

Biocompatible Opaque MED615RGD

MED615RGD™ is an Ivory opaque, rigid, biocompatible PolyJet™ material medically grade for bodily contact. The printed parts are ideal for medical applications requiring precision and patient contact. The material is designed for medical applications and is suitable for permanent (more than 30 days) contact with intact skin, limited (up to 24 hours) contact with mucosal membranes and breached or compromised surfaces, and limited (up to 24 hours) contact with tissue and bone.

MED615RGD has been evaluated and deemed acceptable for the following biological risks				
Test	Standard			
Cytotoxicity	EN ISO 10993-5:2009			
Irritation	EN ISO 10993-10:2013			
Delayed-type hypersensitivity	EN ISO 10993-10:2013			
Genotoxicity	EN ISO 10993-3:2014			
Chemical characterization	EN ISO 10993-18:2009			
USP Plastic Class VI	USP 34 <88>			

Property	Standard / Procedure	Value
Tensile Strength	D-638-03	55 - 65 MPa (7,9477 - 9,427 psi)
Elongation at Break	D-638-05	10% - 25%
Modulus of Elasticity	D-638-04	2,300 - 3,300 MPa (333.5 - 474.6 ksi)
Flexural Strength	D-790-03	80 – 100 MPa (11,603 – 14,503 psi)
Flexural Modulus	D-790-04	2,300 - 3,300 MPa (333.5 - 474.6 ksi)
HDT @ 0.45 MPa	D-648-06	45 - 50 °C (113 - 122 °F)
HDT @ 1.82 MPa	D-648-07	45 - 50 J/m (113 - 122 °F)
Izod Notched Impact	D-256-06	20 - 30 (0.37 - 0.56 ft-lb/in)
Water Absorption	D-570-98 24HR	1.1 – 1.5%
Tg	DMA E	52 - 54 °C (126 - 130 °F)
Shore Hardness	Scale D	83 – 86 D
Rockwell Hardness Scale	Scale M	73 – 76 M
Polymerized Density	ASTM D792	1.17 – 1.18 (g/cm³) (0.676 – 0.682 oz/in³)
Support Removal Type	-	Waterjet or soluble



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Property	Standard / Procedure	Value
Sterilization Methods	-	 Gamma sterilization¹ using a dose of 25–50 kGy Steam sterilization² for four (4) minutes at 132 °C (270 °F) with fractionated pre-vacuum EtO sterilization³ using 740mg EtO /I/6h exposure /45C/40-90%RH/degassing 48h-96h/ up to 2 cycles
Biocompatibility	DIN EN ISO 10993-1:2017	Skin contact – permanent (>30 days) Tissue and bone – short term (up to 24 hours) Mucous membrane – short term (up to 24 hours)

System Availability	Minimum Layer Thickness Capability	Support Structure	
J735/J750	14 microns (0.00055 in.)	SUP705™ (Waterjet removable) SUP706B™ (soluble)	Ivory
J750 Digital Anatomy™ J850 Digital Anatomy™	14 microns (0.00055 in.)	SUP705™ (Waterjet removable) SUP706B™ (soluble) GelMatrix™4 (Waterjet removable)	■ Ivory
J5 MediJet®	18 microns (0.0007 in.)	SUP710™ (Waterjet removable)	Ivory
J5 Digital Anatomy™	18 microns (0.0007 in.)	SUP710™ (Waterjet removable)	Ivory

All data provided herein, which is related to consumables, was collected from specific specimens and test conditions and is provided for information only. Characteristics may vary if different specimens and test conditions are applied. Unless expressly provided in writing, no warranties are made and warranties of merchantability or fitness for a particular purpose are expressly disclaimed.

- ¹ Gamma radiation may result in color change in the part.
- ² Allow the parts to cool down to room temperature before removing them from the autoclave. Flash autoclave may result in part deformations and changes to the flexural strength.
- ³ EtO sterilization may result in part deformations and changes to the flexural strength.
- ⁴ MED615RGD was not tested for biocompatibility with this support material.

For additional information about biological and toxicological assessment and the approved sterilization processes, refer to the <u>Biocompatible page in Stratasys Support Center</u>

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