Biocompatibility Requirements

EPU 40 Printing & Processing Protocols for Carbon M Series Printers

The protocols described in this document were tested by Carbon for printing parts from EPU 40 material so that they are suitable for prolonged skin contact (more than 30 days).

Follow the instructions in this document when using EPU 40 on Carbon M1 and M2 printers to ensure biocompatibility of the resulting part.

Resin Dispensing

EPU 40 is a two-component material supplied in a dual-chamber, light-resistant cartridge. At print time, the A and B components are mixed in a 10:1 ratio using a static mixer tip attached to the end of the cartridge which installed into a Albion motorized dispensing unit. It is suggested that the initial volume (~5 mL) of resin is burned into a waste container to prevent off-stoichiometry. An appropriate volume of the mixed resin (as specified by the print planner software) is then dispensed into the printer cassette and the cassette is placed on the optical deck.

Note: When switching between materials, the cassette should be cleaned with IPA to ensure that residual resin from the previous print is not mixed with the EPU 40 material. For additional information, see the "Cleaning the cassette" section of the User's Guide.

Printing

A cleaned build platform is installed onto the Z-stage and the print process initiated by uploading a suitable STL, entering run parameters (resin type, print orientation, support construction, etc.) and requesting print initiation. Print speed and light intensity are controlled by Carbon's proprietary software to ensure part accuracy and degree of UV network cure.

Part Removal from Build Platform

Once the "green" state part (only the UV network is cured) is built, the build platform is removed from the printer, the part gently removed from the build platform using a variety of scrapers, tweezers and blades.

Washing

Remove excess resin using sponge swabs and wipes and with compressed air (in a cabinet).

Wash the parts with mild agitation in **Vertrel XM™**, an azeotropic mixture of 1,1,1,2,2,3,4,5,5,5-Decafluoropentane and methanol (91-93 to 9-7, w/w, Chemours™) for 3 to 5 minutes. Agitation can be achieved by placing the parts in a stainless steel small-parts basket and rotating the basket at 5-20 rpm in sufficient Vertrel XM™ to cover or using the Carbon Smart Part Washer. In the latter case, the washer will provide the proper wash cycle.

For additional information, see the "Washing parts" section of the User's Guide.

Support Removal

Supports can be removed prior to washing or after the wash and cure cycles. To remove support material from the printed part use clean tweezers or clean protective gloves.

For additional information, see the "Removing supports" section of the User's Guide.

Thermal Cure

Place the parts on a non-stick tray. Then place the tray in a clean, dedicated convection oven at 120°C for 8 hours.

Biocompatibility Testing

Parts printed and processed as outlined in this document were provided to NAMSA for evaluation in accordance with ISO 10993-5, *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*, and ISO 10993-10, *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (specifically the Closed Patch Sensitization Study)*. The results for all tests indicated that EPU 40 passed the requirements for biocompatibility according to the above tests. Carbon makes no representation and is not responsible for the results of any biocompatibility tests other than those specified above.

Disclaimer
Biocompatibility results may vary if protocols are used other than those outlined in this document.

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