Product Information On

Quadrant Flow

Light curing Flowable Composite

Legal manufacturer:	**Cavex Holland BV** **Fustweg 5** **2031CJ Haarlem**
Regulatory evaluator: **Signature:**	**Danny Stoelinga** 
Regulatory manager: **Signature:**	**Richard Woortman** 
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- **Introduction.**

Quadrant Flow is a flowable light curing radiopaque composite filling material, designed as an addition to the existing Quadrant composites. Quadrant Flow has ideal flow properties, which assures perfect coverage of the tooth structure. Quadrant Flow is based on Bis-GMA monomer and contains like all other Quadrant composites Barium-glass and SiO_2 fillers. The unique properties of barium glass are its strong “chameleon effect”, gloss and strength. Quadrant Flow is excellently compatible with other composites in the Quadrant range (Anterior Shine and Universal LC).

Quadrant Flow is available in 4 shades:

- Quadrant Flow A2, A3, A3.5, OA2

Quadrant Flow is the “all-purpose” material, which can be used for a wide range of indications such as:

- minimally invasive fillings
- base under composite restorations
- cavity lining
- restorations to composite
- splints
- retention of threads and brackets
- fissure sealing

Quadrant Flow is available in syringe of 1,8 g (1 ml) and can be easy applied using single-use bendable metal needle tips. Quadrant flow 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.

Quadrant Flow is developed and manufactured by Cavex Holland B.V., a Company that is certified according to the provisions of the
Council Directive 2017/745 concerning Medical Devices,
against ISO 9001 and ISO13485.

Quadrant Flow bears the CE-Mark of conformity.

- **Composition.**

The basic ingredients of Quadrant Flow are:

Methacrylate-based monomers	39	% w
Silica, silicate glass and fluoride containing fillers	> 60	% w
Polymerisation catalysts	< 1	% w
Inorganic pigments	< 1	% w

- **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.

- **Laboratory control.**

Quadrant Flow is in full compliance with the EN 24049 standard for resin-based dental filling materials. The following table gives typical values for the most important properties:

	Quadrant Flow	
Filler content	> 60	% w
Film thickness	< 50	µm
Depth of cure (20 sec)	> 2	mm
Sensitivity to ambient light	60	sec.
Flexural strength	> 50	MPa
Water absorption	< 45	µg/mm³
Water solubility	< 7.5	µg/mm³
Radiopacity	100	% Al

- **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 Flow for a period of 42 month, provided the product is stored below 25 °C/77 °F when not in use.

- **Quality Control.**

A batch of Quadrant Flow, 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.

- **Statement of non-toxicity.**

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

Quadrant Flow 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.