

ONELUX CHROME

One-Shade Universal Composite



Instructions for Use

Product description

ONELUX CHROME is a light cure radiopaque composite for anterior and posterior restorations. ONELUX CHROME can be used for all natural tooth shades due to its continuous color matching properties. Beside its permanent gloss and toothlike opalescence ONELUX CHROME shows excellent physical properties and good handling features. High gloss polishability demands only little effort. ONELUX CHROME contains dimethacrylate based resins and inorganic fillers < 0.2 µm. The total filler content is 80 % by weight and 75 % by volume. Radiopacity of ONELUX CHROME is 200 % aluminium (radiopacity of enamel: ~200 % aluminium, of dentine: ~100 % aluminium).

ONELUX CHROME meets the requirements of ISO 4049, type 1, class 2, group 1.

Indications/Intended use

- Restorations of all cavity classes
- Direct veneers
- Diastema closure
- Repair of ceramic restorations (e.g. veneers, crowns)

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.

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

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

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 pulp capping material (e.g. THERACALM LC or CALCIUM HYDROXIDE LINER).
- Refer to the corresponding user instructions.
- Apply a common adhesive for enamel and dentine bonding according to the corresponding manufacturer instructions.
- The application of the universal adhesive PERFECT—LINK is recommended.
- PERFECT—LINK can be used in combination with an etching gel (NANOFIL Nova ETCHANT GEL) or as a self-etching adhesive (PERFECT—LINK).
- Follow the instructions for PERFECT—LINK.

Application and Curing of ONELUX CHROME

In case of deep and extended cavities best results are obtained with an application of a base liner using a light cure resin modified cement (e.g. NANOCEM ULTIMATE) or a light cure flowable composite (e.g. NANOFIL Nova FLOWABLE LC COMPOSITE), followed by the application of LC CHROME. In case of small cavities ONELUX CHROME can be applied directly.

Note:

In case of cavities of dark or discolored teeth use a blocker (e.g. NANOFIL Nova LC UNIVERSAL COMPOSITE BW) to ensure that the restoration may not appear dark.

Apply ONELUX CHROME in layers of max. 2 mm. Light cure each increment separately. ONELUX CHROME is easy to model. Place it by using a suitable instrument. Matrix strips may be used.

By using a polymerization unit (wavelength range 400-500 nm) with a light intensity of at least 1000mW/cm², cure each increment separately for 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 2°C-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

- APPLIC.-Tips are for single use only due to hygienic reasons.
- The ambient light of the dental lamp may start polymerization of the composite.
- Do not use any resin to adjust viscosity of composite restorative material.
- 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, prepolymerized resin, dental glass, silicon dioxide, photo initiators.

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 product.

Limitation of Liability

Except where prohibited by law, AT&M Biomaterials Co., Ltd. will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.



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