

D L S DENTAL LIFE  
SCIENCES

# S Sealprim

flowable dental composite



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# Sealprim

flowable dental composite

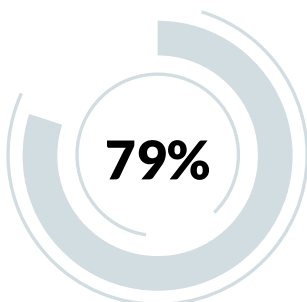


## DENTAL CARIES? SEAL IT OUT!

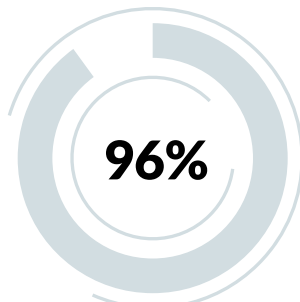
### NOTE!

- SEALING IS A PROCEDURE OF LINING PITS, FISSURES, BLIND HOLES AND OTHER NATURAL IRREGULARITIES OF TOOTH SURFACES; IT IS THE MOST EFFECTIVE METHOD OF PREVENTING DENTAL CARIES.
- SEALING IS A PAINLESS PROCEDURE PERFORMED BY DENTISTS AND DENTAL HYGIENISTS.
- A PROPERLY PERFORMED SEALING PROCEDURE IS AN EFFECTIVE AND LONG-LASTING PROTECTION AGAINST DENTAL CARIES. AS A RESULT, A HIGH DEGREE OF PULP MINERALISATION MAKES THE SEALED TOOTH NATURALLY DECAY-RESISTANT.

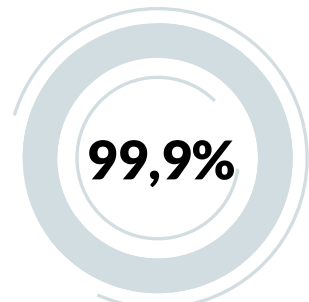
Statistically, dental caries occurs in:



over 79% of 12-year-olds



more than 96% of 18-year-olds



almost entire adult population (99,9%)

## APPLICATION EXAMPLES



### HEALTHY DECIDUOUS TEETH

In the case of deciduous teeth, occlusal surfaces of molars are highly susceptible to dental caries development. Caries is the main cause of toothache in children; it may also lead to malocclusion, sleep problems and long-term learning difficulties.

**50% of children under the age of 3 already have teeth affected by dental caries.**

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### HEALTHY PERMANENT TEETH

In the case of permanent teeth, occlusal surfaces of molars and premolars are highly susceptible to dental caries development.

**96% of 18-years-olds have teeth affected by dental caries.**

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### UPPER THIRD MOLARS (WISDOM TEETH)

Upper third molars are very difficult, or even impossible, for the patient to clean at home and traditional oral hygiene is usually insufficient to prevent the development of dental caries. However, prophylactic extraction of healthy wisdom teeth is unjustifiable. A wisdom tooth which is protected against oral bacteria and harmful oral acids may stay completely healthy for many years. Such a tooth can prevent malocclusion or serve as an attachment place for dental crowns and bridges.

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### HEALTHY TEETH WITH SUPERFICIAL DENTAL CARIES

The mechanical strength of SEALPRIM allows it to be used not only for sealing procedures, but also for fillings. After the carious lesion has been removed, cavity filling, as well as sealing, may be performed using the same composite.

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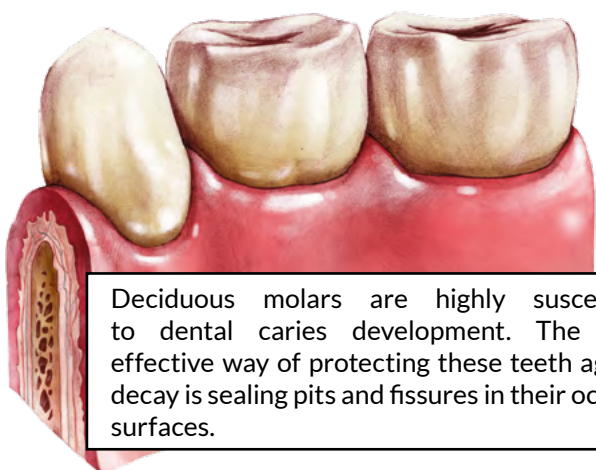


### FORAMINA CAECUM (BLIND HOLES)

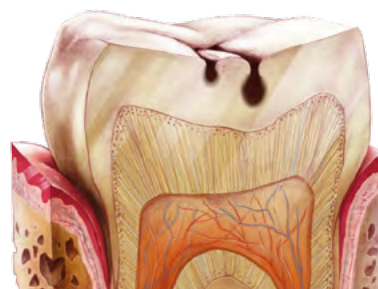
Foramina caecum - small holes which are usually found in palatal surfaces of first and second incisors - create an environment which is conducive to the development of dental caries. Even an insignificant caries in a deep foramen caecum may lead to serious dental fracture - especially in the case of second incisors which tend to be thinner and more fragile. Sealing is the most effective and the least invasive method of protecting such teeth.

