

MD Medical device class IIa

CREATE is a light cured dental composite in a blister intended for one patient only, suitable for all types of fillings and restorations of cavities and defects in anterior, posterior, deciduous and permanent teeth of both caries and non-caries aetiology.

INDICATIONS FOR USE

- Black's class I, II, III, IV and V cavities
- permanent restorations using polyaramid and polyethylene fibre supports: crowns, endocrowns, bridges, inlay/onlay procedures
- temporary crowns and bridges
- dental splints, permanent – external or internal layer
- dental splints, temporary – external layer
- composite and acrylic prosthetic restoration repairs

INSTRUCTIONS FOR USE

1. For fillings, choose the right shade from the CREATE composite shade guide before starting the treatment when the tooth is naturally moisturised.
2. Clean and prepare teeth in the normal way.
3. Wherever it is necessary, etch the surface using ETCHGEL, rinse and dry gently.
4. Apply a bonding system. CREATE can be used with any standard, light cured, dimethacrylate resin-based bonding systems. A bonding system should be applied in accordance with the manufacturer's instructions.
5. Open the blister peeling back the aluminium foil.
6. Load you instrument with the composite.
7. Fill the cavity, light curing each layer in accordance with the polymerisation table provided.
8. Adjust to the bite and polish.

Instructions for use in other clinical cases can be found at www.dentalifesciences.com

POLYMERISATION TABLE

Lamp	CREATE	20 s	30 s
Halogen/LED (500-800 mW/cm ²)	A1, A2, A3, B1, B2, C2, D2	2.0 mm	2.5 mm
	A3.5, OA2, OA3, D3	2.0 mm	2.2 mm
	T	2.8 mm	3.0 mm
LED (>800 mW/cm ²)	A1, A2, A3, B1, B2, C2, D2	2.5 mm	3.0 mm
	A3.5, OA2, OA3, D3	2.0 mm	2.5 mm
	T	3.0 mm	3.5 mm

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

CREATE has a radio-opacity equivalent to approx. 5 mm of aluminium (aluminium has a radio-opacity equivalent to that of dentine; thus 1 mm of material having a radio-opacity equivalent to 1 mm of aluminium has a radio-opacity equivalent to that of dentine and 2 mm of aluminium is equivalent to enamel).

COMPOSITION

Mixture of dimethacrylate resins: BisGMA, TEGDMA, UDMA, BisEMA; mineral fillers (about 78 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.

CONTRAINDICATIONS

Do not use CREATE 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, affecting the mechanical properties of the composite and decreasing the durability of the restoration, which in turn may result in secondary caries formation.

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

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 composite layer, especially in places which are difficult to access. Insufficiently polymerised product can be allergenic.

In case of any contamination of an unpolymerised composite, the contaminated material layer must be removed. In case of contamination or mechanical damage to an already polymerised layer, gently etch its surface and cover it with a bonding system. Cure in accordance with the polymerisation table provided.

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

Protect the blisters against mechanical damage. Do not use if the blister is suspected to be defective or damaged.

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 25°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.

Instruction for use issued on 10.03.2021



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