FUSION CRYSTA MDP ORTHODONTIC ADHESIVE KIT

PREVESTDenPro®
THE FUTURE OF DENTISTRY

LIGHT CURE ORTHODONTIC KIT

Fusion Crysta MDP Orthodontic Adhesive Kit is a light curing composite kit. It is used to bond Metal & Ceramic brackets to tooth surface and for cementation of molar bands.

Ref. : 10024

Kit contents :

1 x 4g Syringe **Fusion Crysta Adhesive** (Ref : 10022), 1 x 5ml Bottle **Fusion Crysta Adhesive Primer**, (Ref : 10021), 1 x 5ml Syringe, **Actino Gel** + 10 Applicator Tips. (Ref : 10006)

FUSION CRYSTA ADHESIVE
Light Cure Orthodontic Adhesive

Product Description : Fusion crysta adhesive bonds metal and ceramic brackets to tooth surfaces providing adequate working time for accurate brackets placement. Highly translucent adhesive designed to compliment traditional and LED curing lights.

Composition : Bisphenol A Glycidyl Methacrylate, Ethoxylated Bisphenol A Dimethacrylate, Fillers, Photopolymerizing agents and Stabilizers.

Intended Purpose / Intended Use : It is intended to be used for attachment of orthodontic barckets over the tooth surface.

Indications For Use : This product is indicated for metal and ceramic orthodontic brackets and bands to be bonded.

Instruction for use :

Tooth preparation : Rinse, isolate, and thoroughly air-dry (clean, oil-and-water-free compressed air) the surface area to be bonded.

Acid Etching : Etch enamel using 37% phosphoric acid (ACTINO GEL) etchant for 15 seconds. Rinse thoroughly. Remove excess water by blotting the surface with an absorbent pellet or high volume evacuation (HVE) for 1-2 seconds, leaving the preparation visibly moist.

Priming Teeth :

a. Dispense 1-2 drops of FUSION CRYSTA ADHESIVE PRIMER into a clean well. Replace the cap onto the bottle promptly to avoid evaporation of solvent.

b. Apply two separate coats of FUSION CRYSTA ADHESIVE PRIMER, scrubbing the preparation with a microbrush for 10-15 seconds per coat.

c. Air-drying using an air syringe for at least 10 seconds till there should be no visible movement of the adhesive. The surface should have a uniform glossy appearance : otherwise, apply an additional coat of FUSION CRYSTA ADHESIVE PRIMER.

d. Light cure for 20 seconds.

Adhesive Application From Syringe and Light Curing : With the syringe apply a small amount of Adhesive paste onto bracket base. Immediately after applying adhesive, lightly place bracket onto the tooth surface. Adjust bracket to final position, press firmly to seat bracket. A small amount of Excess adhesive around appliance base should exude without disturbing the bracket. Final adjustment must be made before the adhesive begins to cure. Using a conventional halogen curing light or a LED light, polymerize entire bonded surface for 20 seconds from the facial, mesial, and distal directions. 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 and 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 sun light.

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.

FUSION CRYSTA ADHESIVE PRIMER
Light Cure Self Etch Orthodontic Primer

Product Description : Fusion crysta adhesive primer is a light-cured single-component ORTHODONTIC PRIMER that combines etching, priming and bonding in one bottle. It is an ethanol-water based dental adhesive containing 10- Methacryloyloxydececyl Dihydrogen Phosphate (10-MDP) a functional monomer which helps in bonding to dentin and enamel.

Composition : Bisphenol A Glycidyl Methacrylate, Triethylene Glycidal Dimethacrylate, Primer, Photo curing agents and Stabilizers.

Intended Purpose / Intended Use : it is intended to be used as an agent for attachment of orthodontic brackets with orthodontic adhesive over the tooth surfaces.

Indications for Use : FUSION CRYSTA ADHESIVE PRIMER is indicated for use as a combined etchant and primer in orthodontic treatment and is used only with light curing direct bonding orthodontic adhesive (FUSION CRYSTA ADHESIVE).

Contraindications : Patients with a history of hypersensitivity to methacrylate monomers.

