

Enigma Gingival Composite Instructions for Use

Introduction

Enigma Gingival Composite is a light curing polymer based dental composite material for laboratory use. Manufactured to EN ISO 4049:2019. When used with acrylic dentures Enigma PMMA Primer should first be applied to the denture.

Indications

Enigma Gingival Composite is suitable for applying to the buccal surfaces of PMMA denture base and other material in order to give a natural gingival colour appearance.

Contra Indications

Not recommended for use where allergies against methacrylates are known.

System Contents



Greu

Preparation of the buccal surface of the denture or framework

The denture should be polymerised using the preferred method. Either model to full contour and cut back after polymerisation or, when waxing-up, allow space for the Enigma Gingival Composite.

Roughen the surface with a coarse grain diamond bur and sandblast the area to be veneered with 50 micron or greater particle sized aluminum oxide at 2 bars pressure. Clean with oil-free compressed air. Steam clean to remove all dust and dry thoroughly.

Do not touch the prepared surface.

Application of Enigma PMMA Primer

The recommended primer is Enigma PMMA Primer. Apply a thin layer with a disposable brush for 15 seconds onto the prepared surface of the freshly cured denture (<24 hours). Leave on for 2-3 minutes and then polymerize (90 seconds with Kulzer UniXS or Dreve EyeVolution Max).

During polymerisation of Enigma PMMA Primer a dispersion layer is formed at the surface. This layer facilitates the bonding between the layers and should never be destroyed, contaminated nor removed. In the event that this happens, roughen and prepare the surface again as described above and apply a thin layer of Enigma PMMA Primer.

Take care not to touch the surface of the Enigma PMMA Primer after it has been cured.

Application of Enigma Gingival Composite

Choose the shades of Enigma Gingival Composite to layer in accordance with the patient's gingiva.

Typical guidance on choice of shades and layering technique may be downloaded from the Schottlander website (www.schottlander.com)

Apply in thin layers using Schottlander Composite instruments, EC1 double ended applicator and EC2 double ended carver. Once each stage of modelling is complete carry out initial polymerisation to fix the layers in accordance with the curing unit used.

Polymerisation

When modelling is complete and the composite has been fixed in position, apply a thin layer of a covering gel over the whole of the surface before light curing. This prevents formation of a further smear layer and facilitates trimming and finishing. Polymerisation times depend on the unit used. For instance, time in the Dreve EyeVolution Max & the Uni-XS unit from Heraeus Kulzer are 3 minutes.

Final Polymerisation

After completing finishing, polymerise for a further $\ensuremath{\mathtt{3}}$ minutes to complete the cure.

NOTE: If the veneer thickness exceeds 1.5mm (or 1mm in the case of intense shades Ruby Red & Red Brown) polymerise in layers for the time shown above. **Do not remove smear layer in between layers.**

Finishing and Polishing

The edges of the denture should be trimmed using a fine cross-cut bur and rubber polisher as necessary. Then polish the surface of the composite using a Schottlander Universal Polisher Extra Fine at 3000-5000 rpm. Final polishing can be carried out with a soft bristle brush with pumice followed by buffing with a calico mop and polishing compound. Very little pressure should be used whilst buffing. This will ensure a smooth, durable and stain resistant surface.

Alternatively, the whole surface can be coated with a suitable nano-varnish and processed in accordance with the manufacturer's instructions.

Storage

If, during warm weather, the composite is kept in a refrigerator it must be removed well before use to resume its original modelling properties. Close the syringe tightly after use and shield from direct light. Turn back the plunger one turn in order to prevent seepage of material.

Store between 5-25°C. Do not use after expiry date.

Enigma PMMA Primer is highly volatile. Close bottle immediately after use.

Shelf Life

The maximum shelf life is printed on the label. Do not use after the expiry date.

Health & Safety

When allergies in particular to acrylates are known to exist, avoid skin contact with Enigma PMMA Primer or composite paste. If accidental contact occurs, wash immediately with soap and water. In case of contact with eyes, rinse immediately with plenty of water and consult a phusician. Keep out of the reach of children.



Refer to the current Safety Data Sheet.

Enigma PMMA Primer



Product contains methyl methacrylate.

Hazard statements: H315 Causes skin irritation, H319 Causes serious eye irritation, H317 May cause alleraic skin reaction.

Precautionary statements:

P280 Wear protective gloves/protective clothing/ eye protection/face protection, P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P302+P352 IF ON SKIN: Wash with plenty of soap and water.

For further information please request a Safety Data Sheet.

Typical Physical Properties

Compressive strength 350 MPa Flexural strength 120 MPa Wavelength for curing 470 nm Depth of cure 1-1.5 mm depending on colour.

Working time minimum 1 minute

Polymerisation time 2×3 minutes depending on light intensity of unit.

Barcol hardness ≥75

Water sorption 20 µg/mm³ Vater solubility 2 µg/mm³ Colour stability Very good Polishability High gloss Radiopacity >200% Al

Average particle size of:

Inorganic filler 0.05 – 1.5 µm Wear (ACTA, 1 month) 550 µm

Typical Composition

Resin based on Bis-GMA radio-opaque glass filler; silica; polymer powder catalyst, stabilisers, piaments.

Total filler content (by weight) 81%

Total filler content (by volume) 65%

Specific gravity (20°C; 68°F) 1.90 g/cm³

Lot Numbers

The lot numbers are shown on the containers.

Warranty

SanaPro Dental GmbH warrants this product will be free from defects in material and manufacture. SanaPro Dental GmbH makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and SanaPro Dental GmbH's sole obligation shall be repair or replacement of the product.

Limitation of Liability

Except where prohibited by law, SanaPro Dental GmbH will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

This product is specifically formulated for use in dentistru.

Distributed by: Davis Schottlander & Davis Ltd.
Fifth Avenue, Letchworth Garden City, Hertfordshire
SG6 2WD Telephone: 01462 480 848



