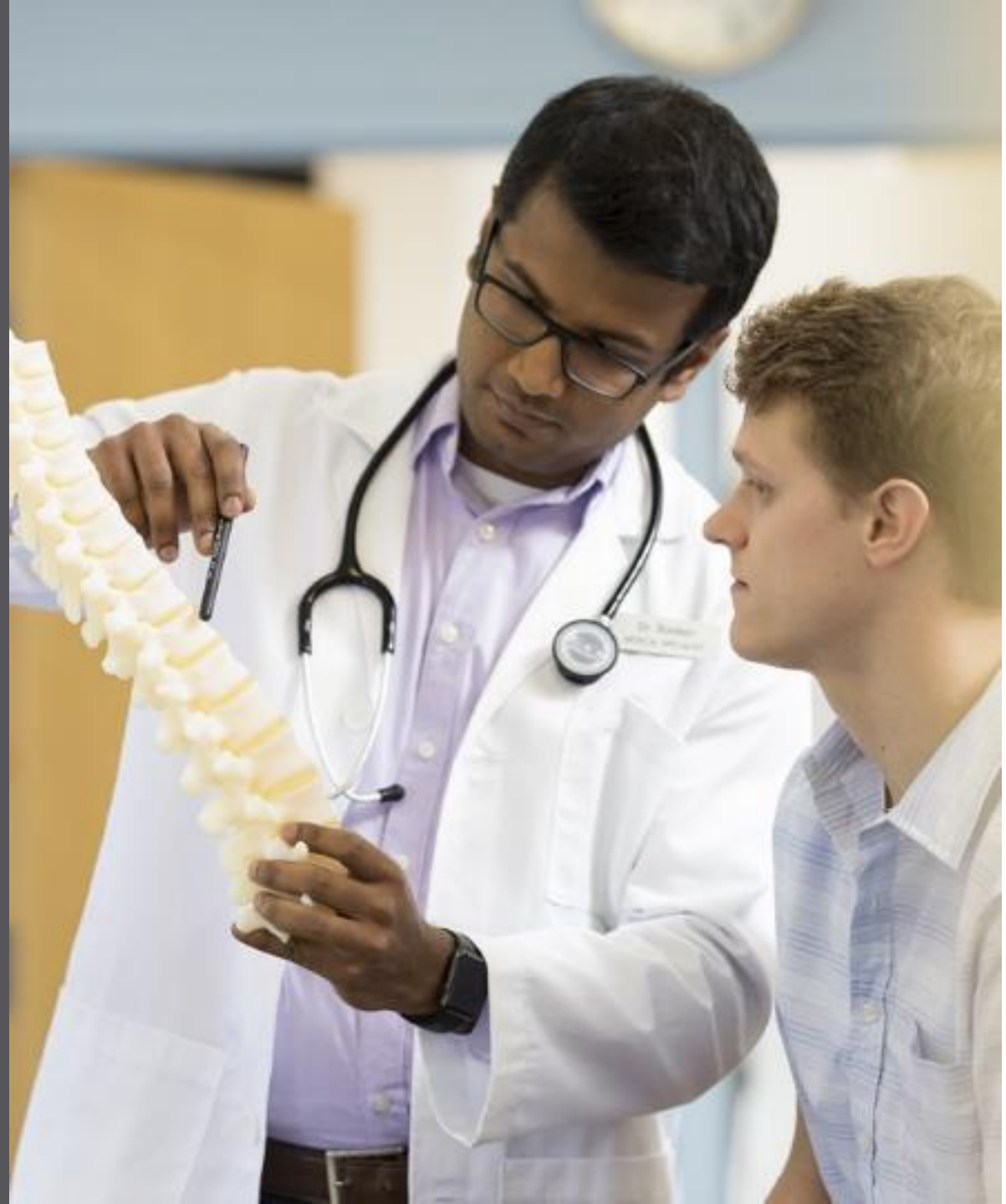
