

# Saremco dental restorative system instructions for use

## 1. Product description

els extra low shrinkage® (els): light-curing, highly-filled, radio-opaque microhybrid composite for anterior and posterior restorations with extremely low shrinkage stress. DIN EN ISO 4049-compliant.

els flow: flowable, light-curing, radio-opaque microhybrid composite with extremely low shrinkage stress. DIN EN ISO 4049-compliant.

cmf etch: dentine-preserving buffered etching gel for the total etch technique. Contains phosphoric acid. Corrosive!

cmf prime: pulp-preserving, light-curing dentine primer and dentine sealer.

cmf bond: pulp-preserving, light-curing bonding material.

A dental adhesive system, such as cmf prime/bond is used in combination with els to achieve a permanent connection between the restoration and tooth.

## 2. Composition:

els: inorganic filler (barium glass 73 % wt, 48 % by volume, particle size between 50 – 3000 nm), BisGMA, BisEMA, catalysts, inhibitors, pigments

els flow: inorganic filler (barium glass 53 % wt, 28 % by volume, particle size between 50 – 3000 nm), BisGMA, BisEMA, catalysts, inhibitors, pigments

cmf etch: water, phosphoric acid, phosphoric salt, gel former, colorant

cmf prime: water, alcohol, acetone, methacrylated phosphoric salt, catalysts, inhibitors

cmf bond: BisEMA, inorganic fillers (barium glass and silica 11 % wt, 4 % by volume, particle size between 4 – 3000 nm), catalysts, inhibitors

## 3. Indication

1. Restoration of class I, II, III, IV and V cavities on anterior and posterior teeth
2. Extraorally tempered inlays and onlays (direct and indirect), veneers
3. Aesthetic corrections of interdental spaces, enamel hypoplasia, discolorations etc.
4. Blockings, fractures

## 4. Contra-indication

Opened pulp, pulpitis, known allergy to methacrylate.

## 5. Side effects

In individual cases, contact allergies have been described in the case of products of a similar composition. To avoid pulp reactions, it is advisable to cover the exposed dentine in the pulp area with suitable underfilling materials (preferably with calcium hydroxide). Note: els, els flow, cmf prime and cmf bond do not contain any TEGDMA or HEMA.

## 6. Interactions

Avoid underfilling materials which may hinder polymerisation owing to their ingredients. All phenolic compounds, such as zinc oxide eugenol, fall under this category.

## 7. Processing stages

### 7.1. Tooth cleaning

Brush the tooth to be treated and the teeth neighbouring it with a fluoride-free toothpaste. Clean interdental spaces using strips and dental floss if necessary.

### 7.2. Shade selection

Under natural light, determine the shade using the Saremco shade guides (alternatively: VITA Lumin Vacuum shade guide).

### 7.3. Drying

Dry sufficiently, apply rubber dam.

### 7.4. Cavity preparation

Prepare the cavity in the usual way. Undercuts and bevelled margins are recommended to improve adhesion and the margin fit. Clean and dry the cavity.

### 7.5. Underfilling

In the case of preparations near pulp, it is advisable to protect the pulp using an underfilling (e.g. calcium hydroxide). Do not use zinc oxide eugenol!

## 7.6. Adhesion with cmf adhesive system

### 7.6.1. Total etch with cmf etch

Apply cmf etch to the enamel and dentine. Allow to take effect on enamel and dentine for 30 seconds. Rinse and dry thoroughly. Keep dry.

### 7.6.2. Prime with cmf prime

Apply cmf prime to the cavity and rub in for 20 seconds. Dry gently but thoroughly. Light-cure for 20 seconds.

### 7.6.3. Bond with cmf bond

Apply cmf bond to the cavity and rub in for 20 seconds. Light-cure for 20 seconds. One layer is sufficient.

Warning: Protect light-curing products from strong sources of light. Attach the correct screw cap after each use. The specified exposure times refer to halogen or LED light-curing devices with a minimum light intensity of 500 mW/cm<sup>2</sup> and a wavelength of 400-500 nm. The exposure time may vary depending on the light source and its recommended use. For further comments, see 7.7.

## 7.7. Restoration with els (and els flow)

Gradually adapt els up to a maximum layer thickness of 2 mm. Light-cure every layer for 40 seconds. When using matrices, after removing them expose filling to light again from lingual and buccal. els flow can be used to care for small cavities or as a liner. Note: els produces an extremely low shrinkage stress and shrinkage.

Warning: After each use, turn the syringe screw back by one turn and re-attach the screw cap. Protect light-curing products from strong sources of light. The specified exposure times refer to halogen or LED light-curing devices with a minimum light intensity of 500 mW/cm<sup>2</sup> and a wavelength of 400-500 nm. They apply to a maximum layer thickness of 2 mm and to all shades. The necessary exposure time may vary depending on the light source and its instructions for use. If in doubt, check the lamp's light output and the necessary exposure time before operation in vitro. During polymerisation, an inhibition layer, which must not be touched or removed if other composite layers are to be applied, forms on the surface.

## 7.8. Finishing, polishing

Prepare the filling with 40 µ and 12 µ diamonds. Polish to a high-gloss using polishing brushes, polishing discs, strips or silicone polishers. The filling can be prepared and polished immediately after polymerisation.

## 8. Storage

Protect light-curing products from strong sources of light and heat! In the case of room temperatures above 28° C, it is advisable to store the products in the refrigerator. Prolonged temperatures above 28° C can shorten the shelf life of the product. Under these conditions, the shelf life is 48 months. The expiry date is specified on the packaging.

## 9. Batch number and expiry date

The batch number should be specified to identify products in the case of enquiries. Products should no longer be used once the expiry date has elapsed.

## 10. Precautionary measures

Close containers after each use using the right lid. Keep out of reach of children. When using tips, ensure before use that the cap has been removed.

## 11. Emergency measures

In the case of direct contact with the oral mucosa, rinse with water. In the case of contact with the eyes, rinse thoroughly with water. Consult an eye specialist.

## 12. Hygiene

Use application instruments for one patient only. Clean and disinfect reusable instruments after use. Dose products away from patients to avoid contamination.

## 13. Warranty

Our liability is restricted to the quality of our products. In the case of a product being of defective quality, only its value is replaced. We accept no liability for other damage, namely that caused by non-compliance with the instructions for use or other improper handling or unintended use of a product. Before using the products, the user should check whether they are suitable for the intended purpose. He alone assumes all of the risks associated with using the product and bears sole responsibility for any damage caused as a result of this.

## 14. Production and distribution

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Class IIa medical devices (EU)  
Class III medical devices (Canada)



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