Vitreobond Copolymer has also been utilized in RelyX® Luting Plus Cement, Vitremer® Core Buildup/Restorative, Adper Single Bond 2 adhesive, Adper Easy One adhesive and now Single Bond Universal adhesive.

Adper Easy One and Single Bond Universal adhesives differ from Adper Single Bond 2 adhesive primarily in the partial replacement of the methacrylate monomers (UDMA and GMDMA) with the phosphorylated methacrylate monomers (MHP or MDP) to allow the acidity for the self-etching capability.
When Adper™ Easy One Self-Etch Adhesive was developed, it was based on the chemistry of the Adper™ Single Bond 2 Adhesive formulation and the addition of the phosphorylated monomers to allow for the self-etching properties. The primary difference between the Single Bond Universal Adhesive and Adper Easy One adhesive is a change in the phosphorylated monomers used in the two systems and the addition of silane. The Adper Easy One adhesive formulation uses methacryloxyethyl phosphate (MHP) where Single Bond Universal adhesive uses methacryloyloxyethyl phosphate (MDP). The MDP allows for better adhesion performance to enamel, greater product stability, and adhesion to metal and non-glass ceramic substrates. The addition of the silane allows for adhesion to glass-ceramic surfaces without the need for a separate primer.

The combination of the Single Bond Universal adhesive components provides for a high degree of conversion and more hydrophobic properties upon polymerization. Prior to curing and during application, Single Bond Universal adhesive is hydropobic for optimum wetting of the tooth structure. After drying and curing, Single Bond Universal adhesive exhibits a high degree of conversion and is hydrophobic for a long-lasting bond. This hydrophilic and hydrophobic nature of Single Bond Universal adhesive is illustrated in Figure 4. One drop of water was placed on an uncured adhesive sample of Single Bond Universal adhesive, as shown in the left photo illustrating the hydrophilic nature of Single Bond Universal adhesive. The photo on the right shows one drop of water on a light cured sample of Single Bond Universal adhesive illustrating the hydrophobic nature after curing.

Irrespective of the substrate, Single Bond Universal adhesive exhibits a high degree of conversion at the interface, as shown in a study by Professor Lorenzo Breschi-University of Trieste, Italy (Figure 5).

<table>
<thead>
<tr>
<th>Adhesive</th>
<th>Substrate</th>
<th>Degree of Conversion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prime &amp; Bond NT</td>
<td>Etched dentine</td>
<td>66% ± 13</td>
</tr>
<tr>
<td>Adper™ Easy One Self-Etch Adhesive</td>
<td>Smear layer</td>
<td>92% ± 10</td>
</tr>
<tr>
<td>Adper™ Easy One Self-Etch Adhesive</td>
<td>Etched dentine</td>
<td>88% ± 8</td>
</tr>
<tr>
<td>Single Bond Universal Adhesive</td>
<td>Smear layer</td>
<td>85% ± 5</td>
</tr>
<tr>
<td>Single Bond Universal Adhesive</td>
<td>Etched dentine</td>
<td>83% ± 4</td>
</tr>
</tbody>
</table>

Figure 5: Dr. Lorenzo Breschi, University of Trieste, Italy: Degree of Conversion.

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Figure 5: Dr. Lorenzo Breschi, University of Trieste, Italy: Degree of Conversion.

Like Adper Single Bond 2 and Adper Easy One adhesives, Single Bond Universal adhesive contains an ethanol/water-based solvent system. In contrast to acetone, ethanol is less volatile and helps maintain a consistent viscosity and handling while the product is in use. At the same time, the solvent system of Single Bond Universal adhesive, in combination with the rest of the formulation, was optimized to avoid phase separation while the adhesive is applied.

Single Bond Universal DCA Dual Cure Activator

The Single Bond Universal DCA Dual Cure Activator consists of sodium toluene sulfinate and ethanol. When the activator is mixed with Single Bond Universal adhesive, it allows for bonding to self- and dual-curing core build-up, composite and cement materials that rely on the self-cure mechanism for polymerizing the material.

Scotchbond™ Universal Etchant

Scotchbond Universal Etchant is available for the selective enamel etch and total-etch placement modes. Single Bond Universal adhesive etchant superficially demineralizes the enamel and dentine in preparation for bonding. The etchant is 34% phosphoric acid by weight and has a pH of approximately 0.1. The viscosity of the phosphoric acid gel etchant is modified with fumed silica and a water soluble polymer.

Scotchbond Universal Etchant has a distinct blue colour to assist in complete rinsing away of the etchant in order to avoid remnants of fumed silica or phosphoric acid on the prepared tooth surface.

