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Version 1.5

Stopgap Surgical Face Mask (SFM) Revision B: Printing and Post-Processing

Introduction

[The SFM Revision B assembly](#) can be printed on a Formlabs Form 2 or Form 3/3B printer. Any portion of the mask that comes into contact with skin should be printed in a biocompatible resin. We have found that BioMed Clear Resin works well for the mask and is certified biocompatible.

BioMed Clear Resin is a hard, strong material for biocompatible applications requiring long-term skin or mucosal membrane contact. This USP Class VI certified material is suitable for applications that require wear resistance and low water absorption over time.

Parts printed with BioMed Clear Resin are compatible with common sterilization methods. BioMed Clear Resin is manufactured in our ISO 13485 facility and is supported with an FDA Device Master File.

NOTE: Only clean Formlabs Resins with soap and water. Cleaning with other solvents may result in material property degradation. Ensure this is suitable for your facility before commencing manufacturing.

Required Materials

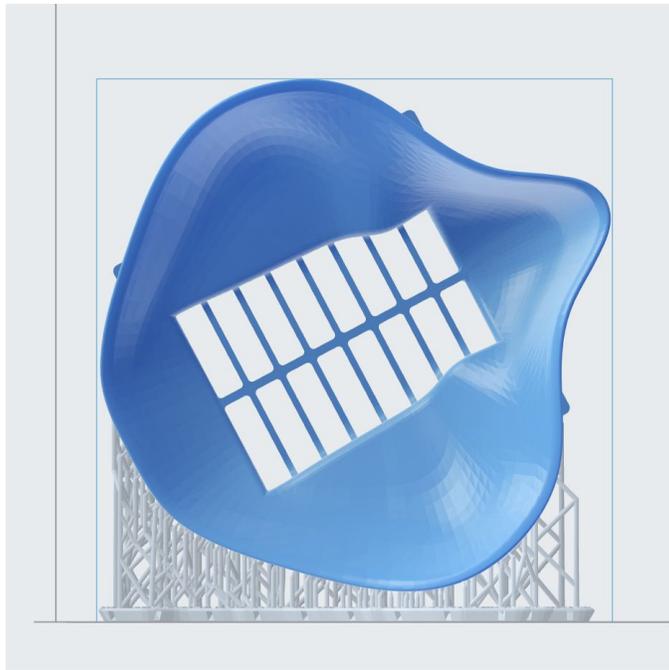
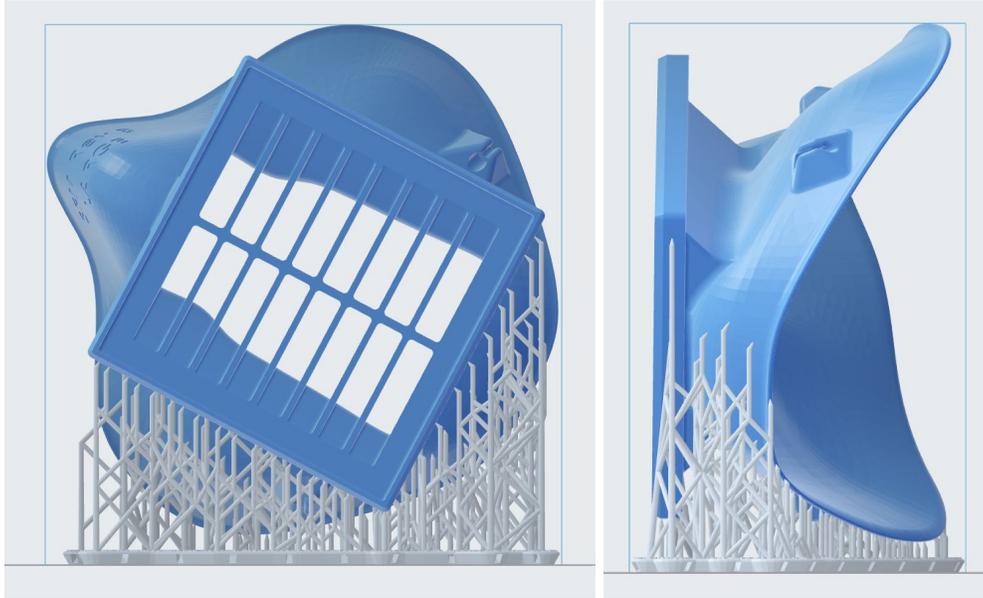
1. Form 2 or Form 3B Printer
2. BioMed Clear Resin and compatible resin tank
3. Build Platform
4. Form Wash and 99% IPA
5. Form Cure

