FUSION UNIVERSAL

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Light Cured Universal Nano Hybrid Composite

Product Description : Fusion Universal is a visible light cured, radiopaque highly filled fine composite restorative material for anterior and posterior restorations of all teeth.

Composition : Bisphenol A glycidyl methacrylate, Urethane dimethacrylate, Triethylene glycol dimethacrylate, Radiopacifiers, Fillers, Photoinitiator and Pigments.

Intended Use/Intended Purpose : It is used as permanent filling material for anterior and posterior teeth.

Indications for Use : Fusion Universal composite is indicated for direct filling of class I, II, III, IV and V Cavities in anterior and posterior teeth, preventive resin restoration and repair of composite / ceramic veneers.

Instructions for use :

1. Prophy Paste : Clean the tooth to be treated and adjacent teeth with a brush and prophy paste.

2. Shade Selection : Select the shade using VITA Classical Shade Guide.

3. Restoration Depth : The amount of colour restorative material exhibits is affected by its thickness. Shade matched should be taken from the portion of the VITA classical shade guide quite most similar to the thickness of the restoration.

4. Isolation : For complete procedure a rubber dam shall be used to avoid saliva contamination.

5. DIRECT RESTORATION :

a) Cavity Preparation : Prepare the cavity using conservative cavity technique. No residual amalgam or other base material should be left in the cavity. Cover the area close to the pulp with hard setting (Cal-LC / ApaCal ART/Fusion I-Seal) Light Cure base, liner materials.

b) Etching and adhesive system: Apply 37% Phosphoric Acid Etchant Gel (Actino Gel) for 15-20 sec. Remove Gel with vigorous water spray and rinse conditioned area for at least 10 sec. Blot dry conditioned area with a moist cotton pellet. Apply Bonding agent (Fusion Bond 5) with a disposable brush to the entire cavity (Note : While using self etch bonding agent (Fusion Bond 7), the primary etching step could be eliminated or a selective etching of enamel could considered). Ensure thorough wetting of the entire cavity. Allow 20 sec air drying and re apply another coat of dentine bonding agent. Remove excess solvent by gently drying with dry air for at least 5sec to ensure uniform glossy surface. Cure adhesive for 20 -30 sec using standard curing light.

c) Dispensing the composite: Remove syringe cap and dispense material into a clean light protected well. Place the material into the cavity using a clean unabraded instrument (Teflon coated). After dispensing, screw plunger should be rotated anti clock wise by half to full turn to release residual pressure inside the syringe. Contour the material in the cavity. Light cure for 40 sec using standard curing light. Note : Build in increments of 2mm maximum using an oblique layering technique and perform finishing and polishing using standard technique.

6. INDIRECT RESTORATION: Repair of Composites and Ceramic Veneers: It is accomplished by using the similar steps as mentioned above. In order to prepare the existing surface, round or smooth any sharp corners or irregular edges, then acid-etch, apply dentine bonding agent and add composite. The dispensed material shall not be placed back in the container and the dose once applied or used shall not be reused.

Product	Light Intensity (mW/cm)	Curing Time (Sec)	Wavelength For Curing (nm)	Depth of Cure (mm)	Filler Particle Size (µ)	Filler loading (% Volume)
Fusion Universal	≤600	40	400-450	2.59 mm (opaque)/ 2.89mm (non-opaque)	2	10
	750	20				
	1200	10				

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

Precautions :

1. Use of Eugenol containing materials should be avoided with this product because they may effect polymerization and interfere with the hardening process.
2. Being sensitive to ambient light, the dental chair light should be turned off while curing and the syringes should be kept away from direct sunlight.
3. The syringe should be properly closed when not in use.
4. To prevent premature setting of the material it is advised to use light protected wells.
5. Dental orange filters should be used in conjunction with dental curing light for extra vision protection.
6. Dental loupe light filters to be used with loupe lights to prevent premature curing.

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 : 3 years from the date of manufacturing.

Presentation :

Ref : 20005

Intro Kit : 4 x 4gm syringe Fusion Universal, 1 x 5ml Bonding Agent (Fusion Bond 5 or Fusion Bond 7), 1 x 2ml syringe Actino Gel , 10 x Micro Brushes, 10 x Applicator Tips.

Ref : 20006

Combo Kit : 7 x 4gm syringe Fusion Universal , 1 x 5ml Bonding Agent (Fusion Bond 5 or Fusion Bond 7) , 1 x 2ml syringe Actino Gel , 10 x Micro Brushes, 10 x Applicator Tips.

Ref : 20006-1

Combo Kit : 7 x 4gm syringe Fusion Universal , 1 x 5ml Fusion Bond 5 , 1 x 5ml syringe Actino Gel , 10 x Micro Brushes, 10 x Applicator Tips.