Summary of Single Bond Universal Adhesive – Unique Chemistry

Powered by “VMS” technology

Vitrebond™ Copolymer
- Provides more consistent bond performance to dentine under varying moisture levels

MDP monomer instead of MHP
- Monomer that provides the self-etching properties
- Higher enamel bond strength
- Higher bond strength to zirconia, alumina, metals
- Higher hydrolytic stability – no refrigeration needed

Silane
- Allows the adhesive to chemically bond to glass ceramic surfaces without using a separate ceramic primer

Ethanol/water-based solvent system
Single Bond Universal Adhesive

Single Bond Universal Adhesive offers the unique advantage that it can be used in a self-etch mode, selective enamel-etch mode or in a total-etch mode for both direct and indirect dental restorative procedures, and provides uncompromised and consistent bond strengths. The microscopic images in this section provide insight into the self-etch, selective-etch and total-etch bonding mechanism of Single Bond Universal adhesive.

Self-Etch Mechanism

The Single Bond Universal adhesive chemistry utilizes phosphorylated monomers in an aqueous solution that provide acidity and allow the adhesive bond to dentine and cut enamel without the use of a separate phosphoric acid etching step, which therefore allows it to be considered self-etching. This is the same basic chemistry and process for Adper™ Easy One adhesive. The self-etching simplifies the technique and provides protection to the dentine surface to reduce the potential for post-operative sensitivity. Figure 6 shows the distinct enamel etch patterns of Single Bond Universal adhesive in the self-etch mode. The distinct formation of the hybrid layer and resin tags of Single Bond Universal adhesive in the self-etch mode are apparent in Figures 7 and 8.

Mechanism of Adhesion

Total-Etch Systems

For total-etch systems (4th and 5th generation), a phosphoric acid etching step is utilized to modify both the dentine and enamel surfaces to allow penetration of the adhesives into the tooth surfaces and achieve a mechanical bond. Phosphoric acid is considered a strong acid with an approximate pH of less than 0.5. It is very effective in dissolving the smear layer and the mineral within the collagen matrix of the dentine and the mineral of the enamel to expose the prismatic crystal structure. On enamel, the phosphoric acid treatment allows for very effective and consistent bonding to both the uncut and cut (prepared) surfaces. Dentists have relied on this high enamel bond integrity to prevent microleakage, marginal degradation and staining. On dentine, the phosphoric acid treatment completely removes the smear layer, leaving the dentine tubules open and exposed. The collagen matrix is also demineralized. In this situation it is imperative to completely seal the tubules to prevent sensitivity and for some systems, the demineralized collagen should be kept moist to prevent the collapse of the collagen fibers and subsequent reduction in bond strength.

Self-Etch Systems

For self-etch systems (6th and 7th generation), the acidity stems from the addition of acidic monomers. Typically, these compounds bear carboxylic or phosphoric acid groups and achieve creation of a mechanical retention pattern by etching the tooth structure, and chemical bonding by complex formation with the calcium ions present at the tooth. Their acidity varies considerably and can be significantly less than that of phosphoric acid. When applied onto the tooth surface, the acidic adhesive will demineralize and penetrate into the surface simultaneously. It is not rinsed away to leave the dentine tubules open and exposed. They remain sealed. The adhesive is then air-dried and light-cured. On dentine, this has clear advantages: the danger of overetching, overdrying of the etched dentine and occurrence of post-operative sensitivity is greatly reduced compared to total-etch adhesives. However, on the enamel surfaces, this reduced acidity can lead to a less pronounced etch pattern compared to phosphoric acid, especially on unprepared or uncut surfaces. Therefore, most self-etch adhesive systems require the incorporation of a separate phosphoric acid etch of these uncut enamel surfaces prior to applying the self-etch adhesives. Self-etch adhesives with a pH < 2 are classified as “strong” self-etch adhesives, whereas those with a pH > 2 are classified as “mild”. Mild self-etch adhesives are preferred over strong ones because they still provide for a strong bond to dentine, however their formulations are less hydrophilic and therefore less prone to undergo hydrolytic degradation, leading to improved shelf life and improved longevity of the restoration.

With the mild self-etch adhesive systems, including Adper™ Easy One Self-Etch Adhesive, a “selective” enamel etch technique is often used and recommended on the enamel (cut and uncut) surfaces to maximize the adhesion to the more highly mineralized enamel. The dentine is not etched to take advantage of the self-etch properties on less mineralized dentine, leaving the surface sealed and offering protection from potential sensitivity.
Selective-Etch Mechanism

The pH of Single Bond Universal Adhesive is 2.7 and considered to be a mild self-etch adhesive. With the higher pH of mild self-etch adhesives compared to phosphoric acid, some dentists prefer to still utilize a phosphoric acid etch on the cut and uncut enamel surfaces. This is commonly referred to as “selective” enamel etching, which will be supported and recommended with Single Bond Universal adhesive. When incorporating the “selective enamel etch” with a self-etch adhesive, the etchant is isolated to the enamel, leaving the dentine intact. Therefore, the clinician can maximize the enamel bond strength and take advantage of the low post-op sensitivity feature that the self-etch adhesive provides for on the dentine and still achieve a strong bond to dentine.

