

Instructions For Use

Quadrant Uni-SE-Bond

CE 0197

Product description

Quadrant Uni-SE-Bond is a light curing self-curing one component adhesive for universal use in combination with adhesive restorations. Quadrant Uni-SE-Bond etches primes and bonds in one step. Quadrant Uni-SE-Bond is an acetone-based formulation of light-activated, adhesive resins.

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

Composition

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

Function	Raw Material	CAS/CI nr.	% Mass
Monomer	Urethandimethacrylate	41137-60-4	20.0
Monomer	4Methacryloxyethyltrimellitanhydrid (4-META)	70293-55-9	18.0
Filler	Amorphous silica	7631-86-9	1.0
Monomer	Carboxylic acid based monomer	110-67-7	1.0
Catalyst	Camphoroquinone catalyst system	10373-78-1	1.0
Solvent	Acetone	67-64-1	39.0
Viscosity	Distilled water	7732-18-5	20.0
Total			100.0

Indication for use

1. Bonding of direct light-cured composite restorations.
2. Bonding of indirect restorations in combination with a light-curing luting cement: porcelain and composite restorations (inlays, onlays, veneers, crowns).
3. Sealing hypersensitive areas of teeth.

Intended use

Quadrant Uni-SE-Bond is an acetone-based formulation of light-activated, adhesive resins. Quadrant Uni-SE-Bond has the properties to etch, prime and bond in one step.

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Contra-indications & Warnings

Contra-indications

In cases of a known allergy to any of the ingredients of Quadrant Uni-SE-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. Bonding of direct light-cured composite restorations.

1.1 Preparation

Do not use Quadrant Uni-SE-Bond directly on exposed pulp tissue.

- Clean tooth with an oil and fluoride-free polishing paste.
- Prepare cavity for bonding.
- Rinse cavity with water and air dry.
- Isolate the cavity (the use of a rubber dam is strongly recommended).
- If indicated, place sub-base (e.g. glass ionomer cement).

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1.2 Dispensing

- Shake bottle briefly before opening.
- Dispense Quadrant Uni-SE-Bond into the well (1 drop for small cavities, 2 drops for larger cavities).
- Replace bottle cap immediately after dispensing.
- Use Quadrant Uni-SE-Bond immediately after dispensing (no later than 3 minutes).

1.3 Application

Roughen or grind enamel before application of Quadrant Uni-SE-Bond. Etching/bonding is less effective on unground enamel.
On sclerotic dentine separate etching with phosphoric acid for 30 sec. is recommended.

- Immediately after dispensing apply a copious amount of Quadrant Uni-SE-Bond to the entire cavity surface and margin with the applicator tip or brush. Make sure that the cavity margin is also sufficiently coated with Quadrant Uni-SE-Bond liquid.
- After application agitate the adhesive slightly for 20 sec. Agitation during the dwell time improves demineralisation and diffusion. Protect the bonding layer from contamination (e.g. by blood or saliva).
- Carefully air-dry Quadrant Uni-SE-Bond with a flow of oil-free air (may take 5–10 sec. or longer depending on the geometry of the cavity). The objective is to evaporate the solvent and water from the bonding layer with - out removing the active ingredients from the tooth surface.

A strong air stream at the start of air-drying will dilute the bonding agent and may result in poor adhesion.

- The surface must be visibly glossy, both after application of Quadrant Uni-SE-Bond and after evaporation of the solvent. The complete cavity surface must be fully coated. If the cavity surface does not appear shiny, apply Quadrant Uni-SE-Bond as described above a second time.
- Light-activate Quadrant Uni-SE-Bond for 20 sec. with a halogen or LED light-curing unit. The light-curing time assumes the use of a Heraeus Kulzer Translux® light-curing unit or other dental curing light of comparable intensity (min. 400–500 mW/cm²). If plasma light-curing units (with an output greater than 1200 mW/cm²) are used, the curing time can be reduced by 8 sec.

Low-intensity light causes poor adhesion. Curing lights should be checked with reliable light testers at regular intervals. The emitting tip should be placed as close as possible to the curing surface.

- Place restorative material according to manufacturer's instructions.

2. Bonding of indirect restorations in combination with a light-curing luting cement: porcelain and composite restorations (inlays, onlays, veneers, crowns).

2.1 Pre-treatment of restoration

- Pre-treat the bonding surface of the indirect restoration according to the manufacturer's instructions.

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2.2 Dispensing and application of Quadrant Uni-SE-Bond

Light-cure the adhesive prior to application of the luting cement.

- Proceed as described in 1.
- Apply and process luting cement according the manufacturer's instructions. The luting cement must be completely light-cured after insertion of the indirect restoration.

3. Sealing hypersensitive areas of teeth.

3.1 Cleaning the tooth



- Clean tooth with an oil and fluoride-free polishing paste.

3.2. Dispensing and application of Quadrant Uni-SE-Bond

- Proceed as described in 1.
- Carefully remove oxygen-inhibited layer with an alcohol-soaked pellet after light-curing.

If the desensitisation effect is not adequate, apply additional coats of Quadrant Uni-SE-Bond as described, light cure and remove the oxygen-inhibited layer with a damp pellet.

Labelling:

 GHS02 Flammable	Symbol use explanation:
	GHS02 Flam. Liq. 3 H226 Flammable liquid and vapour. 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.
 GHS07 Irritation	

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Intended Patient(s)

Quadrant Uni-SE-Bond can be used by anyone that will use the “total-etch-technique”.

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 favor of unborn child or infant given the special circumstances.

Intended User(s)

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

Clinical benefits

The following clinical benefits can be considered for Quadrant Uni-SE-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

- Strong and durable bonding due to 4-META and mild etch
- Integrated desensitizer prevents sensitivity
- Simple user-friendly procedure
- Deep surface penetration
- Can be stored at room temperature

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	Slightly cloudy, homogeneous liquid	Slightly cloudy, homogeneous liquid	
Colour	Yellowish	Yellowish	
Refractive index	1,416 – 1,42	1,416 – 1,42	
pH	< 2	< 2	
Shear bond strength	>20	>20	Mpa
Packaging and marking		Must comply	

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Combination products:

Accessories:

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

- Quadrant Q-brushes

Combination products:

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

- Quadrant Total Etch
- Quadrant FiniSense

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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