ENA® HRi®

(EN) ENA HR*i* esthetic restorative system - Instructions for use

ENA HR*i* is a light curing radiopaque composite for direct and indirect dental restorations in anterior and posterior areas. It follows standard ISO 4049 and it includes:

HR*i* Universal Enamel *for anteriors*

To obtain an enamel composite material that acts like natural enamel it must be highly translucent and must have the same refractive index. When this index is matched, then thicker layers of composite enamel appear whiter (high value/high luminosity/low translucency) and when it is applied in a thinner layer it appears more translucent (low value/low luminosity/high translucency), while increasing the thickness of the enamel layers of standard composite increases the percentage of grey in proportion to its thickness (glass-like effect). The new **Universal Enamels (UE) have the same refractive index as the natural tooth** and the same high luminosity as natural enamel. These two unique properties require the material to be applied with a technique different from any other enamel shade of composite you may be familiar with. UE shades should be **applied at similar thickness, slightly thinner, as enamel on the tooth that is being restored,** showing no visible margin. **Thick layer of UE appear whiter (higher value), thin layer will be more transparent.** In the incisal area, where there is no dentin present, the enamel produces the blue-amber opalescent effect, as this multichromatic opalescent characteristics exhibited by natural enamel has been engineered into these Universal Enamel shades. **Note: If you want to further enhance the opalescence effect in the incisal area, you may use the Opalescent Enamel:**

OBN	Opalescent Blue Natural	**OA**	Opalescent Amber

To reproduce white characterization areas, use intensive white IM, IWS or IW, covering these bodies with a 0,3-0,5 mm layer of Universal Enamel UE (even thinner for enhancing the intensive) as thicker layers can cover these bodies. By carefully observing natural teeth it is possible to distinguish in the enamel different levels of translucency depending on the age of the patient. **Note: no matter which universal enamel is used, value can be increased by increasing thickness (max 0,6-0,8 mm).** Three universal enamel shades are available:

UE1	low value in thin layer; with amber effects; increasing thickness the value increases
UE2	medium value that becomes high value increasing thickness
UE3	very high value, really white, to be used only for very white or bleached teeth

Composition of Universal Enamel

- Monomer matrix: Diurethandimethacrylate, Iso-propyliden-bis (2(3)-hydroxy-3(2)-4(phenoxy)propyl)-bis(methacrylate)(Bis-GMA); 1,4 - Butandioldimethacrylate.
- Content of filler: 80% weight. Glass filler (68%): mean particle size 1,0 µm, Nano zirconium oxide particles (12%): particle size 20nm.

"Function" enamels *for posteriors*

Enamel shades subject to low abrasion and high resistance to compression that are comparable to natural enamel. Ideal for use in posterior areas with direct or indirect technique and especially for prosthetic rehabilitation. Apply with a **minimum thickness of 0,5 mm,** in order to allow occlusal corrections without exposing dentin. Three "function" enamel shades are available:

EF1	low value	**EF2**	medium value	**EF3**	high value

Intensive

These shades are used for further characterization of the enamel (ridges and cusps) and are used within the surface of a Universal Enamel to mimic hypo calcification or other extremely white areas. The intensive white shades represent demineralized enamel areas and can appear in all areas of the tooth (cervical, middle and incisal third).

IM	Intensive Milky	A Warm Opaque White
IWS	Intensive White Spot	An Intensive White intermediate
IW	Intensive White	A Cold Translucent White

Dentin

A modern composite system has to include dentins with a fluorescence degree calibrated to the natural tooth. The average **chroma** of natural teeth (central incisors, lateral incisors and canines) is in the region of 580 nm. The "A" shades of the Vita®* shade guide are closer to the average chroma of natural teeth. For this reason, we developed the new Universal Dentin (UD) shades close to the **hue-chroma (chromaticity)** of natural teeth. These new Universal Dentin shades have a high brightness (higher value) and are calibrated to match the fluorescence and opacity of natural dentin. When determining the basic chroma of the tooth the areas that are most suitable are the cervical and middle third. In complex restorations, the final shade is created by using the basic hue and then next two darker dentins (for this UD5 and UD6 are available). In most restorations only one shade of dentin will be required, as margin is not visible thanks to the new universal enamels. New UD0 and UD0,5 shades are useful to restore very light or bleached teeth.

