Bisco

C€ 0459*

UNIVERSAL PRIMERTM

Dual-Cured Adhesive

Instructions for Use

IN-219R3 Rev. 3/18



BISCO, Inc. 1100 W. Irving Park Rd. Schaumburg, IL 60193 U.S.A. 847-534-6000 1-800-247-3368

Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed Dentist.

UNIVERSAL PRIMER™*

Dual-Cured Adhesive

GENERAL INFORMATION

UNIVERSAL PRIMER is a low film thickness, auto-polymerizing adhesive with a light-curing alternative, designed for the dentist who prefers not to light cure the adhesive layer under indirect restorations. The UNIVERSAL PRIMER chemical formulation allows for the adhesive to be used in either self-etch or total-etch mode, based on the clinical situation and dentist preference. UNIVERSAL PRIMER is compatible with light-cured, self-cured, and dual-cured resin composite, cement, and core materials for direct and indirect procedures, without any additional activators. UNIVERSAL PRIMER is available in either a two bottle system or in the handheld, all-in-one ACE* cartridge system.

Indications for Use:

UNIVERSAL PRIMER is used for:

- Direct Restorations (resin-based composite, resin-modified glass ionomer, core build-ups, etc.)
- Indirect Restorations (metal, glass ceramics, zirconia/alumina, etc.)
- Bonding Resin or Primer for Substrates
- Desensitization/Sealing of Tooth
- Intraoral Repair (chipped porcelain, additions to direct restorations, etc.)
- Cementation of Posts/Dowels

Contraindications:

· Patients who have a history of severe allergic reactions to methacrylate resins.

Warnings:

- · Highly flammable.
- Avoid splashing into the eyes. If UNIVERSAL PRIMER comes into contact with the eyes, flush with copious amounts of
 water and seek medical attention.
- The phosphoric acid in the etchant is a severe eye and skin irritant. Injury may result if the etchant is allowed to remain
 on the skin or mucosa for extended periods of time. If accidentally splashed into the eye, flush with copious amounts of
 water and seek medical attention immediately. In case of contact with other tissues, rinse immediately with plenty of
 water for several minutes.
- When using dental adhesives, contamination will compromise dentin bonding and may result in decreased longevity of the restoration.
- A rubber dam is recommended for all direct restorations and other indications where contamination may be possible.

Cautions:

 Cross-contamination: Product may contain items that are designed for one time use. Dispose of used or contaminated accessories. Do not clean, disinfect or reuse.

Precautions:

- UNIVERSAL PRIMER is a light-sensitive, self-curing material. Use UNIVERSAL PRIMER 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.
- To avoid evaporation of UNIVERSAL PRIMER, keep container tightly closed.
- Avoid contact with the skin; unpolymerized resins may cause skin sensitization in susceptible persons. In case of contact, wash skin with soap and water.
- ACE UNIVERSAL PRIMER may require refrigeration. Refer to specific product storage instructions for complete information prior to use.
- If ZOE containing materials have been used on the tooth structure within 2-3 weeks, adequately clean the tooth surface with an abrasive prior to adhesive use.
- · See individual component labels for specific expiration dates.
- · Safety data sheet available on request.
- · Safety data sheet available at www.Bisco.com.

INSTRUCTIONS FOR USE

Direct Restorations

- 1. Choose either the SELF-ETCHING TECHNIQUE or the TOTAL-ETCHING TECHNIQUE below.
 - SELF-ETCHING TECHNIQUE: Prepare cavity. Wash thoroughly with water spray. Use an absorbent pellet or high volume evacuation (HVE) for 1-2 seconds, to remove excess water (do not desiccate).
 NOTE: BISCO's SELECT HV^{®+} ETCH may be used on cut or uncut enamel to increase mechanical retention. This etchant was designed for precise selective placement.
 - TOTAL-ETCHING TECHNIQUE: Prepare cavity. Wash thoroughly with water spray. Etch enamel and dentin using an
 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.
- If using the ACE delivery system, follow the ACE DISPENSER INSTRUCTIONS FOR USE for dispensation of ACE UNIVERSAL PRIMER. If using bottles, dispense an equal number of drops of UNIVERSAL PRIMER Parts A & B (1:1 ratio) into a clean mixing well. Replace the cap(s) promptly to avoid evaporation of solvent.
- 3. Using a brush, mix adhesive for 5 seconds.

