stratasys

MATERIAL DATA SHEET
MEDICAL

Biocompatible Clear MED610™

MED610™ is a rigid, transparent, biocompatible material. The material is suitable for 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, bone and dentin. The material is also suitable as a component in external communicating gas pathway devices.

MED610 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>
External commutating gas pathways	EN ISO 18562-1:2017

Property	Standard / Procedure	Value
Tensile Strength	D-638-03	50 – 65 MPa (7,252 – 9,427 psi)
Elongation at Break	D-638-05	10 – 25%
Modulus of Elasticity	D-638-04	2,000 – 3,000 MPa (290.1 – 435.1 ksi)
Flexural Strength	D-790-03	75 – 110 MPa (10,878 – 15,954 psi)
Flexural Modulus	D-790-04	2,200 – 3,200 MPa (319.1 – 464.1 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/cm^3) (0.676 – 0.682 oz/in^3)
Biocompatibility	EN ISO 10993-1:2017 EN ISO 18562-1:2017	Skin contact – permanent (>30 days) Mucous membrane – short term (up to 24 hrs) Tissue and bone – short term (up to 24 hours) Component in external communicating gas pathway devices
Sterilization Methods	---	Gamma sterilization[1] using a dose of 25–50 kGy Steam sterilization[2] for four (4) minutes at 132 °C (270 °F) with fractionated pre-vacuum EtO sterilization[3] using 740mg EtO /l/6h exposure /45C/40-90%RH/ degassing 48h-96h/ up to 2 cycles
Support Removal Type	---	Waterjet or soluble

Biocompatible Clear MED610™

System Availability	Minimum Layer Thickness Capability	Support Structure	Available Colors
Objet260/350/500™ Connex3	16 microns (0.0006 in.)	SUP705 (Waterjet removable) SUP706B (soluble)	Transparent
J735/J750	14 microns (0.00055 in.)	SUP705™ (Waterjet removable) SUP706B™ (soluble)	Transparent
J750 Digital Anatomy™ J850 Digital Anatomy™	14 microns (0.00055 in.)	SUP705™ (Waterjet removable) SUP706B™ (soluble) GelMatrix™ (waterJet removable)[4]	Transparent
J5 MediJet®	18 microns (0.0007 in.)	SUP710™ (Waterjet removable) WSS™150 (water soluble)[4]	Transparent
J5 Digital Anatomy™	18 microns (0.0007 in.)	SUP710™ (Waterjet removable) WSS™150 (water soluble)[4] GelMatrix™ (waterJet removable)[4]	Transparent

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] MED610 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 Biocompatible page in Stratasys support center.

Stratasys Headquarters

7665 Commerce Way,
Eden Prairie, MN 55344
+1 800 801 6491 (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)

stratasys.com
ISO 9001:2015 Certified