One concern that a clinician may have with the selective enamel etch is whether they can isolate the etchant to the enamel and not inadvertently etch the dentine in the process. If this occurs, the adhesive must properly infiltrate and wet the etched dentine for thorough sealing and to ensure high bonding and sensitivity prevention. Some self-etch adhesives may have reduced performance when bonding to etched dentine surfaces. The carefully balanced formulas of both Adper™ Easy One Self-Etch Adhesive and Single Bond Universal adhesive containing the Vitrebond™ Copolymer, HEMA and water allow for high and consistent bonding to etched dentine surfaces, even if the dentine surface is accidentally dried. Numerous adhesion studies have been conducted to support this, as well as SEM/TEM studies show that there is a uniform hybrid layer with resin on moist or dry etched dentine. Together, with the high moisture tolerance and robustness and its high degree of polymerization at the tooth interface, Single Bond Universal adhesive leads to virtually no post-operative sensitivity in self-etch and total-etch modes.

Total-Etch Mechanism

Some clinicians prefer to bond to the tooth surface with a total-etch approach where both the enamel and dentine surfaces are directly etched with the phosphoric acid. Typically after a 15-second application, the phosphoric acid is then rinsed to remove any residual acid and the dissolved mineral from the enamel and dentine. This leaves a very well-defined etched enamel surface (Figure 9) and also completely removes the smear layer from the dentine surface, as well as mineral within the collagen network on the dentine surface. The total-etch approach allows for a thicker hybrid layer to be formed, which some clinicians prefer. The TEM by Dr. Bart Van Meerebeek (Figure 10) and the Confocal Laser Scan image by Dr. Mario de Goes (Figure 11) illustrate the well-defined hybrid layer and resin tags with Single Bond Universal adhesive to dentine in the total-etch mode.

This adhesion method can be technique sensitive for the 5th generation adhesives due to the fact the dentine surface must be kept moist after etching to prevent the collapse of the unsupported collagen fiber network. If kept moist, the collagen network will remain intact and the adhesive can be applied or infiltrated to form a well-defined hybrid layer along with resin tags within the tubules. If the dentine surface is dried, the collagen network collapses and does not allow for a proper hybrid layer to be formed with the resin tags and, thus, results in a reduced and compromised bond to the dentine which can lead to decreased performance and an increase in the potential for sensitivity. The primary reason for the technique sensitivity is that the formulations of the 5th generation adhesives have limited or no water available to reverse the collapse of the collagen. Water and other components can act to rehydrate the collagen and allow for the formation of a proper hybrid layer if the dentine was dried after etching.
As mentioned above, the chemistry of Single Bond Universal Adhesive that includes water, HEMA and the Vitrebond™ Copolymer allows it to provide high and consistent bond performance to etched enamel and dentine in the total-etch technique. The unique chemistry will provide consistent performance to etched dentine whether it is kept moist as recommended or dry. The SEMs of Single Bond Universal adhesive to etched moist dentine (Figure 13) and etched dry dentine (Figure 14) illustrate the distinct formation of the hybrid layer and resin tags. This is a major advantage compared to typical 5th generation or 2-step etch-and-rinse systems that require the dentine surface to be moist or result in reduced bond strength and potential sensitivity if the dentine surface is dried prior to the application of the adhesive.

Bonding to Indirect Substrates
Single Bond Universal adhesive utilizes the MDP (methacyrloyloxydecyl phosphate) monomer, as well as incorporates silane into the chemistry. The MDP monomer has been shown to have the ability to bond to zirconia and alumina ceramic surfaces as well as to metals. The silane component allows the adhesive to bond to glass containing ceramic materials used for indirect restorations. These two components will allow the Single Bond Universal adhesive to be used as a bonding agent to these substrates without the need to incorporate a separate ceramic or metal primer prior to the placement of the adhesive. This will simplify the techniques for the intraoral repair of damaged indirect restorations, as well as the priming of indirect restorations prior to cementation.

The hybrid layer and resin tag formation of Single Bond Universal adhesive to moist dentine is similar to a typical 5th generation adhesive, however when a typical 5th generation adhesive is applied to a dried dentine surface, the hybrid layer is not visible (Figure 15).

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Internal and External In-Vitro-Studies

Single Bond Universal adhesive is a very unique and simple-to-use adhesive that offers the dentist the flexibility to use one single adhesive in a variety of application methods and achieve high and consistent bond strengths. The data in this section will show that Single Bond Universal adhesive bonds to enamel, dentine, glass ceramic, zirconia, noble, and non-precious alloys and composites without an additional primer. The data will also show that Single Bond Universal adhesive provides high levels of adhesion to dentine in both the self-etch mode, if the dentine is accidentally or intentionally etched as a result of the selective- or total-etch process, and on dentine that has been etched and left moist or dry. Additionally, the data will show that Single Bond Universal adhesive bonds pit and fissure sealants without etching, that Single Bond Universal adhesive is dual-cure compatible, and that Single Bond Universal adhesive can be used to prime restoration surfaces prior to the application of composite cements.

