

Bisco

CE 0459*

ONE-STEP[®]

Light-Cured

Universal Dental Adhesive

ONE-STEP[®] PLUS

Light-Cured

Filled Universal Dental Adhesive

Instructions for Use

U.S. Patents:
5,749,733 & 5,658,963

IN-130R6
Rev. 10/17



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

ONE-STEP®*
Universal Dental Adhesive
or
ONE-STEP® PLUS
Filled Universal Dental Adhesive

GENERAL INFORMATION

ONE-STEP/ONE-STEP PLUS (OS/OS+) are technological breakthroughs from BISCO. **OS/OS+** are 5th generation (2-step) Universal Adhesives. **ONE-STEP PLUS** is 8.5% filled with a revolutionary proprietary filler with an average particle size of 1µm. **OS/OS+** are designed to bond composite to dentin, enamel, cast metals, treated porcelain and set amalgam. Because of its unique chemistry, and its minimal and uniform film thickness, this system is also designed for indirect techniques when used with a cementation medium as well as amalgam bonding. **OS/OS+** are truly universal adhesives that have been designed to work with light-cured, self-cured and dual-cured composite materials.

Indications for use:

1. All Direct Composite Restorations
2. Directed Shrinkage Composite Restorations
3. Desensitization of Crown Preparations Prior to Impression Making/Provisionalization
4. Indirect Restorative Cementation: Metal, Porcelain and Composite
5. Adhesive (Bonded) Amalgam Restorations
6. Fresh Amalgam to Old Amalgam
7. Composite Core Build-Ups
8. Porcelain Repairs
9. Composite to Composite (Repair)
10. Composite to Metal/Set Amalgam (Direct Veneering)
11. Root Desensitization
12. Endodontic Post Bonding

Warnings:

- Highly Flammable
- When using dental adhesives, saliva contamination will seriously compromise dentin bonding.
- 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.
- A rubber dam is essential to the success of a porcelain repair. Moisture contamination of porcelain or metal is detrimental.

Cautions:

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

Precautions:

- For **ONE-STEP PLUS**, shake bottle well to redistribute any filler particles that may have settled. If needed, invert bottle and tap on hard surface to free agitator. Allow bottle to vent in an upright position prior to dispensation.
- For optimal performance, use when **OS/OS+** are at room temperature.
- Avoid contact with the skin; unpolymerized (meth)acrylate resins may cause skin sensitization in susceptible persons. In case of contact, wash skin with soap and water.
- Refer to HELPFUL HINTS section for additional technique-related precautions.
- See individual component labels for specific expiration dates.
- Safety data sheet available on request.
- Safety data sheet available at www.Bisco.com.

HELPFUL HINTS

1. **OS/OS+** can be used with bases or liners made of composite, resin-modified glass ionomer or glass ionomer.

Precautions:

- ZOE bases may inhibit the set of the adhesive or composite.
- Covering the dentin with a base or liner prior to adhesive application may compromise dentin bonding.

2. In order to facilitate penetration of **OS/OS+** adhesive into the dentin and enamel, the tooth surface should be left slightly but visibly moist with water (not saliva). The optimum method of moistening the tooth with water would be the 'blot' technique with a moistened Foam Pellet. A brief burst of air (2-3 seconds) with an air syringe after rinsing the etchant will also suffice.

3. **OS/OS+** adhesives contain a monomer, BPDM, dissolved in an acetone solvent. Once 2 coats have been applied to the dentin surface, thorough but gentle air drying for at least 10 seconds should be done to remove excess solvent. Begin with a gentle stream initially and increase to a fairly strong stream of air.

Precautions:

- Inadequate air drying will not completely evaporate the solvent and may lead to reduced bond strength and post-operative sensitivity.

4. Proper air-drying is extremely important with all bonding procedures but particular attention should be given to air drying of inlay or onlay preparations. Care should be given to avoid pooling of adhesive in the internal line angles. A stream of air should be directed at all line angles to properly thin adhesive.