Ref : 20006-3

Combo Kit : 7 x 4gm syringe Fusion Universal (Shade A1-2, A2-5) , 1 x 5ml Fusion Bond 7 , 1 x 2ml syringe Actino Gel , 10 x Micro Brushes, 10 x Applicator Tips.

Shades : A1,A2,A3,A3.5,A4,B1,B2,B3,C1,C2,C3,D1,D2,D3, Incisal/Opaque, OA1,OA2,OA3, Extra Bleach, Bleach, Gingival G1,G2,G3,G4

FUSION BOND 5
Light Curing Total Etch One Component Bonding Adhesive

Product Description : Fusion Bond 5 is a light curing, single component bonding agent for use in combination with adhesive restorations. Fusion Bond 5 adhesive was developed for bonding composites and compomers to the tooth structure as well as for bonding amalgams and indirect restorations (e.g. porcelain). Fusion Bond 5 adhesive primes and bonds in one step. Prior to the application of Fusion Bond 5, the tooth structure is conditioned with Actino Etch gel 37%.

Composition : Urethane dimethacrylate, Triethylene glycol dimethacrylate, Bisphenol A glycidyl methacrylate, Primers, Solvent, Photoinitiators and Stabilizer.

Intended Purpose / Intended Use : It is used as an adhesive for the bonding of both direct and indirect restorations.

Indications for Use:

1. Adhesive for direct, light-curing and dual-curing composite and compomer restorations.

2. Adhesive for light-initiated resin cements used in conjunction with indirect all-ceramic and composite restorations (inlays, onlays, veneers and full-coverage crowns).

Instructions for use :

1. Isolation :

Rubber dam is the preferred method of isolation.

2. Cavity preparation :

Prepare cavity with minimal tooth reduction. Bevel cavosurface enamel margins.

3. Etching :

Apply etchant to enamel and dentin. Wait for 15 seconds and then rinse for 10 seconds. Blot excess water using a cotton pellet or mini-sponge. The surface should appear glistening without pooling of water.

4. Adhesive :

Immediately after blotting, apply 2-3 consecutive coats of adhesive to etched enamel and dentin for 15 seconds with gentle agitation using a fully saturated applicator. Gently air dry for 5 seconds to evaporate solvents. Light cure for 20 - 30 seconds.

5. Restorative placement, cure and finishing :

Refer to manufacturer's instructions for placement, cure and finishing of restorative materials.

Instructions for Use :

Bonding porcelain veneers :

1. Silane treatment :

Porcelain bonding surfaces should have been etched using hydrofluoric acid by the dental laboratory. Apply Ceramic Primer to the bonding surface of the veneer. Dry for 5 seconds. Clean the prepared teeth in preparation for seating and bonding using a plain pumice slurry. Rinse thoroughly and dry.

2. Etching :

Apply etchant to both enamel and dentin. Wait for 15 seconds and rinse for 10 seconds. Blot excess water using a cotton pellet or mini-sponge. The surface should appear glistening without pooling of water. An additional 15 second etch time may be appropriate for teeth that were not prepared using a diamond bur. Residual organic matter can also require additional etch time.

3. Adhesive :

Immediately after blotting, apply 2-3 consecutive coats of adhesive to etched enamel and dentin for 15 seconds with gentle agitation using a fully saturated applicator. Gently air thin for 5 seconds to evaporate solvents. Do not light cure.

4. Adhesive application to veneer :

Apply 1 coat of adhesive to the acid etched, silane treated veneer. Dry thoroughly. Do not light cure.

5. Luting material application to veneer :

Apply luting Cement to the bonding surface of veneer.

6. Seating and curing :

Carefully seat the veneer. Clean excess luting cement from the veneer margins. Cure each area of the veneer for times recommended by the luting cement manufacturer. We recommend curing the gingival margin first, followed by the body and the incisal margin. Avoid direct contact with the light-guide during initial curing. The dispensed material shall not be placed back in the container and the dose once applied or used shall not be reused.

Warnings :

Fusion Bond 5 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 comes into contact with the eyes, immediately rinse with copious amounts of water for atleast 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.

Precautionary Information for Patients : This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product.

Precautionary Information for Dental Personnel : This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate in commonly used gloves. If product penetrate glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed.

Contraindications :

1. Do not use Fusion Bond 5 adhesive if a patient is known to be allergic to any of the material's ingredients or if the stipulated working technique cannot be used.

2. Do not use Fusion Bond 5 adhesive for direct pulp capping.

Side effects :

In rare cases, ingredients of Fusion Bond 5 adhesive may cause sensitization. In these cases, the material should no longer be used.

