

### Product Description

ENVY is a dual-cured, self-etch, self-adhesive resin cement. It is used for the adhesive cementation of indirect all-ceramic, composite, or metal restorations and for dental posts. When using ENVY bonding and conditioning of the tooth structure are not necessary. ENVY cement is available in various shades.

**These Instructions for Use must be kept for reference for the duration of product use.**

### Indications

- Final cementation of all-ceramic, composite, or metal inlays, onlays, crowns and bridges; 2 – 3-unit Maryland bridges and 3-unit inlay/onlay bridges (contraindicated for patients with bruxism or periodontitis)
- Final cementation of dental posts
- Final cementation of all-ceramic, composite, or metal restorations on implant abutments
- Final cementation of zirconia build-ups for two-piece abutments – only in accordance with the Instructions for Use

Indications such as Maryland and inlay/onlay bridges (resin bonded bridges) demand especially high adhesive bond strength. Regardless of the manufacturer of the cement and restoration, these indications may be exposed to a higher risk of decementation. To achieve an optimal result when using ENVY, please refer to the sections “Tooth Preparation” and “Pre-treatment of Maryland and Inlay/Onlay Bridges”.

### Precautionary Measures

#### For Patients and Dental Personnel

- Base paste: contact with eyes may cause severe eye damage. Wear eye protection to prevent injury. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

#### For Patients

- This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate and/or peroxide allergies.
- If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use.

#### For Dental Personnel

- This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water.
- The use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If the product contacts the glove, remove and discard the glove, wash the hands immediately with soap and water and then re-glove.
- If allergic reaction occurs, seek medical attention as needed.

Safety data sheets can be obtained from <http://edsdental.com/sds.html>.

#### Precautions During Processing

- Seal temporary restorations using a eugenol-free product. The use of temporary cements containing eugenol can inhibit the polymerization process of ENVY during the final cementing. If a temporary cement containing eugenol has been used, wait a minimum of two weeks before using ENVY.**
- Do not use hydrogen peroxide (H2O2) as the residues can adversely affect the adhesive strength and setting reaction of ENVY.

#### Pulp Protection

To avoid pulpal irritation, cover areas in close proximity to the pulp by applying small amounts of hard-setting calcium hydroxide material. To avoid bite increases during the cementing of the later restoration, the pulp protection should be applied prior to taking an impression for the final restoration.

#### Tooth Preparation

##### Preparation of the Cavity/Tooth Stump

- Prior to final cementation, clean the prepared stump or the cavity thoroughly with pumice slurry, rinse with a water spray, and lightly air dry in only 2-3 bursts of water-free and oil-free air, or use cotton pellets to dry it off. Do not overdry! – The cavity should be just dry enough that the surface has a slightly glossy appearance.

As is the case with any permanent cement, overdrying can lead to post-operative sensitivity.

Do not use substances such as desensitizers, disinfectants, astringents, dentin sealants, rinsing solutions containing EDTA, etc., after the final cleaning with pumice slurry and water. Their residues may have a detrimental effect on the bonding strength and setting reaction of the cement.

#### Preparation of Root Canals

- Treat the root canal endodontically as usual (root canal filling with gutta-percha and removal of the root canal filling, leaving approx. 4 mm of gutta-percha apically).
- We recommend the use of a rubber dam during the cementation of posts.

#### Preparation for Maryland and Inlay/Onlay Bridges

Abutment teeth must have an adequate enamel surface for bonding. They should be healthy or only slightly restored and the periodontal conditions should be good. It is the sole responsibility of the dentist to ensure proper selection of indication and technique. The guidelines of the relevant national professional associations must be observed for such indications.

- Prepare retentive elements such as cingular rests and/or approximal grooves.
- Use a rubber dam and keep the cavity free of any contamination during cementation.
- Etch the enamel surface of the cavity with 37% phosphoric acid for 15-20 sec. Then rinse thoroughly with water and dry with water-free and oil-free air. In the case of exposed dentin, make sure to selectively etch the enamel to avoid post-operative sensitivity.