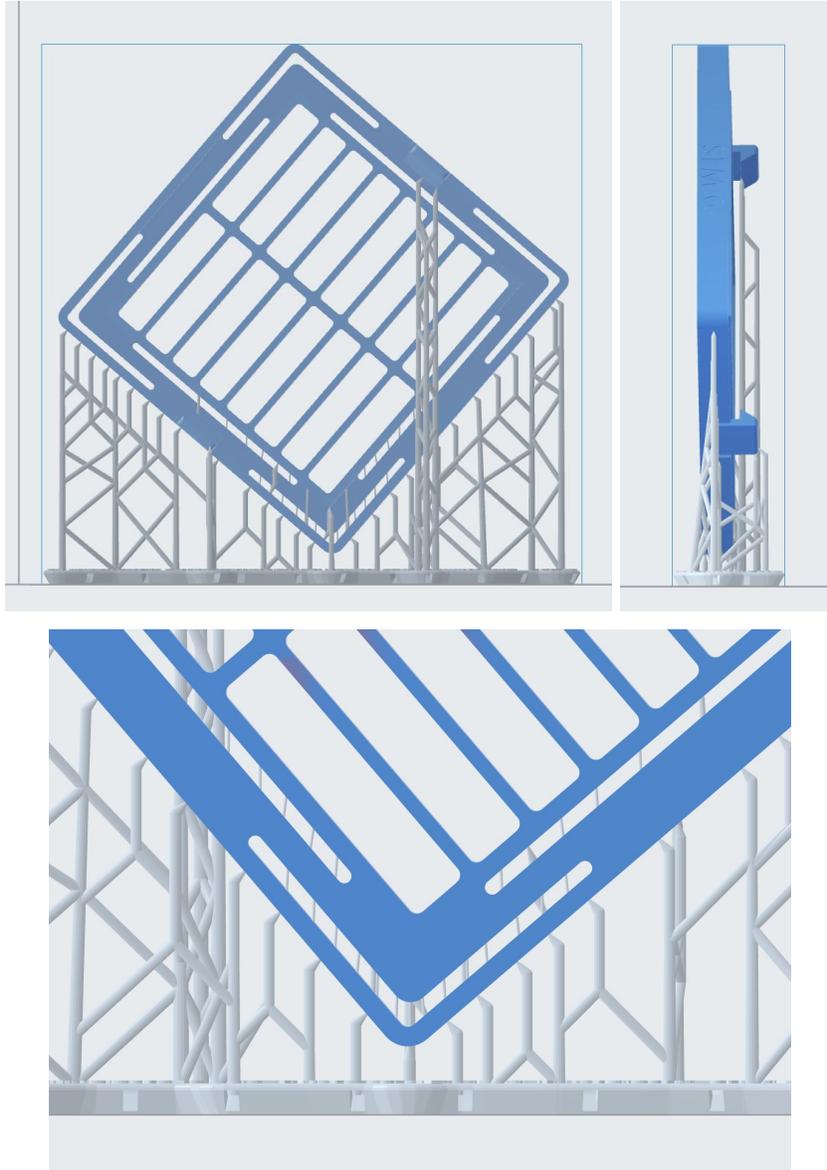
Pre-Print

1. Select a Form 2 or Form 3B printer.
2. Download the STL files or .form files from the NIH 3D print exchange website or access the .form files in different sizes here: [small](#), [medium](#), and [large](#). Orient the parts on their side and auto-generate supports at 1.00mm density and 0.3mm support touchpoints with a full raft. Print at 100um layer height. Remove and add supports as desired. Minimal supports are needed on the front cover portion of the mask, if oriented at an angle.
 - a. Parts should be printed at 100um.

TIP: Avoid adding supports to the inside of the mask, where skin contact is highest, by disabling “Internal Supports”. When oriented on its side, this model does not require any internal supports.