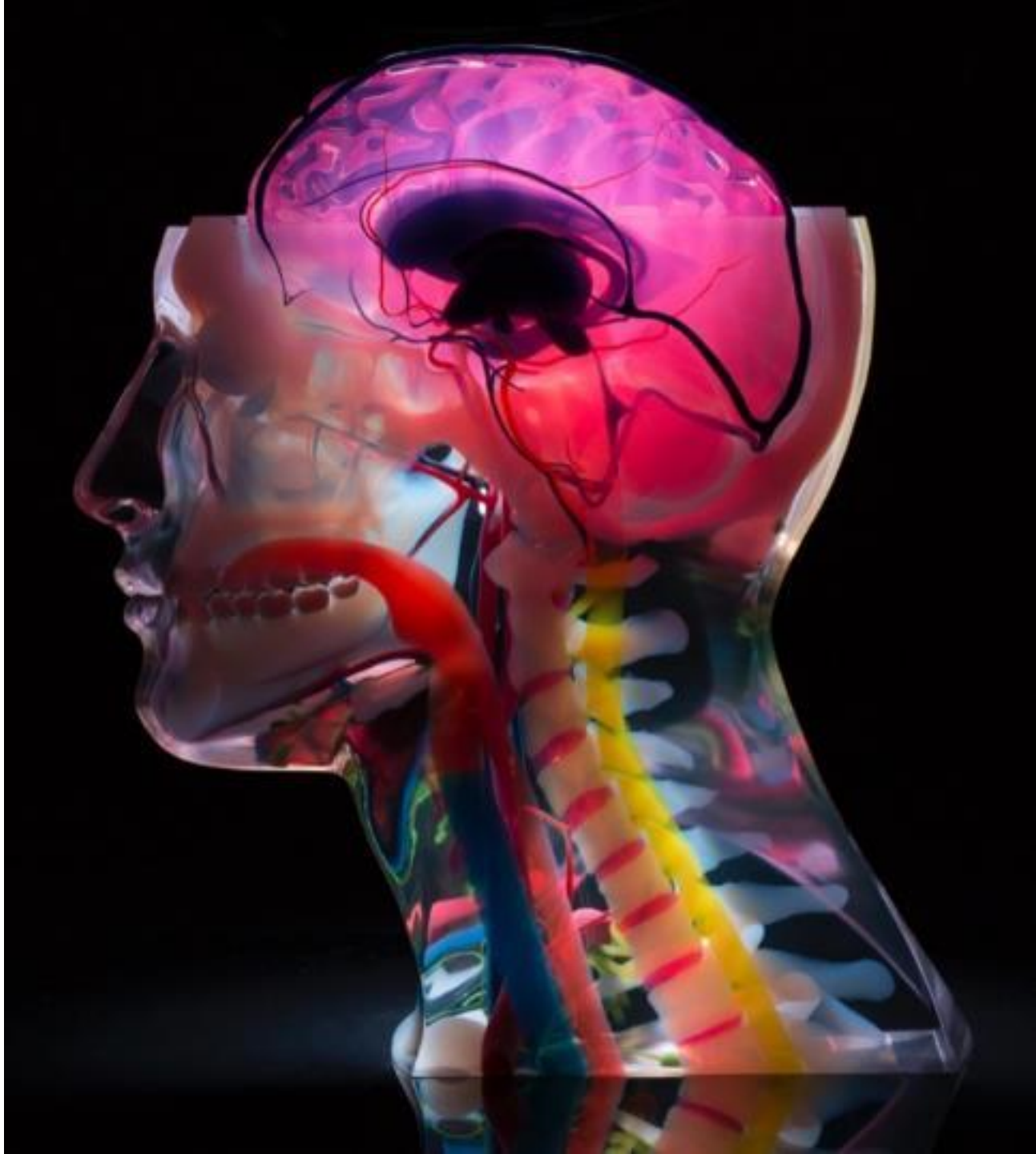


