

Description

DiaPlus[™] is a photopolymerization type dentine and enamel adhesive as a 5th generation dentine adhesion system that can be applied to all types of composite resin restorations.

Indication for Use

As a dentine/enamel total etching bonding system for direct adhesion, it is used in the adhesion of all direct restoration substances.

- Bonding of direct composite
- Bonding to composite and set amalgam
- Bonding of indirect restoration-Porcelain, Composite (Inlays, Onlays, Veneers, Crowns)
- Sealing hypersensitivity areas of teeth

Composition

- Ethyl alcohol / Urethane dimethacrylate / Bisphenol-A-glycidyl methacrylate / mono-2-(Methacryloyloxy)ethyl succinate / Additives

Applications**A. Preparations prior to the use**

- 1) Check the abnormal state of the product including expiry date, presence of foreign matters and impurities, and deformation (do not use those that has hardened), etc. before the use of the product.
- 2) Comply with the application method after having familiarized with the User Manual of the manufacturer.
- 3) Remove the protective cap and prepare device for filling.
- 4) Protect the oral cavity with rubber dam.

B. Recommended Procedure**[Direct adhesion of composite resin]**

1. Thoroughly cleans the damaged area of the teeth with Pumice and water. If the dental pulp is exposed, execute dental pulp capping with calcium hydroxide and glass ionomer in accordance with the indicant.
2. After having acid treated enamel and dentine by using dental acid etching agent (DiaEtch), wash off the etching gel with water and gently dry them for 1-2 seconds to remove excessive moisture on the area of procedure. At this time, make sure to leave small amount of moisture on the area of procedure. (Dry teeth only up to slightly wet condition to avoid excessive drying since it can become the cause of degradation in the adhesion strength.)
3. Put 2 drops of DiaPlus adhesive in the mixing well and wet the brush tip with sufficient quantity of the adhesive to coat the area of procedure twice and wait for 10 seconds after the coating. Dry lightly for 2-5 seconds to allow evaporation of volatile solvent (if there is no luster on the surface of the area of procedure, apply the adhesive by repeating the above procedures) before irradiating light for 20 seconds.
4. Restore and grind in the area of procedure in accordance with the User Manual for the restoration material applied.

[Adhere to the existing composite resin and amalgam restoration substance]

1. Segregate the area to be treated by using rubber dam.
2. Roughen the surface of the existing amalgam or composite resin by using bar, diamond or sand blaster.
3. After having acid treated enamel and dentine with dental acid etching agent (DiaEtch), wash off etching gel with water and gently dry them for 1-2 seconds. At this time, make sure to leave small amount of moisture on the area of procedure. (Dry teeth only up to slightly wet condition to avoid excessive drying since it can become the cause of degradation in the adhesion strength.)
4. Put 2 drops of DiaPlus adhesive in the mixing well and wet the brush tip with sufficient quantity of the adhesive to coat the area of procedure twice and wait for 10 seconds after the coating. Dry lightly for 2-5 seconds to allow evaporation of volatile solvent (if there is no luster on the surface of the area of procedure, apply the adhesive by repeating the above procedures) before irradiating light for 20 seconds.
5. In the case of hardened existing amalgam, thinly apply appropriate masking agent color onto the metal surface with brush prior to subjecting each layer to photopolymerization for 20 seconds.
6. In the case of filling in of restoration substance, subject it to polymerization and finishing in accordance with the User Manual for the corresponding restoration substance.

[Cementing of porcelain and adhesion of indirect restoration substance]

1. After having removed temporary restoration substance, thoroughly clean the area to be restored with Pumice and water. If necessary, trial-fit to evaluate appropriateness and shade, etc.
2. After having acid treated enamel and dentine by using dental acid etching agent (DiaEtch), wash off the etching gel with water and gently dry them for 1-2 seconds to remove excessive moisture on the area of procedure. At this time, make sure to leave small amount of moisture on the area of procedure. (Dry teeth only up to slightly wet condition to avoid excessive drying since it can become the cause of degradation in the adhesion strength.)
3. Put 2 drops of DiaPlus adhesive in the mixing well and wet the brush tip with sufficient quantity of the adhesive to coat the area of procedure twice and wait for 10 seconds after the coating. Dry lightly for 2-5 seconds to allow evaporation of volatile solvent (if there is no luster on the surface of the area of procedure, apply the adhesive by repeating the above procedures) before irradiating light for 20 seconds (If the intensity of the light output of the light irradiator is less than 400mW/cm², extend the period of light irradiation).

