ENA® HRi® TENDER PINK

(EN) ENGLISH
Instruction for use

Intended Purpose
Ena HRi Tender Pink, as resin facing material, is light-curing composite, for reproduction of gum. It fulfills the requirements of EN ISO 10477.
System components
Tender Pink is a unique system for the reproduction of the gum.
It is available in 4 colours: Pink Dark, Pink Light, Pink Orange, Pink Transparent; and 1 Pink Opaque.
Composition
Tender Pink
- Monomer matrix: diurethane dimethacrylate; Bis-GMA; tetramethylene dimethacrylate
- Inorganic filler: 75% wt. (52% vol.): glass filler (average particle size: 0.7 μm), pyrogenic silica (average particle size: 0.04 μm)
- Additives (1%wt.): Initiators, stabilizers, pigments

Tender Pink Paste Opaque
- Monomer matrix: urethane dimethacrylate, tetramethylene dimethacrylate, Bis-GMA
- Inorganic filler: 74% wt. (66% vol.): glass filler (average particle size: 0.7 μm), pyrogenic silica (average particle size: 0.04 μm)
- Additives: (1% wt.): Initiators, stabilizers, pigments

Intended User
Dentist and dental technician
Patient target group and medical condition
Children 6-18 years, adults 19-64 years, elderly 65- above, of any sex and condition. Medical Device intended for patients who have been treated for tooth caries or trauma, or any other dental disease, where the tooth need to be restored directly or indirectly by a dentist.
Indications
Any dental clinical situation that requires a gum build up in one of the following dental treatment
- Veneering of crowns, bridge frameworks, adhesive bridges, partials
- Veneering of implant-supported restorations and over-structures
- Veneering of conical and telescopic crowns
- Adjustments
- Repairs and cosmetic adjustments

Contra-indications
Uncured resin could cause skin allergy. Users should wear gloves. In case of known allergy to some of the components do not use it. Ena Tender Pink must not be applied directly to a metal or opaque surface. In a first step, the metal framework is therefore coated with a layer Tender Pink opaque.
Interactions with other substances
Phenolic substances (such as eugenol) inhibit polymerization. Therefore, do not use materials containing such substances.

APPLICATION AND CURING OF THE COMPOSITE USING THE GENERAL LAYERING TECHNIQUE

a) Take composite from the syringe and apply it, after using Tender Pink opaque if there is any exposed metal structure.
b) The material must then undergo intermediate polymerization, see curing chart. Note: apply very small quantities of material pulling down with a brush in order to avoid any bubbles (e.g. use Enamel plus “M” brush). The thickness of each layer should be between 1.0 - 1.5 mm.
c) Oxygen leaves a thin layer of uncured composite: this layer should not be contaminated or wet because it creates a chemical connection between the different layers of composite. We advise to apply an Air Block (e.g. Shiny G), when restoration is finished and before the final light curing. This glycerine-based product eliminates the oxygen and allows a complete curing of the surface.
d) Curing
   i. Working time under standard light is approximately 3 minutes. During long-lasting build-up cover the composite with an opaque foil or use the black cover of the color palette. Note: Each layer should not be thicker than 2 mm and should be cured for 1,30' min when using LABORLUX3. Thin layers can be cured with a dentist LED or halogen light curing unit for 20-30 sec. You can get a better curing with final curing of 6 minutes in power light curing like LABORLUX3.
   ii. It is necessary to use a light curing unit with spectrum of 310-500 nm. The required physical results can be reached only if using a multi-wall reflecting unit. For this reason we suggest a periodical check of the light intensity following the manufacturer’s instructions.
   iii. Curing chart

Light curing unit	Paste opaque	Tender Pink* Intermediate curing	Tender Pink ** final curing - color fixation
Laborlux3 (Micerium)	3 min.	90 sec.	9+7 min. (6+5 min)***
UNI-XS (Kulzer)	90 sec.	90 sec.	540 sec. + 540 sec.
HiLite (Kulzer)	90 sec.	90 sec.	540 sec. + 540 sec.
Spektramat (Ivoclar)	20 min.	1 min.	10 min + 10 min.
Spektra LED (Schütz Dental)	30 sec.	30 sec.	3 min.
Labolight LV II/III (GC)	1 min.	1 min.	9 min. + 9 min.
Solidilite EX / V (Shofu)	1 min.	90 sec.	9 min. + 9 min.
LicuLite (Dentsply)	3 min.	1 min.	4 min. + 4 min.
Targis Power (Ivoclar)	2 min.	60 sec.	6 min. + 5 min.
LampadaPlus T (Micerium)	4 min.	10 min.	30 min.

