

Bisco

CE 0459

FORTIFY™ / *Light-Cured*

Composite Surface Sealant

FORTIFY™ PLUS / *Light-Cured*

Filled Surface Sealant

Instructions for Use



BISCO, Inc.
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IN-012R7
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CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed Dentist.

FORTIFY™*
Composite Surface Sealant
and
FORTIFY PLUS
Filled Surface Sealant

GENERAL INFORMATION

FORTIFY is a light-cured, low viscosity, unfilled resin formulation.

FORTIFY PLUS is a light-cured, low viscosity, microfilled resin formulation.

Both products are intended for use as a composite surface sealant. Contouring and finishing of posterior composite restorations with rotary instruments can create microcracks and surface irregularities that contribute to composite wear during the first six months of function. Original **FORTIFY**, a surface sealant formulated with an unfilled resin, will reduce the wear of posterior composites by up to 45% at five years¹. A composite surface sealed with **FORTIFY** or **FORTIFY PLUS**, has improved wear resistance and long-term marginal integrity. **FORTIFY/FORTIFY PLUS** is effective with all anterior/posterior composites (Bis-GMA, or UDMA resin base), resulting in enhanced wear properties. Due to the unique formulation, **FORTIFY/FORTIFY PLUS** can be air-thinned significantly, then light-cured, without interfering with the occlusion.

The principle use of **FORTIFY/FORTIFY PLUS** is to penetrate and seal the surface of:

1. Direct Composite Restorations
2. Indirect Composite Restorations
3. Provisional Restorations
4. Amalgam Restorations

Warnings:

- Avoid splashing into the eyes. If product comes into contact with the eyes, flush with copious amounts of water and seek medical attention.

Cautions:

- Cross-contamination: Product may contain items that are designed for one time use. Dispose of used or contaminated unit-dose components and accessories. Do not clean, disinfect or reuse.

Precautions:

- Unpolymerized resins may cause skin sensitization in susceptible persons. Avoid contact with the skin. In case of contact with the skin, wash thoroughly with soap and water.
- Refer to individual component labels for specific expiration dates.
- Safety data sheet available on request.
- Safety data sheet available at www.Bisco.com.

* FORTIFY is a trademark of BISCO, Inc.

¹ Dickinson, GL, Leinfelder, KF. Assessing the Long-Term effect of a Surface Penetrating Sealant. JADA 124:68-72, 1993.

INSTRUCTIONS FOR USE

1. **For Newly Placed Restorations:** Following adjustment, finishing and polishing of the final restoration, rinse the tooth and restoration with copious amounts of water to remove all debris. **OR**

For Previously Placed Restorations: Clean the entire surface with a slurry of pumice and water.

2. Etch the surface of the restoration and approximately 1-2mm beyond the tooth/restoration margin using an etchant according to manufacturer's instructions. For full coverage restorations, etch the entire surface of the restoration.
3. Rinse with copious amounts of water and thoroughly air dry the tooth and restoration.
4. Place a small amount of **FORTIFY** sealant in a mixing well. Or, place a new needle brush-tip on the **FORTIFY PLUS** syringe and push the plunger until the needle brush-tip is soaked with the sealant material. Apply a thin layer to previously etched surfaces using a scrubbing motion. Air-dry by blowing a gentle stream of air over this layer to assure an even distribution.
5. Light cure sealant for 10 seconds. Verify occlusion.

HYGIENE: Re-cap syringes with the luer lock cap. Use of commonly available hygienic protective covering to avoid any contamination of syringes during treatment is recommended.

DISPOSAL: Refer to community provisions relating to waste. In their absence, refer to national or regional provisions relating to waste.

STORAGE: Store at room temperature (20°C/68°F - 25°C/77°F).

WARRANTY: BISCO, Inc. recognizes its responsibility to replace products if proven to be defective. BISCO, Inc. does not accept liability for any damages or loss, either direct or consequential, stemming from the use of or inability to use the products as described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

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