

Instructions For Use

Quadrant Universal LC

CE 0197

Product description

Quadrant Universal LC is a light curing radiopaque composite filling material with fluoride release, designed for the restoration of both anterior and posterior teeth: a composite for universal use. It is available in 6 shades (6 Vita™ shades) for optimal colour matching, packed in syringes of 4 g each or “single use” capsules of 0.25 g each.

Quadrant Universal LC is used to fill cavities, prepared according to the principles of adhesive dentistry, adopting the minimal invasive technique for maximal preservation of sound tooth tissue. This requires the application of an adhesive bonding system such as Quadrant Uni-SE-Bond or Quadrant Uni-1-Bond in the so-called “total etch technique”, in combination with an etching agent such as Quadrant Total Etch.

The normal procedure, after a “lege artis” cavity preparation, conditioning of the tooth tissue involved (both enamel and dentin) and the application of the bonding agent, is as follows:

- the composite resin is applied in the cavity in a layer of max. 2 mm thickness and light cured;
- depending on the situation, one or more layers are applied and light cured;
- after filling the cavity, the restoration is modelled and shaped, and finally finished and polished.

Quadrant Universal LC has been developed as a response to the demand for composites that are suitable for front teeth as well as molars and pre-molars. In such a universal composite, the properties of an anterior composite and a posterior composite have to be combined. Therefore Quadrant Universal LC:

- is available in a variety of shades, including an opaque shade, with a shade guide made of original composite;
- is very easy to handle and to model;
- does not stick to instruments;
- can be polished to a high gloss;

but it also:

- releases fluoride and is radio-opaque;
- shows exceptional strength and abrasion resistance;
- does not damage the antagonist tooth.

Quadrant Universal LC capsules are Centrix-compatible and can be applied with dental compatible capsule applicator(gun).

Quadrant Universal LC in capsules and syringes are available in the following shades: A1, A2, A3, A3.5, B2 and C2.

Quadrant Universal LC is indicated for the following restorations:

- 1) Class I, II and V restorations of posterior teeth
- 2) Class III, IV and V restorations of anterior teeth
- 3) Cervical cavities or defects involving root surfaces

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Composition

The basic composition of Quadrant Universal LC is as follows:

| Function | Raw Material | % Mass |
|----------|----------------------------------|--------|
| Monomer | Bis-GMA | 16.4 |
| Monomer | Triethyleneglycol dimethacrylate | 8.1 |
| Filler | Silicon Dioxide | 7.4 |
| Filler | Ba-Al-F-B- silicate glass | 67.6 |
| Catalyst | Camphoroquinone catalyst system | 0.3 |
| Pigment | Inorganic pigments | 0.2 |

Indication for use

Quadrant Universal LC is used to fill cavities, prepared according to the principles of adhesive dentistry, adopting the minimal invasive technique for maximal preservation of sound tooth tissue. This requires the application of an adhesive bonding system such as Quadrant Uni-SE-Bond or Quadrant Uni-1-Bond in the so-called “total etch technique”, in combination with an etching agent such as Quadrant Total Etch.

Indications

- Restorations of class I,II,III,IV and V cavities, e.g.:
- reshaping
- shade correction
- direct veneers
- closing of diastema
- correction of development abnormalities (e.g. enamel dysplasia)
- splinting of traumatized teeth
- restoration of primary teeth

Contra-indications & Warnings

Contra-indications:

Hypersensitivity- or allergic reactions

Quadrant Universal LC contains monomers which may cause sensitizations with sensitive persons. Contact of uncured material with the skin and eyes should be avoided. In case of eye contact and/or longer contact with the oral mucosa, the product should be rinsed off immediately with water.

Warnings:

Swallowing

A minor risk under normal conditions in the dental surgery. The patient will first react by retching. When swallowed, the Quadrant Universal LC will be excreted the natural way.

Interactions with other materials

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

Instructions for Use not respected

Cavex Dental Medical Devices (i.e. Quadrant Universal LC) are only used by dental professionals (dentist, dental technician, dental nurses) Dental professionals are well-trained and it can therefore be considered that dental professionals are known with the Cavex dental products and normal use is respected.

