

A.C.E. (CERAMIC REPAIR KIT)



Product Description : Comprehensive set for intraoral repairs of ceramic and composite restorations. This comprehensive system comprises the necessary bonding and veneering materials. The entire set is ergonomically arranged and enables you to work from left to right. Due to its outstanding high bonding values, this system is a reliable assistant in inconvenient situations. All the components are available separately.

Intended Purpose / Intended Use : It is intended to be used for intraoral repair of faulty indirect restoration.

Indications for Use: ♦ Repair of porcelain fused to metal crowns ♦ Bridges ♦ Inlays and Onlays ♦ Ceramic-veneered restorations ♦ All-ceramic restorations.

Instruction for use : ♦ Apply Porcelain Etchant Gel (CeraEtch) to porcelain surface for 90 sec. ♦ Rinse with copious amounts of water for two minutes. Dry with air or dry with some drying agent like (UltraDry) to treated surface, followed by gentle air. ♦ Apply Silane-X Bond Enhancer and allow to dry naturally or with gentle flow of air for 1 minute. ♦ Apply Renew Universal bonding agent to the treated area Light-cure for 20 seconds. Apply Fusion Flo opaque to mask the metal if necessary. ♦ Place composite and light-cure for 40 seconds. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Presentation :

Ref: 50002

Kit Contents : 1 x 1.2ml Syringes CeraEtch + 5 Applicator Tips. (Ref: 10012), 1 x 1.2ml Syringes Silane-X + 5 Applicator Tips. (Ref: 10014), 1 x 1.2ml Syringes Fusion Flo, Opaque + 5 Applicator Tips. (Ref: 20008-2), 1 x 1.2ml Syringe Renew Universal + 5 x Applicator Tips (Ref: 10017), 1 x Instruction manual.

CeraEtch

Product Description : CeraEtch is 5% Buffered Hydrofluoric acid in semi gel form. It improves the mechanical bond between porcelain and bonding agent by increasing the surface roughness.

Composition : Hydrofluoric Acid, Ammonium Fluoride, Purified Water and Thickening Agent.

Intended Purpose / Intended Use : It is used as an auxiliary material in dental bonding procedure.

Indication for Use :

1. Repair of porcelain restorations.
2. Cementation of porcelain restorations.

Instruction for Use (for cementation of ceramic restoration) :

1. Protective eye wear and gloves must be worn by the practitioner.
2. Remove cap from the CeraEtch syringe and attach dispensing tip and check the etchant flow through the tip before applying. Apply etchant to the dry porcelain for 90 seconds.
3. Rinse with a copious amount of water and air dry. The etched surface should dull and frosty.
4. Apply 1-2 thin coats of Silane-X with a brush tip applicator to the etched surface and allows to dry for 30 seconds.
5. Apply Renew Universal / Total Etch Bonding adhesive and follow the instructions for bonding and restorative with composites or cements.

Instruction for Use (for repair) :

1. Protective eye wear must be worn by the practitioner and patient and protecting gloves must be worn by the practitioner.
2. Isolate the area to be etched with a rubber dam. Apply gingival barrier around the area to be etched.
3. Remove cap from the CeraEtch syringe and attach dispensing tip and check the etchant flow through the tip before applying intra orally. Apply etchant to the dry porcelain for 90 seconds. Suction the porcelain etchant and rinse with a copious amount of water and air dry. The etched surface should dull and frosty.
4. Apply 1-2 thin coats of Silane-X with a brush tip applicator to the etched surface and allows to dry for 30 seconds.
5. Apply Renew Universal / Total Etch Bonding adhesive and follow the instructions for bonding and restorative with composites or cements.
6. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Warnings : Read the instructions thoroughly before use of this product. Hydrofluoric acid is a very powerful chemical and extreme care must be taken while handling this product.

Precautions :

1. Avoid direct exposure to sunlight.
2. Do not consume on take internally.

Contraindications: Do not use for etching of tooth surface (enamel or dentin).

Storage Condition : 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 stored in a cool dry place.

Shelf Life : 2 years from the date of manufacturing.

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

Silane-X

Product Description : Silane-X is a single component material which is used to enhance bond strength between composites/cements and porcelain. For best results the etched porcelain surface should be completely dry and free of residual moisture before applying Silane-X.

Composition : Organo functional Silane and Solvents.

Intended Purpose / Intended Use : It is used to be applied to dental prosthesis prior to insertion into a tooth structure to promote bonding to a prosthesis components.

