

solaetch

1 Intended Purpose

solaetch is intended for etching enamel and/or dentine surfaces in preparation for further dental or orthodontic treatment.

2 Description of the Product and Users

2.1 Description of the Product

solaetch is a dental etching gel designed to create micro-retentions on tooth surfaces prior to bonding procedures. Its colouring and stable gel consistency enable precise, controlled application.

2.2 Patient Target Group

May be used on all patients requiring micro-retentions on tooth surfaces for restorative or orthodontic procedures.

2.3 Intended Users

solaetch is intended for use exclusively by dental professionals, such as dentists and orthodontists, within a clinical environment.

3 Composition

- Orthophosphoric acid
- Fumed silica

4 Indications for Use

For etching of enamel and dentine.

5 Contraindications

Do not use this product if the patient is known to be allergic or hypersensitive to any of its components. If use is unavoidable, it must be performed only under the strict supervision of the attending dentist or physician.

6 Warnings

Contains phosphoric acid.
Causes severe skin burns and eye damage.

7 Safety Instructions

- IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with plenty of water (or shower).
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing.
- Seek immediate medical advice or contact a Poison Centre /doctor.
- Store the product locked away and out of reach of unauthorised persons.

8 Interaction with Other Materials

solaetch may detach cavity liners (e.g. calcium hydroxide). Only acid-resistant materials should be used. Before application, the dentist must consider known interactions or cross-reactions between this medical device and materials already present in the patient's mouth.

9 Application

9.1 Preparation

Isolate the gingiva and adjacent teeth (e.g. with a rubber dam, Vaseline, or matrices). Ensure enamel areas to be etched are clean, rinsed, and thoroughly dried. Exposed dentine should be protected as deemed appropriate by the operator.

9.2 Etching Procedures

9.2.1 Selective-Etch Technique

Apply Solaetch precisely to the prepared enamel margins and allow it to act for 30 seconds.

Rinse each surface thoroughly with copious water for at least 5 seconds, then dry using oil-free compressed air. Avoid saliva contamination before bonding. If contamination occurs, re-etch for approximately 10 seconds and verify the chalky appearance.

9.2.2 Total-Etch Technique

When using dentine and enamel bonding systems:

- 1 Apply Solaetch to the enamel surfaces and allow it to act for 15 seconds.
- 2 Then, fill the entire cavity with Solaetch and allow a further 15 seconds of reaction time.
- 3 Remove the gel by suction and rinse each surface thoroughly with copious water for at least 5 seconds.
- 4 Dry the etched surfaces with oil-free compressed air.
- 5 Apply bonding agent and composite material as instructed by the manufacturer.

9.2.3 Recommended Etching Times

Surface Type	Reaction Time
Normal enamel	30 seconds
Immature enamel	20–30 seconds
Fluoridated or deciduous teeth	90–120 seconds
Dentine	15 seconds

10 Notes on Handling

- If not using the selective-etch technique, protect dentine areas with a suitable insulating material.
- For hygiene reasons, always use a new application tip for each application.
- After use, remove the application tip and slightly retract the syringe plunger to prevent leakage.
- Close the syringe tightly after each use.

11 Troubleshooting / FAQ List

Problem	Cause	Remedy
Material has dried or thickened	Syringe was left open	Close syringe tightly after each use
Restoration does not adhere properly	Oily polishing paste residue	Do not use oily polishing pastes
	Etching gel was brushed in, causing over-etching	Apply the gel without brushing
	Insufficient rinsing, acid residue affecting polymerisation	Rinse for at least 5 seconds
	Inadequate drying or contaminated air	Use only oil-free compressed air
	Saliva contamination	Re-etch for approx. 10 seconds

12 Storage and Handling

Store at 10°C – 25°C.
Keep container tightly closed when not in use.

13 Shelf Life

The expiry date is printed on the label of each syringe. Do not use after the expiry date.

14 Possible Side Effects

When used correctly, adverse effects are extremely rare.

turn over ▶

However, allergic reactions or local irritation cannot be completely excluded.

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All serious incidents occurring in connection with this medical device must be reported to:

- The manufacturer listed below, and
- The competent authority in accordance with MDR requirements.

15 Disposal

Dispose of any remaining material and packaging in accordance with local or national waste disposal regulations.



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