#### Preparatory Measures

- Remove the temporary restoration and thoroughly clean the tooth surface of any residue from the temporary cement.
- Make a trial insertion of the final restoration and check its fit and contact points.
- If a low viscosity silicone is used for the trial fit, the silicone residue must then be removed completely.
- For glass ceramic restorations, do not check the occlusion until the restoration has been cemented. Breakage could occur if done prior to being cemented in place.
- Avoid any contamination whatsoever of the surface to be treated during pre-treatment and until the final cementation.

### Pre-treatment of Restorations

#### Pre-treatment of Metal Restorations

Please follow the instructions for use of the restoration material. In the absence of deviating instructions, we recommend the following procedure:

- Blast the restoration surface to be luted with aluminum oxide  $\leq 40 \mu\text{m}$ .
- Clean the blasted surface with alcohol and dry it with water-free and oil-free air.

For Maryland and inlay/onlay bridges, please refer to “Pre-treatment of Maryland and Inlay/Onlay bridges”.

#### Pre-treatment of Etchable Glass Ceramic Restorations

Please follow the instructions for use of the restoration material. If the manufacturer has not provided deviating instructions, we recommend the following procedure:

- Use the hydrofluoric acid to etch the glass ceramic restoration surface to be luted.
- Rinse thoroughly with water for 15 seconds and dry with water-free and oil-free air.
- Apply an appropriate silane in accordance with the instructions for use.

#### Pre-treatment of Zirconia and Aluminum Oxide Ceramic Restorations

Please follow the instructions for use of the restoration material. If the manufacturer has not provided deviating instructions, we recommend the following procedure:

##### Alternative 1:

- Blast the restoration surface to be luted with aluminum oxide  $\leq 40 \mu\text{m}$ .
- Clean the blasted surface with alcohol and dry it with water-free and oil-free air.

##### Alternative 2:

- Coat the restoration surface to be luted with an intraoral microblasting unit and a blast-coating agent from a distance of 2-10 mm and vertically to the surface for 15 sec, see instructions for use for the intraoral microblasting unit and coating medium.
- Blow away any residues of the blasting agent with water-free and oil-free air.
- Apply an appropriate silane in accordance with the instructions for use.

#### For Maryland and inlay/onlay bridges, please refer to “Pre-treatment of Maryland and Inlay/Onlay bridges”.

#### Pre-treatment of Composite Restorations

Please follow the instructions for use of the restoration material. If the manufacturer has not provided deviating instructions, we recommend the following procedure:

- Blast the composite restoration surface to be luted with aluminum oxide  $\leq 40 \mu\text{m}$ .
- Clean the blasted surface with alcohol and dry it with water-free and oil-free air.

#### Pre-treatment of Implant Abutments

Please follow the recommendations for the relevant restorative material (e.g., metal, zirconia).

#### Pre-treatment of Maryland and Inlay/Onlay Bridges Metal, Zirconia and Aluminum Oxide Surfaces:

- Coat the restoration surface to be luted with the intraoral microblasting unit and coating medium from a distance of 2-10 mm and vertically to the surface for 15 sec, see instructions for use for the intraoral microblasting unit and coating medium.
- Blow away any residues of the blasting agent with water-free and oil-free air.
- Apply an appropriate silane in accordance with the instructions for use.

#### For etchable glass ceramics, please refer to “Pre-treatment of Etchable Glass Ceramic Restorations”.

### Times

The processing and setting times depend on the ambient and oral temperature. The times shown are based on conditions relevant for practice. As is the case with every composite cement, the setting of ENVY cement slows down significantly at room temperature. ENVY is a dual-cured cement and therefore also sensitive to natural or artificial light. The working time is significantly reduced during application under operating lights!

Working time from start of mixing	min: sec 01:30 (± 0:30)
Light-curing in a lightwave range of 400-500 nm	
• Single surface, from occlusal	00:20
Self-curing	
• Setting time after start of mixing	04:00 (± 1:00)

### Application

- Select a ENVY syringe containing the desired color and place it ready for use.

When using a new ENVY syringe:

- Remove and the syringe sealing cap from the automix syringe and set it aside. Check the syringe openings for blockage.
- Squeeze out a small quantity of paste onto a mixing pad to equal the base paste and catalyst paste in the automix syringe.
- Discard the paste which has been squeezed out.
- Attach mixing stator or mixing stator with angled tip.
- When application is complete, discard mixing stator and mixing tip. Replace syringe sealing cap for storage.

