Product Information On

Quadrant Universal LC

(Light Curing Composite Resin)

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1. Introduction

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 color 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 UniBond 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 applier(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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Quadrant Universal LC is developed and manufactured by Cavex Holland B.V., a Company that is certified according to the provisions of the Regulation (EU) 2017/745 concerning Medical Devices, against ISO 9001 and ISO13485.

Quadrant Universal LC bears the CE-Mark of conformity.

2. 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

3. Manufacturing

Basically, the monomers and fillers are carefully weighed and blended in high-performance kneading equipment under vacuum, in order to obtain a composite paste, free of air bubbles. The last production step is to add the inorganic pigments in order to obtain the various shades in which the product is made available.

Finally, the composite paste is filled into syringes or "single use" capsules.

4. <u>Laboratory control</u>

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

Of every single batch of Quadrant Universal LC, is tested according to an in-house test method. One combination out of a production series is tested according to the entire ISO 4049 Specification, specification valid for all colours.

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In the following table, typical values for Quadrant Universal LC are listed, together with the requirements of ISO 4049 Specification:

Characteristic	ISO 4049	Quadrant Universal LC	
Appearance	Homogeneous	Homogeneous	
Biocompatibility	Must comply	Must comply	
Sensitivity to ambient light	60 ± 5 s unpolymerized	60 ± 5 s unpolymerized	
Depth of cure	1 – 10	1 – 10	mm
Flexural strength	100 – 250	100 - 250	Мра
Water sorption	0 – 40	0 - 40	μg/mm³
Water solubility	0 - 7,5	0 - 7,5	μg/mm³
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		

5. Shelf-life test

There is no official shelf-life test described for composite resins. But it is well-known, that composite dental filling materials may show some deterioration upon storage, in particular at elevated temperature. Therefore, care should be taken to protect the product from a decrease in quality.

Extensive shelf-life studies (e.g. 7 days storage at 50 °C) have been carried out, recording any change in product qualities related to storage conditions.

Based on the results of these tests, we can guarantee the good qualities of Quadrant Universal LC for a period of 36 month, provided the product is stored below 25 °C/77 °F when not in use.

6. **Quality Control**

A batch of Quadrant Universal LC, that has passed all the tests, is released for sales. In case of one or more requirements being not in specification, that batch is withdrawn and not sold.

7. Statement of non-toxicity

We hereby declare that Quadrant Universal LC can be safely used and is non-toxic to the patient as well as to the dental team.

Quadrant Universal LC will also normally not be irritant to oral tissues and it does not contain any hazardous ingredients in sufficient concentration to be harmful to human beings, when used as directed.

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