PROBLEM

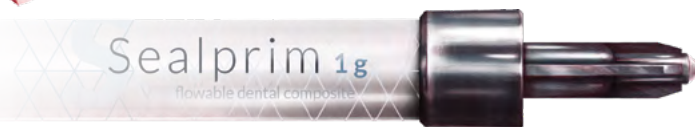
HEALTHY DECIDUOUS TEETH



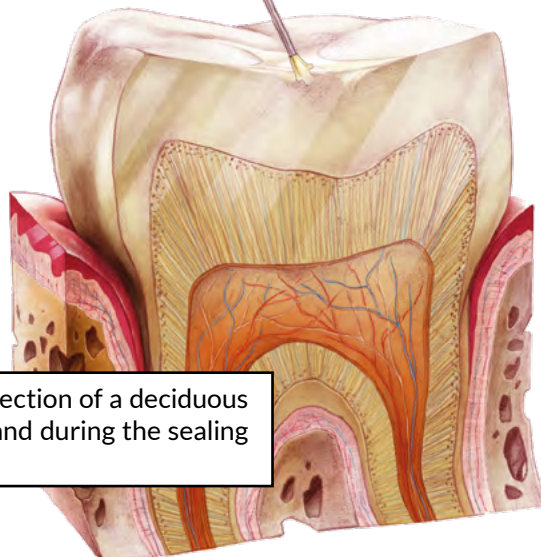
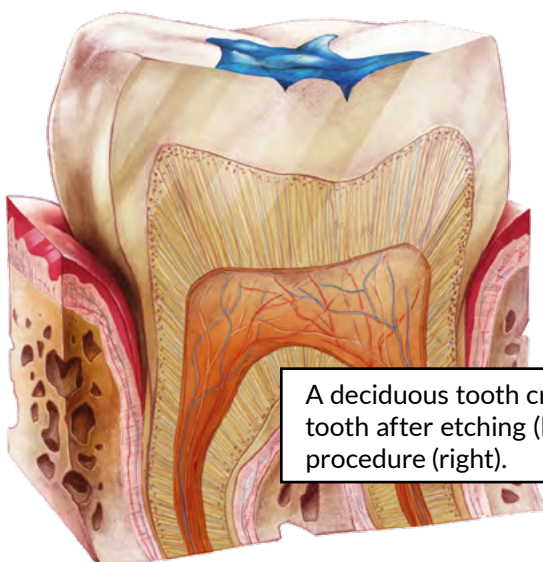
Deciduous molars are highly susceptible to dental caries development. The most effective way of protecting these teeth against decay is sealing pits and fissures in their occlusal surfaces.



Unsealed pits and fissures in deciduous molars create an environment which is conducive to the development of dental caries.

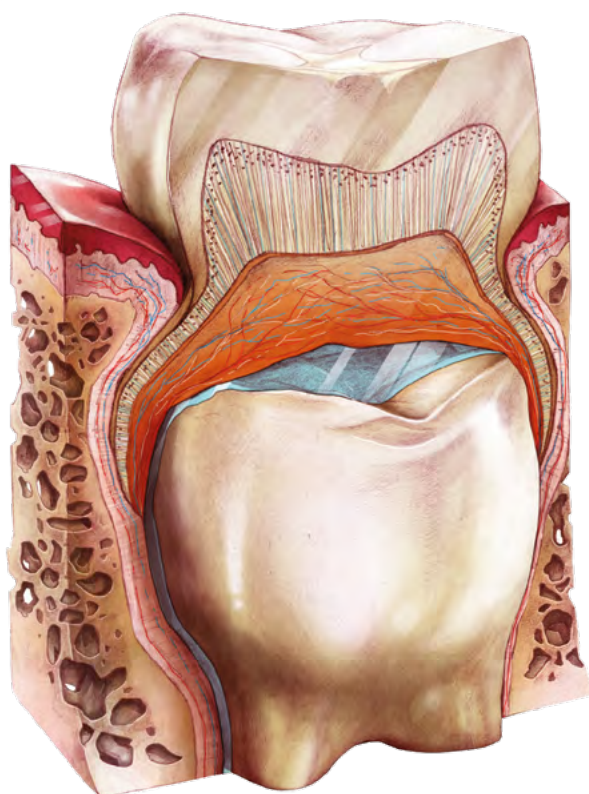


SOLUTION



A deciduous tooth cross section of a deciduous tooth after etching (left) and during the sealing procedure (right).

