

## Terms of Use and Maintenance

### Printing Bio-compatible Parts on Objet 3D Printers with MED610™

The methods and conditions described in this document were tested at Stratasys for printing parts from MED610 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 these instructions when using MED610 to print bio-compatible parts.

#### Printers and Printing Modes

The following Objet 3D printers and printing modes are supported.

Printer Model	Printing Mode
Objet30 OrthoDesk	—
Objet30 Prime	High Speed only
Eden250/260/260V	High Speed and High Quality only
Eden350/350V/500V	
Objet260 Connex	
Connex350/500	
Objet260 Connex1/2/3	
Objet350 Connex1/2/3	
Objet500 Connex1/2/3	

#### Head Cleaning

Clean print heads daily, using the Head Cleaning Wizard.

Refer to the printer user guide, “Cleaning the Printing Heads” section.

#### Ultraviolet (UV) Intensity Check/Calibration

Check UV lamp intensity once a week, and calibrate, if necessary. Perform the UV calibration described in the document *UV Lamp Calibration*, supplied with your UV measurement device.

Optimum UV intensity ensures that models are cured properly.

If you do not have a UV measurement device, contact your Stratasys distributor or Stratasys Customer Support representative.

#### Material Replacement

When switching from a material that is not bio-compatible to MED610, run the Resin/Material Replacement Wizard as described in the following table\*.

Printer Model	Printer Software Version	Resin/Material Replacement Cycle	No. of Cycles
Eden250	25.0.0.5	Short cycle	5
Eden260	26.0.0.2		
Eden260V	27.0.1.16		
Eden330	33.0.0.2		
Eden350	35.0.0.1		
Eden350V	36.0.1.14		
Eden500V	50.0.1.14		
Connex350	37.0.0.33	Single cycle (Single Material Printing Mode)	5
Connex500	57.00.032		

Printer Model	Printer Software Version	Resin/Material Replacement Cycle	No. of Cycles
Objet30 OrthoDesk	30.2.1.12914 and above	High-performance	1
Objet30 Prime	33.2.0.18254 and above		
Eden500V	50.3 and above		
Eden350V	36.3 and above		
Eden260V	27.3 and above		
Objet260 Connex	28.1 and above	High-performance (Single Material Printing Mode)	1
Connex350	37.1 and above		
Connex500	57.1 and above		
Objet260 Connex1/2/3	29.1 and above	Full (Single Material Printing Mode)	1
Objet350 Connex1/2/3	38.1 and above		
Objet500 Connex1/2/3	58.1 and above		

\* Check up-to-date information on supported printer software versions and the material replacement methods applicable to them at [www.stratasys.com](http://www.stratasys.com) > *Materials* > *Bio-Compatible*.

## SUP705 Support Removal

The following instructions apply to SUP705 Support material only.

When removing SUP705 Support material from the printed part, ensure that all work spaces are clean and free of residue from other materials.

Before placing MED610 parts in the WaterJet, clean the WaterJet cabinet thoroughly. Remove all material residue and particles.

Follow this procedure exactly as described below.



**Caution:** Wear clean (new) protective gloves when handling printed parts at each phase, as described below. Touching them with your bare hands can contaminate the parts.

1. Clean printed parts thoroughly (10 rinses on each side) in the WaterJet.
2. Put on *new* protective gloves and remove the parts from the WaterJet.
3. Soak the parts in a container with a freshly prepared 1-percent solution of caustic soda (sodium hydroxide), for three (3) hours at room temperature. (No stirring is required.)



**WARNING:** Caustic soda may cause chemical burns, scarring and blindness. Mixing it with water generates heat that could ignite other materials. Never pour water into a caustic soda solution. When diluting the solution, always add caustic soda to water. Take adequate safety precautions; always use nitrile gloves when handling caustic soda and models soaked in it.

4. Discard the protective gloves that were in contact with caustic soda.
5. Put on *new* protective gloves.
6. Place the parts in a clean container and place the container in the WaterJet.  
The container ensures that parts do not come in contact with any residue in the WaterJet cabinet.
7. Remove and discard the protective gloves.
8. Clean the parts thoroughly (10 rinses on each side) in the WaterJet.
9. Put on *new* protective gloves and remove the parts from the WaterJet.
10. Rinse the parts thoroughly under running water.
11. Soak the parts in a container of analytical-grade isopropanol (IPA—*isopropyl alcohol*) for 30 minutes at room temperature. (No stirring is required.)
12. Using clean tweezers or protective gloves, carefully remove the parts and place them on a clean cloth.

13. Allow the parts to dry at room temperature in the open air for two hours.

**Note:** To prevent the parts from absorbing IPA residue, **do not** place them in a closed container or bag until the IPA evaporates completely.

### Printing Tips

For additional information and printing tips, refer to the relevant MED610 Application Note.

### Biocompatibility Testing

Parts printed and handled as described in this document were evaluated for biocompatibility in accordance with DIN EN ISO 10993-1: 2009, *Biological evaluation of medical devices-Part 1: Evaluation and Testing within a risk management process*. These tests address cytotoxicity, genotoxicity, delayed hypersensitivity, and USP plastic Class VI that includes tests for irritation, acute systemic toxicity and implantation.

**Important:** Bio-compatibility tests were not performed on parts treated after printing (lacquering, polishing, etc.).

### Disclaimer

Customer acknowledges the contents of this document and that Stratasys parts, materials, and supplies are subject to its standard terms and conditions, available on <http://stratasys.com/legal/terms-and-conditions-of-sale>, which are incorporated herein by reference.

When utilizing MED610, it is the responsibility of the customer, its respective customers and end-users to determine the biocompatibility of all of the components, printed parts, and all other materials used in the finished product for their respective purposes, including prolonged skin contact (of more than 30 days) and short-term mucosal-membrane contact (of up to 24 hours). Results may vary if different conditions apply other than those existing at Stratasys laboratories during testing and those applied for the purposes of biological testing under the procedures and provisions of EN ISO 10993-1:2009, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process."

If you have any questions about MED610, please contact your Stratasys distributor or Stratasys Customer Support representative.