Interactions :

Materials containing eugenol or clove oil may inhibit the polymerization of Fusion Bond 5 adhesive.

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 : 3 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 BOND 7
Light Curing Self Etching One Component Bonding Adhesive

Product Description : Fusion Bond 7 combines the ingredients needed for etching, priming, and bonding into a single adhesive, thereby eliminating separate etching and priming steps of the bonding process. Fusion Bond 7 adhesive can be used for the bonding of both direct and indirect restorations.

Composition : Urethane Dimethacrylate, Triethylene Glycol Dimethacrylate, Bisphenol A Glycidyl Methacrylate, HEMA, Primers, Photoinitiators, Solvent and Stabilizers.

Intended Purpose / Intended Use : It is used as an adhesive for the bonding of both direct and indirect restorations.

Indications for Use:

Direct Applications :

1. Light-cured composite and compomer restorations.
2. Composite/ceramic/ metal repairs.
3. Cavity sealing for amalgam restorations.
4. Light-cured or dual-cured core build-ups.

Indirect Applications :

1. Veneers **2.** Porcelain, composite, and metal-based inlays, onlays, crowns, bridges. **3.** Endodontic posts. **4.** Cavity sealing as a pretreatment for indirect restorations.

Instructions for Use :

For bonding direct restorations: (Bonding Composites/Compomers to Dentin/Enamel)

1. Prepare cavity. Wash thoroughly with water spray and air dry (Do not desiccate). Note : For optimal adhesion, always prep (bevel) all enamel and/or margins prior to application of Fusion Bond 7 adhesive.
2. Shake Fusion Bond 7 adhesive bottle briefly. Note : Upon first use, shake Fusion Bond 7 adhesive bottle vigorously for 20 - 30 seconds.
3. Dispense 2-3 drops of Fusion Bond 7 adhesive into a clean well. Replace cap immediately after dispensing.
4. Using the disposable applicator brush, apply a generous amount of Fusion Bond 7 adhesive to the enamel/dentin surface. Scrub the surface with a brushing motion for 20 seconds.
5. Apply a second application of Fusion Bond 7 adhesive with a brushing motion for 20 seconds.
6. Dry the adhesive with gentle air first and then medium air for at least 5 seconds with oil-free air.
7. Light cure for 20–30 seconds.
8. Apply composite according to manufacturer's instructions for use.

Instructions for bonding Indirect Restorations: Veneers, crowns, bridges, inlays, onlays and metal-based restorations (Used in conjunction with luting cement)

1. Clean the preparation. Wash thoroughly with water spray and air dry (Do not desiccate).
2. Shake Fusion Bond 7 adhesive bottle briefly. **Note :** Upon first use, shake Fusion Bond 7 adhesive bottle vigorously for 10 sec.
3. Bottle Delivery : Dispense 2-3 drops of Fusion Bond 7 adhesive into a clean well. Replace cap immediately after dispensing.
4. Using the disposable applicator brush, apply a generous amount of Fusion Bond 7 adhesive to the enamel/dentin surface. Scrub the surface with a brushing motion for 20 seconds.
5. Apply a second application of Fusion Bond 7 adhesive with a brushing motion for 20 seconds.
6. Dry the adhesive with gentle air first and then medium air for at least 5 seconds with oil-free air. Avoid pooling of adhesive before light curing.
7. Light cure for 20–30 seconds.
8. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Warnings : Fusion Bond 7 adhesive is an irritant. Contact with the skin, should be avoided. If case of skin contact, immediately wash with soap and water. If the material come into contact with the eyes, immediately rinse with copious amounts of water for atleast 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. Do not use Fusion Bond 7 for any purpose other than those listed in the indications for use.
2. Do not mix with other adhesives or other products.
3. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should be worn while using the product.

Contraindications :

1. Do not use Fusion Bond 7 adhesive if a patient is known to be allergic to any of the material's ingredients or if the stipulated working technique cannot be used.

2. Do not use Fusion Bond 7 adhesive for direct pulp capping.

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 : 3 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.

ACTINO GEL
DENTAL ETCHING GEL

Product Description : Actino 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, Fillers, Purified Water, Coloring Pigment and Solvent.

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

Indications for Use : Used for etching & conditioning both of 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 the container and the dose once applied or 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 soaked in alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs, discontinue the use and seek medical attention. If the product comes into contact with the eyes, rinse throughly with fresh water and consult a physician. It should not be used in 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 : It's 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 : 3 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" 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 "KEEP OUT OF THE REACH OF CHILDREN" Symbol for "MANUFACTURER" Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"

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

Symbol for "HARMFUL IRRITANT" Symbol for "CORROSIVE" 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, complaint and reporting of unexpected events contact customer care.