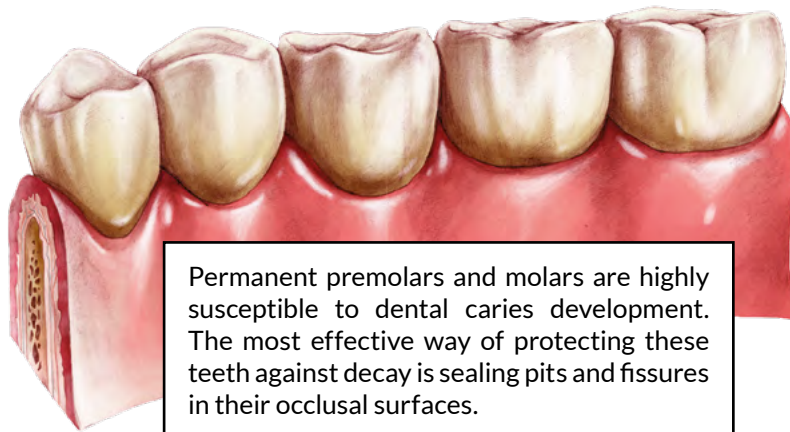
RESULT



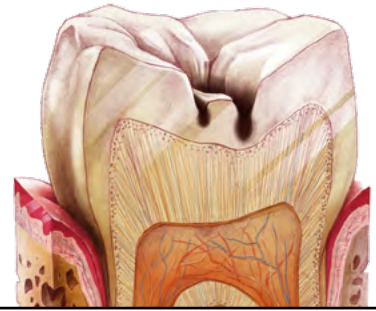
The same tooth after the sealing procedure, at the final stage of the permanent tooth eruption. A tooth which is protected from oral bacteria and harmful oral acids, may remain completely healthy for a number of years, until its permanent counterpart has fully developed.

# HEALTHY PERMANENT TEETH

PROBLEM

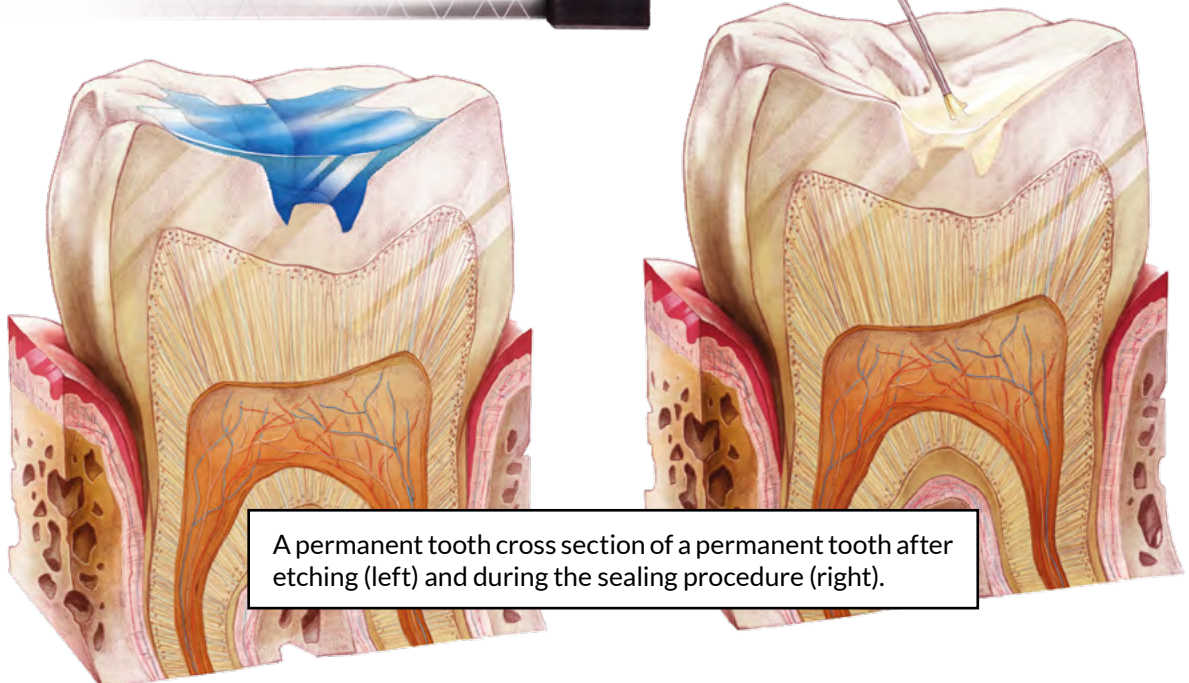


Permanent premolars and molars are highly susceptible to dental caries development. The most effective way of protecting these teeth against decay is sealing pits and fissures in their occlusal surfaces.



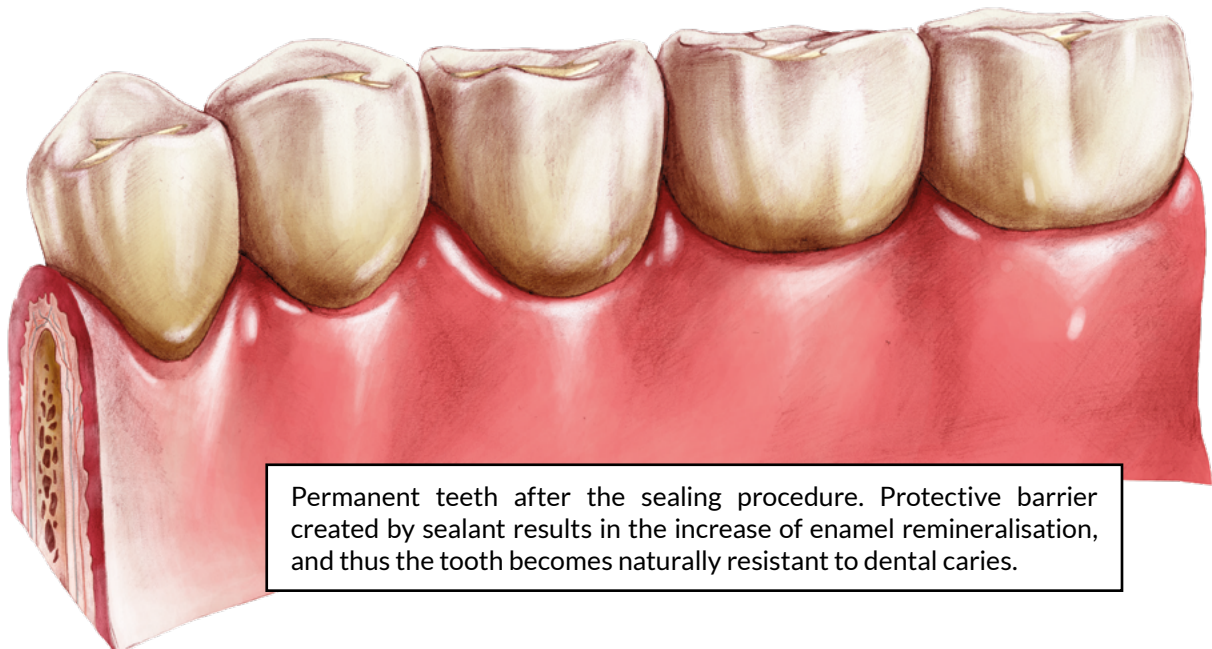
Unsealed pits and fissures in permanent premolars and molars create an environment which is conducive to the development of dental caries.

