Product Information On Quadrant Anterior Shine Light curing Composite Resin

Introduction

Quadrant Anterior Shine is a light curing radiopaque composite filling material with fluoride release, specially designed for the restoration of anterior teeth. It is available in 15 shades (10 Vita™ shades, 2 opaque shades, 1 incisal shade, Bleach and Dark Shade) for optimal color matching, packed in syringes of 4 g each or "single use" capsules of 0.25 g each.

Quadrant Anterior Shine 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, Quadrant Uni-1-Bond or Quadrant Uni-SE-Bond.

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 Anterior Shine has been developed as a response to the demand for composites that are particularly suitable for the aesthetic and cosmetic treatment of front teeth. Therefore Quadrant Anterior Shine:

- is available in an extensive range of shades, including two opaque shades, with a shade guide made of original composite;
- is very easy to handle and to model:
- shows rapid, thorough adaptation to the surface of the tooth as well as between two successive layers;
- 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.

Quadrant Anterior Shine in the Centrix-compatible capsules are applied for instance with the Quadrant Q-Gun.

Quadrant Anterior Shine in capsules and syringes are available in the following shades: A1, A2, A3, A3.5, A4, B2, B3, C2, C4, D3, OA2, OA3.5, I, Bleach and Dark Shade.

Quadrant Anterior Shine is indicated for the following restorations:

- 1) Class III, IV and V restorations of anterior teeth
- 2) Cervical cavities or defects involving root surfaces
- 3) Congenital enamel defects, brushing defects, discoloration, erosion, diastema

Quadrant Anterior Shine is developed and manufactured by Cavex Holland B.V., a Company that is certified according to the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC concerning Medical Devices, against ISO 9001 and ISO13485.

Quadrant Anterior Shine bears the CE-Mark of conformity.

Composition

The basic ingredients of Quadrant Anterior Shine are:

| Methacrylate-based monomers | 23.7 | % w |
|--|------|-----|
| Silica, silicate glass and fluoride containing fillers | 75.6 | % w |
| Polymerisation catalysts | 0.6 | % w |
| Inorganic pigments | 0.1 | % 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 or "single use" capsules.

Laboratory control

Quadrant Anterior Shine 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 Anterior Shine | |
|-----------------------|--------------------------------|--------|
| filler content | 74 | % w |
| | 63 | % vol. |
| compressive strength | 350 | MPa |
| flexural strength | >50 | MPa |
| modulus of elasticity | >3500 | MPa |
| water absorption | <45 | ∓g/mm³ |
| Radiopacity | 100 | % AI |

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 Anterior Shine 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 Anterior Shine, 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 Anterior Shine can be safely used and is non-toxic to the patient as well as to the dental team.

Quadrant Anterior Shine 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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CAVEX HOLLAND B.V.