Adhesion to Dentine and Enamel

The adhesion to enamel will be shown in a variety of methods. For self-etching materials, it is important to show the adhesion performance to both the uncut and the instrument-prepared (cut) enamel surfaces. The uncut enamel surfaces are more mineralized and typically require an additional phosphoric acid etching step prior to the placement of the adhesive. The cut or prepared surface has the harder outer surface removed and can be easily treated in the self-etch mode. Alternatively, a “selective” enamel-etch technique is recommended as an option to enhance the enamel bond strength if desired.

The adhesion to dentine surfaces and the ability to seal the dentine is also the mechanism for providing desensitizing properties for the adhesive. This can be done directly on patients that are currently experiencing sensitivity due to open tubules. The adhesive can be applied to bond and seal the exposed tubules, thus reducing, if not eliminating, the sensitivity. This technique also applies for tooth surfaces that have been prepared for amalgam placement and for indirect restorations. The adhesives can be applied to the dentine surfaces to adhere to and seal the surface prior to the impression and temporization process. This prevents a potential sensitivity situation from arising when the patient has the final restoration seated at a later time.

Virtually No Post-Operative Sensitivity

120 dentists from Germany, Great Britain, Italy, France and Switzerland clinically evaluated Single Bond Universal Adhesive. During the evaluation, dentists placed 3,467 total-etch restorations, 1,544 selective enamel-etch restorations, and 3,495 self-etch restorations. After evaluating, the dentists completed a questionnaire to report their experience with the use of this product.

Out of the 120 dentists, only 5 indicated experiencing sensitivity with some patients during the evaluation. The number of patients experiencing sensitivity for the various treatment types were 14 total-etch, 0 selective-etch, and 2 self-etch. Of these 16 cases, the dentists stated that 2 were very close to the pulp, 2 had prior sensitivity, and 1 had other issues.

Based on the feedback from this evaluation, the calculated sensitivity rates for each treatment type is as follows: 0.4% for total-etch, 0.0% for selective-etch, and 0.06% for self-etch.

Adhesion to Dentine and Enamel

The adhesion to enamel will be shown in a variety of methods. For self-etching materials, it is important to show the adhesion performance to both the uncut and the instrument-prepared (cut) enamel surfaces. The uncut enamel surfaces are more mineralized and typically require an additional phosphoric acid etching step prior to the placement of the adhesive. The cut or prepared surface has the harder outer surface removed and can be easily treated in the self-etch mode. Alternatively, a “selective” enamel-etch technique is recommended as an option to enhance the enamel bond strength if desired.

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Figures 21 and 22 show data generated by Dr. John Burgess at the University of Alabama. The charts show shear bond strength at 24 hours. Single Bond Universal adhesive was compared directly to Adper™ Easy One Self-Etch Adhesive in the self-etch mode to dentine and cut enamel. Single Bond Universal adhesive was compared to Adper™ Single Bond 2 adhesive in the total-etch mode to cut enamel and dentine.

The adhesion data and SEM images of the sealed dentine support this indication. Figures 18 and 19 illustrate the performance of Single Bond Universal adhesive compared to products in the 5th and 7th generation categories. The 7th generation category is also called the one-bottle self-etch category and includes Adper™ Easy One Self-Etch Adhesive, iBond SE and Xeno IV. The 5th generation category is also called the two-step etch-and-rinse category, and includes Adper™ Single Bond 2 Adhesive, Optibond Solo Plus and Prime & Bond NT. Single Bond Universal Adhesive performs equivalently, if not better, than the leading products in those categories.

The bond strength durability of Single Bond Universal adhesive to dentine, cut enamel and uncut enamel is shown in Figure 20.
Dr. Mario de Goes, University of Campinas, conducted a study to evaluate the bond strength of one-step self-etching adhesives on pre-etched dentine and interface bond morphology. The dentine pre-etched using phosphoric acid did not affect the bonding strength of one-step self-etching adhesives (Figure 23).

The results of a study by Dr. Nara, Nippon Dental University (Figures 24 and 25) show that self-etch bond strengths are similar to Clearfil SE, and that bond strength to abrasion lesion dentine is similar to that of sound dentine or enamel.

Adhesion to Etched Dentine (Moist and Dry Conditions)

The data will show that Single Bond Universal Adhesive performs well on dentine that has been etched and left either moist or dry. This is a major benefit of Single Bond Universal adhesive compared to the traditional 5th generation total-etch adhesives which require that the dentine surface be kept moist following etching. If drying occurs and the collagen fibers collapse, there is not sufficient water and hydrating components in the adhesive to overcome the collagen collapse and subsequent poor bond strengths can occur which often can lead to post-operative sensitivity for the patient. Single Bond Universal adhesive performs well in the self-etch mode, etched/moist mode and etched/dry mode. Figure 26 shows the performance of Single Bond Universal adhesive on dentine and cut enamel in moist and dry conditions using Adper™ Single Bond 2 Adhesive as a control.

