

Instructions For Use

Quadrant Total Etch

CE 0197

Product description

Quadrant Total Etch is a phosphoric acid based tooth conditioner. It is used in the so-called "total etch technique" for the pre-treatment of both enamel and dentine, in combination with a bonding agent such as Quadrant Uni-1-Bond. This enables the dentist to operate according to the principles of adhesive dentistry, adopting the minimal invasive technique for maximal preservation of sound tooth tissue.

Quadrant Total Etch is packed in a 3 ml syringe = 2,5 ml net. 0,25 ml per patient application. Sufficient for approximately 10 patient applications..

Composition

Function	Raw Material	% Mass
Acid	Ortho phosphoric acid 85%	40.1
Filler	Silica	5.9
Additive	Fatty alcohol polyglycol ether	0.3
Pigment	CI Pigment blue 15	0.1
Solvent	Distilled water	53.6

Intended use

Quadrant Total Etch is an etching agent based on orthophosphoric acid. It is used to etch enamel and condition dentine in the context of adhesive filling therapy.

Indication for use

Enamel etching and enamel/dentine etching in the context of the total etch technique prior to the adhesive bonding of:

- Composite and compomer restorations
- Laboratory-fabricated, indirect restorations (e.g. inlays, crowns, bridges, veneers)
- Sealants

Contra-indications & Warnings

Contra-indications

Application to dentine close to the pulp (less than 1 mm). In case of known or suspected allergy to components of the product, its use is contraindicated.

Potential side effects

Hypersensitivities to the product or its components cannot be excluded in individual cases.

Storage Conditions

Do not use the material after the expiry date. Do not store at temperatures higher than 25 °C (77 °F) or below -10 °C (14 °F). Always close the syringe tightly after use. Keep out of reach of children.

Warnings

Quadrant Total Etch contains 35% phosphoric acid and can cause chemical burns.

May cause skin and eye irritation:

- Avoid contact with skin. Skin contact may cause sensitization. Wear suitable protective gloves. In case of contact with skin, immediately wash with plenty of water and soap.
- Avoid contact with eyes. Eye protection is recommended for the patient. In case of contact with eyes, rinse with water for several minutes. If symptoms persist, consult an eye specialist.
- The etching agent must not be swallowed by the patient, otherwise incompatibilities may occur. Do not induce vomiting. Give large amounts of water.

Instructions For Use

Handling

Prior to treatment, carefully clean tooth with fluoride-free polishing paste. The use of a rubber dam is recommended. Visually inspect for damage before use. Damaged products must not be used.

1. After preparation in accordance with adhesive filling therapy, rinse the cavity and dry with oil-free air.

2. Starting from the bevelled enamel areas, apply Quadrant Total Etch to the entire cavity surface, including the dentine. Ensure that the enamel is conditioned for at least 20 s, a maximum of 30 s and the dentine for a maximum of 15 s. If desired, only apply Quadrant Total Etch to the enamel and let set for a maximum of 30 s. Etch unprepared enamel, e.g. in case of fissure sealing, for at least 30 s and no more than 60 s. In case of fluoridated enamel, etching for no more than 60 s may also be required.

Caution: Always respect the recommended contact time to overcome extensive tooth demineralization or decalcification.

Caution: In case of deep cavities, we recommend covering the dentine near the pulp with a calcium hydroxide preparation and a base (e.g. glass ionomer cement) prior to etching.

3. Use a water sprayer to completely rinse off Quadrant Total Etch 35 for 20 s under suction. The cavity must be completely free of any remnants.

4. Dry the cavity with oil-free air (do not dry out dentine!). The etched enamel surface should appear chalky white. In case of contamination of the tooth surface (e.g. with saliva), the etching must be repeated (for a maximum of 10 s dwell time).

5. Perform further treatment with adhesive (e.g. Quadrant Uni-1-Bond, Quadrant Uni-SE-Bond) and composite (e.g. Quadrant Universal LC) in accordance with manufacturer directions.