Indications for Use : Used for porcelain repairs and bonding etched porcelain restorations.

Instructions for Use (Cementation of ceramic restorations) :

1. Clean the area to be cemented.
2. Carefully etch the porcelain surface, rinse and dry as instructed.
3. Apply Silane-X Bond Enhancer with a mini brush tip to treated porcelain surface.
4. Allow to dry for one minute. Apply gently moisture free air stream to accelerate drying.
5. Apply bonding resin and proceed with restoration using composites or resin cements.

Instructions for Use (Intraoral repair) :

1. Isolate the area to be repaired with a rubber dam.
2. Gingival Barrier may be used to protect areas where etching is not desired.
3. Carefully etch the porcelain surface, rinse and dry as instructed.
4. Apply Silane-X Bond Enhancer with a mini brush tip to treated porcelain surface. Allow to dry for one minute. Apply gently moisture free air stream to accelerate drying.
5. Apply bonding resin and proceed with restoration using composites or resin cements.
6. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Warnings : Silane-X contains flammable solvents. Keep away from ignition source.

Precautions :

1. One must remove the tip & re-cap the syringe after each use. Always verify material flow prior to applying intraorally.
2. Clinician and patient must wear protective eyewear.
3. Avoid contact with skin, this may cause skin sensitization in susceptible persons.
4. For professional use only.

Contraindications : Do not use in patients, If allergic to any of its components.

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 stored in a cool dry place.

Shelf Life : 2 years from the date of manufacturing.

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

Fusion Flo, Opaque

Product Description : Fusion Flo is an excellent flowable composite that delivers high strength & wear resistance. It is characterized by optimum surface affinity, penetrates into most difficult area. It combines esthetics as well as flow on demand handling for use.

Composition : Bisphenol A Glycidyl Methacrylate, Ethoxylated Bisphenol A Dimethacrylate, Urethane Dimethacrylate, Triethylene Glycol Dimethacrylate, Radiopacifiers, Fillers, Photoinitiators and Pigments.

Intended Purpose / Intended Use : It is intended to be used as a permanent filling material for anterior & posterior teeth.

Indications for Use : Fusion Flo is indicated for direct filling of class V (Cervical Caries), root erosions, wedge shaped defects. Fillings of anterior teeth (Class III & IV), Small fillings in posterior teeth. Repair of composite and ceramic veneers, Block out of undercuts. Adhesive cementing of composite and ceramic restorations.

Instructions for Use : Apply the material with applicator tip directly in the cavity and pre contour with a suitable instrument. The layer should not be thicker than 2mm. Light cure for 40 sec using standard curing light. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Warnings : Avoid prolonged or repeated contact with skin (allergic contact dermatitis), and eyes. Avoid prolonged inhalation. Do not take internally. Contact with the skin may cause irritation, burns of hypersensitivity. If contact with skin

occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention. If the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician.

Precautions : Eugenol containing materials should not be used with this product because they may effect polymerization and interfere with the hardening process. Being sensitive to heat and light, the syringes should be kept away from direct sunlight.

Contraindications : It is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.

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 stored in a cool dry place.

Shelf Life : 2 years from the date of manufacturing.

Shades : Opaque

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

Renew Universal

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 omocers 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.

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"

LOT Symbol for "BATCH CODE" **USE-BY DATE** Symbol for "USE-BY DATE" **NON STERILE** Symbol for "NON STERILE" **KEEP DRY** Symbol for "KEEP DRY"
CAUTION Symbol for "CAUTION" **CONSULT INSTRUCTION FOR USE** Symbol for "CONSULT INSTRUCTION FOR USE" **REF** Symbol for "CATALOGUE NUMBER"
REPRESENTATIVE Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"
DO NOT USE IF PACKAGE IS DAMAGED Symbol for "DO NOT USE IF PACKAGE IS DAMAGED" **KEEP OUT OF THE REACH OF CHILDREN** Symbol for "MANUFACTURER"
TEMPERATURE LIMIT Symbol for "TEMPERATURE LIMIT" **KEEP AWAY FROM SUNLIGHT** Symbol for "KEEP AWAY FROM SUNLIGHT" **FLAMMABLE** Symbol for "FLAMMABLE"
CORROSIVE Symbol for "CORROSIVE" **DANGER** Symbol for "DANGER" **HARMFUL IRRITANT** Symbol for "HARMFUL IRRITANT" **MEDICAL DEVICE** Symbol for "MEDICAL DEVICE"

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.