

StackFlow™

Injectable Light-cured Composite

Indications For Use:

- Direct restorations
- Base and Liner
- Block out undercut
- Repair of (in)direct aesthetic restorations
- Core build-up

Description of Device:

StackFlow is a light-cured radiopaque flowable composite resin used for direct restoration. It has a smooth surface, so it is applied smoothly to the teeth, and has good gloss and aesthetics. In addition, it has high mechanical strength, so it can sufficiently withstand the occlusal force. The inorganic filler of StackFlow has a particle size of approximately 180nm and makes up 65-68 wt.% of the composition. While nano-silica of 10nm accounts for approximately 0.2% wt.

Contents and Setup:

SKU	Description	Contents
3005270	StackFlow Shade Light	2 x 2.5g syringes, 20 applicator tips
3005271	StackFlow Shade Neutral	2 x 2.5g syringes, 20 applicator tips
3005272	StackFlow Shade Warm	2 x 2.5g syringes, 20 applicator tips
3005273	StackFlow Shade Bleached	2 x 2.5g syringes, 20 applicator tips
3005275	20 Gauge Single Use Zero-bubble Applicator Tips	100 pack of tip refills

Composition:

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

Performance characteristics:

Water sorption: ≤ 40µg/mm³

Solubility: ≤ 7.5µg/mm³

Flexural strength: ≥ 80 MPa

Radiopacity: Equal or greater than the same thickness of aluminum

Intended Purpose:

StackFlow™ is a light-cured dental flowable resin which is applied directly to the anterior and posterior teeth for restoration of dental patients.

Intended User:

Dentist who has experience of dental light-cured composite restoration.

Target Patient Group:

Dental patients.

Contraindications:

Do not use this material for patients allergic to or hypersensitive to methacrylic monomers.

PRECAUTIONARY INFORMATION:

- Check the expiration date and appearance condition of product and package.
- Observe the instruction for use after being well acquainted with the instruction for use.
- Do not use if the material has been cured.
- When the product has any problem, user should stop using it and contact our company.

CAUTION:

- This product is intended for sale and use exclusively by licensed dental professionals (Dentist).
- It is prohibited to use this product other than for the intended purpose.
- This product includes methacrylic monomer, which may cause allergic reactions in certain patients.
- If any allergic reaction or oversensitivity occurs while using this product, discontinue its use immediately.
- It is important to avoid any contact of this product with eyes, mucosal membranes, skin, or clothing.
- In case of accidental contact of this product with the skin or eyes, thoroughly clean the affected area with pure water several times. If necessary, consult a medical specialist.
- The use of a rubber dam is recommended to protect the throat during application.
- DO NOT use this product after the expiration date indicated on the package.
- If refrigerated storage is utilized, it is essential to allow the product to reach room temperature before use.
- It is advised to avoid the combination of this product, with phenolic substances or other materials containing phenol. This is because phenolic substances, particularly preparations containing eugenol, can interfere with the curing process of this material.
- It must be reported to the authority any serious side effects and accidents that may occur.
- It should be cleaned after use to prevent cross-contamination.
- Conditions of teeth, anesthesia, and dentist's techniques can affect the safety and performance of the product.
- Do not reuse the tip after use.
- U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

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Side Effects:

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

Directions for Use:

Preparation:

1. **Prophy:** 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.

StackFlow™ Shade	VITA® Shade Guide Equivalent
LIGHT	A1, B1, C1
NEUTRAL	A2, B2, D2, D4
WARM	C2, A3, A3.5, B3, B4
BLEACHED	OM1, OM2, OM3

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3. **Isolation:** Place a rubber dam, if necessary.

Restoration:

1. **Cavity Preparation:** Prepare the cavity. Line and point angles should be rounded. No residual amalgam or other base material should be left in the internal form of the preparation that would interfere with light transmission and therefore, the hardening of the restorative material.
2. **Pulp Protection:** Apply a calcium hydroxide pulp protector if needed. DO NOT USE EUGENOL-BASED MATERIALS to protect the pulp as these materials will inhibit curing of StackFlow.
3. **Adhesive System:** It is recommended that suitable etchant on the market like as Premier® Etch or Spot-On™ Etch is applied and rinse thoroughly according to the manufacturer's instruction and dental bonding agent on the market such as Premier's Bond-PR™ Universal Adhesive is applied and then light-cured according to manufacturer's instructions. All adhesive systems over 4th generations are acceptable.
4. **Application:** Open the syringe cap and attach the enclosed tip to the syringe. Before using it, place the tip away from the patient, then dispense a small amount to make sure the tip is well connected. Apply StackFlow directly into the cavity or dispense it on a mixing pad and apply with suitable instruments. After use, remove the tip and close the cap immediately.

4.1 Direct Restoration: Place the tip close to the surface of the cavity, and apply StackFlow from the deepest part of the area. When dispensing the resin, slowly lift the tip slightly above the applied resin to minimize air bubbles. Do not dip the tip in the applied resin.

4.2 Core build-up: Apply StackFlow into the undercut area around the pin and post. After then, fill the cavity.

5. **Light-curing:** Sufficient exposure to the curing light prevents incomplete polymerization. Use the dental light curing unit with 440-490nm range of wavelength. Keep the curing light close to the resin. Minimum light intensity of 600 mW/cm² and 20 sec of irradiation time is recommended.

Shades	Intensity (mW/cm ²)	Cure Time (Sec)
Light, Neutral, Warm	> 600	20
and Bleached	> 1200	10

For incremental depth of 2mm

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

Storage:

- Store this product at the temperature between 2 - 27°C (36°F – 81°F).
- This product is intended to be used at room temperature.
- Do not expose the material to elevated temperatures, or to intense dental operating light. Polymerization may be started.
- Storage temperatures higher than 27°C/81°F may reduce shelf life.
- Shelf life of this product is 36 months.
- See outer package for expiration date.
- Do not store materials in proximity to products containing Eugenol.
- Do not use StackFlow Injectable Light-Cured Composite past its expiration date

Disposal:

Disposable should be handled according to local laws and regulations.

Customer Information:

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

For Further Information:

To obtain SDS or IFU, visit premierdentalco.com or call Premier at 610-239-6000.

Symbols:

A full explanation of symbols used on Premier® Dental packaging and literature is located at premierdentalco.com/symbol-glossary

Symbols	Symbol Meaning
	Part Number
	Expiry Date
	Date and Country of Manufacture
	Manufacturer
	Batch number
	Caution: See instructions for use
	The upper and lower limits of temperature of use, storage and transportation
	Irritant: An immediate skin, eye or respiratory tract irritant
Rx ONLY	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
	Consult instructions for use
	Keep away from sunlight
	Single Use
	Medical Device
	Keep Dry