ENA HRi® Flow

Instructions for use

(EN) ENGLISH

Ena HRi Flow is a fluorescent flowable, micro hybrid, light-curing, radio-opaque composite (EN ISO 4049) to be used as liner and for adhesive luting, available in the following shades:
UD0 - UD0,5 - UD1 (A1*) - UD2 (A2*) - UD3 (A3*) – UD3,5 (A3,5*) - UD4 (A4*) - UD5 - UD6

Intended Purpose
Direct and indirect aesthetic restorations on posterior teeth or on cervical cavities as a liner.
Characteristics & Benefits:
• Highly Filled
• Highly Fluorescent
• Higher Viscosity
• Higher Elasticity
• Higher Radiopacity
• High Physical Properties
• No bubbles
Composition: Glass powder, diurethane dimethacrylate, tetramethylene dimethacrylate, silicon dioxide.
TOTAL CONTENT OF FILLERS: 77 % weight (57 % volume) inorganic filler (0,005-40 µm)
Indications: Ena HRi Flow is used as liner in cavities of composite restorations, where a low viscosity and high elasticity are required, and for adhesive luting of ceramic and composite laminated veneers, inlays, onlays, jacket crowns, crowns and bridges with a thickness of max. 2 mm, fillings in Black's class V cavities (cervical caries, eroded areas in roots, wedge-shaped defects).
Intended User
Dentist and dental technician
Patient target group and medical condition
Children 3-18 years (also for deciduous teeth), 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.
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 cross reactions of the product with other materials already in the patient's mouth before using the product.
Hazard statement: Contains tetramethylene dimethacrylate. 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.
Side effects: To prevent possible reactions of the pulp in cavities where the dentine 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.

DOSAGE AND DIRECTIONS FOR USE
Preparation: Clean with fluoride-free prophylaxis paste.
Choose colours with Vita® shade guide* or with Ena HRi composite shade guide, and fill in the colour chart.
Preparation: for anterior teeth, use a conservative preparation with bevel, which allows a good enamel etching (for posterior do not make any bevel). We suggest using a rubber dam. In case of interproximal cavities, 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.
Application
Take Ena HRi Flow out from syringes using the application needles and, for direct restoration, apply it as liner in the cavity with a brush (e.g. Ena M brush) before the application of the micro hybrid bodies. In case the Flow is used as a liner for Inlays, apply it before taking the impression. 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. If used for Class V Black cavity, finish and polish immediately after curing using finishing diamond, flexible disk, silicone polisher, polishing brush and felt.
Luting
Remove the temporary appliance and clean the cavity. Try-in the appliance carefully and proceed with eventual corrections. Apply the rubber dam. Clean the surface of the preparation with alcohol and sandblast it. Etch the cavity and apply a bonding, e. g. two coats of Ena Bond, without curing it. Sandblast the internal part of the composite appliance and clean it with alcohol; apply the bonding without curing it. Apply a small amount of Ena HRi Flow in the internal side of the appliance to be luted and position it on the tooth. Remove composite excess 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-curing luting composite such as ENA CEM^{HF} (see instruction)

Special notes
When placing time consuming restorations, to prevent the composite curing prematurely the dental light should be moved away from the working site temporarily.

For hygienic reasons, the curved application tips supplied with the material must only be used once!

Curing information
Use a light polymerization system with an emission range of 350 – 500 nm to polymerize the material. The required physical properties are only reached if the polymerization light functions properly. Therefore, it is necessary to check the light intensity regularly according to the manufacturer's instructions.
• Light intensity for polymerization: ≥ 650 mW/cm^2
• Wavelength for polymerization: 350 – 500 nm
• Polymerization time: 40 sec.

Disinfection / protection from cross-contamination
Place the syringe with attached delivery tip into a suitably shaped barrier sheath; pierce end of sheath with cannula, exposing the cannula for use. Using a barrier sheath facilitates cleaning and disinfection of the syringe between patients. After use of sheathed syringe, remove delivery tip and sheath by grasping on the hub of the delivery tip through the sheath; twist and remove tip along with sheath. Discard used tip and sheath in appropriate waste stream. Replace syringe storage cap.
Disinfection - After removing the application tip and the sheath, disinfect the syringe using an intermediate-level disinfection process (liquid contact) as recommended by the Centre for Disease Control and endorsed by the American Dental Association. Guidelines for Infection Control in Dental Health-Care Settings - 2003 (Vol.52; No. RR-17), Centre for Disease Control and Prevention (USA).

Note: instructions for Flow syringe. Apply the unidose tip on the syringe after unscrewing the cap**.** Being composite flowable, when you push the piston you will activate a thrust and the material will start and continue to come out. To stop the flow it is enough to pull the piston back of only 1 mm. Careful: avoid pulling piston excessively, otherwise air can come into syringe and air bubbles will enter in the following emissions of material. A minimum opposite movement is enough, the piston will return in position elastically, avoiding air bubbles. To avoid the excessive emission of material we suggest to hold the tips of the syringe direct upwards till next application on the same patient. We also suggest starting pushing the piston in this position, so if there would be air in the syringe, bubbles will come out before the material. At the end of the restoration, remove the unidose tip and place again the cap on the syringe screwing it.

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). Due to hygienic reasons flow application needles should be used only once. Use the material at room temperature. 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.
Disposal: parts and accessories in direct contact with patient's mouth must be sterilised before disposal or disposed of as special waste. 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).

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

Troubleshooting

Trouble	Cause	Remedy
Composite does not cure	Luminous intensity of the polymerization unit insufficient	Check luminous intensity; replace light source, if necessary
	Emitted spectral range of the polymerization unit insufficient	Consult manufacturer of polymerization unit; recommended spectral range: 350 – 500 nm
Composite seems to be too hard/ firm inside the syringe	Material was stored at temperatures below 3°C/38°F for a longer period of time	Let composite reach room temperature before use
	Syringe was not closed tightly which caused part of the material to cure	Close syringe correctly with the cap after each use
Inlay / Onlay is not properly retained when fitted.	Restoration is too opaque to be cemented using only light-curing composite.	Use dual-curing luting composite.
Composite does not cure sufficiently	Layer thickness per polymerization cycle too high	Keep to max. layer thickness of 2 mm
Restoration seems too yellow when compared to colour reference	Insufficient polymerization of the composite layers	Repeat polymerization cycle several times, for a minimum of 40 sec.

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