

Instructions For Use

Quadrant Uni-1-Bond

CE 0197

Product description

Quadrant Uni-1-Bond is a light curing, single component bonding agent for universal use in combination with adhesive restorations. Quadrant Uni-1-Bond primes and bonds in one step. Quadrant Uni-1-Bond is an ethanol-based formulation of light-activated, adhesive resins.

Quadrant Uni-1-Bond is meant to be used multiple times. When Quadrant Uni-1-bond is applied using a brush, the brush is to be disposed after use.

Composition

The following materials are used in Quadrant Uni-1 Bond:

Function	Raw Material	% Mass
Monomer	Urethandimethacrylate	31.3
Acid monomer	Methacrylierte Polycarbobacid	5.0
Monomer	Hydroxyethylmethacrylate	18.5
Stabilizer	Butylhydroquinone	0.05
Solvent	Ethanol	30.3
Monomer	4-Methacryloxyethyltrimellitanhydrid (4-META)	4.0
Catalyst	Camphoroquinone catalyst system	0.30
Activator	Poly (methacrylic acid)	0.20
Active	Glutaraldehyde	10.0
Modifier	Ethylcellulose 45	0.35

Indication for use

- Bonding of composite filling material to enamel and dentin.
- Sealing hypersensitive areas of teeth.

Intended use

Quadrant Uni-1-Bond is used in the so-called “total etch technique”, in combination with an etching agent such as Quadrant Total Etch, as the adhesive bonding for composite restorations and for treatment of exposed root surfaces.

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Contra-indications & Warnings

Contra-indications

In cases of a known allergy to any of the ingredients of Quadrant Uni-1-Bond.

Warnings

Swallowing

A negligible risk under normal conditions in the dental office because of the minor quantities used and the way of application.

Exposure to residual monomers

Abundant evidence in the scientific literature shows this to be negligible in view of the low level of exposure.

Hypersensitivity- or allergic reactions

These phenomena are described, but they are relatively rare. Nevertheless it is advised to avoid contact with skin and oral mucous membranes and not to use the device in case of known allergies for methacrylate-based resins or signs of skin irritation appearing in a patient, as described in the Instructions for Use.

The Material Data Sheet with all relevant safety information will be distributed to the customers.

Instructions for Use not respected

It should be acknowledged that the dentist is always responsible for the device to be used on the patient. With a deteriorated product (due to inappropriate storage conditions or use of the product after the expiry date) or an incorrect handling, the quality of the bond might be affected. A restoration made in such a manner might show secondary caries after a while and might have to be replaced earlier than normal.

Interactions with other materials

Do not use in combination with eugenol containing restoratives, as these impair the polymerisation.





Handling

1. Prepare the cavity according to the general directions for composite restorations. Clean and dry the preparation. The use of a rubber dam is recommended. When restoring exposed root surfaces, a preparation may not be necessary.
2. Apply Etch gel onto the enamel and dentin to be restored and leave for 15-30 seconds.
3. Rinse Etch gel thoroughly for at least 5 seconds and remove excess moisture from the preparation with a gentle stream of air. The best bonding effect is obtained when Quadrant Uni-1-Bond is applied to moist and shiny dentin. If you wish to visually verify that enamel etching has taken place, more intense drying of the cavity is necessary. The enamel surface will show frosted-white when sufficiently etched. If this is the case, the entire preparation surface must be re-moistened with water (e.g. a damp pellet) prior to application of Quadrant Uni-1-Bond.
4. Apply Quadrant Uni-1-Bond immediately after having removed the excess water.

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5. Soak the applicator tip or a soft disposable brush (i.e. Quadrant Q-Brushes) in Quadrant Uni-1-Bond and apply a copious amount to the entire cavity surface.
6. Apply two additional coats of Quadrant Uni-1-Bond and wait for 15 seconds.
7. Gently spread Quadrant Uni-1-Bond with a gentle air stream to evaporate the solvent and excess moisture (approximately 2-5 seconds).
8. If the cavity surface is not uniformly shiny after this step, apply additional coats of Quadrant Uni-1-Bond as described above.
9. Light cure Quadrant Uni-1-Bond for 20 seconds with a standard light-curing unit.
10. Place restorative material according to manufacturer's instructions.

Labelling:

 <p>GHS02 Flammable</p>	 <p>GHS05 Corrosion</p>	<p>Symbol use explanation:</p>
 <p>GHS07 Irritation</p>	 <p>GHS08 health hazard</p>	<p>GHS02 Flam. Liq. 3 H226 Flammable liquid and vapour. GHS05 Eye Dam. 1 H318 Causes serious eye damage. GHS07 Skin Irrit. 2 H315 Causes skin irritation. Skin Sens. 1 H317 May cause an allergic skin reaction. STOT SE 3 H335 May cause respiratory irritation. GHS08 Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p>

Intended Patient(s)

Quadrant Uni-1-Bond 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 Uni-1-Bond will only be used by dental professionals (dentist).

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Clinical benefits

The following clinical benefits can be considered for Quadrant Uni-1-Bond:

Adhesive dentistry benefits patients by allowing healthy dental tissue to be conserved through lesion-oriented, minimally invasive caries treatment. In general, direct restorations are considered the first choice materials due to their low cost and less need for removal of sound tooth substance when compared with indirect restorations. Furthermore, adhesive resin technology enables clinicians to add composite resins to tooth surfaces to close gaps and reshape tooth form without tooth preparation. Tooth shape, position, and colour can be altered without loss of tooth tissues.

Claims

- 4-META monomer quality optimization
- Excellent adhesion by dentin penetration abilities
- Prevents bacterial invasion
- Ethanol water base - constant composition
- Less technique-sensitivity

Product characteristics and specifications

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

Characteristic	Product specifications	Release specifications	
Appearance	Clear yellow liquid, homogeneous	Clear yellow liquid, homogeneous	
Refractive index	1,4255 – 1,4295	1,4275 – 1,4295	
Shear bond strength	>20	>20	Mpa
Packaging and marking	Must comply	Must comply	

Combination products:

Accessories:

Quadrant Uni-1-Bond has the following accessory which can be used in combination with the product:

- Quadrant Q-brushes

Combination products:

Quadrant Uni-1-Bond can be used in combination with the following product(s):

- Quadrant Total Etch
- Quadrant FiniSense

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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.

Storage advice

Do not store at temperatures higher than 25°C (77°F) and lower than -10 °C (14°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.

We recommend that the product is stored in a refrigerator when not in use.

Disposal information

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

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Made in The Netherlands

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