**DIRECTIONS FOR USE**

For dental use only. Caution U.S. Federal law restricts this device to sale by or on the order of a dentist.

1. **PRODUCT DESCRIPTION**

   aladdin Total Etch Adhesive is a universal self-priming dental adhesive system designed to bond resin based materials and cements to enamel and dentin as well as to metals and ceramic. When mixed with aladdin Self Cure Activator, aladdin Total Etch Adhesive is compatible with many dual cure/self-cure resin cements to bond indirect restorations including crowns, inlays, onlays, veneers, bridge retainers and endodontic posts and is compatible with many dual cured direct composite restoratives such as core build-up material.

   aladdin Total Etch Adhesive is designed to be used following 34%-36% phosphoric acid conditioning. (See Complete Directions for Use prior to use)

1.1 **Delivery forms**

   aladdin Total Etch Adhesive is available in:

   - 4.5mL bottles

   aladdin Self Cure Activator is available in:

   - 4.5mL bottles

1.2 **Composition**

   aladdin Total Etch Adhesive:

   - Acid modified acrylate and dimethacrylate resin; Urethane Dimethacrylate (UDMA); Triethyleneglycol dimethacrylate (TEGDMA); 2-hydroxyethylmethacrylate (HEMA); Stabilizer; Ethyl-4-dimethylaminobenzoate; Photoinitiator; Functionalized amorphous silica; t-butanol

   aladdin Self Cure Activator:

   - Urethane Dimethacrylate (UDMA); 2-hydroxyethylmethacrylate (HEMA); Catalyst; Photoinitiators; Stabilizers; Acetone; Water

1.3 **Indications**

   1. Direct, light-cured composite restorations and repairs, indirect veneer cementation with light-cured resin cement.
   2. Direct, dual cure or self-cure composite restorations and core build-ups.
   3. Indirect restorations; dual cured and self-cured resin cemented inlays, onlays, crown and bridge retainers and endodontic posts.

1.4 **Contraindications**

   1. aladdin Total Etch Adhesive is contraindicated for use with patients who have a history of allergic reaction to methacrylate resins or any of the components.
   2. aladdin Total Etch Adhesive is contraindicated for direct application to dental pulp tissue (direct pulp capping).

1.5 **Compatible materials**

   aladdin Total Etch adhesive may be used as an adhesive for numerous visible light cured composite restoratives and cements. aladdin Total Etch adhesive (adhesive plus aladdin Self Cure Activator) may be used as an adhesive for dual cure (visible light and chemical cured) or self cured (chemical cured).

2. **GENERAL SAFETY NOTES**

2.1 **Warnings**

   1. aladdin Total Etch Adhesive contains polymerizable methacrylates which may be irritating to skin, eyes and oral mucosa and may cause allergic contact dermatitis in susceptible persons.
   2. Avoid eye contact to prevent irritation and possible corneal damage. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
   3. Avoid skin contact to prevent irritation and possible allergic response. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention.
   4. Avoid contact with oral soft tissues/mucosa to prevent inflammation. If accidental contact occurs, flush mucosa with plenty of water and expectorate water. If sensitization of mucosa persists, seek medical attention immediately.
   5. aladdin Total Etch Adhesive contains t-butanol. aladdin Self Cure Activator contains acetone. Do not breathe vapor.

2.2 **Precautions**

   1. Wear suitable protective eyewear, clothing and gloves.
   2. Use of rubber dam or adequate isolation is recommended.
   3. Use only in well ventilated areas.

2.3 **Interactions**

   Eugenol-containing dental materials should not be used in conjunction with this product. aladdin Total Etch Adhesive with Aladdin Self Cure Activator can shorten working time of a dual cure resin cement system. This effect should be investigated in the laboratory prior to clinical use.

2.4 **Storage**

   aladdin Total Etch Adhesive and aladdin Self Cure Activator should be kept out of direct sunlight and stored in a well ventilated place. Store aladdin Total-Etch Adhesive at temperatures between 10-28ºC/50-82ºF. Store aladdin Self Cure Activator at temperatures between 2-24ºC/35-75ºF. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date.