SOLUTION



A permanent tooth cross section of a permanent tooth after etching (left) and during the sealing procedure (right).

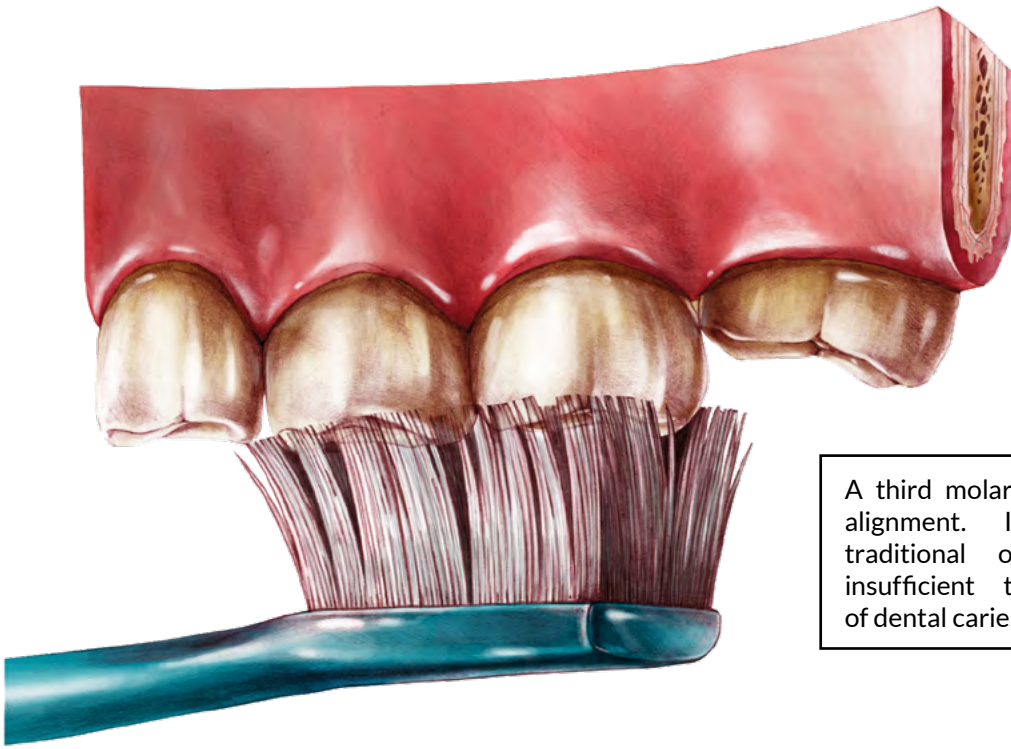
RESULT



Permanent teeth after the sealing procedure. Protective barrier created by sealant results in the increase of enamel remineralisation, and thus the tooth becomes naturally resistant to dental caries.

