ENA CEM HV

(EN) ENGLISH
Instructions for use

Ena Cem HV, High Viscous Flow, is a light-curing, highly radiopaque flow composite with extra high viscosity for cementation of indirect restorations (in particular anterior veneer) and cavity lining. It's available in several colours (BD1-2-3-4). The guidelines of EN ISO 4049 have been complied with.

Intended purpose
Direct and indirect aesthetic restorations on posterior teeth or on cervical cavities as a liner and for luting ceramic and composite indirect restorations. It is specially indicated for luting ceramic and composite veneers
Characteristics & Benefits:
• Highly Filled
• Highly Fluorescent
• Very high Viscosity
• Higher Elasticity
• Higher Radiopacity
• Very high Physical Properties
• No bubbles
Composition: Glass powder, diurethane dimethacrylate, silicon dioxide, tetramethylene dimethacrylate
TOTAL CONTENT OF FILLERS: 80% by weight inorganic fillers (0.005 - 40 µm)
Indications:
Ena Cem HV is indicated where a very high viscous flow dental composite material is required as liner or as cement (particularly for veneer luting).
Intended User
Dentists in dental office and hospitals
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. Patients, who have one of the following clinical situations that require a dental restoration: caries, trauma, occlusal and enamel abrasion problems, or any other dental disease and aesthetic issue.
Contra-indications: Uncured resin could cause skin allergy: 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.
Hazard statements: Contains tetramethylene dimethacrylate. May cause an allergic skin reaction.
Precautionary statements: To reduce the risk of all allergic response, minimize exposure to uncured materials. If allergic reaction occurs, seek medical attention as needed. Be careful not put in contact with eyes and use only in oral cavity. Use protective mask. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves / protective clothing / eye protection/face protection. 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.

CEMENTATION OF INDIRECT RESTORATIONS
Placing the inlay, onlay or veneer
Remove the temporary restoration and clean the cavity. Try-in the restoration carefully. Exert gentle pressure on the inlay to check for fitting accuracy. Do not use force. Proceed with eventual corrections. If necessary, trim the fitting surface to improve the fit. The occlusion and articulation may not be checked when trying to fit the inlay as this could cause fractures.
Cavity preparation
Apply the rubber dam. Clean the surface of the preparation with chlorhexidine, sandblast it and then rinse with water. Etch the cavity and apply a bonding, without curing it.
Fixing the restoration
Sandblast the internal part of the composite restoration and clean it with alcohol. Apply the bonding without curing it. Apply a small amount of Ena Cem HV in the internal side of the restoration to be cemented 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 burs, strips and diamond pastes.
Note: in case the thickness of the appliance is over 2 mm use a dual-curing luting composite such as ENA CEM^{HF} (see instruction)

CAVITY LINING
Cavity preparation
Minimal-invasive preparation of the cavity as generally required for adhesive techniques. All enamel margins in the anterior region must be bevelled. Do not bevel the margins in the posterior region and avoid slice preparations. Spray the cavity with water to clean it, remove all residue and dry it. The cavity must be isolated. It is advisable to place a rubber dam.
Pulp protection
In very deep cavities those areas in close proximity to the pulp must be coated with a calcium hydroxide material and glassionomer cement.
Interproximal contact areas
When filling cavities with interproximal sections, place a transparent matrix and fix it in place.
Adhesive system
Etch and bond according to manufacturer's instructions.
Application from syringes
Fill layers of max. 2 mm thickness of Ena Cem HV directly into the cavity with the application tip or alternatively by using a brush. Avoid

introducing air bubbles when applying the material. Ensure that the prepared tooth is well-coated with the material.

Curing

The curing time for all shades is 40 seconds per layer with a conventional dental curing lamp. Hold the light guide as close to the surface of the filling as possible. Due to the effect of the oxygen in the air, a thin smear layer of unpolymerized material remains on the surface of the material. This layer must not be touched or removed. It forms the chemical bond with the layer of composite applied subsequently.

Finishing

Ena Cem HV can be trimmed and polished immediately after curing using finishing diamonds, flexible discs, silicone polishers and polishing brushes.

Special notes

- The working time under a surgical lamp is approximately 2 minutes.
- When placing time consuming restorations, to prevent the composite curing prematurely the dental light should be moved away from the working site temporarily.
- Use a light-curing unit with an emission spectrum of 350 - 500 nm for the polymerization of this material. As the required physical properties can only be achieved when the lamp works correctly, its luminous intensity must be checked regularly as described by the manufacturer.

Curing information

• 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).

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 sterilized 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).

Troubleshooting

Problem	Cause	Remedy
Composite does not cure properly	Light output of the light-curing lamp is inadequate	Control of the light output. Clean the light guide, if it is dirty. Replace the light source if necessary
	Emitted wavelength range of the light- curing lamp is inadequate	Consult the manufacturer of the light-curing lamp. Recommended wavelength range: 350 - 500 nm
Composite appears too hard and firm in the syringe	Material stored at temperatures < 3°C (38°F) for a long period of time	Let composite reach room temperature before use
	Syringe not properly sealed, composite partially cured	Always seal the syringe properly with the cap after taking out composite
Inlay/onlay is not properly retained when fitted.	Restoration is too opaque or too thick (> 2 mm) to be cemented using only light-curing composite	Use dual-curing luting composite
	Inadequate curing time	Adhere to curing time of min. 80 sec. for cementation of indirect restorations
Composite does not cure sufficiently	Applied layer thickness per polymerization cycle too high	Adhere to a max. thickness of 2.0 mm per layer
	Inadequate curing time	Adhere to curing time of min. 40 sec. per layer for cavity lining
Restoration appears too yellow compared with the shade guide	Inadequate curing of the composite layer	Repeat the exposure cycle several times; min. 40 sec.

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