* Dentist halogen or LED light curing unit: 20-30 sec. each layer ** Dentist halogen or LED light curing unit 40-60 sec. final layer

*** New model with two additional fluorescent bulbs

DESIGNING THE GINGIVA USING TENDER PINK

a) After finalizing dentines / enamels, place the restoration on the model. Apply Tender Pink opaque on the exposed metal if requested. Light cure in Laborlux3 for 3 minutes.
b) Apply Tender Pink composite bodies to create the gum. In case of big volumes, apply first Tender Pink Flow. See the below phases of composite individualization that can be followed also for composite gum.
c) Possible individualization with stains (see corresponding IFU)
   i. Apply a layer of Temp Bonding Fluid and cure it according to IFU.
   ii. Apply Stain Flow White (increases the opacity and shade of ischemic papilla or in bone prominence area), red (increases the chromaticity of pink composite, simulating veins) and blue (increases effects in foramen and small veins).
   iii. Apply Tender Pink Transparent (reproduces the cervical area where the gum covers the tooth and not the bone). Light cure each layer in Laborlux3 for 1:30 min.
   iv. Apply the following composite bodies:
      1. Tender Pink Light reproduces the area over the tooth root where the gum is tight and transparent
      2. Tender Pink Dark reproduces the less tight and less adherent to the bone gum, highly blood supplied with a red blue shade in the area of the foramen.
      3. Tender Pink Orange, used as fist layer or combined with White Stain, reproduces the typical color of bone prominence of natural flanges.
      4. Light cure each layer as described in paragraph "*Application and curing of the composite using the general layering technique*"

FINISHING & POLISHING

a) Silicone polishers as well as carbide cutters or diamond abrasives are suitable for finishing.
b) **Note:** As with all polymers, fine grinder dust is formed during polishing. It is recommended to work over an extraction unit and with protective goggles.
c) Use diamond burs and diamond pastes. We suggest using the complete finishing and polishing system Enamel plus SHINY (Micerium, see separate IFU).
d) Wash with soap and water and dry with oil-free air spray.

Adjustments

Roughen the facings up to 2 mm around the margin of the area to be corrected or repaired, brush a bonding (like Ena Bond) on the surface and light cure (follow manufacturer IFU). If the cured layer looks whitish, it has been polymerized excessively and must be removed. Repeat the above-mentioned procedure but reduce the curing time. Tender Pink opaque (if there is exposed metal) and then Tender Pink composite material should be applied and cured as indicated before.

FAQ

Trouble	Cause	Remedy
Does not harden	Layer applied too thickly	Maximum layer thickness 2mm
	Inadequate polymerization	Observe polymerization timing
		Check lamp / replace lamp if necessary
Chipping of veneers	Opaque not properly polymerized / applied too thickly	Incorrect polymerization times / check lamp / replace lamp if necessary
	Defective adhesive bond	Observe the instructions for use of the bonding agent
		Respect maximum layer thickness
	Inadequate modelling	Optimal modelling of the frameworks so that the masses are supported depending on the bite situation (chewing edge protection)
Material in the syringe is too firm	Syringe stored at below 10°C	Store material at room temperature or bring to room temperature in due time before processing
Surface smudgy	Insufficient polymerization	Observe polymerization timing
		Check curing device / maintain regularly
Material cannot be polished	Insufficient polymerization	Observe polymerization timing
		Check lamp / replace lamp if necessary
	Lusterless surface	Insufficiently polished
		Use suitable polishing paste
Entrapped air	Inadequate processing	Unscrew and remove the paste from the syringe with the rotary piston, do not remove the paste from the syringe with the instrument.
		Apply and distribute sufficient mass for a veneer.
		Do not mix composites with each other, but layer them on top of each other

Warranty

Our technical instructions, regardless of whether they are provided verbally, in writing or during practical demonstrations, are based on our own experience and should only be considered guidelines. Our products are subject to continued development. We therefore reserve the right to make changes.

Use and storage

The material must be stored at 3-25°C (38°-77°F). If Tender is stored in the refrigerator because of high external temperatures, it must be removed in due time prior to processing. Use the material at room temperature. After use, close container with cap and keep it closed. Turn back the spindle after taking out the material, to avoid sticking of the material.

Shelf life

Do not use the product after the expiration date (see label on syringe).

Side effects

With proper preparation and use of this medical device, adverse effects are extremely rare. Immune reactions (such as allergies) or local discomfort, however, cannot be ruled out completely. If you become aware of any adverse effects – even in cases of doubt – please notify us.

Disposal

Disposal of the medical device must be carried out in accordance with local regulations. Contaminated packaging can be disposed of, after cleaning, in the separate collection of rubbish in accordance with the identification symbols, if applicable (97/129 EC).

GRUPPO MICERIUM

MICERIUM S.p.A.
Via G. Marconi 83 - 16036 Avegno (GE) Italy
Tel. (+39)0185-7887880 www.micerium.com e-mail: hfo@micerium.it

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