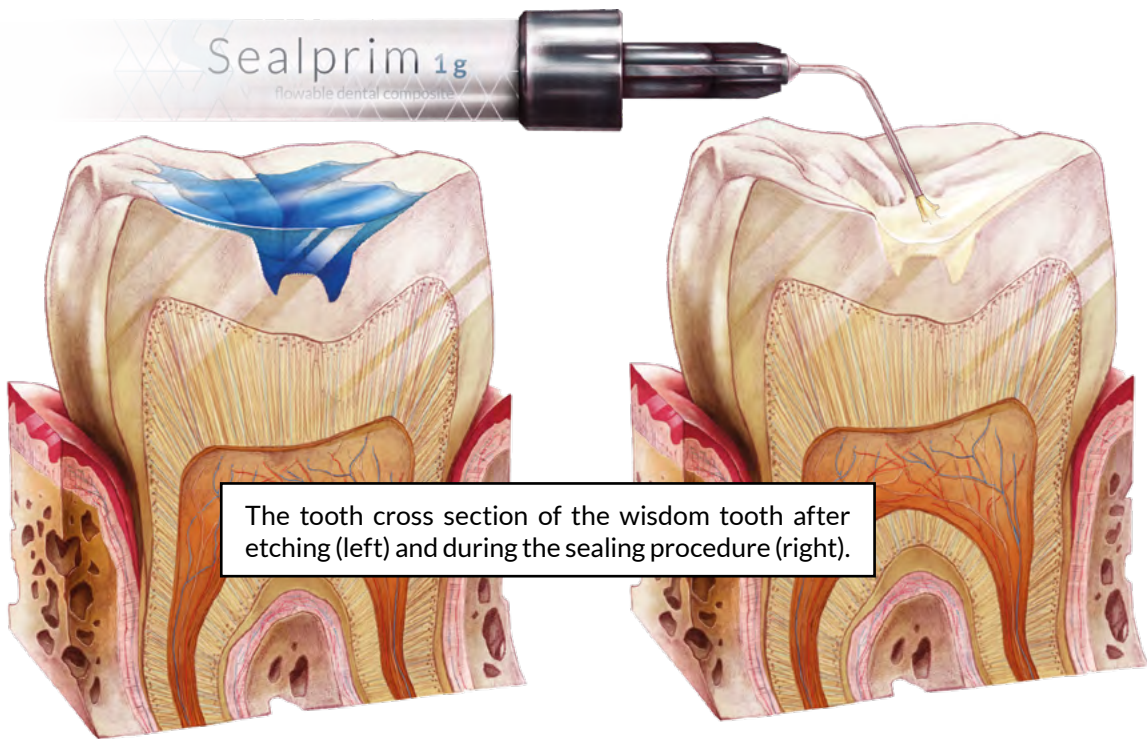
# UPPER THIRD MOLARS (WISDOM TEETH)

PROBLEM



A third molar placed out of its natural alignment. In such circumstances, traditional oral hygiene is usually insufficient to prevent development of dental caries.

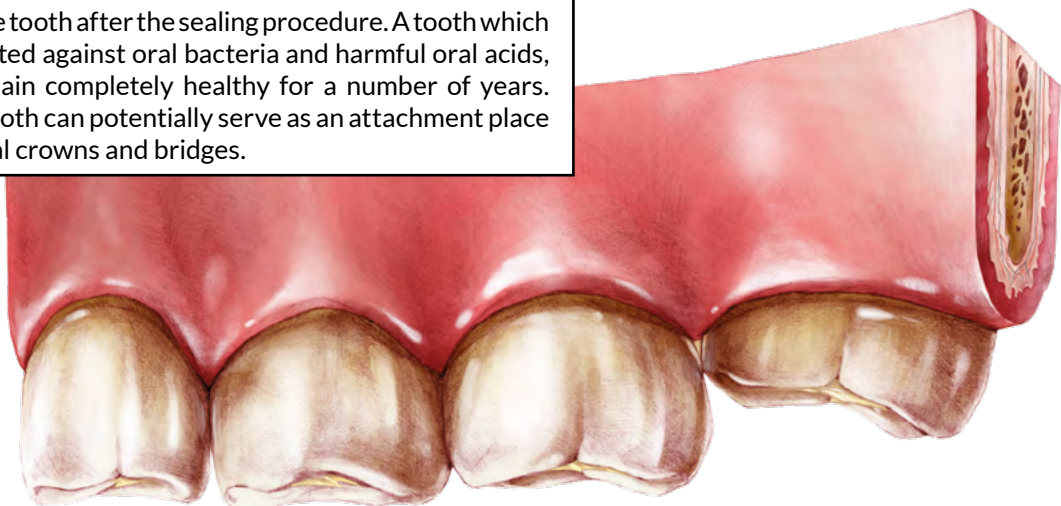
SOLUTION



The tooth cross section of the wisdom tooth after etching (left) and during the sealing procedure (right).