9 Fluorescent Dentin	UD0 - UD0,5 - UD1 (A1*) - UD2 (A2*) - UD3 (A3*) - UD3,5 (A3,5*) - UD4 (A4*) - UD5 - UD6

Composition of dentin, intensives, opalescents and "function" enamels
- Monomer matrix: Diurethandimethacrylate, Iso-propyliden-bis (2(3)-hydroxy-3(2)-4(phenoxy) propyl)-bis(methacrylate)(Bis-GMA); 1,4 - Butandioldimethacrylate.
-Total content of fillers: 75% weight (53% volume); glass filler: mean particle size 0.7 µm; highly dispersed silicone dioxide: mean particle size 0.04 µm.

Intended Purpose

Direct and indirect aesthetic restorations on anterior and posterior teeth.

Patient target group and medical condition

Children 3-18 years (also for deciduous teeth), adults 19-64 years, elderly 65- above, of any sex (including pregnant). MD 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.

Clinical indications

Class I (all cavities)	Class II (small and medium cavities)	Class III (all cavities)
Class IV (all cavities)	Class V (all cavities)	Sealing
Total and partial vestibular covering	Cosmetic corrections	Complex restorations
Inlays Class I (all cavities)	Inlays Class II (all cavities)	Inlays Class IV (all cavities)

Hazard statements

Contains tetramethylene dimethacrylate. Warning: May cause an allergic skin reaction.

Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves. If skin irritation or rash occurs: Get medical advice/attention.

Contra-indications

If a patient has known hypersensitivities towards a component of this product, we recommend not to use it or to do so only under strict medical supervision. In such cases, we will supply the composition of our medical device upon request. The dentist should consider known interactions and crossreactions of the product with other materials already in the patient's mouth before using the product.

Side effects

To prevent possible reactions of the pulp in cavities where the dentin is exposed, the pulp must be protected adequately (apply e. g. a calcium hydroxide preparation). With proper use of this medical device, unwanted side-effects are extremely rare. Reactions of the immune system (allergies) or local discomfort, however, cannot be ruled out completely. Should you learn about unwanted side-effects – even if it is doubtful that the side-effect has been caused by our product – please kindly contact us. Any serious incident relating to the device must be reported to the manufacturer (Micerium S.p.A.) and to the competent authority of the Member State in which the user and/or patient is established.

Materials to be avoided

Materials containing phenolics (like eugenol) could inhibit composite curing. Avoid the use of these materials as liners.

MD = Medical Device

* colors of Vita® shade guide. Vita® is a registered trademark of Vita Zahnfabrik H. Rauter mbH & Co. KG, Bad Säckingen - D

DIRECT TECHNIQUE

FILLINGS AND DIRECT AESTHETIC RESTORATIONS OF CLASS I-II-III-IV-V.

Preparation

Clean with fluoride-free prophylaxis paste. Choose colors with Vita® shade guide or with **ENA HR*i*** composite shade guide, and fill in the "Color Chart". Preparation: for anterior teeth, use a conservative preparation with bevel, which allows a good enamel etching (for posterior restorations, no bevel is needed). We suggest ENA Shiny preparation kit of Dr. L. Vanini, where Shiny 33 rubber, for polishing preparation, is included. We suggest using a rubber dam. In case of interproximal restorations, use a sectional matrix; we recommend Ena Matrix.

Etching and bonding

Regular etching and bonding techniques are applicable. We recommend Ena Etch / Ena Bond. Alternatively to the Etch & Rinse technique, it is possible to use a self-etching bonding like Ena Bond SE. Please consult and follow the instructions given in etching / bonding manuals.

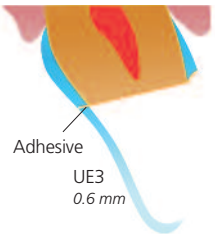
Composite application

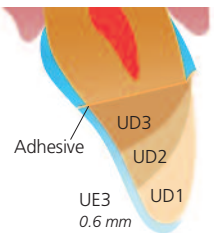
Take **ENA HR*i*** out of the syringe or "tips"; we suggest to warm the composite in the ENA HEAT composite warmer to 39°C/102°F. Apply very small quantities of material by pulling it down with a brush (Micerium "M" brush for anterior and "F" for posteriors, and Micerium Silicone Brushes) in order to avoid any bubbles. **NOTE: do not wet Universal Enamel with any resin or bonding because it will change the refraction index and cause the composite to become too opaque.** Use a "waves" application technique in order to allow a better light diffusion effect. Follow the stratification technique described in the next paragraph. Cure layers of 1-1,5 mm (no more than 2 mm) for 40 seconds, from all sides of the build up; keep the light-curing tip as close as possible to the restoration. Oxygen leaves a thin layer of uncured composite: this layer should not be contaminated or wetted because it creates a chemical connection between the different layers of composite. We advise to apply an Air Block (Shiny G), when the restoration is finished and before the final light curing takes place. This glycerine based product eliminates the oxygen inhibition layer. **CURING:** Working time under standard light is approximately 3 minutes. During a long procedure, cover the composite with an opaque foil or use a color palette with orange or black cover (COSSTAIN01). **NOTE:** avoid direct light of the overhead light and turn off if possible. Cure each layer for 40 seconds.

