formlabs BioMed Elastic 50A Resin Instructions

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BioMed Elastic 50A Resin is a USP Class VI certified, light-curable polymer based material designed for the additive manufacturing of medical grade, biocompatible, elastic parts for long-term skin contact(more than 30 days) as well as short-term (less than 24 hours) mucosal membrane contact. Users should independently verify the suitability of the printed materials for their particular application and intended purpose. This Manufacturing Guide will give equipment, printing and post-processing recommendations and requirements to ensure the correct and safe usage of this material.

Specific Manufacturing Considerations
BioMed Elastic 50A Resin specifications have been validated using the hardware and parameters indicated below. For biocompatibility compliance, validation used a dedicated resin tank and mixer, build platform, wash unit and post-processing equipment that were not mixed with any other resins.

1. **Hardware:**

a. Formlabs 3D Printer: Form 3B/3B+, Form 3BL, Form 4B

b. Print Accessories: Formlabs Build Platforms, Formlabs Resin Tanks

2. Software:

a. Formlabs Preform

3. Printing Parameters:

a. Layer Thickness: 100 µm

4. Recommended Post-Processing Equipment and Accessories:

a. Formlabs Processing Accessories: Resin Pumping System

b. Formlabs Validated Wash Unit: Form Wash, Form Wash (2nd Generation), Form Wash L

c. Formlabs Validated Cure Unit: Form Cure, Form Cure L

A. PRINTING

1. **Shake cartridge:** Shake the cartridge before every print job. 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. Insert resin tank and attach mixer to the tank.
3. **Printing:**

   a. Prepare a print job using PreForm software. Import desired part STL file.

   b. Orient and generate supports if needed.

   c. Send the print job to the printer.

   d. Optional: If starting with an empty resin tank, save time by manually pre-filling the tank by pouring in resin directly from the cartridge.

   e. 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.

B. PART REMOVAL

Remove the build platform from the printer. To remove parts from the build platform, wedge the part removal tool under the printed part raft, and rotate the tool. For detailed techniques visit support. formlabs.com.

C. WASHING

Place the printed parts in a Formlabs-validated wash unit with 99% Isopropyl Alcohol (IPA).

1. Form Wash, Form Wash (2nd Generation) – High speed*, or Form Wash L:

a. Wash for 20 minutes or until clean.

b. If parts do not appear clean after washing, consider replacing used Isopropyl Alcohol in the wash unit with fresh solvent.

*For Form Wash (2nd Gen), High speed settings are validated for use.

D. DRYING

1. Remove parts from Isopropyl Alcohol and leave to air dry at room temperature for at least 30 minutes. Drying for an additional hour may improve surface feel. NOTE: Dry times can vary depending on the design of parts and ambient conditions. Do not let parts sit in Isopropyl Alcohol for longer than needed.
2. Inspect printed parts to ensure that parts are clean and dry. No residual solvent, excess liquid resin or residue particles should remain on the surface before proceeding to subsequent steps.
3. If the residual solvent is still present, dry parts longer. If resin residue is still visible, rewash parts until clean and dry.

E. POST-CURING Place the printed parts in a Formlabs-validated post-curing unit and cure for the required

time.

4. **Form Cure or Form Cure L:**

   a. Submerge parts in a transparent, water filled container. Place the container inside the cure unit, and cure for 30 minutes at 70 °C.

   b. Allow the cure unit to cool down to room temperature between cure cycles.

   c. Optional: Soaking in water for an additional hour may improve surface feel.

   F. SUPPORT REMOVAL & POLISHING

5. Remove supports, with assistance of cutting pliers or other appropriate finishing tools as needed.
6. Inspect the parts for any cracks. Discard if any damage or cracks are detected.

   G. CLEANING & DISINFECTION

7. Parts may be cleaned, disinfected and/or sterilized according to facility protocols. Tested disinfection method: soaking the finished part in fresh 70% IPA for 5 minutes. The manufacturer is responsible for validation of part performance depending on the application requirements post cleaning, disinfection and/or sterilization.

   NOTE: If alcohol-based disinfectants are used, do not leave parts in alcohol solution for an extended time.

8. After cleaning, disinfection and/or sterilization, inspect the parts for damage or cracks to ensure that the integrity of the designed parts meets performance requirements. Discard if any damage or cracks are detecte.

H. HAZARDS, STORAGE & DISPOSAL

1. Cured resin is non-hazardous and may be disposed of as regular waste.
2. See SDS for more information at support.formlabs.com.

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References

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- User Manual