

Biocompatibility Requirements

RPU 70: Printing & Processing Protocols for Carbon M Series Printers

The protocols described in this document were tested by Carbon for printing parts from RPU 70 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 RPU 70 on Carbon M1 and M2 printers to ensure biocompatibility of the resulting part.

Resin Dispensing

RPU 70 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 is 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 isopropanol (IPA) to ensure that residual resin from the previous print is not mixed with the RPU 70 material. For additional information, see the "Cleaning the cassette" section of the User's Guide.

Printing

A cleaned build platform is installed onto the platform latch 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 4 hours.

Biocompatibility Testing

Parts printed and processed as outlined in this document were provided to NAMSA and Pacific BioLabs 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 RPU 70 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.

Subscriber acknowledges the contents of this document are subject to the Terms and Conditions outlined in the Subscription Agreement, including the Restrictions on Use section.

DO NOT USE CARBON MATERIALS IN MEDICAL APPLICATIONS INVOLVING IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED FROM CARBON UNDER A WRITTEN CONTRACT THAT IS CONSISTENT WITH THE CARBON POLICY REGARDING MEDICAL APPLICATIONS AND EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE. CARBON MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THESE MATERIALS FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH BODY FLUIDS OR TISSUES.

If Carbon has permitted in the Subscription Agreement use of the Carbon printer for applications that require biocompatibility, Subscriber acknowledges that it is the responsibility of Subscriber, its respective customers and end-users to determine the biocompatibility of all printed parts for their respective uses.

Carbon, Inc. | www.carbon3d.com

1089 Mills Way

Redwood City, CA 94063

1 (650) 285-6307