

Injectable+ Light-cured Composite Resin

Product Description

Belixa is a light cured, radiopaque, flowable composite resin designed for direct restorations. Its smooth consistency allows it to be applied evenly to the teeth, providing excellent gloss and aesthetic results. It also offers high mechanical strength, allowing it to withstand occlusal forces effectively. The inorganic filler of Belixa has a particle size range of 0.01 to 0.5 µm, and a volume ratio of about 47% depending on the model.

Composition

- Organic Matrix: Bis-EMA
- Inorganic Fillers: Ba glass, Silica
- Additives: Initiator, Catalyst, Stabilizer, Others

Intended Purpose

Belixa is a light cured, flowable dental composite resin used for the direct restoration of anterior and posterior teeth.

Intended User Dentists experienced in performing light cured composite restorations

Target Patient Group Dental patients

Indications

Belixa is a light cured, flowable dental composite resin used for the direct restoration of anterior and posterior teeth.

- Direct restorations
- Repair of indirect aesthetic restorations
- Base and Liner
- Block out undercut
- Core build-up

Contraindications

This product should not be used on patients with known allergies to any of its components. Do not use this material for patients allergic to or hypersensitive to methacrylic monomers. The list of components can be found in the Safety data sheets: <http://edsdental.com/sds.html>.

Performance characteristics

Injectable Depth of cure: $\geq 1.5\text{mm}$.
Water sorption: $\leq 40\mu\text{g}/\text{mm}^3$
Solubility: $\leq 7.5\mu\text{g}/\text{mm}^3$

Shade

Belixa Injectable: A1, A2, A3, BW

Precautionary Information

1. Verify the product's expiration date and ensure both the product and its packaging are in proper condition.
2. Review and follow the instructions for use after thoroughly familiarizing yourself with them.
3. Do not use the product if the material has already cured.
4. If any issue occurs with the product, discontinue use immediately and contact Essential Dental Systems.

Application Preparation

1. Prophyl: Teeth should be cleaned with pumice and water to remove surface stains.
2. Shade Selection: Before isolating the tooth, select the appropriate shade(s) of restorative material.
3. Isolation: Place a rubber dam, if necessary.

Restoration

1. Cavity Preparation: Prepare the cavity, ensuring that line and point angles are rounded. Remove any residual amalgam or other base materials from the preparation, as these may obstruct light transmission and impair proper curing of the restorative material.
2. Pulp Protection: Apply a pulp protective base or liner such as Bio-LCB* if needed. DO NOT USE EUGENOL-BASED MATERIALS to protect the pulp as these materials will inhibit curing of Belixa.
3. Adhesive System: EDS recommends first using an etchant and dental bonding agent before application of Belixa. These should be applied according to manufacturer's instructions. All adhesive systems greater than 4th generations are applicable.
4. Application: Remove the syringe cap and attach the provided dispensing tip. Before use, point the tip away from the patient and express a small amount to ensure the tip is securely connected and functioning properly. Dispense Belixa directly into the cavity, or place it onto a mixing pad and apply it using a suitable instrument. After use, remove the dispensing tip and promptly replace the syringe cap.
- 4.1 Direct Restoration: Place the dispensing tip close to the cavity surface and apply Belixa starting from the deepest area. While dispensing, gradually lift the tip slightly above the material to reduce the risk of trapping air bubbles. Avoid inserting the tip into the material that has already been applied.
- 4.2 Core build-up: Apply Belixa into the undercut areas surrounding the post, then proceed to fill the remainder of the cavity.
5. Light-curing: Ensure adequate light exposure to achieve complete polymerization. Use a dental curing unit operating within the 440–490 nm wavelength range and position the light source close to the resin. Refer to the following table for recommended exposure times and light intensity.

Minimum Intensity 600 mW/cm²

Product	Depth of Cure	Irradiation Time
Belixa Injectable	1.5 mm	30 Sec

6. Finishing: Remove excess material with suitable instruments after polymerization.
7. Adjust Occlusion: Check the occlusion and adjust the restoration.
8. Polishing: Use silicone polishers as well as polishing discs and polishing strips to polish the restorations to durable high gloss.

Caution

1. Federal law restricts this device to sale by or on the order of licensed dentist.
2. This product must not be used for any purpose other than its intended use.
3. This product contains methacrylate monomers, which may cause allergic reactions in susceptible patients.
4. If any allergic reaction or hypersensitivity occurs during use, discontinue the product immediately.
5. Avoid contact of the product with the eyes, mucous membranes, skin, or clothing.
6. In the event of accidental contact with the skin or eyes, rinse the affected area thoroughly with clean water several times. Seek medical attention if necessary.
7. The use of a rubber dam is recommended to protect the throat during application.
8. DO NOT use this product after the expiration date indicated on the packaging.
9. If the product has been stored under refrigerated conditions, it is essential to allow it to reach room temperature before use.
10. Avoid using this product in combination with phenolic substances or materials containing phenol. Phenolic compounds, particularly those containing eugenol, may interfere with the curing process.
11. Any serious adverse events or accidents associated with use of this product must be reported to the appropriate regulatory authority.
12. Clean the product after use to prevent cross contamination.
13. Clinical factors such as tooth condition, anesthesia, and the clinician's technique may affect the safety and performance of the product.

There are three known side effects associated with light-cured flowable composite resin: secondary caries, sensitivity, debonding. They may be caused by the operator's technique, patient's oral hygiene, or use with other devices.

Storage & Use

1. Store this product at the temperature between 35°F (2°C) - 80°F (27°C).
2. This product is intended to be used at room temperature.
3. Do not expose the material to elevated temperatures, or to intense dental operating light. Polymerization may be started.
4. Storage temperatures higher than 80°F (27°C) may reduce shelf life.
5. Shelf life of this product is 36 months.
6. See outer package for expiration date.
7. Do not store materials in proximity to products containing Eugenol.
8. This product may be used until fully consumed, provided it remains within the expiration date.

Warranty

Essential Dental Systems (EDS) warrants this product will be free from defects in material and manufacture. EDS MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and EDS's sole obligation shall be repair or replacement of the EDS product.

Limitation of Liability

Except where prohibited by law, EDS will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Disposal

It should be handled according to local laws and regulations.

If a serious incident occurs in relation to our device after it has been placed on the market, our Quality Management representative will notify the Notified Body and the competent authority in accordance with the vigilance procedure.

Caution: U.S. Federal Law restricts this device to sale by or use on the order of a dental professional.

