

## Instructions for Use

### Product description

ONELUX One-Shade Universal Composite is a light cure radiopaque universal composite for anterior and posterior restorations. It is based on methacrylate-resin and inorganic filler particles of 0.05-1.5 µm. The total filler load is 81 %. The total filler volume is 65 %. Radiopacity of ONELUX One-Shade Universal Composite is 180 % aluminium (radiopacity of enamel: ~200 % aluminium, of dentine: ~100 % aluminium).

The composite meets the requirements of: ISO 4049, type 1, class 2, group 1.

### Indications/Intended use

Restorations of all cavity classes

### Performance features

The performance features of the product meet the requirements of the intended use.

### Contraindications

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore, for pulp protection, areas close to the pulp should be covered with a thin layer of pulp capping material.

### Patient target group

Persons who are treated during a dental procedure.

In case of small cavities, ONELUX One-Shade Universal Composite can be applied directly.

For an optimum result, apply ONELUX One-Shade Universal Composite in layers of max. 2 mm. Light cure each increment separately.

By using a polymerization unit (wavelength range 400-500 nm) with a light intensity of at least 1000mW/cm<sup>2</sup>, cure each increment 20 seconds.

Hold the light emission window as close as possible to the filling material.

### Finishing

Depending on the shape of the area, contour with finishing diamonds, flexible grinding discs, or carbide burs. Polish to high gloss with polishing discs or polishing brushes.

### Storage

Do not store above 25°C (77°F). Protect from direct sunlight. Do not use after expiry date.

Close syringe immediately after use to avoid exposure to light.

### Additional Notes/Warnings

- The ambient light of the dental lamp may start polymerization of the composite.
- Do not use any resin to adjust viscosity of the composite restorative.
- Avoid contact with skin, mucous membrane, and eyes.
- Unpolymerized composite may have an irritant effect and can lead to sensitization against methacrylates.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

### Composition

Dimethacrylates, dental glass, silicon dioxide, photo initiators.

### Intended users

This medical device should only be used by a professionally trained dental practitioner.

### Incompatibility with Other Materials

Do not use in combination with substances containing eugenol, because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

### Application

Preparation of Tooth and Color Matching

Clean the tooth with a fluoride-free polishing paste (e.g. flour of pumice with water) prior to preparation.

### Cavity Preparation

After isolation (best with a rubber dam) prepare the cavity with minimal tooth reduction.

For pulp protection, areas close to the pulp should be covered with a thin layer of pulp capping material (e.g. CALCIUM HYDROXIDE LINER). Condition and apply a bonding agent according to the manufacturer instructions. The total etch technique with ETCHING GEL (e.g. NANOFIL® Etchant Gel) and subsequent application of a light cure bonding agent (e.g. NANOFIL® Dental Bonding Agent) is recommended. Otherwise, use a self etching bonding agent before application of ONELUX One-Shade Universal Composite.

### Application and Curing of ONELUX One-Shade Universal Composite

Apply ONELUX One-Shade Universal Composite using a suitable instrument. ONELUX One-Shade Universal Composite is easy to model. Matrix strips may be used.

In case of deep and extended cavities, best results are obtained with a build-up of a base liner using a light cure resin modified cement or a light cure flowable composite (e.g. NANOFIL® Flowable Dental Filling Resin), followed by the application of ONELUX One-Shade Universal Composite.

### Disposal

Disposal of the product according to local authority regulations.

### Reporting obligation


Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

### Warranty

AT&M Biomaterials Co., Ltd. warrants this product will be free from defects in material and manufacture. AT&M Biomaterials Co., Ltd. makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and AT&M Biomaterials Co., Ltd.'s sole obligation shall be repair or replacement of the AT&M Biomaterials Co., Ltd. product.

### Limitation of Liability

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