Silkflow

light cured dental flowable composite

DLS DENTAL LIFE SCIENCES

MD Medical device class IIa

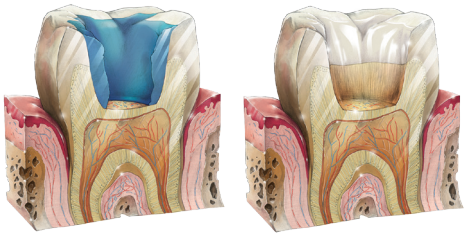
SILKFLOW is a flowable polymer dental material type 1 (class 2, group 1), which meets the requirements of the ISO 4049 standard. SILKFLOW composite undergoes free radical polymerisation activated by visible light from the blue region (400-500 nm).

SILKFLOW has radio-opacity equivalent to 4 mm of aluminium (aluminium has radio-opacity equivalent to that of dentine; thus 1 mm of material having radio-opacity equivalent to 1 mm of aluminium has radio-opacity equivalent to that of dentine and 2 mm of aluminium is equivalent to enamel).

INDICATIONS FOR USE

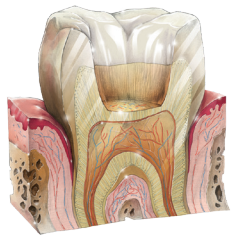
- Black's class I, II, III, IV and V cavities
- first composite layers, before final modelling of the chewing surface with condensable composite, in places with difficult access, such as very deep class II cavities with matrix bands, tunnel restorations, composite and acrylic prosthetic restoration repairs
- dental splints, permanent – external or internal layer
- dental splints, temporary – external layer

INSTRUCTIONS FOR USE



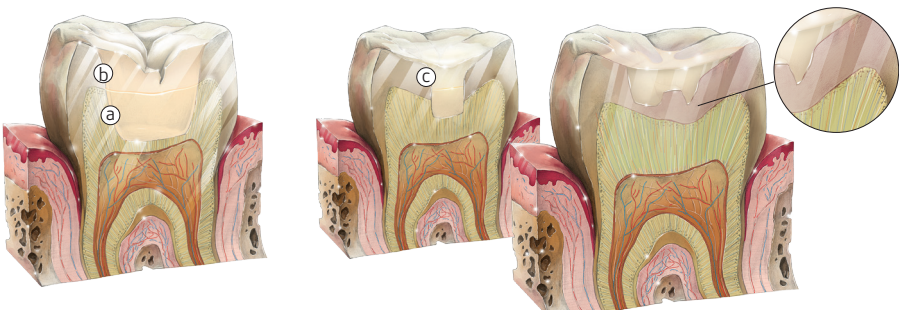
Etch the surface using ETCHGEL, rinse and dry gently.

Thoroughly cover the cavity with a thin layer of a bonding system. SILKFLOW 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.



In order to properly dispense the material from the syringe, unscrew the cap and then attach the disposable applicator by screwing it to the syringe luer-lock. Make sure the dispensing system is working properly by extruding a small amount of material onto a mixing pad or gauze. If the process is succesfully completed, you can start working with the patient. If it is impossiblel to extrude the material, replace the applicator with a new one. Unscrew and throw away the used applicator and recap the syringe after use.

In the case of very deep cavities, cover the bottom of such a cavity with a thin layer of liner and then apply layers (not thicker than 2 mm) of SILKFLOW composite (a). Cure each layer in accordance with the polymerisation table provided. The chewing surface can also be modelled with solid condensable materials (b). Small or medium-sized cavities and teeth with surface cavities already prepared (after etching and applying a bonding system) can be fully covered with SILKFLOW, following the polymerisation rules (c).



COMPOSITION

Mixture of dimethacrylate resins: BisGMA, TEGDMA, UDMA, BisEMA; mineral fillers (about 62 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.

POLYMERISATION TABLE

Lamp	SILKFLOW	Polymerisation depth dependent on duration of the exposure	
		20 s	30 s
Halogen/LED (500-800 mW/cm^2)	A1, A2, A3	2.0 mm	3.0 mm
	A3.5, OA2	2.0 mm	2.5 mm
LED (>800 mW/cm^2)	A1, A2, A3	2.0 mm	3.5 mm
	A3.5, OA2	2.0 mm	3.0 mm

If needed, choose the right shade from the SILKFLOW composite shade guide before starting the treatment when the tooth is naturally moisturised.