Stratasys PolyJet Biocompatible Materials

ROW Material Business Unit
March 2020 Update

Disclaimer

“Stratasys is formally not responsible for the biocompatibility assessment of a particular final medical device printed with any of our biocompatible materials, final product classification and chemical or biological evaluations remain the sole responsibility of the final medical device manufacturer”.



Contents

What are PolyJet Biocompatible Materials?

What are PolyJet Biocompatible Materials?

Stratasys materials, which are denoted biocompatible, have gone through the following biocompatibility evaluations:

• Cytotoxicity	EN ISO 10993-5:2009
• Irritation	EN ISO 10993-10:2013
• Delayed type hypersensitivity	EN ISO 10993-10:2013
• Material mediated pyrogenicity (USP <151>)	EN ISO 10993-11:2018
• Acute systemic toxicity	EN ISO 10993-11:2018
• USP Plastic Class VI	USP <88>
• Genotoxicity	EN ISO 10993-3:2014
• Chemical characterization	ISO 10993-18:2019
• Allowable limits for leachable substances	EN ISO 10993-17:2009

For the assessment of biological risks, 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, were applied.

What are PolyJet Biocompatible Materials? Cont.

Stratasys Bio-Compatible materials evaluations cover the following medical purposes:

- “Surface device” with “long term” (> 30 days) contact to “intact skin”
- “Surface device” with “limited” (≤ 24 hours) contact to “mucosal membranes”
- “Surface device” with “limited” (≤ 24 hours) contact to “breached or compromised surfaces”
- “External communicating device with “limited” (≤ 24 hours) contact to “tissue/bone/dentin”
- “Implant device” with “limited” (≤ 24 hours) contact to “tissue/bone”.

PolyJet Biocompatible Materials List

PolyJet Biocompatible Materials - List

The applicable biocompatible materials based on the evaluations described above are:

- MED610, Clear
- MED620, Dental
- MED630, Hearing aid material
- MED655, Hearing aid material
- MED615, Rigid Ivory Biocompatible Material
- MED625, Flexible Clear Biocompatible Material
- MED515, Digital ABS Plus, Biocompatible Material Component
- MED531, Digital ABS Plus, Biocompatible Material Component

All tests involve printed parts and not liquid formulations

The above approvals relate to specific systems, with specific support materials and are subject to post processing of parts as described in Stratasys regulatory documents per each material (Declaration Of Compliance).

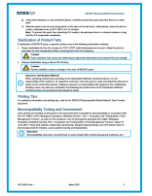
PolyJet Biocompatible Materials Documentation

PolyJet Biocompatible Materials - Documentation

Stratasys PolyJet Biocompatible materials apply the following compliance documentation in order to allow our customers to use Stratasys Materials in various Bio required

Document Type	Description and Purpose
CE Declaration of Compliance	A Stratasys self-declaration based on UL declaration and prepared for our customers for assuring compliance of biocompatible materials
PolyJet Material Biocompatibility Requirements	A Stratasys document which describes what are the methods and conditions the customer must perform when printing with the different bio materials , 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)
UL Declaration of Compliance	A document created by UL which perform the relevant tests and prepare for us declaration of all medical aspects for biocompatible product compliance

Example of PolyJet Biocompatibility Requirements:



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Biocompatib

Printing Biocompatible P
MED610™, Rigid

The methods and conditions described in this doc
MED610™ material so that they are suitable for p
(up to 24 hours) contact to mucosal-membranes
hours) contact to tissue and bone (via external co

Important: Customer Responsibility
When utilizing MED610, it is the respons
determine the sterilization and biocompa
used in the finished product for their resp
contact to intact skin, limited (up to 24 h
compromised surface, and limited (up to
communication or implantation). Results
existing at Stratasys laboratories during
under the procedures and provisions of
Part 1: Evaluation and Testing within a R
International Standard ISO 10993, 'Biolo
Testing within a Risk Management Proc

Make sure that you follow the instructions bel

Printers and Printing Modes

The following PolyJet™ 3D printers are supported

Printer Model	Printi
Objet30 OrthoDesk™	—
Objet30 Prime™	• Dr
Objet30 Dental Prime™	• Hi • Hi
Eden250™/Eden260V™/ Eden260™VS/Dental Advantage™	• Hi
Eden350™/Eden350V™/Eden500V™	• Hi
Connex260™ (Objet260 Connex™)	
Connex350™/Connex500™	
Objet260 Connex1,2,3™	
Objet260 Dental™	• Hi • Hi
Objet260 Dental Selection™	• Di
Objet350 Connex1,2,3™	
Objet500 Connex1,2,3™	
Objet500 Dental Selection™	