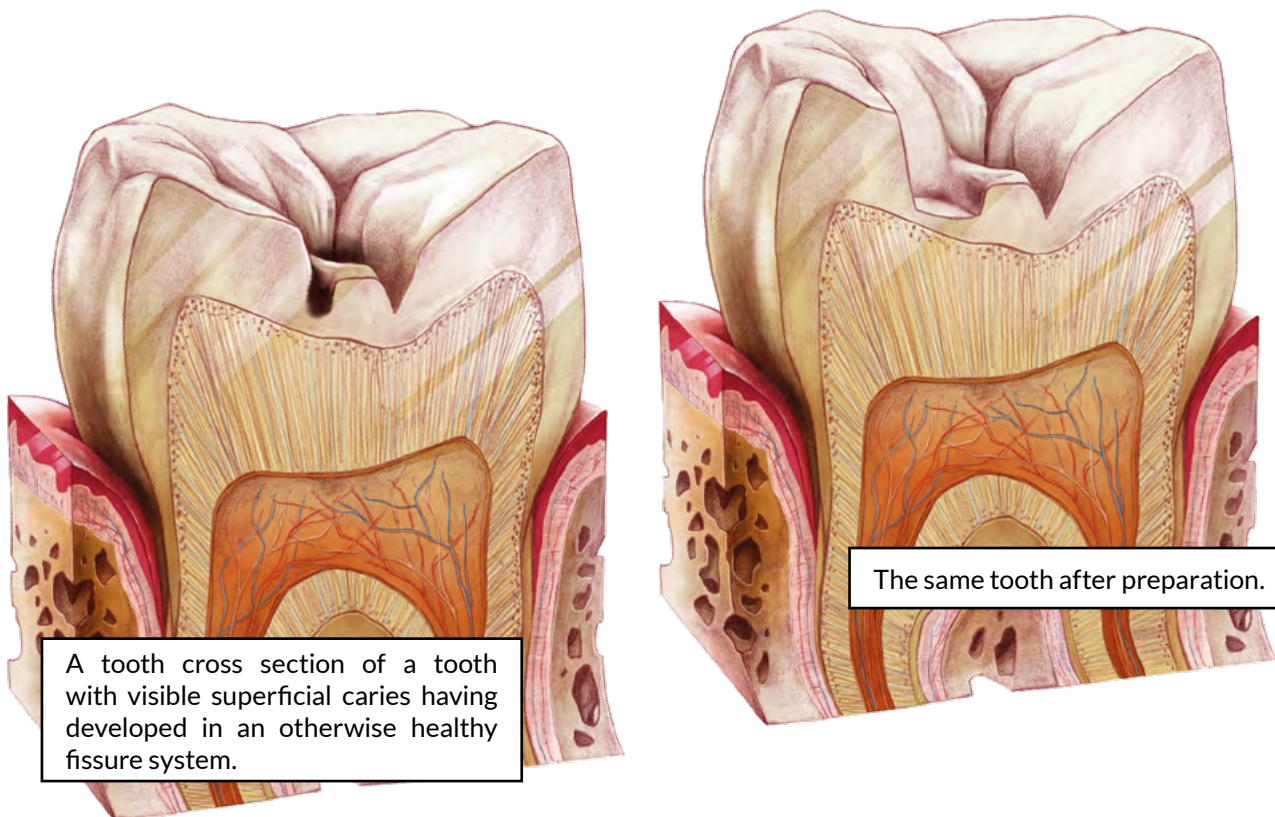
The same tooth after the sealing procedure. A tooth which is protected against oral bacteria and harmful oral acids, may remain completely healthy for a number of years. Such a tooth can potentially serve as an attachment place for dental crowns and bridges.

