Biocompatibility Requirements

CE 220: Printing and Processing Protocols for Carbon M Series Printers

The protocols described in this document were tested by Carbon for printing parts from CE 220 material so that they are suitable for prolonged skin contact (more than 30 days) and short-term mucosal-membrane contact (up to 24 hours).

Follow the instructions in this document when using CE 220 on Carbon M1 and M2 printers to ensure biocompatibility of the resulting part.

Resin Dispensing

CE 220 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 1:1 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 CE 220 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.

Initial Wash

To remove excess resin from the part after printing, complete the following steps:

- Wash the part in an orbital shaker for 30 seconds in a 50/50 isopropanol (IPA)/deionized water (DI) mixture
- Immerse the part in 99/1 IPA/DI for less than 3 seconds to displace water from surface of part
- Remove excess resin using foam swabs and/or air spray

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.

Initial Thermal Cure

Place the parts on a non-stick tray. Then place the tray in a dedicated programmable oven in an air atmosphere and initiate the cure program (2 hours total).

- Place in programmable oven
- Ramp from room temperature to 95° C over 60 minutes
- Hold at 95°C for 60 minutes
- Leave parts in oven to cool for 30 minutes
- Remove from oven

Secondary Wash

- Wash parts in 50/50 IPA/DI for 60 seconds in orbital shaker
- Immerse part in 99/1 IPA/DI for less than 3 seconds to displace water from surface of part
- Immediately dry with compressed air in cabinet

Secondary Thermal Cure

Place the parts on a non-stick tray. Then place the tray in a dedicated programmable oven in an air atmosphere and initiate the cure program (8+ hours total).

- Place in programmable oven
- Ramp from room temperature to 95°C over 60 minutes
- Hold at 95°C for 60 minutes
- Ramp to 120°C over 60 minutes
- Hold at 120°C for 30 minutes
- Ramp to 180°C over 2 hours
- Hold at 180°C for 60 minutes
- Ramp to 200°C over 60 minutes
- Ramp to 220°C over 45 minutes
- Let cool to room temp (typical time in recommended oven is 4 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 (GPMT)*. The results for all tests indicated that CE 220 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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