Figure 27 shows the contribution of Vitrebond™ Copolymer on the performance to etched and dry dentine with Single Bond Universal adhesive. Vitrebond Copolymer is a 3M ESPE proprietary polyalkenoic acid copolymer that enhances the wetting characteristics of the adhesive onto the dentine surface. It is present in Scotchbond™ Multi-Purpose Dental Adhesive, Adper™ Single Bond 2 Adhesive and Adper™ Easy One Self-Etch Adhesive, as well as the majority of 3M ESPE resin-modified glass ionomer materials. The Single Bond Universal adhesive formulation contains 1 to 5% of the copolymer. This aids in reducing the technique sensitivity, provides for more consistent performance, and reduces potential for post-op sensitivity as shown earlier in the “Virtually No Post-Operative Sensitivity” section.
Another common clinical concern is the ability to adequately isolate the prepared tooth surface from saliva contamination. It is very important to try and maintain a clean and isolated bonding surface, however, if the adhesive system could be tolerant to a slight amount of saliva contamination prior to the adhesive placement, that would be very beneficial clinically. Single Bond Universal adhesive is tolerant to light/moderate saliva contamination prior to adhesive application (Figure 30).

### Adhesion to Various Indirect Substrates

There are a wide range of materials that can be used to fabricate indirect dental restorations, including a variety of metals, composites and ceramic materials.

Metals range from base, non-precious metals to semi-precious and precious. Metal substrate bonding typically relies on a mechanical bond aided by the surface roughening by air abrasion with aluminum oxide. The adhesive will flow in and around the roughened surface and, when cured hard, will provide a mechanical bond to the surface. If additional bond strength is desired, a metal primer may be used to enhance the bond with some additional chemical bond to the surface.

Composite substrate bonding is very straightforward. The surface may be roughened, but when the adhesive is applied, a chemical bond is formed between the methacrylate groups of the composite and the adhesive.

Ceramic materials vary considerably in their composition. From a bonding perspective, they can be grouped into two categories: glass-containing ceramics (i.e., feldspathic porcelain, leucite reinforced glasses, and glass-infiltrated alumina and zirconia) and non-glass containing ceramics (polycrystalline zirconia and alumina).

For glass ceramics, the surfaces are typically etched with hydrofluoric acid to etch or dissolve some of the glass to create a microporous surface for mechanical retention. The surfaces are then treated with a ceramic primer/silane primer that will chemically bond to the glass and will also chemically bond to the adhesive, thus creating a chemical bond between the glass surface and the adhesive in addition to the mechanical bond.
For non-glass ceramics, these surfaces are relatively inert and are typically treated in the same manner as metals. The surfaces are air abraded with aluminum oxide to create a roughened surface for mechanical retention. Recently, new primers have been introduced that can provide an additional chemical bond to the metal oxides. These primers are primarily based on the MDP monomer. This monomer is a part of various cements, primers and adhesives currently in the market and has been shown to provide adhesion to the zirconia, alumina surfaces and metal surfaces. It is important not to pre-treat these surfaces with phosphoric acid, as this will create a strongly bonded phosphate layer that will be detrimental to the bond strength.

Dr. Markus B. Blatz, University of Pennsylvania, conducted a study to look at bonding composite (to simulate a repair situation or indirect bonding situation) to sandblasted zirconia, alumina and glass ceramic surfaces (Figure 33). The blasted surfaces were treated either with Single Bond Universal Adhesive or with Z-PRIME Plus primer and adhesive, cured and then composite bonded over that. Samples were subjected to 10,000 thermocycles between 5° and 60°C. Dr. John Burgess, University of Alabama in Birmingham, conducted three indirect shear bond strength studies. The first study (Figure 34), looked at the shear bond strength of Single Bond Universal adhesive to Paradigm™ C Glass Ceramic Block [Leucite-reinforced glass ceramic]. The Paradigm C glass ceramic block surfaces were sandblasted and treated with hydrofluoric acid. The two surface treatments were applied, followed by bonding a cylinder of Z100™ Restorative on top. The second study looked at bonding of non-glass ceramic (Figure 35). The Lava™ Zirconia samples were sandblasted and then treated with the various surface treatments. Z100 restorative was then bonded over the top in a cylinder. The third study (Figure 36) looked at bonding to metal surfaces. The metal samples were sandblasted and then treated with the primer/adhesive or the Single Bond Universal adhesive, followed by bonding a Z100 restorative cylinder on top.

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SEM Images – Dentine Sealing

A proper seal to the dentine is important to be able to provide high adhesion and to prevent sensitivity or to reduce sensitivity if it is present. Dental adhesives have the ability to prevent or reduce sensitivity if they can provide for a high bond strength to both unetched and etched dentine, effectively seal any open tubules, and provide a hard cured film that can act as a barrier to the external environment.

