

Bisco

ETCHANTS

*Semi-
Gel*

Phosphoric Acid Etchant

UNI-ETCH® (32%) C € 0459

UNI-ETCH® (32%) W/BAC

ETCH-37™ (37%) C € 0459

ETCH-37™ (37%) W/BAC

Instructions for Use



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

IN-039R17
Rev. 8/18

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

ETCHANTS

UNI-ETCH[®]* (32%) UNI-ETCH[®]* (32%) W/BAC

ETCH-37[™]* (37%) ETCH-37[™]* (37%) W/BAC

Phosphoric Acid Etchant

GENERAL INFORMATION

BISCO ETCHANTS are phosphoric acid (H₃PO₄), intended for use on enamel, dentin, and as a cleaning agent for restorative substrates. BISCO ETCHANTS will effectively remove the smear layer, etch and demineralize enamel and dentin, producing the necessary microretentive surface for successful bonding. The etchant rinses away cleanly and quickly, leaving no residue. BISCO ETCHANTS are also available with benzalkonium chloride (BAC), an antimicrobial agent. Research confirms the development of residual bacterial inhibition zones of up to 7 mm, when challenged (in-vitro) with *Actinomyces viscosus*².

NOTE: The inclusion of benzalkonium chloride has not been shown to correlate with a reduction in secondary decay in patients. In-vivo clinical studies to evaluate the effects of benzalkonium chloride on oral bacteria or caries have not been performed.

Indications For Use:

1. Etching dentin and enamel
2. Selective enamel etching
3. Cleaning agent on dental restorative materials

Warnings:

- 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. In case of contact with other tissues, rinse immediately with plenty of water for several minutes.
- If accidentally splashed into the eye, flush with copious amounts of water and seek medical attention immediately.

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:

- Keep away from direct sunlight. Prolonged exposure to sunlight could cause a discoloration of the etchant; this will not compromise the efficacy of the product.
- Test the application of Etchant on a mixing pad or a glass slab, BEFORE use on patients so as to become familiar with the pressure required to dispense the Etchant from the tip. Never use intraorally before checking flow from tip. Never use force on plunger to start flow intraorally; this could result in a subsequent uncontrolled discharge of material. If resistance to flow is experienced, DO NOT proceed. Replace with new tip and verify flow before use on patient.
- Prophylactic pastes containing oil or fluoride should not be used as these additives may interfere with etching.
- See individual component labels for specific expiration dates.
- Safety data sheet available on request.
- Safety data sheet available at www.Bisco.com.

30 ML BULK SYRINGE

30 ml bulk syringe

- Properly connect and secure the bulk syringe to the unit dose syringe. System must be fully engaged prior to extruding material.
- Do not apply force to connect the two systems as it could result in breakage of either syringe connecting luer.
- Do not apply force to the back of the piston while syringe is capped, has unit dose syringe attached or is without tip or syringe.
 - a. If capped or has unit dose syringe attached, material may spurt back around piston, filling space between piston and barrel wall or extrude out the back end of the syringe.
 - b. If bulk syringe is neither capped nor has attached unit dose syringe, material may burst out from tip from syringe.
- Recap bulk syringe while not in use to keep material from drying and gently place back into box. Do not forcefully place syringe down with tip in the air as material may extrude.
- Do not transfer material back and forth between bulk and unit dose syringe as it may cause air pockets and possible cross-contamination.

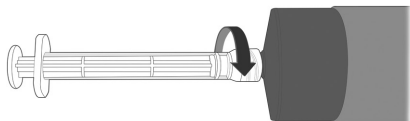
NOTE: Be sure to observe the 30 ml bulk syringe.

1. Material may be contained between the piston and wall of barrel. Product is still in workable condition.
2. If observed that material does not extrude into unit dose syringe, secure unit dose syringe onto bulk syringe system and gently pull back to suction the air from the bulk syringe. Disengage unit dose syringe, and release air. Repeat as necessary until material begins to extrude into unit dose syringe.

NOTE: Be sure to observe the unit dose syringe.

1. Unit dose syringe plunger may pop out back if pulled too quickly. Gently pull back on unit dose syringe plunger to extrude material.
2. Connect dispensing tip securely, which may otherwise result in leakage or excess spattering.
3. Single use only. Otherwise may result in cross-contamination. Discard after use.

1. If using BISCO ETCHANTS 30 ml bulk syringe system, proceed as follows:
 - a. Attach the pre-labeled unit dose (1.2 ml) syringe to the end of the bulk syringe by turning the luer lock to the unit dose syringe tightly on to the male thread of the bulk syringe system syringe.



- b. Once connection is secure, pull the unit dose syringe plunger back slowly to intake material to the desired amount.



- c. Promptly replace cap back onto the 30 ml syringe.
- d. If loaded syringe is not to be used immediately, replace the lock cap.
- e. When ready for use, remove the cap and twist to attach the light blue 25 gauge tip. Dispense as indicated.

INSTRUCTIONS FOR USE

1. Etching dentin and enamel

2. Selective enamel etching

1. Remove white cap from etchant syringe.
2. Attach the light blue 25 gauge tip.
3. Verify flow of etch before intraoral application. Dispense a small portion of gel onto a pad or gauze to familiarize yourself with its viscosity.
4. If surface to be etched is not freshly cut, clean with a pumice-water slurry. Prophy pastes containing oil or fluoride should not be used as these additives may interfere with etching. Rinse well.
5. Isolate: Rubber dam is the preferred method of isolation.
6. Extrude etchant directly onto the surfaces to be etched. Leave etchant in place for 15 seconds.
7. Thoroughly rinse for 5 seconds with suction. If selectively etching enamel, suction prior to rinsing to avoid etchant flowing on to dentin.
8. Immediately proceed with the bonding procedure.
9. Discard all single use components.

3. Cleaning agent on dental restorative materials

1. BISCO ETCHANTS may be used on restorative substrates to effectively remove organic contaminants. Apply etchant to the surface for 30 seconds and rinse thoroughly with water.

NOTE: BISCO recommends priming the substrate with PORCELAIN PRIMER*, BIS-SILANE™* or Z-PRIME™* Plus prior to try-in and subsequent cleaning with phosphoric acid.

HYGIENE: Re-cap syringes with the luer lock cap. Use of commonly available hygienic protective covering to avoid any contamination of syringes during treatment is recommended.

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

STORAGE: Store at room temperature (20°C/68°F - 25°C/77°F). Store away from direct sunlight.

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.

* UNI-ETCH is a registered trademark of BISCO, Inc.

PORCELAIN PRIMER is manufactured at BISCO, Inc.

ETCH-37, BIS-SILANE and Z-PRIME are trademarks of BISCO, Inc.

1. Kanca, J. J. "Etchant Composition and Bond Strength to Dentin". Am J Dent 1993;6:162-164.

2. Dr. Daniel Chan, University of Texas Health Science Center at San Antonio Dental School. Residual Effect of 1 and 2% Benzalkonium Chloride Incorporated into an Etchant on the Susceptibility of *Actionomyces viscosus* T14V 1993.

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

 BISCO France
208, allée de la Coudoulette
13680 Lançon De Provence
France
33-4-90-42-92-92