



formlabs IBT RESIN Light-Curable Polymer Based Material Designed for 3D Printing Biocompatible Instruction Manual

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Biocompatible Instruction Manual 



Instructions for Use IBT RESIN

The following instructions for use are for Formlabs biocompatible photopolymer IBT Resin. Basic information about safety and environmental concerns are also included. For more detailed safety and environment information please refer to the Safety Data Sheet, available at dental.formlabs.com. For further information regarding the use of the material, please contact Formlabs.

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Introduction And Indications For Use

INDICATIONS FOR USE

IBT Resin is a light-curable polymer-based material designed for 3D printing biocompatible, indirect bonding trays for dental bracket placement.

Users should independently verify the suitability of the printed materials for their particular application and intended purpose.

IBT Resin is a photopolymer resin made of a mixture of methacrylic esters and photoinitiators.

Specific Manufacturing Considerations

NOTIFICATION

The device specifications have been validated using the printer process parameters indicated below.

REQUIREMENTS

Use dedicated accessories for IBT Resin. For biocompatibility, IBT Resin requires a dedicated resin tank, build platform, Form Wash, and finishing kit, which should not be mixed with any other resins.

RECOMMENDED 3D PRINTER AND PRINTING PARAMETERS

a. Hardware: Formlabs SLA 3D Printer

- Laser wavelength: 405 nm
- Resin Tanks: Form 2 Resin Tank LT and Form 3 Resin Tank (version 2.1 and up)

b. Software: Formlabs PreForm

- STL file import
- Manual/Automatic rotation and placement
- Manual/Automatic generation of supports

c. Printing Parameters

- Layer thickness: 100 μm
- Orientation: Intaglio surface facing away from the build platform
- The minimum wall thickness of ≥ 2 mm

d. Recommended Post-Processing Equipment:

- Formlabs Form Wash
- Isopropyl alcohol (IPA) $\geq 99\%$
- Formlabs Form Cure

Hazards And Precautions

HAZARDS

1. IBT Resin (uncured) contains polymerizable monomers which may cause skin irritation (allergic contact dermatitis) or other allergic reactions in susceptible persons. If resin contacts skin, wash thoroughly with soap and water. If skin sensitization occurs, discontinue use. If dermatitis or other symptoms persist, seek medical assistance.
2. **Eye contact:** High vapor concentration may cause irritation.
3. **Skin contact:** May cause sensitization by skin contact. Irritating to skin. Repeated and/or prolonged contact may cause dermatitis.
4. **Inhalation:** Irritating to the respiratory system. Prolonged or repeated exposure may cause headache, drowsiness, nausea, weakness (severity of effects depends on the extent of exposure).
5. **Ingestion:** Low oral toxicity, but ingestion may cause irritation of the gastrointestinal tract.

6. **Protection:** Protective glasses and nitrile gloves should be worn while handling IBT Resin. Detailed information about the handling of IBT Resin can be found in the Safety Data Sheets at dental.formlabs.com.

PRECAUTIONS

1. When washing the printed part with solvent, it should be in a properly ventilated environment with proper protective masks and gloves.
2. Expired or unused IBT Resin shall be disposed of in accordance with local regulations.
3. IPA shall be disposed of in accordance with local regulations.
4. As bracket shapes can vary, make sure to add adequate bracket retention while designing the indirect bonding trays and check the bracket retention before clinical use. If retention is not sufficient, the brackets may fall out while placing the indirect bonding tray in the patient's mouth.

Manufacturing Procedure With IBT Resin

A. PRINTING AND POST-PROCESSING

1. **Shake cartridge:** Prior to using, shake cartridge well. Color deviations and print failures may occur if the cartridge is shaken insufficiently.
2. **Set up:** Insert resin cartridge into a compatible Formlabs 3D printer.
3. **Printing:**
 - a. Prepare a print job using PreForm software. Import desired part STL file. Orient and generate supports. For recommendations on print orientation and support placement, see the detailed application guide at dental.formlabs.com.
 - b. Send a print job to the printer. Begin print by selecting a print job from the print menu. Follow any prompts or dialogs shown on the printer screen. The printer will automatically complete the print.
4. **Part removal:**
 - a. Remove the build platform from the printer.
 - b. Printed parts can be removed from the build platform before or after cleaning in a Form Wash. To remove, wedge the part removal tool under the printed part raft, and rotate the tool. For detailed techniques visit support.formlabs.com.
5. **Rinsing:** Place the printed parts in a Form Wash filled with Isopropyl Alcohol (IPA, $\geq 96\%$) and wash for 20 minutes.
6. **Drying:**
 - a. Remove parts from IPA and leave to air dry at room temperature for at least 30 minutes.
 - b. Inspect printed parts to ensure that parts are clean and dry. No residual alcohol, an excess liquid resin or residue particles must remain on the surface before proceeding to subsequent steps.
7. **Post cure:** Place the dried printed parts in a Form Cure and post-cure at 60°C for 60 minutes.
8. **Support removal:**
 - a. Remove supports using a cutting disk and handpiece, or with other part removal tools.
 - b. Inspect the parts for any cracks. Discard if any damage or cracks are detected.

B. CLEANING

1. Fully post-processed parts can be cleaned using neutral soap and room temperature water.
2. After cleaning, always inspect parts for any cracks. Discard if any damage or cracks are detected.

C. DISINFECTION

1. The indirect bonding tray may be cleaned and disinfected according to facility protocols. A tested method of disinfection includes: soaking the finished indirect bonding tray in fresh 70% IPA for 5 minutes.

Note: Do not leave the part in the alcohol solution for longer than 5 minutes.

2. After disinfection, inspect the part for cracks to ensure the integrity of the indirect bonding tray.










D. STORAGE

1. When not in use, place printed parts in closed, opaque, or amber containers.
2. Store in a cool, dry place out of direct sunlight. Excess light exposure over time may affect the color of printed parts.
3. Store the cartridges at 10°C – 25°C (50°F – 77°F).
4. Do not exceed 25°C (77°F) when in storage.
5. Keep away from ignition sources.

E. DISPOSAL

1. Any cured resin is non-hazardous and may be disposed of as regular waste.
 - a. Follow facility protocols for waste that may be considered biohazardous.
2. Liquid resin should be disposed of in accordance with government regulations (community, regional, national).
 - a. Contact a licensed professional waste disposal service to dispose of liquid resin.
 - b. Do not allow waste to enter storm or sewer drainage systems.
 - c. Avoid release into the environment.
 - d. Contaminated packaging: Dispose of as unused product.

Symbols & Manufacturer Information

	Keep away from sunlight
	Consult instructions for use
	Batch Code
	Manufacturer
	European Conformity
	Use-by date
	Authorized Representative in the European Community
	Catalog Number
	Temperature Limit



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Documents / Resources