The adhesion data presented earlier shows that Single Bond Universal adhesive can provide for high adhesion to dentine in the self-etch mode with the smear layer present, but also to etched moist and dry dentine where the tubules are exposed. The fact is that Single Bond Universal adhesive performs well in both dry and moist conditions to etched dentine, allows for consistent high adhesion and good sealing, and removes the technique sensitivity from the clinician.

This ability to seal the dentine allows for low sensitivity potential for direct and indirect procedures. It allows the adhesive to be used for

- cervical root surface desensitization,
- sealing cavity surfaces prior to amalgam placement, and
- sealing tooth surfaces that have been prepared for indirect procedures prior to placement of the temporary restoration.

Based on the results for adhesion testing, SEMs showing the adhesive sealing/bonding capability and the literature study reviews would indicate that the Single Bond Universal adhesive should perform well as a dentine sealing agent.

The SEM images below show how Single Bond Universal adhesive provides an effective seal to the dentine surface. Figure 39 shows how Single Bond Universal adhesive provides a sealed surface over the exposed dentine tubules. The upper half of the image shows the exposed tubules following etching. The lower half shows the surface after placing a single coat of the Single Bond Universal adhesive. The tubules in the lower half are completely sealed. Figure 40 shows a cross sectional SEM image of the bonding interface to dentine.

Marginal Integrity

An important aspect of bonding is the ability of an adhesive to resist the polymerization forces of the dental composite and maintain a sealed, continuous interface between tooth structure and composite. Dr. Blunck from Berlin, Germany, performed an in vitro study of class V and II restorations comparing Single Bond Universal Adhesive and other adhesive systems and found the new adhesive to have high percentages of continuous margins in the total-etch and self-etch modes (Figure 37). Figure 38 shows the results of an in vitro study by Dr. Roland Frankenberger from Marburg, Germany, of Class II restorations comparing Single Bond Universal adhesive and other adhesive systems.

In-Vitro-Marginal Integrity Study – Class V Restoration

<table>
<thead>
<tr>
<th>Adhesive System</th>
<th>Enamel Margin %</th>
<th>Dentine Margin %</th>
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<tr>
<td>Single Bond Universal (TE)</td>
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</tr>
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<td>Xeno V (SE)</td>
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<td>88</td>
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<tr>
<td>iBond SE (SE)</td>
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<td>85</td>
</tr>
<tr>
<td>Prime &amp; Bond NT (TE)</td>
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<td>75</td>
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<tr>
<td>Syntac (TE)</td>
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<td>70</td>
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</table>

In-Vitro-Marginal Integrity Study – Class II Restoration

<table>
<thead>
<tr>
<th>Adhesive System</th>
<th>Enamel Margin %</th>
<th>Dentine Margin %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scotchbond ™ Universal (TE)</td>
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<td>95</td>
</tr>
<tr>
<td>Scotchbond ™ Universal (SE)</td>
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<td>75</td>
</tr>
<tr>
<td>Xeno V (SE)</td>
<td>75</td>
<td>70</td>
</tr>
</tbody>
</table>

Figure 37: Dr. Blunck, Berlin, Germany – Marginal Integrity Study, Class V restorations.

Figure 38: Dr. Frankenberger, Germany – Marginal Integrity Study – Class II restorations.
Bond Strength and Dye Penetration – Veneers

For glass ceramic bonding, the cementation of veneers was evaluated separately. Due to the highly aesthetic demands for porcelain veneers, the bonding and marginal seal were evaluated individually. It is very important to make sure that the veneer is bonded tightly and sealed to prevent any leakage or staining at the margin. For the veneer indication, it is recommended that the enamel surfaces, whether cut or uncut, be phosphoric acid etched prior to the placement of the adhesive. This will provide additional assurance that the restoration will be properly sealed. Figure 41 shows the bond strength comparisons of Single Bond Universal Adhesive to Adper™ Single Bond 2 Adhesive made with RelyX™ Veneer Cement. Glass ceramic wafers were bonded to etched and cut enamel. The bond strengths were statistically the same. Additionally, a dye penetration study was done where veneers were bonded to an etched enamel substrate, subjected to thermocycling, and subsequent dye penetration. Figure 42 shows the image of a prepared sample with a tight seal and no dye penetration at the veneer/enamel margin.

Figure 41: 24-hour shear bond strength of veneers bonded to etched and cut enamel for Single Bond Universal Adhesive/RelyX™ Veneer Cement compared to Adper™ Single Bond 2 Adhesive/RelyX™ Veneer cement. Source: 3M ESPE internal data.

Figure 42: Dye penetration images for bonded veneer using Single Bond Universal Adhesive and RelyX™ Veneer Cement. No dye penetration seen at the margin interface after 5000 thermocycles (5 – 55°C, dwell time 30 seconds). Source: 3M ESPE internal data.

