



Enigma Gingival Composite Instructions for Use

Product Description

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 / Intended Use

Adults or children requiring the introduction of teeth in the oral cavity for aesthetic and/or functional reasons and where an aesthetic base is required. To form part of an aesthetic denture (partial or complete) that is used to replace missing teeth in humans.

Contra Indications

Not recommended for use where allergies against methacrylates are known.

Patient Target Group

Persons who are treated during a dental procedure.























Intended Users

This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Shades & Product Codes

	Pink	 0924-02
	Medium Pink	 0924-04
	Dark Pink	 0924-08
	Lavender Pink	 0924-09
	Flamingo Pink	 0924-011
	Violet Pink	 0924-010
	Extra Pale Pink	 0924-03
	Pale Pink	 0924-01
	Ruby Red	 0924-05
	AP A2	 0924-012
	AP A3	 0924-013

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 aluminium 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.

Apply in thin layers using suitable composite instruments. 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 Kulzer are 3 minutes.

Final Polymerisation

After completing finishing, polymerise for a further 3 minutes to complete the cure.

NOTE: If the veneer thickness exceeds 1.5mm (or 1mm in the case of intense shade Ruby Red) 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.

Additional Notes / Warnings

- The ambient light of the dental lamp may start polymerization of the composite.
- Do not use any resin to adjust viscosity of composite material.
- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.
- 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 physician.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

Additional warnings for Enigma PMMA Primer:

- Product contains methylmethacrylate.
- Enigma PMMA Primer is highly flammable. Avoid sources of ignition and do not store in direct sunlight.
- Irritates the eyes, respiratory system and the skin.
- Can possibly cause skin sensitization on contact.
- In case of contact with oral tissue or skin, flush immediately with water.
- In case of contact with eyes, flush immediately with water and seek medical attention.
- Store the container in a well-ventilated room.

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 x 3 minutes depending on light intensity of unit.
Barcol hardness	>75
Water sorption	20 µg/mm ³
Water solubility	2 µg/mm ³
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)	<50 µm

Typical Composition

Enigma Gingival Composite:
Dimethacrylates, dental glass, silicon dioxide, photo initiators.

Enigma PMMA Primer:
Dimethacrylates, methyl methacrylate, photo initiators.
Total filler content (by weight) 81%
Total filler content (by volume) 65%
Specific gravity (20°C; 68°F) 1.90 g/cm³

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Note

The summary of safety and clinical performance of the medical device can be found in the European database on medical devices.

(EUDAMED – <https://ec.europa.eu/tools/eudamed>).

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 dentistry.