2.5 **Adverse reactions**

   1. Product may irritate the eyes and skin. (See Warnings)
   2. Product may cause pulpal effects. (See Contraindications)

3. **STEP-BY-STEP INSTRUCTIONS**

3.1 Light cured direct restorations, composite/ceramic/amalgam repairs, indirect veneer cementation with light cured resin cement

   3.1.1 Gating: Clean un-instrumented enamel and dentin with a rubber cup and pumice or a cleaning paste. Wash thoroughly with water spray and air dry. Clean freshly instrumented enamel and dentin with water spray and then air dry.
• For repairs, roughen the fractured restoration surface with a fine diamond bur. Create mechanical retention where possible. Clean as above. Etch ceramic restoration repair area with hydrofluoric acid according to manufacturer’s instructions.

• For indirect veneers, treat surface of veneer according to manufacturers or dental laboratory’s instructions, i.e., etching, mechanical roughening and/or silane coupling agent (available separately), see complete Directions for Use) application. Apply a single coat of Aladdin Total Etch Adhesive to the internal bonding surface of the restoration. Immediately air dry for 5 seconds.

3.1.2 Pulp Protection: cover the dentin close to the pulp (less than 1mm) with a hard setting calcium hydroxide liner.

3.1.3. For endodontic posts, following rinsing of the Tooth Conditioner, the post space should be thoroughly dried with a gentle air blast and paper points to remove residual moisture, but do not desiccate dentin.

3.2.5 Cure mixed adhesive/activator for 10 seconds using a curing light.

3.3.4 Preparation of restoration

Treat surface of restoration according to manufacturers or dental laboratory’s instructions, i.e., etching, mechanical roughening and/or silane coupling agent (available separately, see complete Directions for Use) application.

• Apply a single coat of mixed adhesive/activator to the internal bonding surface of the restoration. Immediately air dry for 5 seconds.

• Light curing: Cure mixed adhesive/activator for 10 seconds using a curing light.

3.3.5 Cementation: Prepare and apply dual cured resin cement, according to manufacturer’s instructions.

3.3.6 Rinsing and Blot Drying: Remove gel with aspirator tube and/or vigorous water spray and rinse conditioned areas thoroughly for at least 15 seconds. Remove rinsing water completely by blowing gently with an air syringe or by blot drying with a cotton pellet. Do not desiccate dentin.

• Once the surfaces have been properly treated, they must be kept uncontaminated. If salivary contamination occurs, thoroughly clean with vigorous water spray, dry, and repeat conditioning procedure of enamel for 5 seconds only. Rinse and dry as described above.

3.1.4 Application of aladdin Total-Etch Adhesive

• Dispense aladdin Total-Etch Adhesive into a clean mixing well. Replace cap promptly. Mix contents for 1-2 seconds with a clean, unused brush tip.

• Apply mixed adhesive/activator to wet all the tooth surfaces uniformly. Avoid pooling. These surfaces should remain undisturbed for 20 seconds.

• Evaporate solvent by thoroughly drying with clean, dry air for at least 5 seconds. Surface should have a uniform glossy appearance. If not, repeat application and air dry.

• Cure aladdin Total Etch Adhesive for 10 seconds.

3.1.5 Place light-cured restorative material or veneer loaded with resin cement over the cured aladdin Total Etch Adhesive as per restorative material manufacturer’s directions.

3.3 Dual Cured; Direct restorations (Dual Cure or Self-cure composite/core build-up)

3.2.2 Place pin, post or matrix as needed.

3.2.3 Tooth Conditioning/Dentin Pretreatment: follow the total etch technique described in Section 2.4. For endodontic posts, a paper point pre-wetted with the adhesive mixture may aid in bringing the adhesive mixture down to the deepest portion of the post.

3.1.1-3.1.2. Manufacturing for:

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4. HYGIENE

4.1 Cleaning and disinfection

To prevent contamination of the bottle, the use of a protective barrier is recommended. Properly dispose of used brushes and containers.

5. LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard is used: “YYYY/MM”

2. The following numbers should be quoted in all correspondence:

• Rerorder Number
• Lot number on bottle
• Expiration date on bottle

3. The following numbers should be quoted in all correspondence:

• Lot number on bottle
• Expiration date on bottle

1 Check curing light for minimum curing output of at least 800 mw/cm². Cure for at least 20 seconds if light output is between 500 and 800 mw/cm².