4. After having applied Silane on the inner aspect of the restoration substance processed with acid or sand blast, allow it to be dried (in the case of composite resin, apply sealant processing according to the need).
5. Apply the area treated with sealant with DiaPlus adhesive once by using brush.
6. Evaporate the volatile solvent of DiaPlus adhesive. There is no need for photopolymerization.
7. After having mixed the dual polymerization type cement with appropriate shade well, apply it onto the inner aspect of the area of restoration. It is easy to remove excessive cement if partial hardening (roughly 2-3 seconds) is used.
8. Comply with the User Manual of the manufacturer for settlement and polymerization of restoration substance.

C. Storage and management after the use

- Inappropriate storage of the product can induce degradation of the performances and shorten the expiry date of the product.
- 1) Avoid high temperature and direct sunlight.
- 2) Keep it in dry and cool location (store at room temperature range of 2°C ~ 27°C).
- 3) Do not store in close vicinity of product that contains eugenol.
- 4) Since it is a product with volatility (contains ethanol ingredient), make sure to put the cover on tightly immediately after the use.
- 5) Keep it out of reach of children.
- 6) Do not store near fire
- 7) As this is a medical waste, seal and dispose the product responsibly.

Caution**A. Contraindication**

- 1) This product contains substance that can induce allergy depending on the person if it comes in contact with skin. Do not use this product on patients with allergy against acrylate.

B. General precautions

- 1) It must be used by dentist or dental specialist by complying with the application method and precautions.
- 2) Use of the product for purposes other than the prescribed purpose of use is prohibited.
- 3) Cannot be prescribed for internal use.

C. Interaction

- 1) It is presumed that dental photopolymerization device is used at the time of the use of DiaPlus adhesive. The appropriateness of the output of the light from the photopolymerization device must be checked frequently by using reliable light intensity measurement device.

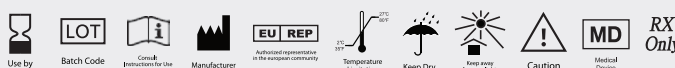
Recommended condition : **Light intensity = 400 mW/cm²**
Wavelength = 460 nm

D. Precautions for Using

- 1) It is recommended that you wear protective gloves when using the product.
- 2) Do not use the product with expired period of validity.
- 3) Take precaution to avoid coming in contact with product that has not been hardened. If exposed to skin, sufficiently wash off with soap and water.
- 4) Etching process for enamel and dentine is included in the use of DiaPlus adhesive. Remove excessive moisture on the teeth after having removed etching agent by blotting.
- 5) If it has been in contact with oral soft tissue for prolonged period of time, wash off with large quantity of water. If there is allergic reaction, undergo examination by physician and, if necessary, remove the product and stop using this product thereafter.
- 6) Since manifestation of temporary postoperative sensitivity is possible depending on the patient, make sure to use the product only after having undergone consultation with dental specialist.
- 7) Air used at the time of drying must not be polluted by oil or water.
- 8) If the contents of the product enter eyes or come in contact with oral soft tissue, wash off immediately with a large quantity of water.
- 9) Do not use it by mixing it with other product.
- 10) Very rarely, this product may cause hypersensitivity reactions. In such cases, discontinue use and consult a doctor.

Expiration

2 years from the manufacture date when stored according to the directions

Symbols

For Dental Professional Use Only

Warranty

DiaDent Group International will replace product that is 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. If there are any serious incident that has occurred in relation to our device, it should be noticed to DiaDent Group International and the competent authority of the Member State in which the user and/or patient.

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