Quadrant Total Etch may be applied using a brush or cannula. Both brushes and cannulas are for onetime use only and must be disposed after use.

After applying the gel release the plunger and close Quadrant Total Etch with the cap. The syringe can be used until expiry date.

When using syringes in mouth, use common hygienic protective sleeves to prevent contamination. Do not re-use after contamination.

Labelling:

This information is in compliance with NEN-EN-ISO 20417:2021 en – Information supplied by the manufacturer of medical devices.

	Symbol use explanation:
	Contains ortho-phosphoric acid which is a strong acid and corrosive.
	Skin Corr. 1B H314 Causes severe skin burns and eye damage. Eye Dam. 1 H318 Causes serious eye damage.
GHS05 Corrosion	

Instructions For Use

Intended Patient(s)

Quadrant Total Etch will be used on any patient(s) in the context of adhesive filling therapy.

Children as population are highly unlikely for the use of dental medical devices for prosthetic custom-made devices since these kinds of custom-made devices are usually prescribed for indications that occur through damage in and on the adult teeth. This is however purely based on the timing when such defects occur within a patient life and not based in the toxicological potential of chemicals utilized in such products.

For pregnant women and nursing mothers, the treatment risks must be weighed carefully against the benefits of the treatment in favour of unborn child or infant given the special circumstances.

Intended User(s)

Quadrant Total Etch will only be used by dental professionals (dentist).

Clinical benefits

The ability to prepare enamel and dentin for bonding, resulting in high bond strength and low marginal integrity.

Claims

- Ultimate concentration for total etching technique
- Distinctive blue colour for easy residue detection
- Perfect visual overview of the etching process

Product characteristics and specifications

At present, a product standard for etching agents is not available. Therefore, quality control is carried out according to a number of in-house standards.

Characteristic	Product specifications	Release specifications	
Filling weight	2 x 2,5	2 x 2,5	ml
O-phosphoric acid	34 - 36	34 - 36	%
Shear bond strength dentin (ISO29022):			
- Quadrant Uni-1-Bond	>20	>20	MPa
- Quadrant Uni-SE-Bond	>20	>20	MPa

Combination products:

Accessories:

Quadrant Total Etch does not require specific combinations with accessories.

Combination products:

Quadrant Total Etch can be used in combination with the following product(s):

- Quadrant Uni-1-Bond (etch & rinse for dentin and enamel)
- Quadrant Uni-SE-Bond (selective enamel etching)

Special advice

According to EU Medical Device Regulation users/ patients are obliged to report serious incidents with a medical device to the manufacturer and to the competent authority of the country, the incident occurred.

Instructions For Use

Storage advice

Do not store at temperatures higher than 25°C (77°F). Do not use this material beyond its expiry date. Avoid direct exposure to sunlight. Close containers firmly after use and keep out of reach of children.

Shelf life

We are able to guarantee the good quality of Cavex Quadrant Total Etch for a period of 3 years, when kept in its original packaging, provided the syringe is unopened and stored in a cool and dry place.

Disposal information

Dispose of in accordance with local regulations. Do not dispose of contents or partially emptied packaging in household waste or allow them to enter the sewage system.

Cavex Holland BV
Fustweg 5
2031CJ Haarlem
The Netherlands
T +31 23 5307700
dental@cavex.nl

Made in The Netherlands

Our technical advice, whether verbal, in writing or by way of trials, is given in good faith but without warranty, and this also applies where proprietary rights of third parties are involved. It does not release you from the obligation to test the products supplied by us as to their suitability for the intended processes and uses. The application, use and processing of the products are beyond our control and, therefore, entirely your own responsibility. Should, in spite of this liability be established for any damage, it will be limited to the value of the goods delivered by us and used by you. We will, of course, provide consistent quality of our products within the scope of our General Conditions of Sale and Delivery.

Version: ZF730.06

Date: 25-10-2024