

Biocompatibility Requirements

Printing Biocompatible Parts on PolyJet™ 3D Printers with MED610™, Rigid Clear Biocompatible Material

The methods and conditions described in this document were tested at Stratasys for printing parts from MED610™ material so that they are suitable for permanent (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).

Important: Customer Responsibility



When utilizing MED610, it is the responsibility of the customer, its respective customers and end-users to determine the sterilization and biocompatibility of all the components, printed parts, and all other materials used in the finished product for their respective purposes, including permanent (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 MED610 to print biocompatible parts.

Printers and Printing Modes

The following Objet® Eden™ and Connex™ series 3D printers are supported.

Printer Model	Printing Mode
Objet30 OrthoDesk™	—
Objet30 Prime™	<ul style="list-style-type: none"> • Draft
Objet30 Dental Prime™	<ul style="list-style-type: none"> • High Speed • High Quality
Eden250™/Eden260V™/ Eden260™ VS/Dental Advantage™	<ul style="list-style-type: none"> • High Speed
Eden350™/Eden350V™/Eden500V™	<ul style="list-style-type: none"> • High Quality
Objet260 Connex™	<ul style="list-style-type: none"> • High Speed • High Quality • Digital Material
Connex350™/Connex500™	
Objet260 Connex1,2,3™	
Objet260 Dental™	
Objet260 Dental Selection™	
Objet350 Connex1,2,3™	
Objet500 Connex1,2,3™	
Objet500 Dental Selection™	

Printing and Material Loading Guidelines for Connex Printers

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

- Do **not** print biocompatible and non-biocompatible parts on the same tray.
- To print mixed trays (DM mode) with 2 biocompatible materials:
 - If you print *only* biocompatible jobs, load one biocompatible material in the M1 or M2 cartridge slots; load the other biocompatible material in the M3 cartridge slots.
 - If you switch between *biocompatible* and *non-biocompatible* print jobs, load one biocompatible material in the M1 cartridge slots; load the other biocompatible material in M2 cartridge slots. In the M3 cartridge slots, you can load a non-biocompatible material that you typically use.
- 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.

Head Cleaning

Clean print heads daily, using the Head Cleaning Wizard.
Refer to “Cleaning the Printing Heads” in the printer user guide.

Roller and Roller Waste Collector Cleaning

Clean the roller and roller waste collector after printing with a material that is not biocompatible.
Refer to the following printer user guide sections: “Cleaning the Print Heads and the Roller” and “Cleaning the Roller Waste Collector and Inspecting the Roller Scraper.”

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 biocompatible to MED610, run the Resin/Material Replacement wizard as described in the following table.

Printer Model	Number of Resin/Material Replacement Cycles
Objet30 OrthoDesk	1 High-performance cycle
Objet30 Prime	
Objet30 Dental Prime	
Eden250	5 Short/Single cycles Or— 1 High-performance cycle
Eden260V/260VS/Dental Advantage	
Eden350	
Note: In Connex printers, use the Single-Material Printing mode.	

Printer Model	Number of Resin/Material Replacement Cycles
Eden350V	5 Short/Single cycles Or— 1 High-performance cycle Note: In Connex printers, use the Single-Material Printing mode.
Eden500V	
Objet260 Connex (Connex260)	
Connex350	
Connex500	
Objet260 Connex1/2/3	To ensure biocompatibility of parts printed on these printers, refer to “Changing the Printing Material” in the printer user guide.
Objet260 Dental	
Objet260 Dental Selection	
Objet350 Connex1/2/3	
Objet500 Connex1/2/3	
Objet500 Dental Selection	

Support Removal

Support material must be removed using one of the methods described in this section.

- with water pressure (SUP705™, SUP706™, and SUP706B™)
- with caustic soda and sodium metasilicate solution (SUP706 and SUP706B only)
This method requires a neutralization process after the Support material is removed.

Support Removal with Water Pressure | SUP705, SUP706, SUP706B


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

When removing 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. 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.

Support Removal with Caustic Soda and Sodium Metasilicate Solution | SUP706, SUP706B

This procedure applies to parts printed with SUP706 and SUP706B that are soaked in an alkaline solution of 2% NaOH and 1% Na₂SiO₃, for up to 24 hours.

1. Remove the Support material with a 2% NaOH and 1% Na₂SiO₃ solution. For instructions, refer to the “SUP706 Support Removal” application note.
2. After removing the Support material, neutralize the parts as follows:

Important:

- Before you begin this procedure, make sure that all the Support material has dissolved and that the parts are *completely* free of Support material residue.
- Make sure that all work spaces are clean and free of residue from other materials.

- a) Put on *new* protective gloves and remove the printed parts from the cleaning station.
- b) Fill a container with domestic vinegar (CAS 8028-52-2). Alternatively, you can use a 5% acetic acid solution.
- c) Place the parts in the container and make sure that they are completely immersed in the vinegar and that the vinegar fills all cavities.
- d) Stir gently for approximately 1 minute.
- e) Remove the parts from the vinegar and rinse each part separately under running water for approximately 1-2 minutes. If a printed part has internal cavities, it is recommended that you soak it in water for an additional 5 minutes.

Note: To effectively neutralize the parts, the vinegar must have a pH of 2-3. After soaking several parts in the vinegar, check the pH of the vinegar using a pH test strip. If the pH is not 2-3, replace the vinegar in the container.

- f) Soak the parts in a container of analytical-grade isopropanol (IPA—*isopropyl alcohol*, CAS 67-63-0) for 30 minutes at room temperature. (No stirring is required.)
- g) Using clean tweezers or *new* protective gloves, carefully remove the parts and place them on a clean cloth.
- h) 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 MED610 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 deformations (geometry dependent) and reduced flexural strength.

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



Caution:

Gamma radiation causes a change in the color of MED610 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.

Printing Tips

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

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.

Stratasys | www.stratasys.com | info@stratasys.com

7665 Commerce Way Eden Prairie, MN 55344 +1 888 480 3548 (US Toll Free) +1 952 937 3000 (Intl) +1 952 937 0070 (Fax)	1 Holtzman St., Science Park, PO Box 2496 Rehovot 76124, Israel +972 74 745-4000 +972 74 745-5000 (Fax)
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