- Apply two separate coats of UNIVERSAL PRIMER, scrubbing the preparation with a microbrush for 10-15 seconds per coat. Do not light cure between coats.
- 5. Evaporate excess solvent by strongly air-drying with an air syringe for at least 10 seconds; there should be no visible movement of the adhesive. The surface should have a uniform glossy appearance; otherwise, apply an additional coat of UNIVERSAL PRIMER and repeat Step 5.
- 6. Light cure for 10 seconds.
- 7. Continue with placement of restorative material.

Indirect Restorations

- 1. Choose either the SELF-ETCHING TECHNIQUE or the TOTAL-ETCHING TECHNIQUE below.
 - SELF-ETCHING TECHNIQUE: Prepare cavity. Wash thoroughly with water spray. Use an absorbent pellet or high volume evacuation (HVE) for 1-2 seconds, to remove excess water (do not desiccate).
 NOTE: BISCO's SELECT HV ETCH may be used on cut or uncut enamel to increase mechanical retention. This etchant
 - was designed for precise selective placement.
 TOTAL-ETCHING TECHNIQUE: Prepare cavity. Wash thoroughly with water spray. Etch enamel and dentin using an etchant for 15 seconds. Reinse 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.
- If using the ACE delivery system, follow the ACE DISPENSER INSTRUCTIONS FOR USE for dispensation of ACE UNIVERSAL PRIMER. If using bottles, dispense an equal number of drops of UNIVERSAL PRIMER Parts A & B (1:1 ratio) into a clean mixing well. Replace the cap(s) promptly to avoid evaporation of solvent.
- 3. Using a brush, mix adhesive for 5 seconds.
- Apply two separate coats of UNIVERSAL PRIMER, scrubbing the preparation with a microbrush for 10-15 seconds per coat. Do not light cure between coats.
- Evaporate excess solvent by strongly air-drying with an air syringe for at least 10 seconds; there should be no visible movement of the adhesive. The surface should have a uniform glossy appearance; otherwise, apply an additional coat of UNIVERSAL PRIMER and repeat Step 5.
- 6. Refer to next section for restoration treatment, and continue with cementation.

Bonding resin or primer for substrates

Priming of Metal, Zirconia, Alumina, Composite and Post Restorations:

- Prepare the surface of the restoration according to instructions provided by the laboratory or the manufacturer (e.g. particle abrasion).
- 2. Clean the bondable surfaces of the restoration; rinse and air dry.
- Apply 1 coat of Z-PRIME™* Plus or UNIVERSAL PRIMER, uniformly wetting the bondable surface. Dry strongly with an air syringe.
- 4. Proceed with cementation.

Priming of Porcelain (silica-based) or Lithium Disilicate Restorations:

- Since different ceramics require different surface treatments (e.g. etching or particle abrasion), contact the laboratory or manufacturer for proper internal surface treatment instructions.
- 2. Clean the bondable surfaces of the restoration; rinse and air dry.
- Apply 1 coat of silane, such as BISCO's PORCELAIN PRIMER*, or UNIVERSAL PRIMER. Dry with an air syringe. NOTE: BISCO's research demonstrates silane maintains bond durability, maximizing longevity to glass ceramics.
- 4. Proceed with cementation.