Bond Strength and Dye Penetration – Pit and Fissure Sealants

Pit and fissure sealants are used to seal the deep crevices of molars in primary teeth. Historically, the application technique has been to first treat the uncut or unprepared enamel surfaces with phosphoric acid followed by a water rinse and dry. The sealant was then placed over the etched enamel surfaces and allowed to flow down into the fissures. The sealant was then light-cured or allowed to self-cure, depending on the type of initiation system. Typically, sealants are applied in a quadrant (3-4 teeth) at one time. This procedure allowed for high bond strengths and good retention of the sealant. The negative effect of this process was that following rinsing of the acid – the young patients would object to the taste of the rinsed acid and for the length of time it required to sufficiently rinse the acid and place the sealant – contamination of the surface with saliva was a concern. With the advent of the self-etch adhesives, the option to replace the phosphoric acid step with a self-etch adhesive used as a primer for the sealant became attractive. Adper™ Prompt™ Self-Etch Adhesive is a two-step self-etching adhesive that was investigated thoroughly for use as a self-etching primer for the placement of Clinpro™ Sealant and is indicated for the technique.

The pH of phosphoric acid is in the range of 0.5. Single Bond Universal adhesive has a higher pH in the range of 2.7. It is generally not indicated for use on uncut enamel surfaces without a prior phosphoric acid etching step for direct or indirect restorative procedures. However, in contrast to these restorations, the fissures to be sealed are typically not exposed to direct occlusal contact. With the incorporation of the MDP monomer and ViTBond™ Copolymer in the Single Bond Universal adhesive and resulting chemical bonding, investigations were conducted to determine if equivalent performance could be achieved with the Single Bond Universal adhesive and the light-cured Clinpro sealant.

Figure 43 provides 24-hour shear adhesion data for Single Bond Universal adhesive, Adper Prompt adhesive and Scotchbond™ Etchant with Clinpro sealant to uncut enamel. The technique for using the Single Bond Universal adhesive was to apply the adhesive onto the tooth surface and rub or scrub the surface to be sealed for 20 seconds, air dry, apply the sealant, and light cure simultaneously.

Figure 43: 24-hour shear bond strength of Single Bond Universal Adhesive, Adper™ Prompt™ Self-Etch Adhesive and Single Bond Universal Adhesive Etchant used with Clinpro™ Sealant to uncut enamel. Source: 3M ESPE internal data.
A second study was conducted to look at the microleakage or dye penetration of extracted molars treated with the Single Bond Universal Adhesive and Clinpro™ Sealant. Extracted molars were cleaned by treating the surface with polishing paste, rinsed and dried. The Single Bond Universal adhesive was then applied to the tooth surface and rubbed into the surface for 20 seconds. The adhesive was air dried to remove the solvents. Clinpro™ Sealant was applied in a thin layer. Both materials were then light cured simultaneously for 20 seconds. The samples were then thermocycled for 5000 cycles from 5°C to 55°C. High magnification images were taken of the images prior to immersion into the dye. The teeth were then subjected to the dye. Following the dye immersion, the samples were removed, rinsed and high magnification images were taken to evaluate the margins for any dye penetration or staining. Figure 44 shows the images before and after the dye penetration. No staining of the margins was noted and therefore a strong seal of the margins was present.

The following before and after photos (Figures 45, 46 and 47) are from an in-vitro 2 & 3 body wear study conducted at the Minnesota Dental Research Center for Biomaterials and Biomechanics (MDRCBB). The study compared three techniques for the application of Clinpro sealant. Photos were taken immediately after preparing samples according to the traditional phosphoric acid etch technique and according to the self-etch techniques of Adper™ Prompt™ L-Pop™ Self-Etch Adhesive and Single Bond Universal adhesive. The “after” photos were taken after subjecting the samples to 300K cycles of chewing media which simulates approximately 1 year of actual chewing.
The second study looked at the ability to protect the cured surface of the glass ionomer restorative to staining with coffee. This would also indicate the ability to protect the surface from water uptake. Samples of Ketac™ Molar restorative and Ketac™ Fil Plus Aplicap™ Glass Ionomer Restorative were prepared and coated with Ketac™ Glaze Light-Cured Varnish and Single Bond Universal adhesive. Fuji IX samples were also prepared and coated with the G-Coat Plus. The samples were immersed in coffee for 24 hours. Figure 21 shows the images of the actual samples that were immersed. The baseline (before) samples are shown on the right side. No distinct colour change is visible for any of the sample sets. The samples were measured for colour and the changes or Delta E values were calculated for each sample set. Figure 49 shows a graph of the colour change or Delta E for the five groups.