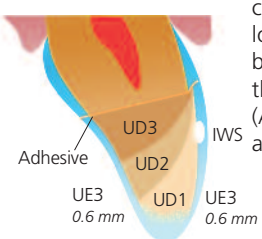
Anatomic stratification technique of Dr. L. Vanini

In order to maximise the characteristics of the **ENA HR*i*** System, we suggest following the anatomic stratification technique of Dr. Lorenzo Vanini; any other stratification technique that does not respect the anatomy of a natural tooth would considerably limit the aesthetic performance of this system.

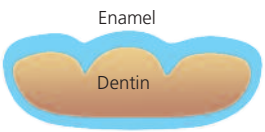
Anterior complex restorations / master technique

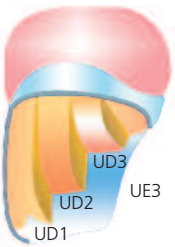


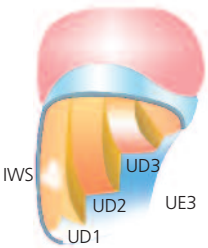




You can use the "Color Chart" to register the 5 color dimensions of teeth. The lingual enamel is applied by means of a silicone matrix, using a Universal Enamel (UE1, UE2, UE3). The interproximal enamel wall is built up using the same Universal Enamel. The thickness of all enamel layers is the same as if the natural enamel was still there (max 0,6-0,8 mm). To obtain a natural chromatic composition in complex restorations, **two-three dentin** shades are used depending on size of restoration. Once the final shade is established, increase the dentin shade by two for the first layer. For example, if the desired shade is A1, the first shade used cervically would be UD3. This can be covered with UD2 and then with UD1, or directly with UD1 (in case of restorations that don't reach the cervical area), to be applied more incisally to create the structure and the characterization of mamelons. Now if necessary you can use intensives IM-IWS-IW to reproduce also mamelons and margin characterizations (for margin characterizations you can also use OA). For intense characterizations **ENA Stains** are available (white, yellow, orange, blue, brown, dark brown). HR*i* gives a blue-amber opalescent effect. If we need to reinforce this effect, Opalescent shades OBN (Blue) and OA (Amber) can be used. Finally the vestibular enamel is applied using a Universal Enamel.



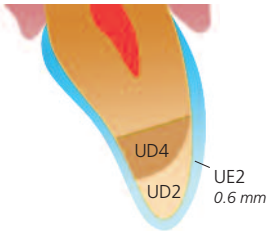




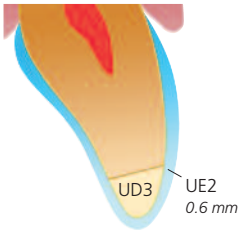
Complex Restorations (2-3 dentins, 1 enamel)

Anterior medium and small restoration / basic technique

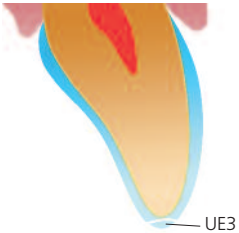
Medium Size restorations
(2 dentins, 1 enamel)



Common restorations
(1 dentin, 1 enamel)

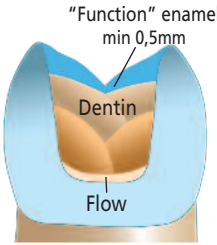


Enamel Only restorations
(1 enamel)



Finishing and polishing
Use diamond burs and diamond pastes. Do not use any disc buccally in order to avoid destroying the texture surface. We suggest to use the complete finishing and polishing system ENA Shiny.

Posterior direct restoration



(1 or 2 dentins, 1 enamel)

INDIRECT TECHNIQUE

INLAY, ONLAY AND VENEERS, COMBINATION PROSTHESIS AND IMPLANTS, REHABILITATIONS

ENA HR*i* can be used indirectly for anterior or posterior, inlays, onlays, veneers, over implants and in combination cases. The dental technicians use **ENA HR*i*** with the same stratification technique as they use with modern ceramic systems.

Preparation

Preparation should be made without undercuts, and for posterior restorations, slightly tapered diamonds are recommended to round out internal edges. Minimum thickness of composite layers should be >1.5 mm to avoid breakage. Close undercuts by using ENA HR*i* Flow composite.

