

Colourant

light cured flowable dental composite

INDICATIONS FOR USE

COLOURANT is used locally to increase colour intensity of composite restorations and composite fillings.

Available in White, Gingival or A, B, C (respectively darker shades).



INSTRUCTIONS FOR USE

Apply a thin layer of COLOURANT anywhere on the restoration where colour or opacity would improve its aesthetics. For example, on the occlusal surface and/or to increase the opacity of the cervical part of the tooth.

Apply and cure in accordance with the polymerisation table provided. The use of COLOURANT as the outer layer is adequate, but best results are obtained when COLOURANT is covered with a layer (1-2 mm thick) of external composite used to make the restoration.

POLYMERISATION TABLE

Lamp	COLOURANT	20 s	30 s
Halogen/LED (500-800 mW/cm ²)	A,B	1.0 mm	1.5 mm
	C, White, Gingival	-	1.0 mm
LED (>800 mW/cm ²)	A,B	1.5 mm	2.0 mm
	C, White, Gingival	1.0 mm	1.5 mm

MD Medical device class IIa

COLOURANT is a flowable polymer dental material type 1 (class 2, group 1), which meets the requirements of the ISO 4049 standard. COLOURANT composite undergoes free radical polymerisation activated by visible light from the blue region (400-500 nm).

COMPOSITION

Mixture of dimethacrylate resins: BisGMA, TEGDMA, UDMA, BisEMA; mineral fillers (about 60 wt%): Al-Ba-B-Si glass, Ba-Al-B-F-Si glass, fumed silica, pigments; photoinitiator (CQ : DMAEMA). The size of inorganic filler particles is between 20 nm and 2.0 µm.

COLOURANT can be used with all composite materials based on dimethacrylate resins.

CONTRAINDICATIONS

Do not use COLOURANT composite in patients with a known allergy to any of the components.

ADVERSE REACTIONS

None known. However, an allergic reaction cannot be excluded in particularly sensitive individuals. In case of an immediate allergic reaction, stop using the product. In case of a delayed allergic reaction, remove the restoration.

LIMITATIONS IN USAGE, INTERACTIONS

Do not use if it is impossible to completely isolate the area from saliva, blood or moisture. Contamination may disrupt the polymerisation process.

Do not use with materials containing phenolic compounds, especially eugenol and thymol. Such materials may disrupt polymerisation of COLOURANT.

PRECAUTIONS

Avoid contact of unpolymerised product with skin, eyes and the soft tissues of the mouth. In case of such contact, rinse with plenty of water. In case of any symptoms, consult a doctor giving information about the product. To minimise the risk of contact, always wear personal protective equipment such as gloves, face masks and safety glasses.

In case of swallowing or aspiration into the respiratory tract, seek immediate medical attention.

To isolate the operative field and to protect the patient, the use of a rubber dam is recommended.

Ensure sufficient polymerisation of the entire COLOURANT layer, especially in places which are difficult to access.

In case of any contamination of unpolymerised composite, the contaminated material layer must be removed.

In case of insufficient polymerisation, remove the incorrectly polymerised layer and apply another one, curing it correctly.

Avoid contamination of the syringe surface (the risk of cross infection).

When applying COLOURANT directly from the syringe, for hygienic reasons, the applicator should only be used on one patient.

To avoid accidental polymerisation of COLOURANT in the applicator, always pull back the syringe plunger immediately after use.

WARNINGS



Keep out of reach of children and unauthorised persons. Protect from light. Polymerisation of the composite may be initiated by ambient light or by a dental operating lamp. Protect from heat. Do not freeze. Use in accordance with the manufacturer's instructions.

Do not use after the expiry date.

STORAGE

Store at a temperature under 30°C. Do not expose to direct sunlight. If stored at a lower temperature, bring back to room temperature before use.

For use by dentists and dental technicians only.

WARRANTY

ARKONA will replace products that have been proved to be defective or will refund the price of purchase. ARKONA is not liable for any loss or damage caused by misuse or improper use of the product.

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