MANUFACTURING GUIDE

Surgical Guide Resin

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Surgical Guide Resin is a light-curable polymer-based resin designed for fabricating biocompatible, short-term use, endosseous dental implant accessories such as dental surgical guides by additive manufacturing. 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

Surgical Guide Resin specifications have been validated using the hardware and parameters 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 2, Form 3B/3B+, Form 3BL, Form 4B, Form 4BL
   b. Print Accessories: Formlabs Build Platforms, Formlabs Resin Tanks
2. **Software:**
   a. Formlabs Preform
3. **Printing Parameters:**
   a. Part Orientation: Horizontal orientation with the intaglio surface facing away from the build platform
   b. Layer Thickness: 50 µm and 100 µm
   c. Part Thickness: 2 mm minimum
   d. Suggested Offsets
      - From Teeth: 0.050 to 0.070 mm
      - From Sleeve: 0.000 to 0.040 mm
4. **Recommended Post-Processing Equipment and Accessories:**
   a. Formlabs Processing Accessories: Form Auto, Resin Pumping System
   b. Formlabs Validated Wash Unit: Form Wash, Form Wash (2nd Generation), Form Wash L, Form Wash L (2nd Generation), Ultrasonic Wash Unit
   c. Formlabs Validated Cure Unit: Form Cure, Form Cure L, Fast Cure, Form Cure (2nd Generation)

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.
   c. Send the print job to the printer.
   d. 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. Formlabs Build Platform 2 or Build Platform 2L may be used for easy, tool free removal. For detailed techniques visit support.formlabs.com.

C. WASHING

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

1. Form Wash, Form Wash (2nd Generation) - High speed*, Form Wash L, or Form Wash L (2nd Generation):
   a. Wash for 5 minutes or until clean.
   b. If parts do not appear clean after the 5 minute wash, replace the used Isopropyl Alcohol in the wash unit with fresh solvent, and wash parts for an additional 1-2 minutes.

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

2. Ultrasonic Wash Unit:

NOTE: Using Isopropyl Alcohol in an ultrasonic bath presents a risk of fire or explosion. When using an ultrasonic wash read and follow all safety recommendations from the ultrasonic wash manufacturer.

   a. Use clean 99% Isopropyl Alcohol for each wash.
   b. Place parts in a secondary disposable plastic container or plastic resealable bag then fill with 99% Isopropyl Alcohol, ensuring parts are fully submerged.
   c. Place the secondary container in the ultrasonic unit water bath and sonicate for 2 minutes or until clean*

**Washing efficacy depends on the ultrasonic unit size and power. Formlabs testing was conducted with ultrasonic units at 36 W/L or higher.*

D. DRYING

1. Remove parts from Isopropyl Alcohol and leave to air dry at room temperature for at least 30 minutes. **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. Cure for 30 minutes at 60 °C
   b. Allow the Form Cure or Form Cure L unit to cool down to room temperature between cure cycles.
2. Fast Cure:
   a. Cure for 5 minutes at Light Intensity 9
   b. Allow the Fast Cure unit to cool for at least 10 minutes between cure cycles.
3. Form Cure (2nd Generation):
   a. Cure for 5 minutes at 60°C.
   b. Allow the Form Cure (2nd Generation) unit to cool down to room temperature between cure cycles.

NOTE: During post-curing, a color change from translucent yellow to translucent orange will occur.

F. SUPPORT REMOVAL & POLISHING

1. Support marks can cause abrasion if not removed and polished. Remove supports using a cutting disk and handpiece, cutting plier, or other appropriate finishing tools.
2. Inspect the parts for any cracks. Discard if any damage or cracks are detected.

G. CLEANING & DISINFECTION

1. The appliances may be cleaned and disinfected according to facility protocols. Tested disinfection method: soaking the finished appliance in fresh 70% Isopropyl Alcohol for 5 minutes. Do not leave the part in the alcohol solution for longer than 5 minutes.
2. Printed appliances do not require sterilization prior to use. Surgical Guide Resin has not been validated to show an SAL of 10-6, but has been evaluated to show that biocompatibility and mechanical properties do not change after sterilization.
   a. Surgical guides may be steam sterilized according to CDC recommended cycles (132°C/270°F for 4 minutes in a pre-vacuum steam sterilizer or 30 minutes at 121°C/250°F in a gravity displacement autoclave), or according to facility/autoclave manufacturer's protocol, as long as cycles do not exceed 20 minutes for 134°C/273°F or 30 minutes at 121°C/250°F. Autoclave cycles should include a dry cycle to best maintain accuracy. For example, wrapped instruments sterilized in a prevacuum autoclave should be dried for 20-30 minutes according to CDC recommendations. Longer or hotter autoclave cycles than those listed above may result in degradation of physical properties and accuracy.

NOTE: A color shift will be observed after autoclaving, this is normal.

3. After cleaning, disinfection and sterilization, inspect the part for damage or cracks to ensure that the integrity of the designed part meets performance requirements. Discard if any damage or cracks are detected.

[1] *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, Centers for Disease Control and Prevention (CDC), Updated: May 2019*

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