

Biocompatibility Requirements

EPU 41 Resin: Printing & Processing Protocols for Carbon M-Series Printers

The protocols described in this document were used by Carbon for printing parts from EPU 41 Resin material that were evaluated and found to meet the requirements of ISO 10993-5 and ISO 10993-10.

Resin Dispensing

EPU 41 Resin is a two-component material with each part supplied in a jerry can. At print time, an appropriate amount of the A and B components (as specified by the print planner software) are weighed in a mixing container at 13:1 weight ratio and mixed using a planetary mixer. The mixed resin is then transferred 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 EPU 41 Resin. For additional information see the "Cleaning the cassette" section of the User 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 is gently removed from the build platform using a variety of scrapers, tweezers and blades.

Washing

Remove excess resin using sponge swabs, wipes and compressed air (in a blow-off 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 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 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)*. These tests are typically performed in order to establish suitability of materials in prolonged skin contact (greater than 30 days). The results for all tests indicated that EPU 41 Resin 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