

**Device Description**

Dia-X Bond Universal is a universal adhesive capable of total, self, and selective etching as it consists of a single bottle of etching, primer, and adhesive resin. It can be used for both direct and indirect bonding of restorations.

**Indications for Use**

- All direct restorations
- All indirect restorations
- Desensitizing/sealing of tooth
- Intra-oral repairs

**Instructions for use****1. Preparations before the use**

- 1) Select an appropriate method according to the application case and follow the instructions.
  - All direct restorations: resin-based composite, resin-modified glass ionomers, core build-up, resin cement, etc.
  - All indirect restorations: metal, glass ceramics, zirconia/alumina, etc.
  - Desensitization/Sealing of tooth
  - Intra-oral repairs
- 2) An approved rubber dam is recommended for all restorations as saliva and blood contamination could compromise dentin bonding.
- 3) Do not use materials that contain eugenol for dental pulp protection or temporary sealing as eugenol may interrupt the polymerization process.
- 4) Do not use hemostatic agents containing iron compounds. Residual iron ions may impair adhesion or cause discoloration in the marginal area of teeth and around the gingiva.
- 5) When using hemostatic agents containing aluminum chloride, use only the minimal amount needed as it may reduce the adhesive strength if it comes in contact with the adjacent restorative site.
- 6) Dia-X Bond Universal contains a large amount of solvent, use immediately once it is dispensed in the mixing well.
- 7) Shake before use.

**2. Instructions****[Direct restoration]****Total Etching Technique**

- 1) Isolate the tooth with an approved rubber dam, prepare the cavity and clean it thoroughly with water.
- 2) Apply a phosphoric acid etching gel (such as DiaEtch™) to the dentin and enamel layers for 15 seconds, wash thoroughly with water, and remove excess water. (Dry the area leaving some moisture, but do not desiccate. Drying too much may cause hypersensitivity.)
- 3) Follow the steps for self-etching technique outlined below.

**Self-Etching Technique**

- 1) Shake the bottle before application and dispense the required amount into a mixing well.
- 2) Using a disposable brush, apply Dia-X Bond Universal to the entire cavity wall and rub it in for 20 seconds.
- 3) Be careful not to contaminate the treated surface with saliva or secretions.
- 4) Gently, but thoroughly dry the adhesive for 5 seconds with air until the bonding agent does not move and use a vacuum suction device to prevent the bonding agent from being dispersed.
- 5) The surface should have a uniform glossy appearance. If not, apply an additional coat of Dia-X Bond Universal and repeat the steps above.
- 6) Light cure for 10 seconds at a wavelength range of 385~515 nm with a curing light that has the appropriate wavelength range such as D-Lux+.
- 7) This process can also facilitate to seal off the hypersensitive areas.
- 8) Attach the restorative material directly onto the photopolymerized adhesive.
- 9) It is possible to repair the oral cavity by self-etching, total etching, and selective etching on the side requiring adhesion with the method outlined above.

**[Indirect restoration]****Total Etching Technique**

- 1) Isolate the tooth with an approved rubber dam, prepare the cavity and clean it thoroughly with water.
- 2) Apply a phosphoric acid etching gel (such as DiaEtch™) to the dentin and enamel layers for 15 seconds, wash thoroughly with water, and remove excess water. (Dry the area leaving some moisture, but do not desiccate. Drying too much may cause hypersensitivity.)
- 3) The subsequent steps are the same as the self-etching technique below.

**Self-Etching Technique**

- 1) Shake the bottle before application and dispense the required amount into a mixing well.
- 2) Using a disposable brush, apply Dia-X Bond Universal to the entire cavity wall and rub it in for 20 seconds.
- 3) Be careful not to contaminate the treated area with saliva or secretions.
- 4) Gently, but thoroughly dry the adhesive for 5 seconds with air until the bonding agent does not move and use a vacuum suction device to prevent the bonding agent from being dispersed.
- 5) The surface should have a uniform glossy appearance. If not, apply an additional coat of Dia-X Bond Universal and repeat the steps above.
- 6) Light cure for 10 seconds with a curing light such as D-Lux+ that has a wavelength range of 385~515 nm.
- 7) Place the indirect restorations onto the photopolymerized adhesive.

\* Dia-X Bond Universal is designed for use with dual-cured and self-cured composites/cement. If light curing is not successful, use a porcelain-compatible primer together before applying the bond to provide adequate strength and retention.

[Do not use phosphoric acid on the surface of zirconia, aluminum oxide, or metal materials.]