RESULT

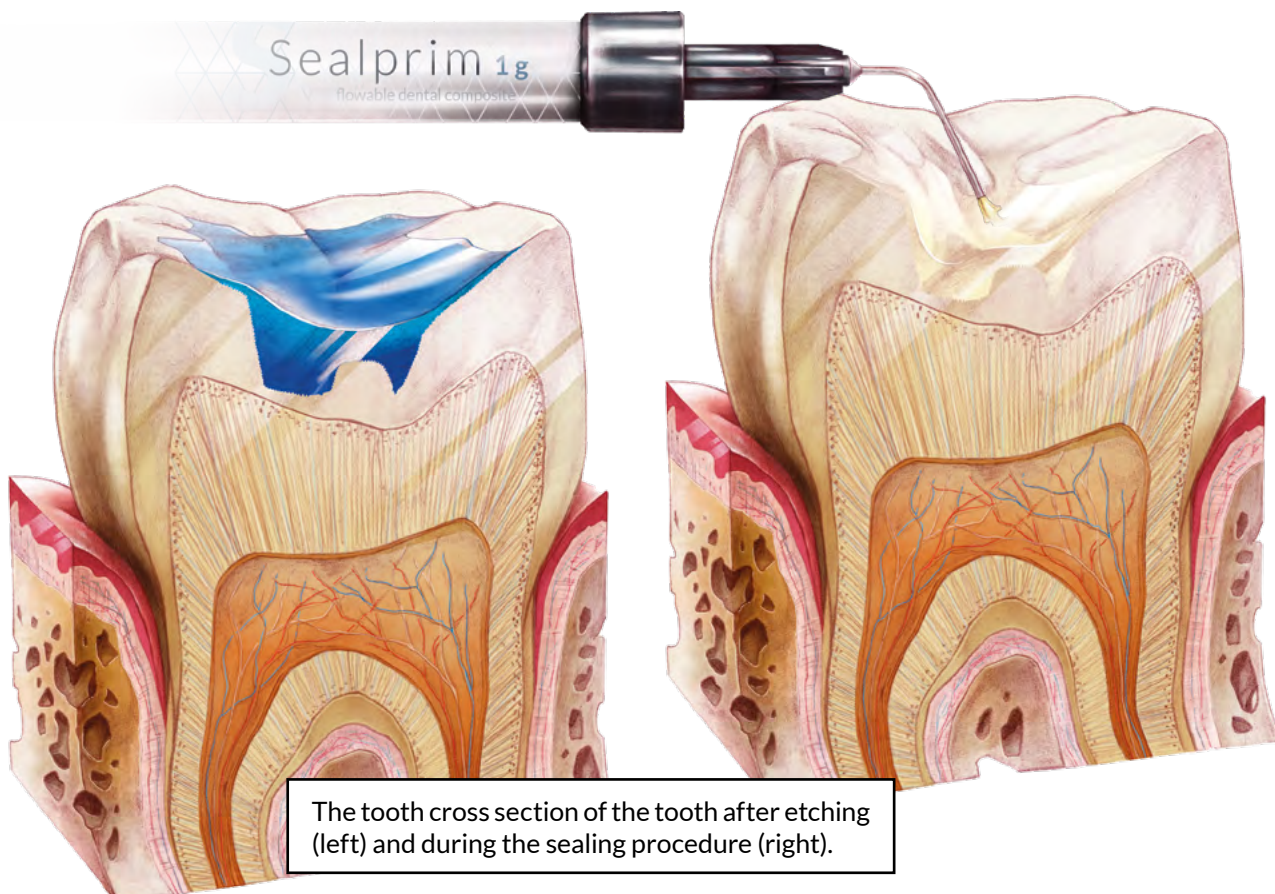


# HEALTHY TEETH WITH SUPERFICIAL DENTAL CARIES

PROBLEM



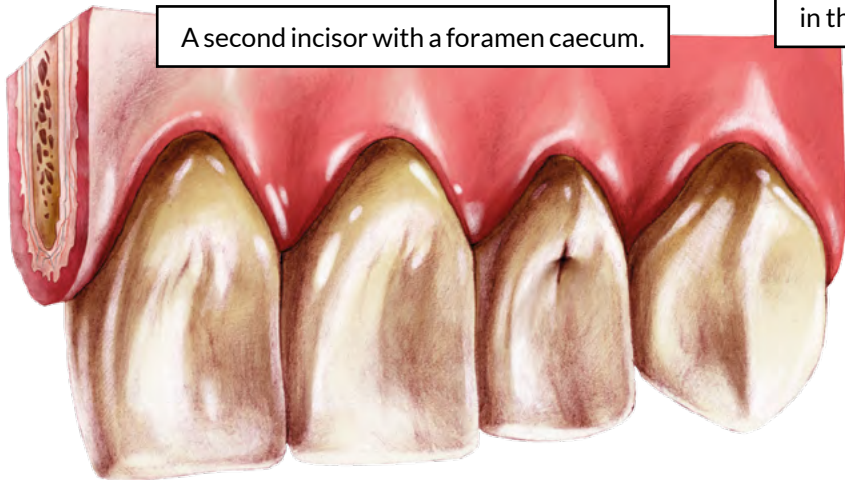
SOLUTION



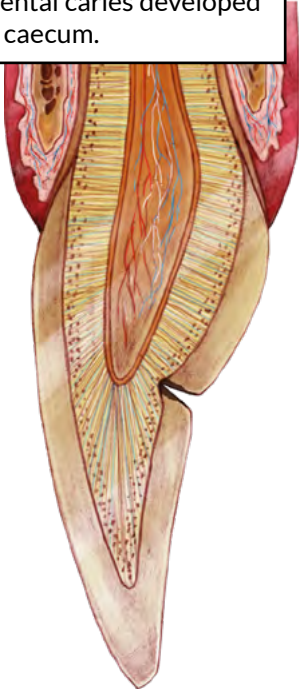


**FORAMINA CAECUM**

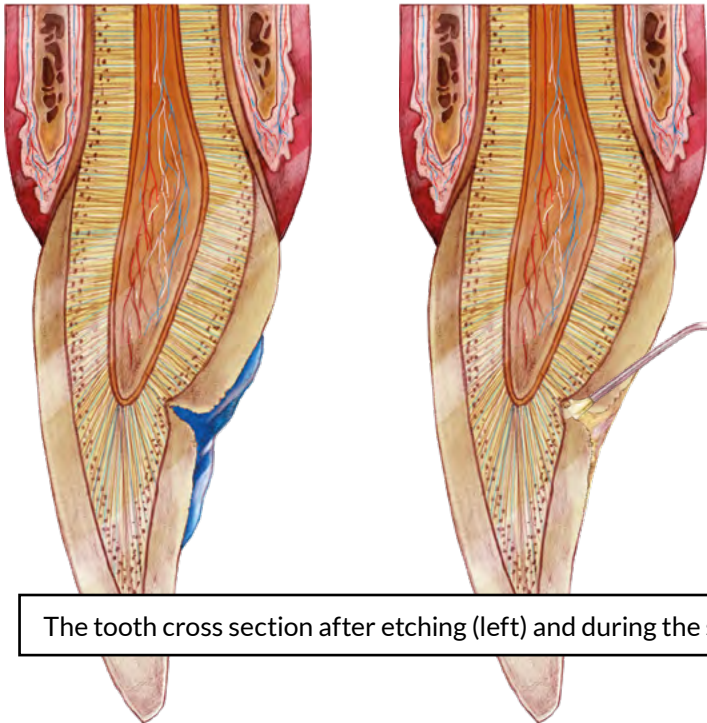
PROBLEM



The same tooth cross section with a visible dental caries developed in the foramen caecum.