Impression and Temporary

Take an impression and use ENA Temp for temporary inlay and cement it with eugenol-free cement. For inlays it is possible to use ENA Soft elastic composite. Its elastic properties allow for the complete and easy removal of the temporary inlay which leaves the preparation clean.

Laboratory procedure

Pour a model with extra-hard plaster. After the plaster sets, remove the impression and apply an oil-free separator (TEMP SEP) to the model. Follow the same stratification technique as in the direct method. For inlays, first build up the external walls and then the occlusal areas. It is possible to use ENA Stain between Dentin and Enamel. Each layer should not be thicker than 2 mm and should be cured for 40 sec. Recommended final curing time is 11 minutes using a high power light curing unit such as LaborluxL or if using an 86W light box like LampadaplusT final curing time is 30 minutes. Finish with burs and polish with ENA Shiny brushes and diamond pastes. Wash with soap and water and dry with oil-free air spray.
Note. For further technical instructions also on restorations on metal and fiber structure, please consult the manual "ENA HR*i* Tender, laboratory procedures".

Luting

Remove the temporary appliance and clean the preparation. Try-in the restoration carefully and proceed with any adjustments. Post-cure in an oven like LampadaplusT for 9 min. Apply the rubber dam. Clean the surface of the preparation with alcohol and sandblast. Etch the cavity and apply two coats ENA BOND but do not cure. Sandblast the internal part of the composite restoration, then clean it with alcohol; apply the bond resin but do not cure. Warm a small amount of ENA

HR*i* enamel or a light dentin shade (according to the depth of the cavity, after heating up to 55°C/131°F into ENA HEAT syringe heater) and apply it to the inside of the restoration. When restoration is in place, apply a small amount of pressure either mechanically or manually. Remove composite excess at margins and cure for at least 80 seconds from each side of the tooth. Check the occlusion, finish and polish with ENA Shiny system, using burs, strips and diamond pastes.
Note. in case of inlay thickness over 2 mm use a dual luting composite such as ENA Cem^{HF} (see instructions for details).

Curing information

A perfect curing is granted for layers not thicker than 2 mm as from ISO 4049. It is necessary to use a light-curing unit with a spectrum of 350 - 500 nm. We suggest a periodical check of the light intensity following the instructions of the manufacturer.
We recommend light-curing units having a light intensity of around 1200 mW/cm². The intensity must not be reduced below 650 mW/cm² (= minimum intensity).

Laboratory curing times:

- Laborlux3 (MICERIUM)	approx. 90 sec. (final curing 16 min.)
- Spektra LED (Schütz-Dental)	approx. 90 sec. (final curing 16 min.)
- Spektramat (Ivoclar)	approx. 60 sec. (final curing 20 min.)
- LampadaplusT with light 71- 86W (Micerium)	approx. 10 min. (final curing 30 min.)

Dental office curing times:

- Translux CL (Kulzer)	approx. 40 sec. per layer
- CLED2 (Micerium)	min. 40 sec per layer
- Blue Phase (Ivoclar)	min. 40 sec per layer

USE AND STORAGE

Do not store below 3°C (38°F) and above 25°C (77°F). Avoid direct exposure to sunlight. Do not use the product after the expiration date (see label on syringe or on "tips" container). Due to hygienic reasons ENA HR*i* "Tips" should be used only once. If "Tips" are used more than once, a contamination of the material and/or the transmission of germs cannot be excluded. Use the material at room temperature. To avoid material waste, turn back the spindle after removing the material. After use, close container with cap and keep it closed. If the material is not completely cured, it may discolour, mechanical properties deteriorate and pulpal inflammation can occur. Medical device, for dental use only: keep away from children. This product was developed specifically for the described range of applications. It must be used as described in the instructions. The manufacturer is not liable for damage caused by handling or processing the material incorrectly.

Functional rehabilitations

Direct and indirect restorations with ENA HRi Function

Anterior Veneers, Inlays and Crowns

Incisors to be restored with indirect technique

Preparation of anterior inlays

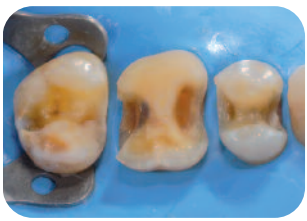
Inlay details

Inlay cementation

Lateral view

Integration pointed out with polarized photo

Posterior Crowns and Onlays



Restorations fabricated using 2 dentins shades and 1 enamel shade (Function)

Implants and Combination Cases

In laboratory Primer, Opaque, opaque Tender dentins with higher elasticity, HRi dentins and Function enamels are used

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