During every application:

Protect the working area from contamination with water, blood, saliva and sulcal fluid during the application and setting phase.

- Attach mixing stator or mixing stator with angled tip.
- The mixing stator is used without an angled tip for application in easily accessible areas.
- The paste requires a certain amount of time to flow through the mixing tip. The flowthrough speed cannot be accelerated by increasing the pressure on the plunger.
- As soon as the pressure on the plunger decreases, the material flow stops and the paste begins to set up. Do not use force to press out paste that has set as this could cause damage to the mixing tip and the automix syringe.
- Apply ENVY evenly to the entire cavity and as appropriate to the bottom side of the inlay/onlay, or fill the crown with cement.
- Keep the opening of the mixing stator or angled tip immersed in the material during the entire application to prevent the inclusion of any air bubbles.
- Seat the restoration firmly and stabilize long enough for the cement to set fully.
- Replace the syringe sealing cap until the next application.

#### Application in the Root Canal

- See instructions under “Application” for handling of the automix syringe.
- Do not use Lentulo-Spirals to insert the cement in the root canal as this can excessively accelerate setting.
- Attach an Intra Canal Tip for application in the root canal.
- Insert the Intra Canal Tip as deeply as possible in the root canal and apply ENVY, beginning apically. Keep the tip of the Intra Canal Tip immersed in the cement and slowly move the Intra Canal Tip upwards as the level of the paste rises.
- Do not remove the Intra Canal Tip from the cement until the root canal has been completely filled.
- This so-called immersion filling should not be carried out in less than 5 sec; this will minimize the entrapment of air bubbles.
- Place the dental post in the root canal filled with cement as accordance with the Instructions for Use.

#### Removal of Excess

Notes on oxygen inhibition: As is the case with all composite materials, ENVY is subject to oxygen inhibition, i.e., the upper layer (about 50  $\mu\text{m}$ ) which is in contact with atmospheric oxygen during the polymerization does not harden. Leaving sufficient excess permits the removal of the uncured layer during shaping/polishing without leaving behind a deficit.

#### From Restorations

Using light-curing:

- After brief curing (about 2 sec using a standard polymerization device), use a suitable instrument (e.g., scaler) to remove the excess. Larger volume excess can be removed more easily.
- Immediately light-cure after removal (see Polymerization and Shaping)

Using self-curing:

- Use a suitable instrument (e.g., scaler) to remove the excess during the self-curing phase (about 3 min after beginning the mixing in the “gel phase”).
- Immediately cover the edges of the restoration with a glycerin gel to prevent oxygen inhibition.
- Alternatively:
  - Remove the excess before polymerization, e.g., using a sponge pellet, while using a suitable instrument to hold the restoration in position.
  - Cover the edges of the restoration with a glycerin gel to prevent oxygen inhibition.
  - Immediately light-cure or wait for the self-curing to finish (see Polymerization and Shaping).

#### Polymerization and Shaping

- We recommend light-curing the cement through the restoration when doing ceramic and composite work. Select the exposure times appropriate for the number of surfaces (please refer to “Times”). Polymerize the cement through the post when using translucent posts. The exposure time depends on the translucency of the post being used.
- Shape any remaining uneven areas on the edges of restorations and polish the marginal area with diamond devices, aluminum oxide coated discs and diamond polishing paste.
- Then check the occlusion.

#### After Shaping

- Carefully check the sulcus of the treated teeth and the surrounding areas; remove any cement residues still remaining. This is especially important when cementing on implant abutments.

#### Hygiene and Disinfection

- We recommend the use of commonly available hygienic protective covering to avoid any contamination of the ENVY syringes during the treatment.
- Clean contaminated ENVY syringes with cleaning agents commonly used in the dental practice.
- Use a cloth soaked in a disinfectant commonly used in the dental practice to disinfect the automix syringe.

#### Notes

- ENVY can prematurely polymerize when exposed to natural or artificial lighting. Therefore avoid intensive light exposure during application.

#### Storage and Stability

Store ENVY at 4°-25°C/ 39°-77°F. Constantly high humidity accelerates the setting and must be avoided.

**Do not store materials in proximity to eugenol-containing products.**

