

## Biocompatibility Requirements

### UMA 90 Gray Resin Printing & Processing Protocols for Carbon M Series Printers

The protocols described in this document were tested by Carbon for printing parts from UMA 90 Gray resin 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 UMA 90 resin on Carbon M1 and M2 printers to ensure biocompatibility of the resulting part.

#### Resin Dispensing

UMA 90 Gray resin is a single-component material supplied in an 800 mL or 3.2 L black plastic jug. An appropriate volume of the resin (as specified by the print planner software) is poured into the printer cassette and the cassette 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 UMA 90 Gray resin. 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 part 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.

#### Support Removal

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

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

#### Washing/UV Post-Cure

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. Samples are then placed on a clean non-stick tray and cured in a Dymax Model 5000-ECE UV flood cure chamber for 120 sec each side. The above process is repeated once for a total of 240 seconds of UV flood cure on both surfaces.

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

## 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 UMA 90 Gray 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.

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