MANUFACTURING GUIDE

BioMed Flex 80A Resin

Prepared: 08/30/2023 PRNT-0111 Rev 00

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BioMed Flex 80A Resin is a USP Class VI certified, light-curable polymer based material designed for the additive manufacturing of medical grade, biocompatible, flexible 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 Flex 80A Resin specifications have been validated using the hardware and parameters indicated below. For biocompatibility compliance, validation used a dedicated resin tank, 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
   b. Print Accessories: Formlabs Build Platform, Formlabs Stainless Steel Build Platform, Formlabs Build Platform 2, Formlabs Build Platform 2L, Formlabs Tanks
2. **Software:**
   a. Formlabs Preform
3. **Printing Parameters:**
   a. Layer Thickness:
      - Form 3B/3B(+): 100 µm & 50 µm
      - Form 3BL: 100 µm
4. **Recommended Post-Processing Equipment:**
   a. Formlabs Validated Wash Unit: Form Wash, Form Wash L
   b. 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.
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 or Form Wash L:
   a. Wash for 20 minutes in the wash unit, then either rinse down parts completely with fresh IPA from a spray bottle, or soak parts in fresh IPA for 10 minutes.
   b. If parts do not appear clean after washing, consider replacing used Isopropyl Alcohol with fresh solvent.

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.

1. 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.

F. SUPPORT REMOVAL & POLISHING

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

G. CLEANING & DISINFECTION

1. 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.
2. 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.