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Printer Model	Printing Mo
J735™	• High Spe
J750™	• High Qua
J750™ Digital Anatomy™	• High Mix
J720™ Dental	

Printing and Material Loading Guid

Follow these guidelines to ensure that the print parts are

- When printing with MED610, do not print mixed part
- For J7™ series printers, to eliminate the need for sy cartridges in the even Model cartridge slots (M2, M4
- For Connex™ printers:
  - If you mostly print *non-biocompatible* parts (for e or HQ) and only occasionally print *biocompatible* biocompatible material. This setup enables you t using DM mode, and eliminates the need for sys
  - If you mostly print *biocompatible* parts in single-r *biocompatible* parts, reserve the M3 cartridge slo Vero materials). This setup enables you to easily DM mode, and eliminates the need for system fl

Head Cleaning

Clean print heads daily, using the Head Cleaning Wizar
Refer to "Cleaning the Printing Heads" in the printer user

Roller and Roller Waste Collector Clean

Clean the roller and roller waste collector after printing w
Refer to the following printer user guide sections: "Clean
Roller Waste Collector and Inspecting the Roller Scrape

Ultraviolet (UV) Intensity Check/Calibrati

Check UV lamp intensity once a week, and calibrate, if r
document *UV Lamp Calibration*, supplied with your UV r
Optimum UV intensity ensures that models are cured pr
If you do not have a UV measurement device, contact y
representative.

Material Replacement

When switching from a material that is not biocompatible
Replacement wizard as described in the following table.

Printer Model	Number of Res
Objet30 OrthoDesk	1 High-perform
Objet30 Prime	
Objet30 Dental Prime	

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Printer Model	Number of Resin
Eden250	5 Short/Single cyc Or— 1 High-performanc Note: In Connex p
Eden260V/260VS/Dental Advantage	
Eden350	
Eden350V	
Eden500V	
Connex260 (Objet260 Connex)	
Connex350	
Connex500	
Objet260 Connex1/2/3	To ensure bloc refer to "Changi
Objet260 Dental	
Objet260 Dental Selection	
Objet350 Connex1/2/3	
Objet500 Connex1/2/3	
Objet500 Dental Selection	
J735	
J750	
J750 Digital Anatomy	
J720 Dental	

Support Removal

Support material must be removed using one of the metho

- with water pressure (SUP705™, SUP705B™, and SUP7
- with caustic soda and sodium metasilicate solution (SU
  This method requires a neutralization process after the

Support Removal with Water Pressure | SUP7

The following instructions apply to the removal of Support m

When removing Support material from the printed part, ens
from other materials.

Before placing MED610 parts in the waterjet, clean the wat
and particles.

Follow this procedure exactly as described below.

Caution:
Wear clean (new) protective gloves when handlin
Touching them with your bare hands can contam

1. Clean printed parts thoroughly (10 rinses on each side)
2. Put on *new* protective gloves and remove the parts fro

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3. Soak the parts in a container with a freshly pre for three (3) hours at room temperature. (No s

Warning:
Caustic soda may cause chemical heat that could ignite other materia the solution, always add caustic so nitrile gloves when handling caust

4. Discard the protective gloves that were in cont
5. Put on *new* protective gloves.
6. Place the parts in a clean container and place The container ensures that parts do not come
7. Remove and discard the protective gloves.
8. Clean the parts thoroughly (10 rinses on each
9. Put on *new* protective gloves and remove the
10. Rinse the parts thoroughly under running wate
11. Soak the parts in a container of analytical-gra room temperature. (No stirring is required.)
12. Using clean tweezers or protective gloves, ca
13. Allow the parts to dry at room temperature in t clean, dedicated oven at 30°C (86°F) for 15 m
    Note: To prevent the parts from absorbing IPA the IPA evaporates completely.

Support Removal with Caustic Soda a

This procedure applies to parts printed with SUP7 1% Na_2SiO_3, for up to 24 hours.

