Biocompatibility Requirements

Printing Biocompatible Parts on PolyJet™ 3D Printers with *MED Digital ABS™ Biocompatible Material*

The methods and conditions described in this document were tested at Stratasys for printing parts from MED Digital ABS™ 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:
When utilizing MED Digital ABS 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 10993-1:2020 “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 September 8, 2023.

Make sure that you follow the instructions below when using MED Digital ABS to print biocompatible parts.

Printers and Print Modes

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

Printer Model	Print Mode	Support Material
Objet260 Connex3™	• Digital Materials (DM mode)	SUP705/SUP705B/SUP706B
Objet350 Connex3™		
Objet500 Connex3™		
J735™	• High Speed • High Quality • High Mix	SUP705/SUP705B/SUP706B
J750™		
J750™ Digital Anatomy™		
J850™ Digital Anatomy™		
J5 MediJet®	• High Quality Speed • Long Print • High Speed	SUP710/SUP710S
J5 Digital Anatomy™	• High Quality Speed • High Speed • Long Print	SUP710S

Printing and Material Loading Guidelines

- MED Digital ABS is fabricated using two material components: MED515S and MED531S. The material components are loaded in the material cabinet and selected in the software as part of the fabrication process.
- Printing parts and trays—

Part and Tray Combinations	J5 MediJet and J5 Digital Anatomy Printers	All Other Printers
Mixed Tray with parts made of different single biocompatible materials*	✓	X
Mixed Part with different biocompatible materials	X	X
Mixed Tray and/or Mixed Part of biocompatible and non-biocompatible materials	X	X

*For example, in a J5 MediJet printer, a tray can contain parts made of MED Digital ABS and parts made of MED610.

- For J7™ Series and J850 Digital Anatomy printers, to eliminate the need for system flushing, it is recommended to load biocompatible cartridges in the even Model cartridge slots (M2, M4, M6) or in the odd Model cartridge slots (M1, M3, M5).
- For Connex™ printers—
  - 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.

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 (All Printers, Except J5 Series)

Check UV lamp intensity once a week, and calibrate, if necessary. Perform the UV calibration described in the *UV Lamp Calibration* document, 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 non-biocompatible material to MED Digital ABS, run the *Material Replacement* wizard as follows:

<table>
<tr><th>Printer Model</th><th>Material Replacement Instructions</th></tr>
<tr><td>Objet260 Connex3
Objet350 Connex3
Objet500 Connex3
J735
J750
J750 Digital Anatomy
J850 Digital Anatomy</td><td>1. Open Material Replacement wizard.
2. Select the same material for both cartridges, by selecting Both cartridges and run the Full flushing cycle.
3. Open the Material Replacement wizard again.
4. In the Material Replacement Options screen, select Advanced Settings.
5. Select Enable “flush again” options and tap Apply.
6. In the Material Replacement Options screen, select Flush again and tap Next.
7. Tap Start to run the wizard.</td></tr>
<tr><td>J5 MediJet
J5 Digital Anatomy</td><td>To switch to biocompatible materials, run the Material Replacement wizard 3 times, as follows:
1. Run the Material Replacement wizard.
For the selected channel, in the Material Selection screen, select the biocompatible material components. For example, select MED515 and MED531.
2. Run the Material Replacement wizard again.
For the selected channel, in the Material Selection screen, select the same biocompatible material components. For example, select MED515 and MED531 again.
3. Repeat step 2.</td></tr>
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Support Removal

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

- with water pressure (SUP710™, SUP710S™, SUP705™, SUP705B™, and SUP706B™)
- with caustic soda and sodium metasilicate solution (SUP706B only)
  This method requires a neutralization process after the Support material is removed.

Support Removal with Water Pressure | SUP710, SUP710S, SUP705, SUP705B, SUP706B

The following instructions apply to the removal of the 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 MED Digital ABS 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.

> 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 | SUP706B

This procedure applies to parts printed with SUP706B that are soaked in an alkaline solution of 2% NaOH and 1% Na_2SiO_3, for up to 24 hours.

1. Remove the Support material with a 2% NaOH and 1% Na_2SiO_3 solution.
   For instructions, refer to the section “SUP706B Support Material” Best Practice document.
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 workspaces 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 minute. If a printed part has internal cavities, it is recommended that you soak it in water for an additional 5 minutes.

> 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.

> 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 MED Digital ABS parts is required, you can 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 MED Digital ABS parts.

> **Important: Sterilization Method**
> When sterilizing printed parts according to the sterilization method 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 10993-1:2020 “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 September 8, 2023. 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 this material or process, please contact your Stratasys distributor or Stratasys Customer Support representative.

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