

**Product**

The product belongs to Group 1, Class 2 of Type 1 according to the ISO 4049 classification standards. It is a light-activated restorative composite resin for both anterior and posterior aesthetic restorations.

DiaFil is paste that unpolymerized dimethacrylate monomer, inorganic filler, and photo initiators mixture. After polymerizing with a curing light, DiaFil hardens as a final restoration.

**Indication for use**

A composite material which has resin organic and inorganic fillers or complex fillers as ingredients, which are being used for aesthetic restoration by getting polymerized directly in the oral cavity.

- Direct anterior and posterior restorations
- Core build-ups
- Splinting

**Composition**

- Diurethane dimethacrylate / Bisphenol-A-glycidyl methacrylate / Trimethylol propane trimethacrylate / Barium-aluminosilicate / Silicon dioxide  
Inorganic Filler (average particle size of 0.05~2.5µm) Content: about 77%

**Instruction for use****A. Preparation before Use**

- 1) Check the expiration date and the abnormality of the product such as foreign substances and product defects before use
- 2) Familiarize yourself with the instructions from the manufacturer and follow the instructions for use
- 3) Remove the cap and prepare the needed filling tools
- 4) Protect the oral cavity with a rubber dam

**B. Directions for use**

- 1) Select the shade  
Isolate the area to be treated using rubber dam. Wash the area. Select the appropriate shade.
- 2) Treat the cavity  
Remove amalgams or bases and foreign substances in the area to be treated that can be intruding during the treatment
- 3) Pulp protection  
If a pulp exposure has occurred, cap the pulp with calcium hydroxide and glass ionomer.
- 4) Treatment of the enamel and the dentine  
For pre-treatment, etch the surface first and then apply the adhesive system according to the method of use of the products in use.
- 5) Application  
Syringe type: Remove the cap from the syringe, dispense an adequate amount of the product and fill the area to be treated. Make sure to close the cap after use to prevent exposure to the light.  
Capsule type: Dispense the product directly from the capsule. The capsule is disposable after use.
- 6) Curing  
Place a curing light (recommended: D-Lux+ Cordless Curing Light) as close as possible to the surface of the treated area and cure for 20 seconds vertically. (This product is intended to be cured by exposure to an LED light with a minimum intensity of 400 mW/cm². Increase the amount of curing time when the light intensity of the curing light is below 400mW/cm². If it is 400mW/cm² or higher, reduce the amount of curing time.)
- 7) Finishing  
After restoring with resin, remove the remaining resin with a flame-shaped finishing bur and contour the shape. Finish up the final grinding using a rubber polishing point and aluminum oxide polishing paste.

**C. Storage & Transportation**

- 1) Avoid high temperatures and direct sunlight.
- 2) Keep it in a dry and cool place (2° C ~ 27° C).
- 3) Close the cap immediately after use.
- 4) Keep away from children.
- 5) As this is a medical waste, seal and dispose the product responsibly.

**Caution****A. Contraindication**

- 1) Do NOT use the product on a patient with medical history of hypersensitivity and allergy such as rashes and dermatitis to the product or methacrylate monomers.

**B. General Cautions**

- 1) The product must be used by a dentist or a dental professional, according to the directions of use listed.
- 2) It is prohibited to use the product for reasons other than the intended purpose of use.
- 3) It cannot be prescribed for internal use.

**C. Application notes**

- 1) Wear respiratory protective wear before treatment.
- 2) Syringe type: close the cap on the syringe immediately after use.
- 3) Capsule type: dispose immediately after use for it is intended for one-time use.
- 4) Do not use the product past the expiration date.
- 5) Do not mix with other products
- 6) The unhardened resin can affect susceptible skin depending on the individual. If the product is in contact with the skin, wash off with soap and water.
- 7) The product is to be used for the dental purpose only. Wear protective goggles to prevent it from getting into eyes. If material gets into eyes, wash with running water immediately and seek medical help.
- 8) If a patient shows hypersensitivity such as a rash while using the product, stop using the product and advise the patient to seek medical help.
- 9) It is rare for patients to have sensitivity to the product. In sensitivity occurs, stop using the product and consult with a doctor.

**Shelf Life**

3 years from the manufacture date when stored according to the directions.

**Symbols**

Medical Device



Use by



Batch Code



Consult Instructions for use



Manufacturer



Temperature Limitation



Keep Dry



Protect From Sunlight



Caution



Authorized representative in the European Community

**Rx Only , 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 is any serious incident that occurs while using the device, the incident should be reported to DiaDent Group International the related authorities and/or the dealer where the purchase was made.

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144 x 205mm