formlabs | medical

BioMed Amber

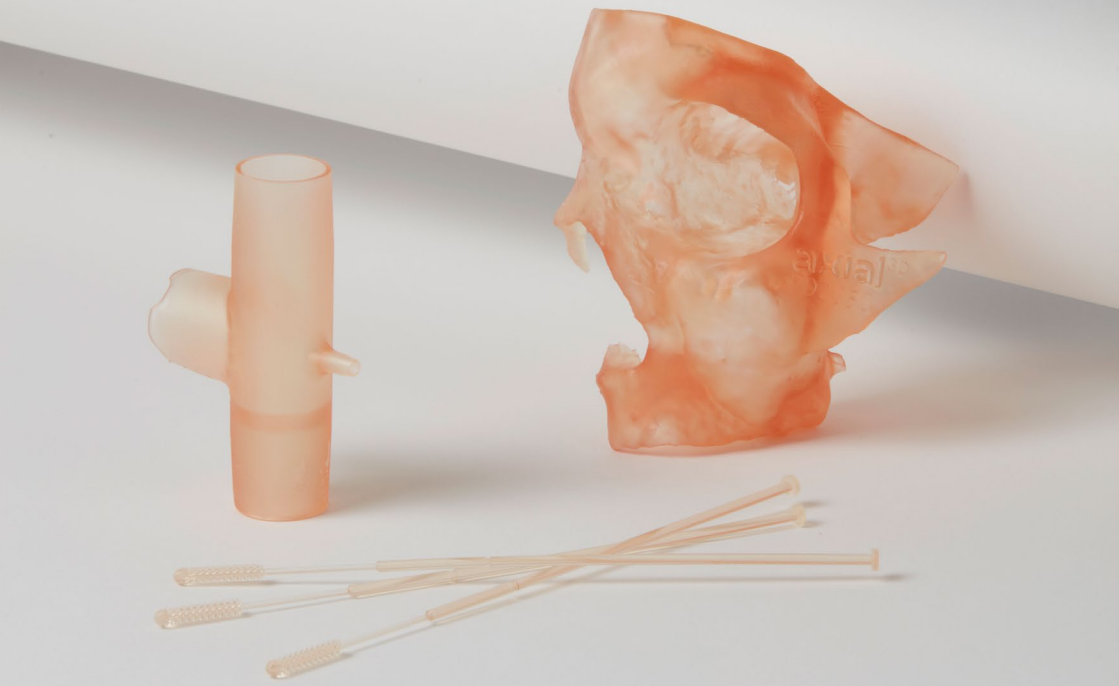
Biocompatible Photopolymer Resin for Formlabs SLA Printers

BioMed Amber Resin is a rigid material for biocompatible applications requiring short-term contact. Parts printed with BioMed Amber Resin are compatible with common solvent disinfection and sterilization methods. BioMed Amber Resin is manufactured in our ISO 13485 facility.

Medical devices and device components

Research and development

Surgical planning and implant sizing tools



V1 **FLBMAM01** *** May not be available in all regions**

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To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.

MATERIAL PROPERTIES DATA

BioMed Amber Resin

	METRIC [1]	IMPERIAL [1]	METHOD
	Post-Cured [2]	Post-Cured [2]	
Tensile Properties			
Ultimate Tensile Strength	73 MPa	11 ksi	ASTM D638-10 (Type IV)
Young's Modulus	2900 MPa	420 ksi	ASTM D638-10 (Type IV)
Elongation	12%	12%	ASTM D638-10 (Type IV)
Flexural Properties			
Flexural Strength	103 MPa	15 ksi	ASTM D790-15 (Method B)
Flexural Modulus	2500 MPa	363 ksi	ASTM D790-15 (Method B)
Hardness Properties			
Hardness Shore D	67 D	67 D	ASTM D2240-15 (Type D)
Impact Properties			
Notched Izod	28 J/m	0.53 ft-lbf/in	ASTM D256-10 (Method A)
Unnotched Izod	142 J/m	2.6 ft-lbf/in	ASTM D4812-11
Thermal Properties			
Heat Deflection Temp. @ 1.8 MPa	65 °C	149 °F	ASTM D648-18 (Method B)
Heat Deflection Temp. @ 0.45 MPa	78 °C	172 °F	ASTM D648-18 (Method B)
Coefficient of Thermal Expansion	66 µm/m/°C	37 µin/in/°F	ASTM E831-14

Sterilization Compatibility	
E-beam	35 kGy E-beam radiation
Ethylene Oxide	100% Ethylene oxide at 55 °C for 180 minutes
Gamma	29.4 - 31.2 kGy gamma radiation
Steam Sterilization	Autoclave at 134°C for 20 minutes Autoclave at 121°C for 30 minutes

For more details on sterilization compatibilities, visit formlabs.com/medical

Disinfection Compatibility	
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

BioMed Amber Resin has been evaluated in accordance with ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, and ISO 7405:2009/(R)2015, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, and passed the requirements for the following biocompatibility risks:

ISO Standard	Description [3]	ISO Standard	Description [3]
ISO 10993-5:2009	Not cytotoxic	ISO 10993-11: 2017	No evidence of acute systemic toxicity
ISO 10993-10:2010/(R)2014	Not an irritant	ISO 10993-11: 2017/USP, General Chapter <151>, Pyrogen Test	Non-pyrogenic
ISO 10993-10:2010/(R)2014	Not a sensitizer		

The product was developed and is in compliance with the following ISO Standards:

ISO Standard	Description
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices

[1] Material properties may vary based on part geometry, print orientation, print settings, temperature, and disinfection or sterilization methods used.

[2] Data for post-cured samples were measured on Type IV tensile bars printed on a Form 2 and Form 3B (impact and thermal measurements) printers with 100 µm BioMed Amber Resin settings, washed in a Form Wash for 20 minutes in 99% Isopropyl Alcohol, and post-cured at 60 °C for 30 minutes in a Form Cure.

[3] BioMed Amber Resin was tested at NAMSA World Headquarters, OH, USA.