MEDICAL RESIN

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BioMed Durable

For Strong and Impact Resistant Medical Devices and Instruments

BioMed Durable Resin is a clear material for biocompatible applications requiring impact, shatter, and abrasion resistance. This USP Class VI material is made in an FDA-registered, ISO 13485 facility and can be used in applications for long-term skin (>30 days), and short-term tissue, bone, and dentin contact (<24hrs).

Other biocompatibility endpoints have not been evaluated and may be added over time.

End-Use Devices and Components Requiring Biocompatibility and Impact Resistance

Patient-Specific Instruments

Single-Use Instruments

V1 **FLBMDU01** *** May not be available in all regions**

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MATERIAL PROPERTIES DATA

BioMed Durable Resin

	METRIC [1]	IMPERIAL [1]	METHOD
	Post-Cured [2]	Post-Cured [2]	
Tensile Properties			
Ultimate Tensile Strength	29.1 MPa	4230 psi	ASTM D 638-14 (Type IV)
Young's Modulus	994 MPa	144 ksi	ASTM D 638-14 (Type IV)
Elongation	33%		ASTM D 638-14 (Type IV)
Flexural Properties			
Flexural Stress at 5% Strain	21 MPa	92 ksi	ASTM D 790-15 (Procedure B)
Flexural Modulus	643 MPa	3070 psi	ASTM D 790-15 (Procedure B)
Hardness Properties			
Hardness Shore D	75D		ASTM D 2240-15 (Type D)
Impact Properties			
Notched IZOD	98 J/m	1.84 ft-lbf/in	ASTM D 256-10 (Method A)
Unnotched IZOD	1340 J/m	25.1 ft-lbf/in	ASTM D 4812-11
Thermal Properties			
Heat Deflection Temp. @ 1.8 MPa	40 °C	104 °F	ASTM D 648-18 (Method B)
Heat Deflection Temp. @ 0.45 MPa	46 °C	115 °F	ASTM D 648-18 (Method B)
Coefficient of Thermal Expansion	102.9 um/m/C		ASTM E 831-13

Sterilization Compatibility

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

Disinfection Compatibility

Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

Samples printed with BioMed Durable Resin have been evaluated in accordance with the following biocompatibility endpoints:

ISO Standard	Description [3]	ISO Standard	Description [3]
EN 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	USP <88> Biological Reactivity Tests, In-vivo	USP Class VI Certified

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 were measured on post-cured samples printed on a Form 3B with 100um BioMed Durable Resin settings, washed in a Form Wash for 10 minutes in 99% Isopropyl Alcohol, and post-cured at 60°C, 20 minutes in a Form Cure.

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

SOLVENT COMPATIBILITY

BioMed Durable Resin

Percent weight gain over 24 hours for a printed and post-cured 1 x 1 x 1 cm cube immersed in respective solvent:

Solvent	24 hr weight gain, %	Solvent	24 hr weight gain, %
Acetic Acid 5%	0.7	Mineral oil, heavy	0.1
Acetone	12.4	Mineral oil, light	0.1
Bleach ~5% NaOCl	0.5	Salt Water (3.5% NaCl)	0.5
Butyl Acetate	5.0	Skydrol 5	0.6
Diesel Fuel	0.1	Sodium hydroxide solution (0.025% pH = 10)	0.5
Diethyl glycol monomethyl ether	3.0	Strong Acid (HCl Conc)	0.7
Hydraulic Oil	0.2	TPM	1.1
Hydrogen peroxide (3%)	0.6	Water	0.5
Isooctane	0.02	Xylene	4.8
Isopropyl Alcohol	2.0		