

OptiFlow II Instruction for use

FLOWABLE COMPOSITE, LC

OptiFlow II is a resin based, low viscosity, flowable light cure restorative dental composites. The restorative is packaged in syringes. The inorganic fillers make up approximately 57% of the mass (40% by volume). All shades have a radiopacity of 200%.

INDICATIONS FOR USE

Restoration of minimally invasive cavity preparations (including non-stress bearing areas), pit and fissure sealant, class III-V restorations, repair of porcelain restorations, and repair of ceramic/composite veneers.

CONTRAINDICATION

OptiFlow II is contraindicated in a patient who is known to be allergic to any of the ingredients. Acrylate-based resin in OptiFlow II is a common ingredient in composites which can trigger allergic reactions in sensitized individuals. These reactions can range from mild (such as skin irritation or rash) to severe (such as anaphylaxis, which is a potentially life-threatening condition).

COMPOSITION

Bis-GMA, Bis-EMA, ETPTA, EHA, and barium glass.

Total content of inorganic fillers: approximately 57% by weight.

Average particle size of inorganic filler: 0.7 µm

PRECAUTIONS AND WARNINGS

1. If any allergic reactions are experienced, discontinue the use of the product and refer to a physician.
2. Avoid contact of paste with skin. If accidental contact occurs, wash the area immediately with soap and water. In case of contact with eyes, rinse with copious amounts of water and consult a physician immediately.

Composition	Range (% by weight)
Bis-phenol-A-bis-(2-hydroxy-3-methacryloxypropyl) ether	7.8-10.0
Ethoxylated bis-phenol-A-dimethacrylate	18-22.5
Ethoxylated Trimethylolpropane Triacrylate	13-17
Barium aluminoborosilicate	46-54
2-(Ethylhexyl)-4-(dimethylamino) benzoate	<1



Hazard statements as per MSDS

- Causes skin irritation.
- May cause an allergic skin reaction.
- Causes eye irritation.
- May cause respiratory irritation.

Precautionary statements as per MSDS

- Avoid breathing vapor.
- Avoid release to the environment.
- Wear protective gloves / protective clothing / eye protection / face protection.
- Use only outdoors or in a well-ventilated area.
- If inhaled: Call a poison center / doctor if you feel unwell.
- If skin irritation or rash occurs: Get medical advice / attention.
- If eye irritation persists: Get medical advice / attention.
- Dispose of contents / container as per local and national regulations.

INTENDED PURPOSE

OptiFlow II is a light curable dental resin-based composite intended for restoration of functionally compromised teeth.

INTENDED USER

For use only by a dental professional in the recommended indications.

INTENDED PATIENT POPULATION

Patient requiring dental restorations as recommended by a dentist.

CLINICAL BENEFIT

Restoration of tooth esthetics and function.

NOTICE

Any serious incident that has occurred in relation to the device due to a malfunction should be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.

The Summary of Safety and Medical Performance (SSCP) can be retrieved from the European Database on Medical Devices (EUDAMED) at <https://ec.europa.eu/tools/eudamed>.

DIRECTIONS FOR USE

- Cavity Preparation**
Using a bur or air abrasion unit, slightly roughen the surface to be built-up.
- Use of Light-cured Bonding System**
Apply bonding agent in a thin layer according to manufacturer's instructions.
- Shade Selection**
Select desired shade of OptiFlow II.
- Placement of OptiFlow II**
 - Avoid intense light in the working place. Exposure of paste to intense light may cause premature polymerization.
 - Dispense OptiFlow II: Start dispensing in the deepest portion of the preparation, holding the tip close to the preparation surface. As material is extruded, slowly raise the tip so it is slightly above the dispensed material to minimize air entrapment. Do not allow the tip to be immersed in the material.
 - Place and light cure restorative in increments as indicated in Section 5. The thickness of each layer should not be more than 2mm.
- Light Curing**
Light cure the OptiFlow II using a light curing unit for 30 seconds. The light curing unit should have a minimum intensity of 1000mW/cm². Cure each increment by exposing its entire surface.

Note:
 - When light curing the material, wear protective glasses.
 - Light curing units should have 450nm output and should be checked regularly.
 - Place the light as close as possible to OptiFlow II.
- Shaping and Finishing**
Shape and finish with diamond burs and flexible disks of increasing grits.

PROPERTIES

Flexural strength (MPa)	134	Wavelength (nm) for curing	450-470
Compressive strength (MPa)	370	Depth of cure (mm)	5.0
Light intensity (mW/cm ²) for curing	1400	Curing time (Sec)	30
Water absorption (µg/mm ³)	25	Radiopacity	200%
Water solubility (µg/mm ³)	0	Sensitivity to light	Homogenous at 60 sec

STORAGE

Store at room temperature (64-73°F). Do not use after expiry date. (Shelf life: 2 years from the date of manufacture).

SHADES

A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4

Note: All shades are based on Vita shade.

COMPOSITION

4-pack: 4X1.5gm Syringes and 20 Blue Flo-Tips

High Viscosity 4-pack: 4X1.5gm Syringes and 20 Blue Flo-Tips

DISPOSAL

- Before disposal:** Never dispose of paste directly into the trash or down the drain. Uncured composite should be fully cured before disposal.
- Sunlight curing:** Put the composite into a clear container and expose it to direct sunlight. UV light will cure the resin composite. Alternatively, use a UV lamp if sunlight is not sufficient.
- Solidification:** Once the composite is fully cured and solidified, it can generally be disposed of as regular trash. However, always verify with local regulations, as there may be specific guidelines for cured resin composites.

- **Gloves and masks:** Used gloves, masks, and any other PPE contaminated with the composite should be disposed of in accordance with hazardous waste regulations.
- **Cleaning materials:** Materials used to clean spills or tools, such as paper towels or cloths, should also be cured if saturated with uncured composite before disposal.
- **Stay informed:** Regularly review disposal practices and stay informed of any changes in regulations.

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EC REP

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GINGI-PAK®



Manufactured by

The Belpo Company, Inc.
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 Made in USA



This side up Temperature Do not use Keep away from Medical Device Use by Catalogue Lot number Date of manufacture For professional use only
 Limit if package sunlight date number use only
 is damaged