**[Desensitization/Sealing of tooth]****Total Etching Technique**

- 1) Isolate the tooth with a rubber dam, prepare the cavity and clean it thoroughly with water.
- 2) Apply a phosphoric acid etching gel (such as DiaEtch™) to the dentin and enamel layers for 15 seconds, wash thoroughly with water, and remove excess water but do not desiccate as it may cause hypersensitivity.

**Self-Etching Technique**

- 1) Isolate the tooth with an approved rubber dam, prepare the cavity, clean it with water, and remove excess water.

- 2) Shake the bottle before application and dispense the required amount into a mixing well.
- 3) Using a disposable brush, apply Dia-X Bond Universal to the entire cavity wall and rub it in for 20 seconds.
- 4) Be careful that saliva or secretions do not adhere to the treated surface.
- 5) Gently, but thoroughly dry the adhesive for 5 seconds with air until the bonding agent does not move, and use a vacuum suction device to prevent the bonding agent from being dispersed.
- 6) The surface should have a uniform glossy appearance. If not, apply an additional coat of Dia-X Bond Universal and repeat the steps above.
- 7) Light cure for 10 seconds with a curing light such as D-Lux+ that has a wavelength range of 385~515 nm.
- 8) Remove the oxygen-inhibited layer with a cotton pellet or gauze moistened with alcohol.

**[Intraoral Repair]**

- 1) Roughen any surface that will be bonded. Rinse and air dry.
- 2) For optimal adhesive strength and durability, apply a primer suitable for the ceramic material.
- 3) Shake the bonding agent before application and dispense the required amount into a mixing well.
- 4) Apply the bonding agent to the repair site, gently air dry the adhesive to remove excess solvent for 5 seconds, light cure for 10 seconds with a curing light such as D-Lux+ that has a wavelength range of 385~515 nm. Place the composite, light cure, and polish according to manufacturer's instructions.

**Total Etching Technique**

Etch the prepared enamel and dentin with an etching gel (such as DiaEtch™) for 15 seconds. Rinse thoroughly to remove all etchants before proceeding. Gently air dry and apply Dia-X Bond Universal to the repair site and light cure for 10 seconds.

**Self-Etching Technique**

Apply Dia-X Bond Universal directly to the prepared enamel and dentin without any etching gel. Light cure for 10 seconds.

**Selective Etching Technique**

Etch the margin of the enamel with a phosphoric acid etching gel (such as DiaEtch™) for 15 seconds. Rinse thoroughly to remove all etchants before proceeding. Gently air dry and apply Dia-X Bond Universal to the repair site and light cure for 10 seconds.

**3. Storage and management after the use**

- 1) Do not use after the expiry date.
- 2) Replace the cap onto the bottle promptly and store under appropriate storage conditions (2°C/35°F ~ 27°C/80°F).
- 3) Store away from excessive heat, direct sunlight, or open flame.
- 4) Store in locations that are only accessible by dentists.
- 5) Keep out of reach of children.

**Precautions for use****1. General caution**

- 1) Use for purposes other than the outlined in this Instruction for Use is prohibited.
- 2) For dental professionals only, and the instructions for use and precautions for use must be observed.
- 3) Avoid contact with the skin or eyes. In case of contact, flush with copious amounts of water and seek medical attention immediately.
- 4) An approved rubber dam is recommended. Contamination may reduce the adhesive strength and longevity of the restoration.
- 5) This product cannot be prescribed for internal use.

**2. Application notes**

- 1) Use an airway protection device before the procedure.
- 2) Do not use if the product is expired.
- 3) Do not mix with other products.
- 4) Do not use hemostatic agents containing iron compounds. Residual iron ions may impair adhesion or cause discoloration in the marginal area of teeth and around the gingiva.
- 5) When using hemostatic agents containing aluminum chloride, use only the minimal amount needed as it may reduce the adhesive strength if it comes in contact with the adjacent restorative site.
- 6) When drying with air, it should not be contaminated with water or saliva.
- 7) Use a light-blocking plate to prevent the material from being exposed to any light source.
- 8) Use a curing light with a power intensity of 900mW/cm<sup>2</sup> or more.
- 9) Seal it with medical waste and dispose of it.

**Contraindications**

- 1) Very rarely, hypersensitivity to this product may occur. In this case, discontinue use and consult a doctor.
- 2) Do not use on patients who have a history of severe allergic reactions to the product.

**Shelf Life**

2 years from the manufacture date.

**Symbols****Rx Only , For Dental Professional Use Only****Warranty**

DiaDent Group International will replace products that are proven to be defective. DiaDent Group International does not accept liability for any damage or loss, direct or consequential, stemming from the use of or inability to use the product described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith. In the event of a serious accident involving the user and/or patient-related to the device, it should be reported to the competent authority and the manufacturer.

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