CONTRAINDICATIONS

Do not use the product in patients with a known acrylates allergy.
Do not use the product in patients with a hypersensitivities to any of the components.

ADVERSE REACTIONS

None known. However, an allergic reaction cannot be excluded in particularly sensitive individuals.

LIMITATIONS IN USAGE, INTERACTIONS

Do not use with materials containing phenolic compounds, especially eugenol and thymol. Such materials may disrupt polymerisation of the composite.
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 if the syringe or the applicator are suspected to be defective or damaged.
Do not use when any change in product properties is found.

PRECAUTIONS FOR PATIENTS

This device contains substances that may cause an allergic reaction in certain individuals. Do not use in patients with a known acrylates allergy. Avoid contact of an unpolymerised product with skin, eyes and soft tissues of the mouth. If a prolonged contact occurs, rinse with plenty of water. If an allergic reaction occurs, seek medical attention as needed; remove the product if necessary and discontinue future use of the product.
In case of swallowing or aspiration into the respiratory tract seek immediate medical attention.
If any changes in the work are noticed, attend a dental check-up.

PRECAUTIONS FOR DENTAL PERSONNEL

This device contains substances that may cause an allergic reaction in certain individuals. To avoid the risk of such reaction, minimise the contact with an unpolymerised composite. If contact with skin occurs, rinse with plenty of water. To minimise the risk of contact, always wear personal protective equipment such as gloves, face masks and safety glasses. Acrylates may penetrate some commonly used gloves.
If any contact with a glove occurs, remove the glove and discard it; wash your hands with soap and water and put on a new glove. If an allergic reaction occurs, seek medical attention as needed. The applicators provided with the syringe are blunt in order to reduce the risk of injury, but they should always be handled with care.

ADVICE FOR DENTAL PERSONNEL

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. Insufficiently polymerised product can be allergenic and the lifetime of the work may be shortened. In case of insufficient polymerisation remove the incorrectly cured layer and apply another one, curing it correctly.
In case of any contamination of an uncured composite the contaminated layer must be removed. In case of contamination or mechanical damage to an already polymerised layer gently etch its surface and reapply the composite. Cure in accordance with the polymerisation table provided. To minimise the risk of the potential release of unwanted substances, always clean and rinse the surface immediately after curing. Examine the work at a preventive visit or a check-up. In case of any changes in the performance of the restoration (e.g. wear, chipping), remove the defective work and replace it with a new one. Inform the patient about the need to maintain proper oral hygiene.

WARNINGS

⚠ Avoid contamination of the syringe surface (the risk of cross infection). The syringe cannot be reprocessed using heat sterilisation or immersion in a high-level disinfectants. Do not reuse the syringe if it becomes contaminated. If you apply the product directly from a syringe, use one applicator for one patient only due to hygiene reasons. Always ensure the syringe is recapped properly after use. Polymerisation of the composite may be initiated by ambient light or by a dental operating lamp. To avoid accidental polymerisation of the composite in the applicator, always pull back the syringe plunger immediately after use. Keep out of reach of children and unauthorised persons. Use in accordance with the manufacturer's instructions. Do not use after the expiry date.

STORAGE

Protect against mechanical damage. Store at a temperature under 30°C. If stored at a lower temperature, bring back to room temperature before use. Do not expose to direct sunlight. Protect from light. Do not overheat. Do not freeze. For use by dentists, dental hygienists and dental technicians only.

PACKAGE CONTENTS

1 syringe with a luer-lock cap (2 g) and 1 disposable applicator or a set of 3 syringes with luer-lock caps (2 g each) and 3 disposable applicators

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.
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the state in which the user and/or patient is established.

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ARKONA
ARKONA Laboratorium Farmakologii Stomatologicznej
Nasutow 99C, 21-025 Niemce, Poland, EU
www.arkonadent.com

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