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 : FUSION CRYSTA ADHESIVE PRIMER 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.

Instructions for Use :

Self-Etching Technique :

a. Wash thoroughly with water spray. Use an absorbent pellet or high volume evacuation (HVE) for 1-2 seconds, to remove excess water (do not dessicate). Dispense 1-2 drops of FUSION CRYSTA ADHESIVE PRIMER into a clean well. Replace the cap onto the bottle promptly to avoid evaporation of solvent.

b. Apply two separate coats of FUSION CRYSTA ADHESIVE PRIMER, scrubbing the preparation with a microbrush for 10-15 seconds per coat.

c. Air-drying using an air syringe for at least 10 seconds till there should be no visible movement of the adhesive. The surface should have a uniform glossy appearance; otherwise, apply an additional coat of FUSION CRYSTA ADHESIVE PRIMER and repeat Step 2 and 3.

d. Light cure for 20 seconds.

e. Continue with placement of the orthodontic adhesive (FUSION CRYSTA ADHESIVE) restorative material according to the manufacturer's instructions.

Selective-Etching Technique : Wash thoroughly with water spray. Etch enamel using 37% phosphoric acid (ACTINO GEL) etchant for 15 seconds. Rinse thoroughly. Remove excess water by blotting the surface with an absorbent pellet or high volume evacuation (HVE) for 1-2 seconds, leaving the preparation visibly moist.

a. Dispense 1-2 drops of FUSION CRYSTA ADHESIVE PRIMER into a clean well. Replace the cap onto the bottle promptly to avoid evaporation of solvent.

b. Apply two separate coats of FUSION CRYSTA ADHESIVE PRIMER , scrubbing the preparation with a microbrush for 10-15 seconds per coat.

c. Air-drying with an air syringe for at least 10 seconds till there should be no visible movement of the adhesive. The surface should have a uniform glossy appearance; otherwise, apply an additional coat of FUSION CRYSTA ADHESIVE PRIMER and repeat Step 2 and 3.

d. Light cure for 20 seconds.

e. Continue with placement of the orthodontic adhesive (FUSION CRYSTA ADHESIVE) restorative material according to the manufacturer's instructions.

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.

ACTINO GEL
Dental Etching Gel

Product Description : Actino gel is a blue tinted viscous gel of 37% Phosphoric acid for etching tooth enamel and dentin conditioning or composite surfaces prior to the bonding of any composites, sealants or bonding adhesives.

Composition : Phosphoric Acid, Glycerine, Solvent, Purified Water, Fillers and Coloring Pigments.

Intended Purpose / Intended Use : It is intended to be used as enamel and dentin etching gel.

Indications for Use : Used for conditioning both dental enamel and dentine surfaces prior to the placement of an adhesive restoration.

Instructions for Use : Clean the area to be etched, rinse and dry thoroughly. Place the tip against the surface to be etched and slowly dispense the gel on the surface to lay a fine line or paint a thin layer to the areas to be etched. Allow the gel to stay for 10-15 seconds and rinse thoroughly with water spray. Dry etched tooth surface with clean, dry air. 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 of 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. It should not be used with patients who have a history of severe allergic reaction to any of the components.

Precautions : The product contains phosphoric acid. It can burn and cause irritation to the tissues and therefore confine the use to areas to be etched. Fix the applicator tip to the syringe and check the flow of gel before applying on the etching surface. Avoid contact with eyes and prolonged contact with skin.

Contraindications : Its use is contraindicated in patients who are allergic to or sensitive to phosphoric acid.

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.

Prevest DenPro Limited
Unit II, Export Promotion Industrial Park,
(EPIP), Bari Brahmana, Jammu-181133,
India. www.prevestdenpro.com
Customer Care No. : + 91 8899074151
Email : customercare@prevestdenpro.com
Made in India

E C REP
Obelis s.a
Boulevard General Wahis 53
1030 Brussels, Belgium
Tel: +(32) 2 732 59 54, Fax. +(32) 2 732 60 03
E-mail : mail@obelis.net

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

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" REF Symbol for "CATALOGUE NUMBER"

EC REP 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" MD 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 & reporting of unexpected events contact customer care.