Desensitization/Sealing of Tooth

- · Prepared tooth surface / Immediate Dentin Sealing
- Uncut tooth surface / Root surface desensitization

Prepared tooth surface / Immediate Dentin Sealing

- 1. Choose either the SELF-ETCHING TECHNIQUE or the TOTAL-ETCHING TECHNIQUE below.
 - SELF-ETCHING TECHNIQUE: Prepare cavity. Wash thoroughly with water spray. Use an absorbent pellet or high volume evacuation (HVE) for 1-2 seconds, to remove excess (do not desiccate).
 NOTE: BISCO's SELECT HV ETCH may be used on cut or uncut enamel to increase mechanical retention. This etchant was designed for precise selective placement.
 - TOTAL-ETCHING TECHNIQUE: Prepare cavity. Wash thoroughly with water spray. Etch enamel and dentin using an 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.
- If using the ACE delivery system, follow the ACE DISPENSER INSTRUCTIONS FOR USE for dispensation of ACE UNIVERSAL PRIMER. If using bottles, dispense an equal number of drops of UNIVERSAL PRIMER Parts A & B (1:1 ratio) into a clean mixing well. Replace the cap(s) promptly to avoid evaporation of solvent.
- 3. Using a brush, mix adhesive for 5 seconds.
- Apply two separate coats of UNIVERSAL PRIMER, scrubbing the preparation with a microbrush for 10-15 seconds per coat. Do not light cure between coats.
- Evaporate excess solvent by strongly air-drying with an air syringe for at least 10 seconds; there should be no visible movement of the adhesive. The surface should have a uniform glossy appearance; otherwise, apply an additional coat of UNIVERSAL PRIMER, and repeat Step 5.
- 6. Light cure for 10 seconds.
- Continue with provisionalization procedure. It is recommended to coat the preparation with a waterbased lubricant such as PRO-V COAT**prior to application of the provisional material, such as PRO-V FILL**.

Uncut tooth surface

- Clean root surface/uncut tooth by scrubbing with a cleanser such as BISCO's CAVITY CLEANSER™* and pumice or BISCO's CAVITY CLEANSER on an absorbent pellet.
- 2. Rinse with warm water and blot dry with an absorbent pellet.
- If using the ACE delivery system, follow the ACE DISPENSER INSTRUCTIONS FOR USE for dispensation of ACE UNIVERSAL PRIMER. If using bottles, dispense an equal number of drops of UNIVERSAL PRIMER, Parts A & B (1:1 ratio) into a clean mixing well. Replace the cap(s) promptly to avoid evaporation of solvent.
- 4. Using a brush, mix adhesive for 5 seconds.
- Apply two separate consecutive coats of UNIVERSAL PRIMER, scrubbing the preparation with a microbrush for 10-15 seconds per coat. Do not light cure between coats. Helpful Hint: The "cold" from the initial application will often cause a mild response from the patient. However,
- UNIVERSAL PRIMER immediately permeates and seals the dentinal tubules, eliminating sensitivity.
 6. Evaporate excess solvent by strongly air-drying with an air syringe for at least 10 seconds; there should be no visible movement of the adhesive. The surface should have a uniform glossy appearance; otherwise, apply an additional coat of UNIVERSAL PRIMER and repeat Steps 6.
- 7. Light cure for 10 seconds.
- 8. Remove the oxygen-inhibited layer with an alcohol-moistened cotton pellet or gauze

Intraoral Repairs

- 1. Roughen any surface that will be bonded. Rinse and air dry.
- Any porcelain or lithium disilicate surfaces present should be treated with hydrofluoric acid for the specified time and handled according to the manufacturer's instructions. Apply a silane primer (e.g.PORCELAIN PRIMER) for optimum bond strength and durability of the interface.
- If using the ACE delivery system, follow the ACE DISPENSER INSTRUCTIONS FOR USE for dispensation of ACE UNIVERSAL PRIMER. If using bottles, dispense an equal number of drops of UNIVERSAL PRIMER Parts A & B (1:1 ratio) into a clean mixing well. Replace the cap(s) promptly to avoid evaporation of solvent.
- 4. Using a brush, mix adhesive for 5 seconds.
- Apply 1 coat of UNIVERSAL PRIMER to the repair site and strongly air dry to remove excess solvent. Light cure for 10 seconds.
- If Metal Masking is desired, BISCO's OPAQUER* may be used to successfully mask the dark metal hue without influencing the subsequent shade of restorative materials.
- 7. Proceed with composite layering and finishing.

