

Biocompatibility Requirements

Printing Biocompatible Parts on PolyJet™ 3D Printers with MED625FLX™, CL: Flexible Clear Biocompatible Material

The methods and conditions described in this document were tested at Stratasys for printing parts from MED625FLX™, CL material so that they are suitable:

- for long term (more than 30 days) contact to intact skin.
- for limited (up to 24 hours) contact to mucosal-membranes and breached or compromised surface.
- for limited (up to 24 hours) contact to tissue and bone (via external communication or implantation).

Important: Customer Responsibility

When utilizing MED625FLX, CL material, it is the responsibility of the customer, its respective customers and end-users to determine the biocompatibility of all the components, printed parts, and all other materials used in the finished product for their respective purposes, including long term (more than 30 days) contact to intact skin, limited (up to 24 hours) contact to mucosal-membranes and breached or compromised surface, and limited (up to 24 hours) contact to tissue and bone (via external communication or implantation). Results may vary if different conditions were applied 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 10993-1:2018 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process", as well as FDA Guidance "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process", dated 16. June 2016.



Make sure that you follow the instructions below when using MED625FLX to print biocompatible parts.

Printers and Printing Modes

The following PolyJet™ 3D printers and printing modes are supported.

Printer Model	Printing Mode
Objet260 Dental™	<ul style="list-style-type: none"> • High Speed • Digital Material
Objet260 Dental Selection™	
Objet500 Dental Selection™	
J720™ Dental	High Speed
J850™ Digital Anatomy™	
J5 DentaJet™	<ul style="list-style-type: none"> • High Quality Speed • High Quality High Speed • Long Print
J3 DentaJet™	<ul style="list-style-type: none"> • High Quality Speed • High Quality High Speed • Long Print

Printing and Material Loading Guidelines

Follow these guidelines to ensure that the print parts are biocompatible:

- Printing mixed trays—
 - Do not print biocompatible and non-biocompatible materials on the same tray.
 - You can print parts made of different biocompatible materials on the same tray on dental printers.
- Printing mixed parts—

Do not print parts that are made of mixtures of materials, including biocompatible materials.
- Objet260/500 printers—
 - If you mostly print non-biocompatible parts (for example, using Vero materials) in single-material mode (HS or HQ) and only occasionally print biocompatible parts, reserve the M3 cartridge slots (R&L) for the biocompatible material. This setup enables you to easily switch to printing with the biocompatible material using DM mode and eliminates the need for system flushing.
 - If you mostly print biocompatible parts in single-material mode (HS or HQ) and only occasionally print non-biocompatible parts, reserve the M3 cartridge slots (R&L) for the non-biocompatible material (for example Vero materials). This setup enables you to easily switch to printing with the biocompatible material using DM mode and eliminates the need for system flushing.
- For J720 Dental and J850 Digital Anatomy printers—

To eliminate the need for system flushing, it is recommended to load biocompatible cartridges in the even-numbered Model cartridge slots (M2, M4, M6) or in the odd-numbered Model cartridge slots (M1, M3, M5).
- J5 DentaJet printers—
 - Models printed on this printer must have a matte surface finish.
 - Do not load MED625FLX in M5 in the material cabinet.

Routine Cleaning

- Daily cleaning routine—

Perform the cleaning wizard to clean the following printer components:

 - Print heads
 - Roller surface
 - Wiper
 - UV lamp
 - Build tray and its surrounding areas

Refer to “Cleaning the Print Heads, Roller and Wiper” in the printer user guide.
- For all printers, except J5 DentaJet, after printing with a non-biocompatible material—

Clean the roller and roller waste collector.

Refer to the following printer user guide sections: “Cleaning the Print Heads, Roller and Wiper” and “Cleaning the Roller Waste Collector and Inspecting the Roller Scraper.”

Ultraviolet (UV) Intensity Check/Calibration (all printers, except J5 DentaJet)

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 biocompatible to MED625FLX, run the Material Replacement Wizard as follows:

Printer Model	Material Replacement Instructions
Objet260 Dental	<ol style="list-style-type: none"> 1. Select Single material for both cartridges and run the <i>Full</i> flushing cycle. 2. Open the Material Replacement wizard again. 3. In the <i>Material Replacement Options</i> screen, select Advanced Settings. 4. Select “Flush again” options and click Apply. 5. In the <i>Material Replacement Options</i> screen, select Flush again and click Next. 6. Click Start to run the wizard.
Objet260 Dental Selection	
Objet500 Dental Selection	
J720 Dental	
J850 Digital Anatomy	
J5 DentaJet	<p>To switch to biocompatible materials, run the Material Replacement wizard 3 times, as follows:</p> <ol style="list-style-type: none"> 1. Run the Material Replacement wizard. For the selected channel, in the <i>Material Selection</i> screen, select the biocompatible material. For example, select MED625FLX. 2. Run the Material Replacement wizard again. For the selected channel, in the <i>Material Selection</i> screen, select the same biocompatible material. For example, select MED625FLX again. 3. Repeat step 2.
J3 DentaJet	

Support Removal with Water Pressure—SUP711™/SUP705™/SUP705B™

The following instructions apply to the removal of Support material using a waterjet.

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

Before placing MED625FLX 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. Alternatively, place the parts in a clean, dedicated oven at 30°C (86°F) for 15 minutes.
Note: To prevent the parts from absorbing IPA residue, **do not** place them in a closed container or bag until the IPA evaporates completely.

Sterilization of Printed Parts

If sterilization of MED625FLX parts is required, perform one of the following sterilization methods:

- *Steam sterilization* for four (4) minutes at 132°C (270°F) with fractionated pre-vacuum. Allow the parts to cool down to room temperature before removing them from the autoclave.



Caution:

Flash autoclave may cause part deformation (geometry dependent) and may slightly modify the mechanical properties.

- *Gamma sterilization* using a dose of 25–50 kGy.



Caution:

Gamma radiation causes a change in the color of MED625FLX parts.



Important: Sterilization Methods

When sterilizing printed parts according to the Sterilization Methods mentioned above, it is the responsibility of the customer, its respective customers, and end-users to verify and determine that part is sterile and to control the process. Stratasys assumes no responsibility with regards to this. Additionally, Stratasys does not make any verification that following the performance of the Sterilization Methods mentioned above the printed part will indeed be sterile.

Biocompatibility Testing and Assessment

Parts printed and handled as described in this document were evaluated for biocompatibility in accordance with EN ISO 10993-1:2018 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process”, as well as FDA Guidance “Use of International Standard ISO 10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process’”, dated 16 June 2016. These tests address cytotoxicity, genotoxicity, delayed hypersensitivity, and USP plastic Class VI that includes tests for irritation, acute systemic toxicity, and implantation.



Important:

Biocompatibility tests were not performed on parts treated after printing (lacquering, polishing, etc.).

Other Terms

Customer acknowledges and accepts the contents of this document and that the provision by Stratasys and/or the use of goods, materials, and supplies are subject to its standard terms and conditions, available on <http://www.stratasys.com/legal/terms-and-conditions-of-sale>, which are incorporated herein by reference. If you have any questions about material or process, please contact your Stratasys distributor or Stratasys Customer Support representative.

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