

# Instructions For Use

## Quadrant Flow

CE 0197

### Product description

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<sub>2</sub> 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).

### Composition

Quadrant Flow contains fillers, 38% by volume and 62% by weight. The filler particle size is 0.005 - 5 µm. It contains: Barium Aluminium Boro Fluor Silicate Glass, E2BADMA, TEGDMA, Silica, BHT, Titanium Dioxid, Fluorescent Pigments, Metallic Oxide Pigments, Organic Pigments, Aminobenzoicacidester, Camphorquinone.

### Indication for use

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

### Contra-indications & Warnings

#### Contra-indications:

#### Hypersensitivity- or allergic reactions

multi-functional (meth)acrylic acid ester), which may cause irritations in particularly sensitive individuals. If signs of such irritations appear or if allergies to methacrylate-based resins are known to exist, the product should not be used. Wear suitable protective gloves and avoid skin contact. In the event of contact with the eyes or extended contact with oral mucous membranes, the affected area should be thoroughly rinsed with water. In case of contact with the eyes consult a doctor.

#### Warnings:

#### Swallowing

A minor risk under normal conditions in the dental surgery. The patient will first react by retching. When swallowed, the Quadrant Flow 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 Flow) 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 Flow in layers of max. 2 mm.

4. Cure with an appropriate curing light. The curing time is indicated below. During 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 Flow can be finished and polished with fine diamonds, flexible discs and silicon polishers.

### **Shade**

A2, A3, A3.5

OA2


### **Polymerization time per 2 mm**

20 sec.

40 sec.

Quadrant Flow radiopacity is equivalent to 1.5 - 2.0 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/cm<sup>2</sup>. The indicated polymerization times are minimum times and, to obtain an optimal polymerization, should under no circumstances be reduced.

## Labelling:

 GHS07 Irritation	Symbol use explanation:
	<b>GHS07</b> Skin Sens. 1 H317 May cause an allergic skin reaction.

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## **Intended Patient(s)**

Quadrant Flow is used for the restoration of both anterior and posterior teeth: a composite for universal use. Quadrant Flow 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 Flow will only be used by dental professionals (dentist).

## **Clinical benefits**

The following clinical benefits can be considered for Quadrant Flow:

Patients:

- Durable and wear-resistant
- Natural fluorescence
- Available in four shades
- 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:

- Thixotropic character
- Does not stick to instruments
- Radiopaque

Based on ISO 4049 standards we can guarantee with internal testing that Quadrant Flow is radiopaque.

- Prism-shaped filler particles for optimal light scattering
- Suitable for mono layering and multi-layering technique

## **Claims**

- Easy to apply
- Available in four shades
- Barium-glass composite
- Minimally invasive composite fillings
- Does not stick to instruments
- Compatible with other composite materials
- Thixotropic
- Three-year shelf life
- BPA-free (Bisphenol A)
- Light-curing
- Radiopaque

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## **Product characteristics and specifications**

Quadrant Flow is in full compliance with the EN ISO 4049 standard for resin-based dental filling materials. The following table gives typical values for the most important properties:

<b>Characteristic</b>	<b>Product specifications</b>	<b>Release specifications</b>	<b>Unit</b>
Appearance	Coloured, homogeneous paste flowable	Coloured, homogeneous paste flowable	
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	50 - 250	50 - 250	Mpa
Water sorption	0 – 40	0 – 40	µm/mm <sup>3</sup>
Water solubility	0 – 7,5	0 – 7,5	µm/mm <sup>3</sup>
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	

## **Combination products:**

### **Accessories:**

Quadrant Flow has the following accessories which can be used in combination with the product:

- Quadrant Flow shade guide

### **Combination products:**

Quadrant Flow 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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