

# aladdin™ ONE

## Universal Hybrid Composite

### ***DIRECTIONS FOR USE***

For dental use only.

**Caution:** US Federal Law restricts this device to the sale by or on the order of a dentist.

#### **1. PRODUCT DESCRIPTION**

aladdin One Universal Hybrid Composite material is a visible light activated, radiopaque composite restorative material for anterior and posterior restoration of primary and permanent teeth. The resin and particle filler combination results in a hybrid composite with good strength and wear resistance for posterior use, combined with high surface luster and smoothness which is an essential property for anterior use of a composite. Shade matching has been optimized to the Vita® System.

##### **1.1 Delivery forms**

aladdin One Universal Hybrid Composite material is available in:

- Unit dose ampules and traditional syringes
- 10 Vita® shades and 3 accessory shades

##### **1.2 Composition**

Bis-GMA adduct; Bis-EMA adduct; triethylene glycol dimethacrylate; Photoinitiator; Stabilizer; Pigments; silicate glass; nanofiller silica

##### **1.3 Indications**

aladdin One Universal Hybrid Composite material is indicated as a direct restorative for all cavity classes in anterior and posterior teeth.

##### **1.4 Contraindications**

aladdin One Universal Hybrid Composite material is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.

##### **1.5 Compatible adhesives**

aladdin One Universal Hybrid Composite is used following application of a suitable dentin/enamel adhesive designed for use with visible light cured composite restoratives

### **2. GENERAL SAFETY NOTES**

#### **2.1 Warnings**

1. aladdin One Universal Hybrid Composite material contains polymerizable methacrylate monomers 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 tissue/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.

#### **2.2 Precautions**

1. Use of rubber dam or adequate isolation is recommended.
2. Wear suitable protective eyewear, mask, clothing and gloves.
3. Interactions: Eugenol-containing dental materials should not be used in conjunction with this product
4. Ampules are designed for one time use. Discard after use. Do not reuse.

### **2.3. Storage**

aladdin One Universal Hybrid Composite material ampules are for single use and should be discarded after use. Keep out of sunlight. Store in a well ventilated place at temperatures between 2-24°C/ 35-75°F. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date.

### **2.4 Adverse reactions**

Product may irritate the eyes and skin (See Warnings)

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

1. Pulp protection, Tooth Conditioning/Dentin Pretreatment, Adhesive Application: Refer to adhesive manufacturer's directions for pulp protection, tooth conditioning and/or adhesive application.
  - 1.1 Optional Flowable Liner: Placement of a compatible flowable liner (available separately) prior to placement of aladdin One Universal Hybrid Composite material is optional. If desired, follow manufacturer's directions for use.
2. Placement of aladdin One Universal Hybrid Composite material:
  - 2.1 Syringe: Dispense the necessary amount of aladdin One Universal Hybrid Composite material from the syringe onto the mix pad. Recap the syringe. Protect dispensed aladdin One Universal Hybrid Composite material from ambient light
  - 2.2 Unit dose ampules: To dispense the material into a cavity preparation, use a slow, steady pressure. Do not use excessive force.
  - 2.3 Dispense aladdin One Universal Hybrid Composite material directly into the cavity preparation/tooth (unit dose) or onto a clean pad (syringe) and carry to the preparation with suitable placement instrument. Material may be placed and light cured in increments up to 2mm.
3. Curing: Light cure each area of the restoration surface with a suitable visible light curing unit. Minimum light output must be at least 550mW/cm<sup>2</sup> exposure for at least 20 seconds. Cure through the proximal, lingual, and buccal enamel walls following matrix removal for the recommended time.
4. Finish and Polish immediately after curing.

## **4. HYGIENE**

### **4.1 Cleaning and disinfection**

To prevent contamination of the syringe, the use of a protective barrier is recommended. Do not attempt to clean, disinfect or re-use unit dose ampules. Properly dispose of used unit dose ampules.

## **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:
  - Reorder Number
  - Lot number on unit-dose ampule/syringe
  - Expiration date on unit-dose ampule/syringe

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Manufactured for:



Sultan Healthcare  
1301 Smile Way • York, PA 17404-0807 • USA  
Toll Free: 800-637-8582 • Phone: 201-871-1232  
Fax: 201-871-0321 • www.sultanhealthcare.com

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