1. Remove the Support material with a 2% NaO
   For instructions, refer to the "SUP706B Suppo
2. After removing the Support material, neutraliz

Important:
- Before you begin this procedure, the parts are completely free of
- Make sure that all workspaces a

a) Put on *new* protective gloves and remove
b) Fill a container with domestic vinegar (CA Alternatively, you can use a 5% acetic ac
c) Place the parts in the container and make that the vinegar fills all cavities.
d) Stir gently for approximately 1 minute.
e) Remove the parts from the vinegar and rin approximately 1-2 minutes. If a printed pa water for an additional 5 minutes.
   Note: To effectively neutralize the parts, t in the vinegar, check the pH of the vinega in the container.
f) Soak the parts in a container of analytical- 30 minutes at room temperature. (No stir

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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 "MED610 Biocompatible Model Material" Best Practice document.

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.).

Document Name	What was the update?
MED610 Biocompatibility requirements	• Added the J7 printer and printing modes. • Added material loading guidelines for J7 printers. • Removed SUP706 and added SUP705B (applicable at this time for NASA only) • Revised the printing guidelines to stricter ones that do not allow for printing mixed parts or mixed trays.
MED620 Biocompatibility requirements	• Added the J7 printer and printing modes. • Added material loading guidelines for J7 printers. • Removed SUP706 and added SUP705B (applicable at this time for NASA only) • Revised the printing guidelines to stricter ones that do not allow for printing mixed parts or mixed trays.
MED625FLX Biocompatibility requirements	• Removed SUP706 and added SUP705B (applicable at this time for NASA only) • Revised the printing guidelines to stricter ones that do not allow for printing mixed parts or mixed trays
MED615RGD Biocompatibility requirements	• Removed SUP706 and added SUP705B (applicable at this time for NASA only) • Revised the printing guidelines to stricter ones that do not allow for printing mixed parts or mixed trays.
MEDDABS+ Biocompatibility requirements	• Removed SUP706 and added SUP705B (applicable at this time for NASA only) • Revised the printing guidelines to stricter ones that do not allow for printing mixed parts or mixed trays. • Added Steam Sterilization instructions.

PolyJet Material Biocompatibility Requirements Updated Documents

The updated documents could be found on our **Material Business Section under Material Certifications**: https://my.stratasys.com/Sales-and-Marketing/Products/materials/Materials-Business/Material-Certification-Module/Medical-Approvals

They are also available for download under **Stratasys Compliance section** here: https://support.stratasys.com/materials/polyjet-materials/biocompatible

PolyJet Sterilization Approvals

PolyJet Sterilization* Approvals

Model type	Sterilization type
MED610	Steam
MED620/MED615RGD	
MEDABS+	
MED610	Gamma Irradiation
MED620/MED615RGD	

*These approvals could be found in the Declaration of Compliance of the relevant Material.

DECLARATION OF COMPLIANCE with ISO 10993-1, Overall Biological Risk Assessment for the 3D Printing Material

- MED610 ™ Rigid Clear Biocompatible Material
- MED620™: Rigid Ivory Biocompatible Material
- MED625FLX ™, CL: Flexible Clear Biocompatible Material
- MED615RGD ™, IV: Rigid Ivory Biocompatible Material
- MED DABS+ ™, IV: Digital ABS Plus ™ Biocompatible Material (Ivory)

COVID-19 Update

COVID-19: MED610 for Respiratory Device Parts

We received Biocompatibility report of MED610 to be used as a component in Gas Path Devices

- The report indicates that the risk of using MED610 in gas pathway devices is minimal.
- The assessment is for the current emergency COVID-19 situation and not a general approval.

Note: It is based on biocompatibility tests done according to ISO 10993 even though not all tests defined under ISO 18562-1 (standard for devices that contact gases which are inhaled by a patient) were completed

The conclusion as phrased in the report:

"The minimal biocompatibility risks associated with use of 3D printed MED610 material in gas pathway devices is acceptable in emergency situations associated with the COVID-19 pandemic. The lowest risk use scenarios are those in which the material is used to print minority components in a dry or humidified gas pathway, where the part is not expected to be submerged in liquids."

This report can be shred with 3rd parties who would like to consider printing Respiratory/Ventilator system components on our systems using MED610.

Important Note:

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Thank You