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Handling

1. Prepare the cavity according to the general directions for composite restorations. Clean and dry the cavity. The use of rubber dam is recommended. When restoring exposed root surfaces, a preparation may not be necessary.
2. Apply Quadrant Uni-SE-Bond or Quadrant Uni-1-Bond (or another universal bonding system) following the instructions for use for that product. The oxygen inhibited layer should remain intact.
3. Apply Quadrant Universal LC in layers of max. 2 mm onto the cavity walls. Intensely discoloured teeth may require a block-out with an opaquer.
4. Cure with an appropriate curing light. The curing time is indicated below. During the polymerization, an oxygen inhibited layer develops on the surface. Do not touch or remove this layer, as it is essential for the chemical bond of the next layer.
5. Quadrant Universal LC can be finished and polished with fine diamonds, flexible discs and silicon polishers.

Shade


A1, A2, A3, A3.5, B2, C2

Polymerization time per 2 mm

20 sec.

Quadrant Universal LC radiopacity is equivalent to 2.0 - 2.5 mm of aluminium (dentine = 1 mm, enamel = 2 mm). Use a curing light with a wavelength of 440 – 480 nm and a minimum output of 600 mW/cm². The indicated polymerization times are minimum times and, to obtain an optimal polymerization, should under no circumstances be reduced. To prevent premature setting of Quadrant Universal LC in cases that take more time, the operating light may be dimmed or turned away.

Labelling:

| | |
|---|---|
|  <u>GHS07 Environment</u> | Symbol use explanation: |
| | <p>Hazard-determining components of labelling: Quadrant Universal LC contains the substance: (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]bismethacrylate.</p> <p>The symbol on the secondary packaging was based on:</p> <p>ISO 20417:2021, Chapter 6 – 6.1.1 C)</p> <p>1) The size of the medical device or accessory does not allow fixation of this information on the medical device or accessory.</p> <p>GHS07 Skin Sens. 1 H317 May cause an allergic skin reaction.</p> |

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Intended Patient(s)

Quadrant Universal LC is used for the restoration of both anterior and posterior teeth: a composite for universal use. Quadrant Universal LC is a filling material and can be used for any patient suffering from cavities. The medical condition should be considered during the anamneses made by the dentist or dental specialist.

The dentists has to take in consideration if the product can be safely used on pregnant women and children under the age of 18.

Intended User(s)

Quadrant Universal LC will only be used by dental professionals (dentist).

Clinical benefits

The following clinical benefits can be considered for Quadrant Universal LC:

Patients:

- Durable and wear-resistant
- Natural fluorescence
- Perfect chameleon effect
- BPA-free (Bisphenol A)
As it is free of BPA (Bisphenol A), there are no possible hormone-like properties that mimic the effects of estrogen in the body which can be caused by BPA.

Dentists:

- Perfect aesthetics
- Radiopaque
Based on ISO 4049 standards we can guarantee with internal testing that Quadrant Universal LC is radiopaque.
- Prism-shaped filler particles for optimal light scattering
- Suitable for mono layering and multi-layering technique

Claims

- Optimal light scattering by prism-shaped filler particles
- Radiopaque
- Suitable for mono layering and multi layering technique
- Durable and wear-resistant
- Natural Fluorescence
- Perfect filler mix enriched with sub-micron particles
- BPA-free (Bisphenol A)
- Perfect chameleon effect

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Product characteristics and specifications

Quadrant Universal LC is in full compliance with the EN ISO 4049 standard for Dentistry – Resin based filling materials.

| Characteristic | Product specifications | Release specifications | |
|------------------------------|-------------------------------|-------------------------------|--------------------|
| Appearance | Coloured, homogeneous paste | Coloured, homogeneous paste | |
| Biocompatibility | Must comply | Must comply | |
| Sensitivity to ambient light | 60 ± 5 s unpolymerized | 60 ± 5 s unpolymerized | |
| Depth of cure | 1,5 – 5,0 | 1 – 10 | mm |
| Flexural strength | 100 – 250 | 100 - 250 | Mpa |
| Water sorption | 0 – 40 | 0 – 40 | µg/mm ³ |
| Water solubility | 0 - 7,5 | 0 - 7,5 | µg/mm ³ |
| Colour | According shade guide | According shade guide | |
| Colour stability | Must comply | Must comply | |
| Radio opacity – X-ray | More than 1 mm aluminium | More than 1 mm aluminium | mm |
| Packaging and marking | Must comply | Must comply | |

Combination products:

Accessories:

Quadrant Universal LC has the following accessory which can be used in combination with the product:

- Quadrant ULC shade guide

Combination products:

Quadrant Universal LC can be used in combination with the following product(s):

- Quadrant Total Etch
- Quadrant Uni-1-Bond
- Quadrant Uni-SE-Bond

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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.

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.

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Made in The Netherlands

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