Precautions:

- Excessive pooling could interfere with the seating of the definitive restoration.

- To increase adhesion to exposed metal, a sandblaster is highly recommended for surface roughening. Diamond bur abrasion may not provide enough surface area for proper bonding.
- Always lubricate the matrix band prior to amalgam bonding procedures to prevent adhesion of amalgam to the band. Hard inlay wax or a crayon works well. Copalite or vaseline are not always dependable and therefore, not recommended.
- Adhesive (Bonded) Amalgam Restorations require the use of RESINOMER™, a dual-cured Amalgam Bonding/Luting System (sold separately). RESINOMER bonds tenaciously to OS/OS+ as well as amalgam. Mechanical adhesion is created as amalgam is condensed into the uncured RESINOMER, while chemical adhesion occurs due to the diarylsulfone dimethacrylate (DSDM).

INSTRUCTIONS FOR USE

- Isolate tooth and prepare the cavity in a conservative manner. Clean the entire surface with a slurry of pumice and a cleanser, such as CAVITY CLEANSER™, or water.
- Etch enamel and dentin using an etchant, such as UNI-ETCH™ w/BAC or ETCH-37™ w/BAC for 15 seconds.
- Preferred method:** Rinse thoroughly. Remove excess water by blotting the surface with a Foam Pellet, leaving the dentin and enamel visibly moist with a shiny surface.
- Alternative method:** Rinse thoroughly. Air dry for 2-3 seconds. **Do not allow enamel or dentin to dry for an excessive period of time.** Immediately apply a rewetting/desensitizing agent such as AQUA-PREP™ F or water to the enamel and dentin, using a Foam Pellet. Allow dwelling for 20-25 seconds. Blot the preparation dry with a Foam Pellet or gently air dry for 1-2 seconds to remove excess moisture.

4. For bottle delivery:

Precautions:

- When using **ONE-STEP PLUS**, shake bottle once the mixing element inside the bottle is audible. If needed, invert bottle and tap on hard surface to free agitator.

Hold bottle at a 45° angle and dispense 1-2 drops of OS/OS+ into a mixing well. Using a brush, apply a **minimum of 2 generous coats** to the entire preparation, rewetting brush between coats. Agitate slightly for 10-15 seconds.

NOTE: Use of a flocked brush (e.g., Microbrush™) will require additional coats.

For unit-dose delivery:

Precautions:

- Unit-dose components are for single use only. Do not clean, disinfect or reuse.

If using **ONE-STEP PLUS** unit-dose, see instructions on pouch for activation. Apply directly. A mixing well is not required.

- Beginning with a gentle stream, gently but thoroughly air dry to evaporate solvent.
NOTE: After drying, the surface should be shiny with OS/OS+ visible on the preparation. If not, apply more OS/OS+ and air dry. **An excessively thin layer of OS/OS+ will not provide maximum bond strength.**
 - Light cure for 10 seconds.
OPTIONAL FOR CLASS V RESTORATIONS*: Apply 1-2 additional coats of OS/OS+ to the entire internal surface of the preparation, agitating slightly for 10 seconds. Thoroughly air dry and light-cure for 10 seconds.
 - Proceed with restorative treatment.
- Research indicates a thicker layer of adhesive will help dissipate the effects of tooth flexure²³ while providing a wet air-inhibited resin layer to help adapt dry, viscous composites.**

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).

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.

- Kanca, J. One-Step bond strength to enamel and dentin. *Am J Dent* 1997;10:1 5-8.
- Kemp-Scholte CM, Davidson CL. Marginal integrity related to bond strength and strain capacity of composite resin restorative systems. *J Prosthet Dent* 1990b;64:658-664.
- Van Meerbeek, B. Dentine Adhesion: Morphological, physico-Chemical and Clinical Aspects. Thesis, Leuven (Belgium) 1993.

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