Test Sample Preparation

FDM Biocompatibility Testing of ABS-M30i and PC-ISO-T

Any customer seeking to use a Fortus™ system to print biocompatible materials must take precautions to eliminate risks of cross-contamination. Stratasys recommends dedicating the system to one material type upon initial installation.

It is recommended that parts printed using bio-compatible materials are not made on a machine that has run FDM® Nylon 12CF or any electrostatic dissipative or other composite materials.

If you choose to convert your system to a controlled printer as documented below, switching materials is not recommended. Below are the procedures and steps Stratasys took when preparing the printer, printing the part and post-processing them prior to having the test cubes tested for biocompatibility.

The following procedure outlines the test sample preparation process for ABS-M30i™ and PC-ISO™-White, and PC-ISO T materials. We recommend that you contact Stratasys and schedule the Fortus system part replacements with a Stratasys certified technician. They will be able to provide all the parts required for your printer.

Biocompatibility test geometries Stratasys printed were: 3.2 x 3.2 x 3.2 mm cubes.

Procedure

Setup

1. Select one 3D printer system for building the sample (Fortus 360mc™, Fortus 400mc™, Fortus 380mc™ or Fortus 450mc™).
2. Verify the system dryer is working properly.
3. Unload any existing material that may be in the printer.
4. Allow the printer to cool to room temperature.
5. Remove the drip tray from the printer. (We also recommend using a separate drip tray for biocompatible materials.)
6. Clean out/vacuum the printer's door and build chamber.
7. Install new material filament tubes.
8. Replace the Kapton barriers located on the purge buckets. (We also recommend that you replace these additional parts: Y Blocks, Drive blocks.)
9. Install new T16/T12SR30 tips.
10. Insert new build sheets as appropriate for the model material you will be printing. (We also recommend that you wipe the build trays with IPA and a lint free cloth, and allow to thoroughly dry before printing.)

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Calibration

1. Check the moisture levels of the material filament canisters.
2. Document the serial number, lot number and date of the canisters.
3. Install and document the latest released Insight™ software version.

Post-Build

1. After the test sample build is complete, allow the printer to thermally stabilize overnight.
2. Handle the completed test samples with latex-free clean gloves and tools.
3. Verify the post-build moisture content of the canisters used to build the test samples
4. Ensure the support removal tank was cleaned and fresh solution has been added.
5. Immerse the test samples in the support removal tank for eight hours to dissolve the support material or break away the support materials for PC-ISO.
6. Rinse with fresh water and air dry.

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