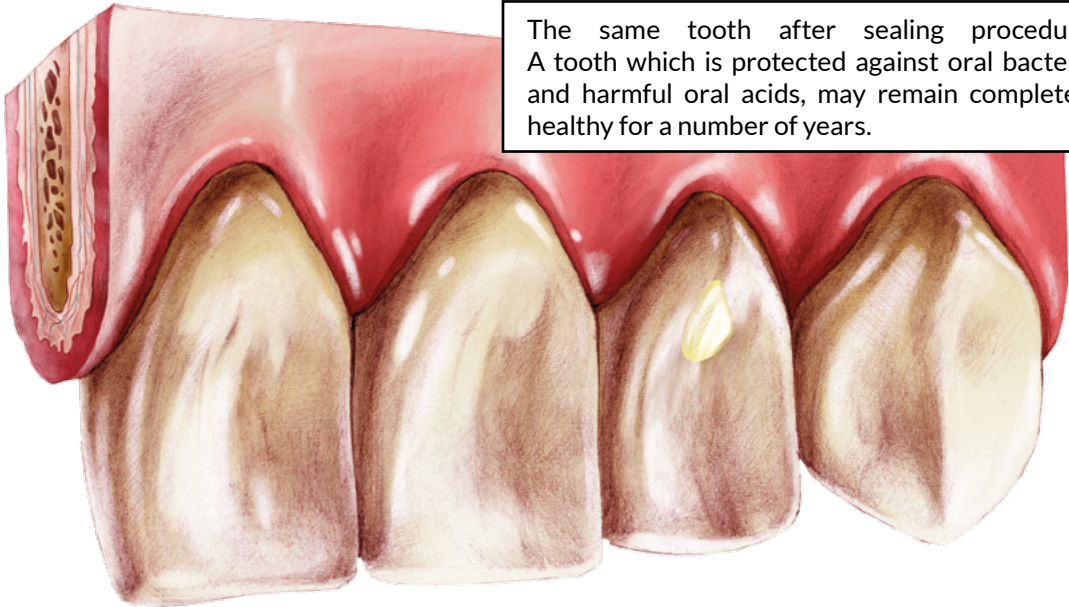


SOLUTION



The tooth cross section after etching (left) and during the sealing procedure (right).

RESULT



The same tooth after sealing procedure. A tooth which is protected against oral bacteria and harmful oral acids, may remain completely healthy for a number of years.

## INSTRUCTIONS FOR USE

## POLYMERISATION TABLE

## COMPOSITION

## CONTRAINDICATIONS

## ADVERSE REACTIONS

## LIMITATIONS IN USAGE, INTERACTIONS

## PRECAUTIONS FOR PATIENTS

## PRECAUTIONS FOR DENTAL PERSONNEL

## ADVICE FOR DENTAL PERSONNEL

## WARNINGS

## STORAGE

## PACKAGE CONTENTS WARRANTY

### ETCHING

1. Etch the surfaces intended for sealing with ETCHGEL for 20-40 s, paying special attention to placing it also in the bottom of the fissure.
2. 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 re-etched for about 10 s.

### SEALING

1. 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.
2. Thoroughly apply SEALPRIM onto the etched tooth surface.
3. Cure in accordance with the polymerisation table.
4. Use an explorer to ensure pits and fissures are sealed.
5. Clean and rinse sealed surfaces immediately after applying sealant.

Lamp	5 s	10 s
Halogen/LED (500-800 mW/cm <sup>2</sup> )	2.0 mm	3.0 mm
LED (>800 mW/cm <sup>2</sup> )	3.0 mm	4.0 mm

Mixture of dimethacrylate resins: BisGMA, TEGDMA, UDMA, BisEMA; mineral fillers (20 wt%): Al-Ba-B-Si glass, fumed silica, photoinitiator (CQ : DMAEMA). The size of inorganic filler particles is between 20 nm and 2.0 µm. SEALPRIM does not require the use of a bonding system however, if needed, it can be used with any standard, light cured bonding systems.

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

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

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

Do not use if it is impossible to completely isolate the area from saliva, blood or moisture. Such contamination may disrupt polymerisation of the composite.

Do not use if the syringe or the applicator tip is suspected to be defective or damaged.

Do not use when any change in product properties is found.

This product contains substances that may cause an allergic reaction in certain individuals.

Avoid the use of this product in patients with known acrylate allergies.

Avoid contact of uncured 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 any future use of the product.

In case of swallowing or aspiration into the respiratory tract, seek immediate medical attention. If any changes in the sealing performance are noticed, please attend a dental check-up.

This product contains substances that may cause an allergic reaction in certain individuals. To reduce the risk of such reaction, minimise any exposure to uncured product. 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 contact with a glove occurs, remove and discard the glove, immediately wash your hands with soap and water and then re-glove. If an allergic reaction occurs, seek medical attention as needed. The device is equipped with the blunt-ended applicators to minimise the risk of injury, but always handle them carefully.

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 may be allergenic or its lifespan 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 uncured 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 reapply the composite. Always cure the material in accordance with the polymerisation table provided.

To minimise the risk of potential releasing of unwanted substances always clean and rinse sealed surfaces immediately after curing the sealant.

Examine the sealing at preventive appointment or check-up. In case of any changes in the performance of sealing (e.g. wear, chipping), remove the defective part and apply a new one.

Inform the patient that standard proper oral hygiene should be maintained.



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.

Protect the device against mechanical damage. Do not store above 30°C. If stored at a lower temperature, bring back to room temperature before use. Do not expose to direct sunlight. Protect from light. Protect from heat. Do not freeze.

1 luer-lock syringe (1 g) and 5 applicator tips.

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.

Report any serious incident to the manufacturer and the competent authority.



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