

Renew Universal

One Component Self Etch Universal Bonding Agent



Product Description :

Renew Universal is a light-cured single-component dental bonding agent that combines etching, priming and bonding in one bottle. A novel universal dental adhesive containing a unique combination of functional monomers such as 10-MDP and 4-META. It has excellent bonding capabilities to dentin and cut / under-cut enamel. As a universal adhesive, **Renew Universal** has been designed to be fully compatible with light-cured and dual-cured composite materials. **Renew Universal** can be used for the bonding of both direct and indirect restorations and may be used with or without phosphoric acid etchant.

Composition : BisGMA, Triethylene Glycol Dimethacrylate, Urethane Dimethacrylate, 2-HEMA, Camphorquinone, Dimethyl Amino Ethyl Methacrylate, Ethyl-4 Dimethyl Amino Benzoate, Ethanol, Water, 10-Methacryloyloxydecyl Dihydrogen Phosphate, 4-META (4MET) Water, Butylated Hydroxy Toluene.

Intended Purpose / Intended Use : Renew Universal can be used for bonding of both direct & indirect restorations and may be used with or without phosphoric acid etchants.

Indications for Use :

1. Direct bonding of light-cured composites, compomers and ormocers to tooth structure.
2. Bonding of dual-cured core build up composites to tooth structure as long as these materials are light-cured.
3. Intraoral repair of composite, metal-based and zirconia/alumina-based restorations.
4. Intraoral repair of ceramic restorations in combination with a silane coupling agent.
5. Treatment of hypersensitive teeth.
6. Sealing of tooth preparation (cavity or abutment).

Instructions for Use :

1. BONDING PROCEDURE

Cavity Preparation : Prepare tooth using standard techniques. Make sure that the temporary material is thoroughly removed from the surface. Use rubber dam for protection. Rinse and dry the prepared tooth surfaces by gently blowing with an air syringe.

2. TREATMENT OF TOOTH SURFACES

Select out of the following 3 technique options :

a) Self-etch technique : Apply Renew Universal to bur-cut enamel and dentin, without a separate etching step. **Note :** Non bur-cut enamel should always be treated with a 35-40% phosphoric acid gel for 10 seconds, rinsed with water for 5 seconds and gently dry.

b) Selective etching of enamel : Prior to applying Renew Universal to enamel and dentin, etch enamel only with 35-40% phosphoric acid gel for 10-15 seconds, rinse for 5 seconds and gently dry.

c) Total-etch technique : Prior to applying Renew Universal to enamel and dentin, etch enamel and dentin with 35-40% phosphoric acid gel for 10-15 seconds, rinse for 5 seconds and gently dry.

3. APPLICATION OF RENEW UNIVERSAL

a) Bottle type : Prior to dispensing, shake the bottle of Renew Universal thoroughly. Dispense a few drops in to a clean dispensing dish. Replace bottle cap immediately.

Syringe type : Dispense the bonding agent on to the applicator tip. Using the disposable applicator provided.

b) IMMEDIATELY apply to all repaired surfaces using the disposable applicator.

c) Leave undisturbed for 10 seconds after the end of application. Renew Universal can provide sufficient bonding strength even when dried immediately after application without waiting time.

d) Dry thoroughly for 5 seconds with oil free air under MAXIMUM air pressure. Use vacuum suction to prevent splatter of the adhesive. The final result should be a thin adhesive film with a glossy surface and which does not visibly move under further air pressure.

4. LIGHT CURING : Light cure using a visible light curing unit for 20 seconds.

5. PLACEMENT OF LIGHT-CURED COMPOSITES/COMPOMERS : After having light-cured the adhesive, follow manufacturer's instructions for use in order to place, contour and light-cure the composite resin material of choice.

6. FINISHING : Adjust restoration, finish and polish using standard techniques.

TREATMENT OF HYPERSENSITIVE TEETH AND IMMEDIATE DENTIN SEALING

(I) APPLICATION RENEW UNIVERSAL : Refer to 1. BONDING PROCEDURE, 2. TREATMENT OF TOOTH SURFACES and 3. APPLICATION OF RENEW UNIVERSAL. Wait 10 seconds before drying. **Note :** For the treatment of hypersensitive teeth, the self-etch technique is recommended.

(II) LIGHT CURING : Refer to 4. LIGHT-CURING

(III) REMOVE UN POLYMERIZED LAYER : Remove the un polymerized layer of RENEW UNIVERSAL using a moist cotton pellet. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Warnings : Renew universal adhesive is an irritant. Contact with the skin, mucous membranes or eyes should be avoided. If case of skin contact, immediately wash with soap and water. If the material should come into contact with the eyes, immediately rinse with copious amounts of water for at least 15 minutes and consult a physician or ophthalmologist. In rare cases, contact with the skin may lead to a sensitization towards methacrylates. Commercial medical gloves do not provide protection against the sensitizing effects of methacrylate.

Precautions :

1. Safety Precautions : The material contains certain methacrylates and other ingredients which may cause irritation or sensitivity in some individuals. If contact occurs with skin, immediately wash with soap and water. Improper use may result in allergic reaction or skin and tissue irritation. If this occurs, discontinue use of this product. Protective gloves and eye wear should be worn while handling this product. If contact occurs with eye. Flush immediately with large volumes of water and seek medical attention immediately. Do not expose materials to elevated temperatures or intense light.

2. Material Precautions :

◆ **Renew Universal** is a light-curable material. Use it Immediately once it is dispensed in the mixing well. Prolonged exposure to air and light may lead to solvent evaporation and thickening of the adhesive.

Contraindications : 1. Patients with a history of hypersensitivity to methacrylate monomers. 2. Do not use as a pulp capping agent. 3. Not to be used with chemical curing composites. 4. Do not use eugenol-containing materials prior to the use of Renew Universal, since the eugenol can retard the curing process. 5. Not to be used with desensitizers.

Storage Conditions : Store at temperature between 10°C(50°F) to 24°C(75°F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stores in a cool dry place.

Shelf Life : 2-years from the date of manufacturing.

Presentation :

Ref: 10017

Intro Pack : 1 x 1.2ml Syringe, 5 x Applicator Tips, 1 x Instruction manual.

Ref: 10018

Regular Pack : 1 x 5ml Bottle, 1 x Instruction manual.

Ref: 10019

Kit Pack : 2 x 5ml Bottle, 40 x Micro Brushes, 1 x Instruction manual.

Disposal Conditions : To be disposed off based on the prevailing rules of the country in which it is used.

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

MDI Symbol for "MEDICAL DEVICE" Symbol for "CORROSIVE"

LOT Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY"

Symbol for "CAUTION" Symbol for "CONSULT INSTRUCTION FOR USE" Symbol for "CATALOGUE NUMBER"

Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"

Symbol for "DO NOT USE IF PACKAGE IS DAMAGE" Symbol for "KEEP OUT OF THE REACH OF CHILDREN" Symbol for "MANUFACTURER"

Symbol for "TEMPERATURE LIMIT" Symbol for "KEEP AWAY FROM SUNLIGHT" Symbol for "FLAMMABLE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.