Single Bond Universal Adhesive as a Protective Coating/ Varnish for Glass Ionomer-based Restorative Materials

Glass ionomer restorative materials have a requirement that after placement they require a protective coating or varnish to be placed over the exposed surfaces to avoid water loss at the surface. The water loss would cause the surface to weaken upon setting and cause surface cracking and weakness in the physical properties of the material at the surface. Therefore, a varnish or protective coating is applied over the exposed surfaces during the curing process. The coating will be cured and act as a barrier to allow the restorative material to cure properly without the water loss. Once cured, the restoration can be finished and polished. If any of the underlying glass ionomer material is exposed, the coating can be reapplied to further protect the surface from water loss and also provide a smoother surface.

The following internal studies show the ability of Single Bond Universal Adhesive to provide a hard cured surface over the surface of the glass ionomer restorative and the ability of the Single Bond Universal adhesive to protect the surface from water uptake in the form of a coffee staining test. Figure 48 compares the Vickers surface hardness for Ketac™ Molar Glass Ionomer Restorative coated with both the conventional Ketac™ Glaze Light-Cured Varnish and then with the Single Bond Universal adhesive. The Fuji IX glass ionomer restorative from GC was also tested with the G-Coat Plus coating.

Figure 49: Images of coated samples of Ketac™ Molar Glass Ionomer Restorative, Ketac™ Fil Plus Aplicap™ Glass Ionomer Restorative with Ketac™ Glaze Light-Cured Varnish and Single Bond Universal Adhesive compared to Fuji IX coated with G-Coat Plus following immersion in coffee.

Source: 3M ESPE internal data.
Bonding Self- or Dual-Cure Composite or Cement Materials with the Single Bond Universal DCA Dual Cure Activator

The ability to bond self- and dual-curing composite and cement materials with conventional adhesives has been a challenge. The slightly acidic or acidic nature of the adhesives can protonate the amine component of commonly used peroxide/amine initiator systems and therefore have a retarding effect on the self-curing mechanism of the composite or cement and not allow the interface between the adhesive and the composite/cement to polymerize completely, resulting in low bond strengths. Dual- or self-cure activators are available for some adhesive systems that, when mixed with the adhesive, allow for better polymerization at the interface and subsequent higher bond strengths. Single Bond Universal Adhesive has an activator available as part of its system. The activator consists of 2% sodium toluene sulfinate and 98% ethanol. This sulfinate salt, when mixed with the Single Bond Universal adhesive, allows for bonding to these materials. Figure 19 shows bond strength data when Single Bond Universal adhesive was mixed with Single Bond Universal DCA, and alloy cylinders were bonded to dentine and enamel with various non-3M ESPE cements in both the self-etch and total-etch modes. The bond strengths are all within or above the 20 MPa range and are acceptable. Figures 51 and 52 show the wire loop shear bond strengths of various core build-up materials and self-cure composite materials. Single Bond Universal adhesive was mixed with Single Bond Universal DCA (1 drop of each), applied to the tooth surface and light cured. Cements were used per their instructions for use to cement stainless steel buttons, which were tested in shear mode after 24 hours at 36°C.

Cements were used per their instructions for use to cement stainless steel buttons, which were tested in shear mode after 24 hours at 36°C. Core build-up materials were applied in a 5 mm increment in order to simulate a worst-case scenario, light cured from the top, and tested in shear mode after 24 hours at 36°C.
Customer Feedback

As mentioned earlier, 120 dentists from Germany, Great Britain, Italy, France and Switzerland evaluated Single Bond Universal Adhesive. After evaluating, the dentists were asked for their feedback. The following summarizes their responses regarding the improved flip-top vial and their overall satisfaction with Single Bond Universal adhesive.

Improved Vial Delivery

The new and improved flip-top vial is designed for opening, dispensing and closing with one hand (Figure 56). 82% of the evaluators rated the opening and closing of the flip-top vial with one hand as “Easy” or “Very Easy” (Figure 57). The improved vial also has a unique nozzle which was specifically designed for dispensing control. Cleanliness of the vial after repeated use was rated as “Clean” by 39% and “Very Clean” by 42% of the evaluators (Figure 58).

Source: 3M ESPE internal data.

Figure 56: Vial Dispensing

Figure 57: Response to ease of opening and closing vial with 1 hand

Figure 58: Response to cleanliness of vial tip after repeated use

Source: 3M ESPE internal data.

Figure 59: Response to amount of adhesive in one drop of Single Bond Universal Adhesive.

Source: 3M ESPE internal data.
Overall Satisfaction

Overall, 89% of the evaluators were “Satisfied” or “Very Satisfied” with Single Bond Universal Adhesive. 81% responded with “Probably would” or “Definitely would recommend this new adhesive to their colleagues” and 84% “Probably would” or “Definitely would purchase Single Bond Universal adhesive if price was not an issue.”

Please rate your overall satisfaction of Single Bond Universal Adhesive: N=120

How likely would you recommend Single Bond Universal Adhesive to your colleagues, if it was available soon? N=118

How likely would you be to purchase Single Bond Universal Adhesive if it was available and price was not an issue? N=118