Cementation of Posts/Dowels:

Please follow the preparation instructions for use of the post to be used. The following procedure for cementation is recommended:

Treatment of Post/Dowel

- 1. Clean the post with alcohol and dry it with water-free and oil-free air.
- Apply one to two coats of Z-PRIME Plus, uniformly wetting the entire post surface. Dry with an air syringe for 3-5 seconds.
 Z-PRIME Plus is recommended for bonding all metal, oxide-ceramic, and composite/fiber posts.

Preparation of Root Canals

- 1. Isolate the area and treat the root canal endodontically as usual.
- 2. Clean and irrigate. Rinse with water, dry with paper tips.
- If using the SELF-ETCHING TECHNIQUE, proceed directly to step #4. If using the TOTAL-ETCHING TECHNIQUE, etch
 the canal with phosphoric acid for 15 seconds. Rinse thoroughly and remove excess water with a brief burst of air and
 paper point(s) to remove any pooled water from the canal; proceed to step #4.
- 4. If using the ACE delivery system, follow the ACE DISPENSER INSTRUCTIONS FOR USE for dispensation of ACE UNIVERSAL PRIMER. If using bottles, dispense an equal number of drops of UNIVERSAL PRIMER Part A & B (1:1 ratio) into a clean mixing well. Replace the cap(s) promptly to avoid evaporation of solvent.
- 5. Using a brush, mix adhesive for 5 seconds.
- With an endodontic brush, apply and scrub two separate coats of UNIVERSAL PRIMER into the canal. Do not light cure between coats.
- Remove excess pooling of material with paper points and light suction. Strongly air dry. NOTE: The paper point step is important for removal of any pooled adhesive so that there is no interference in complete seating of the post.
- 8. Continue with cementation.

ACE® DISPENSER INSTRUCTIONS FOR USE

To Load and Activate The New Cartridge

NOTE: Ensure the two red plungers of the ACE Dispenser are fully retracted by pressing the eject button. (Plungers should not be visible prior to loading cartridge.)

- 1. With label facing up, insert cartridge into the ACE Dispenser.
- 2. Remove cap.
- 3. Press orange button repeatedly until drops dispense from both tips of the cartridge.

To Dispense Product For Use

- Position both cartridge tips over a mixing well and press orange button 1 time. The correct proportion of material will be dispensed. If needed, touch the tips to the side of the mixing well to release the drops.
- 2. Replace cap tightly on the cartridge. It is recommended the cartridge be left in the ACE Dispenser until depleted.

To Eject The Cartridge

- To remove cartridge, turn the ACE Dispenser so the logo is facing down. With cap removed, slide the eject button.
 Pull the cartridge out of the ACE Dispenser.
- 3. Discard cap and cartridge.
- Load a new cartridge.

DISPOSAL: Refer to community provisions relating to waste. In their absence, refer to national or regional provisions relating to waste.

DISINFECTION: Dispenser - Use surface disinfectant spray or wipes recommended for ABS, PVC and polycarbonate (PC) plastics according to manufacturer's instructions. Avoid direct contact of disinfection solution with the adhesive material at the cartridge tips. Do not submerge or autoclave.

Mixing Well - Soak in a cold chemical bath materials compatible with polypropylene according to manufacturer instructions.

STORAGE: Store UNIVERSAL PRIMER adhesive Parts A&B bottles at 2°C/36°F-25°C/77°F. Refrigerate (2°C/36°F-8°C/46°F) ACE UNIVERSAL PRIMER cartridge in its sealed pouch. Do not open pouch until ready to use. Allow Refrigerated ACE UNIVERSAL PRIMER cartridge to reach room temperature before use. If refrigerating a partially used cartridge, it should be kept in the ACE Dispenser. Refrigeration is not required if the cartridge is depleted within sixty days.

WARRANTY: BISCO, Inc. recognizes its responsibility to replace products if proven to be defective. BISCO, Inc. does not accept liability for any damages or loss, either direct or consequential, stemming from the use of or inability to use the products as 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.

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BISCO, INC. 1100 W. Irving Park Rd. Schaumburg, IL 60193 U.S.A. 1-847-534-6000 1-800-247-3368 www.bisco.com

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