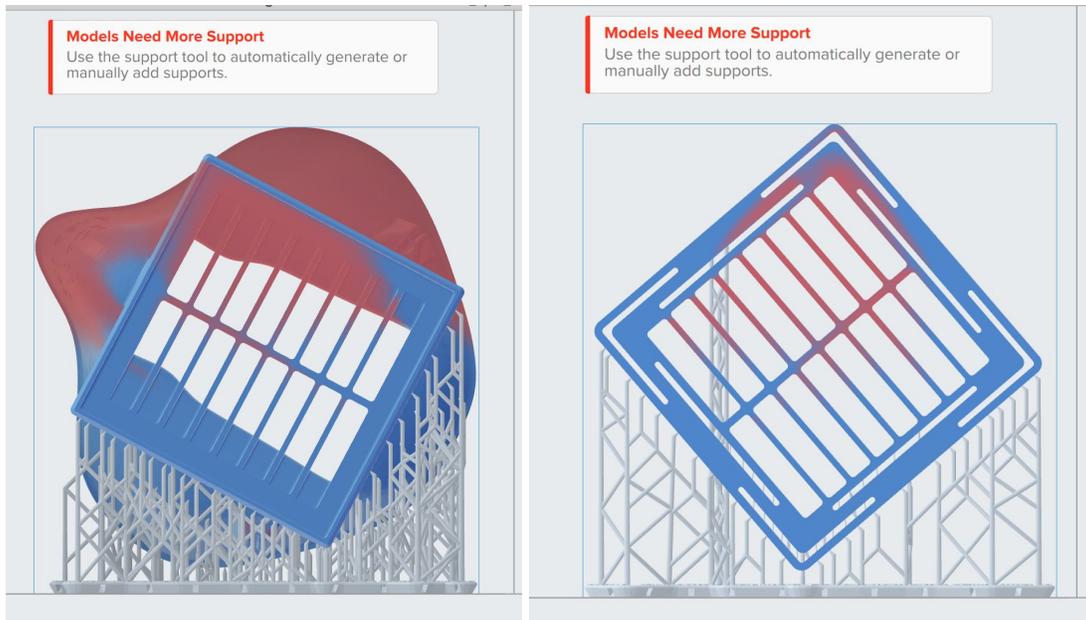
TIP: Layout the mask and cover models perpendicular to the “Mixer Side” message in PreForm to reduce forces on the part.





Oriented parts in PreForm Software

CAUTION: PreForm may show the message “Models Need More Support” in this orientation. This is OK and will not prevent the print from uploading or starting. Formlabs has found that models in this orientation with sufficient support structures are repeatedly printable.



3. Insert a cartridge of BioMed Clear Resin. If using a Form 2, insert an LT Resin Tank.

Printing

1. If necessary, using a “PEC” pad, clean the optical window and underside of the Resin Tank associated with the selected printer.
2. Use only build platforms designated for use with BioMed Clear Resin.
3. Print parts.



Printed parts

Washing

1. Gently remove the parts from the build platform.
2. Wash the parts in a Form Wash using clean 99% IPA for 15 then soak the parts in clean 99% IPA for 5 minutes.
 - a. Form Wash should be clean and unused of any resin besides BioMed Clear Resin. This includes the IPA as well as the entire Form Wash itself.
3. After cleaning, allow the parts to dry for at least 30 minutes.
4. Inspect parts to ensure no uncured resin remains after the wash cycle.
5. Check wash IPA every 10 full wash cycles to ensure it is not saturated with resin. If it is, replace it with fresh 99% IPA. If you suspect the IPA may be saturated, use the hydrometer to check.

Curing

NOTE: Follow Formlabs post-cure instructions to ensure biocompatibility. Uncured resin may result in a non-biocompatible part.

1. Verify that the Form Cure is cooled to room temperature (50°C or lower).
2. Insert parts into the Form Cure.
 - a. Ensure cover parts and the filter portion of the mask are lying flat on the baseplate of the Form Cure. If they are stacked on top of each other, they may warp during the cure cycle.
3. Post cure the parts according to the following parameters:
 - a. BioMed Clear Resin:
 - i. Form 2/3B Parts: 60°C for 60 minutes

Assembly

Check the NIH 3D Print Exchange for the most up-to-date assembly instructions and IFU.

Cleaning, Disinfection, and Sterilization

CLEANING

1. Fully post processed parts can be cleaned using a dedicated soft brush with neutral soap and room temperature water.
2. Do not use any abrasive cleaning products on parts printed with BioMed Clear Resin. Such cleaning products may adversely affect surface finish.
3. After cleaning, always inspect parts for any cracks. Discard if any damage or cracks are detected.

DISINFECTION

Parts may be disinfected in 70% IPA for 5 minutes.

STERILIZATION

Information on the sterilization process and testing for BioMed Clear Resin can be downloaded from [this link](#).