Biocompatible PolyJet Materials

Rapidly produce medical and dental models and devices

Stratasys Biocompatible PolyJet materials support a full range of advanced medical and dental applications, for example:

Dental applications:

- Accurate and repeatable Dental models
- Try-ins models
- Drilling guides
- Direct printing of indirect bonding trays
- Soft gingival masks for implantology cases

Medical applications:

- Biocompatible anatomical models, prototypes and end use parts
- Patient-specific models for sizing and molds
- Surgical guides* for more accurate cuts for orthopedic procedures
- Biocompatible jigs, and fixtures

* with approved 3rd party 510k cleared segmentation software.

Compatible printers (on the main platforms)

	Medical platforms (Digital Anatomy Printer and J5MediJet)	Dental platforms (J5DentaJet and J720)
MED610	v	V
MED615RGD		N/a
MED DABS		
MED620	N/a	V
MED625FLX		

* The approved printing methods per printer can be found in the biocompatibility requirement document per material

* Supported Legacy Printer list can be found in the biocompatibility requirement document per material

Materials biocompatibility matrix

- The evaluation has been performed according to 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” and 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.
- The evaluation tests address the following tests:
- cytotoxicity, genotoxicity, delayed hypersensitivity, and USP plastic Class VI that includes tests for irritation, acute systemic toxicity, and implantation.
- All the Materials are manufactured in an ISO 13485 certified facility.
- Biological evaluation report (BER) will be provided upon request.

Categories	Contact	Description	MED610 transparent rigid material	MED615RGD Opaque rigid material	MED- DABS Improved mechanical properties rigid material	VeroGlaze MED620 A2 shade rigid material	MED625FLX flexible, transparent material
Surface Device	Skin	Devices that contact intact skin surfaces only.			Permanent (> 30 days)		
	Mucous membrane	Devices communicating with intact mucosal membranes.			Limited (< 24 hours		
	Breached or compromised surfaces	Devices that contact breached or otherwise compromised external body surfaces.			Limited (< 24 hours)		
External Communicating Device	External Communicating Device	Devices that contact the blood path at one point and serve as a conduit for entry into the vascular system.			Limited (< 24 hours)		
	Tissue/bone/dentin communicating	Devices communicating with tissue, bone, and pulp/dentin system.			Limited (< 24 hours)		
Approved sterilization process			Steam Gamma EtO	Steam Gamma EtO	Steam Gamma	Steam Gamma EtO	Steam Gamma

MED610 also evaluated for a component in external communicating gas pathway devices, according to EN ISO 18562-1:2017 “Biocompatibility evaluation of breathing gas pathways in healthcare applications” - Part 1: Evaluation and testing within a risk management process.

For more information regarding Biocompatibility requirements, Approved sterilization processes, Safety Guidelines and datasheets, please visit our support center webpage or contact us.

- Download the Data Sheet Download the Safety Data Sheet
- Images
- Use cases

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