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Last Edited: 06/22/2020
Version 1.0

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 part and is certified biocompatible.

BioMed Clear Resin is non cytotoxic, not a sensitizer, non irritating and complies with ISO 10993-1:2018.

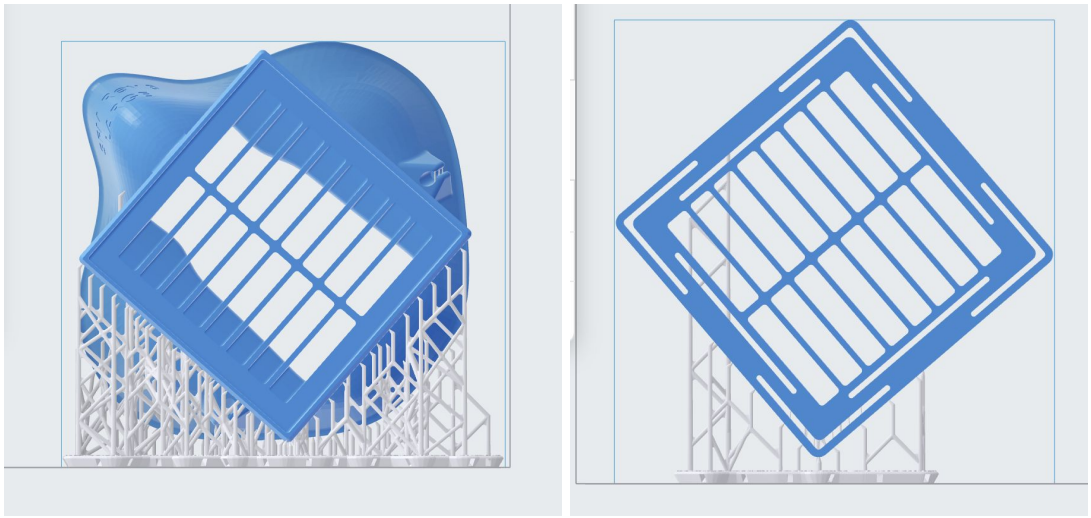
NOTE: Only clean Formlabs Resins with soap and water. Cleaning with other solvents may result in material property degradation. Ensure this is suitable for your facility before commencing manufacturing.

Required Materials

1. Form 2 or Form 3/3B 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 3/3B printer.
2. Download your STL from the Bellus3D app. 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.
    a. Parts should be printed at 100um.

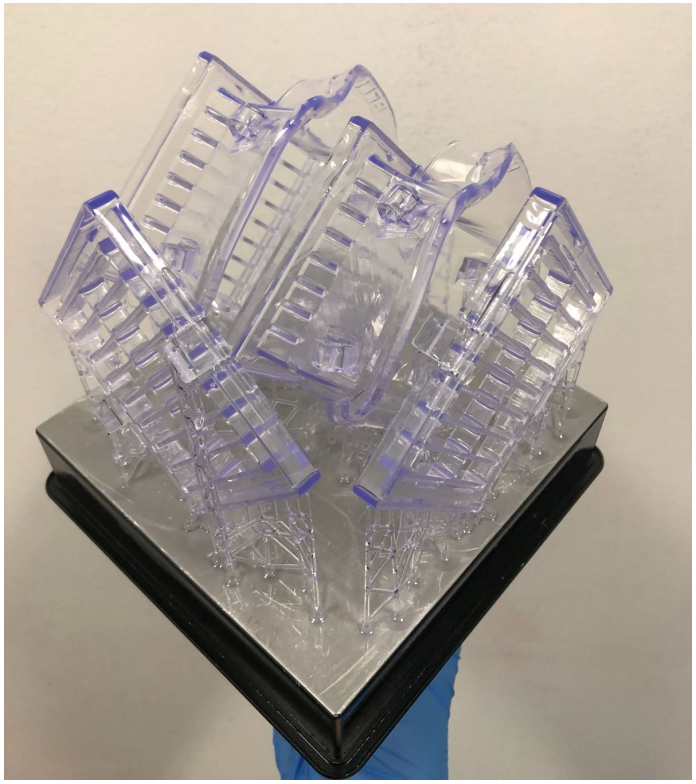


Oriented parts in PreForm Software

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 Surgical Guide 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 20 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 (50C 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: 80C for 20 minutes

Assembly

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

Part Care

Formlabs 3D printed parts can be gently cleaned with soap and water. Cleaning with other solvents such as Super Sani Wipes or CaviWipes has not been tested and should be performed at your own risk.

BioMed Clear Resin is autoclavable, but has not been tested for degradation of mechanical properties after more than one autoclave cycle.