Sealprim

flowable dental composite

DLS DENTAL LIFE SCIENCES

MD Medical device class IIa

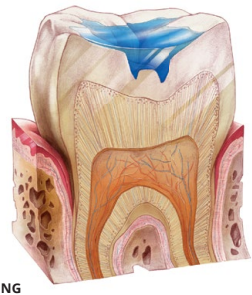
SEALPRIM is a transparent composite for sealing pits and fissures, activated by visible light.

INDICATIONS FOR USE

- protecting against caries through sealing of natural fissures, pits and foramina caeca in the surfaces of deciduous and permanent teeth.

INSTRUCTIONS FOR USE

1.



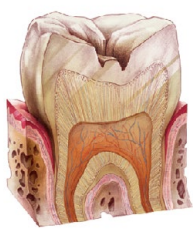
Etching

- apply ETCHGEL on surfaces intended for sealing making sure the bottom part of the fissure is properly etched; etch for 20-40 s.
- rinse thoroughly with a strong stream of water and carefully dry the tooth surface.

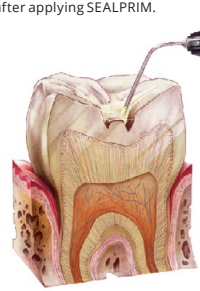
If the appearance of the etched enamel is not chalky white, repeat the etching process. If any contamination occurs, the surface should be reetched for about 10 s.

2. SEALING

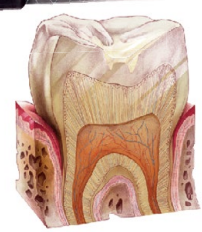
- In order to properly dispense the material from the syringe, unscrew the cap and attach the disposable applicator tip by twisting it securely onto the luer-lock of the syringe. Make sure the dispensing system is working properly by dispensing a small amount of the material onto a mixing pad or gauze. If this is completed satisfactorily, you can start working with the patient. If the material does not flow out properly, replace the applicator tip with a new one. After you have finished working with the patient, unscrew and discard the used applicator and recap the syringe.
- Thoroughly apply SEALPRIM onto the etched tooth surface.
- Cure in accordance with the polymerisation table.
- Use a probe to make sure the fissures and pits are filled.
- Clean and rinse the sealed surfaces immediately after applying SEALPRIM.



A. After etching



B. During the sealing procedure



C. After the sealing procedure

POLYMERISATION TABLE

Lamp	5 s	10 s
Halogen/LED (500-800 mW/cm²)	2.0 mm	3.0 mm
LED (>800 mW/cm²)	3.0 mm	4.0 mm

SEALPRIM is a flowable polymer dental material class 2, which meets the requirements of the ISO 6874 standard.
SEALPRIM undergoes free radical polymerisation activated by visible light from the blue region (400-500 nm).
SEALPRIM does not require the use of a bonding system however, if needed, it can be used with any standard, light cured bonding systems.

COMPOSITION

Mixture of dimethacrylate resins: BisGMA, TEGDMA, UDMA, BisEMA; mineral fillers (20 wt%): Al-Ba-B-Si glass, fumed silica, photoinitiator (CQ : DMAEMA).

CONTRAINDICATIONS

Do not use SEALPRIM composite in patients with a known acrylates allergy.
Do not use the product in patients with a hypersensitivity 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 SEALPRIM.
Do not use if it is impossible to completely isolate the area from saliva, moisture or blood. 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; however, 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 sealant 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 sealant 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 sealant. Cure in accordance with the polymerisation table provided. To minimise the risk of a 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 work (e.g. wear, chipping), remove it 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 its syringe, use one applicator for one patient only due to hygiene reasons. Always ensure the syringe is properly re-capped after use. Polymerisation of the composite may be initiated by ambient light or by a dental operating lamp. To avoid accidental polyme-risation 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 and dental hygienists only.

PACKAGE CONTENTS

1 syringe with a luer-lock cap (1 g) and 5 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 the patient is established.

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