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MEDICAL RESIN

# BioMed Elastic 50A Resin

## For Soft, Biocompatible, Transparent Medical Devices and Models

BioMed Elastic 50A Resin is a soft, elastic, medical grade material for applications requiring comfort, biocompatibility, and transparency. This ISO 10993 and USP Class VI certified material is made in an FDA-registered, ISO 13485 facility and can be used in applications for long-term skin contact ( > 30 days ), and short-term mucosal membrane contact ( < 24hrs ).

**Elastic Biocompatible Medical Devices**

**Soft Tissue Models to Assist in Surgeries**

V1 **FLBMEL01**

Prepared 20/09/2023

Rev. 02 24/06/2024

| Material Properties | METRIC [1] | IMPERIAL [1] | METHOD |
|---|---|---|---|
| | Post-Cured [2] | Post-Cured [2] | |
| **Mechanical Properties** | METRIC [1] | IMPERIAL [1] | METHOD |
| Ultimate Tensile Strength [3] | 2.3 MPa | 339 psi | ASTM D412-06 (A) |
| Stress at 50% Elongation | 1 MPa | 145 psi | ASTM D412-06 (A) |
| Stress at 100% Elongation | 1.3 MPa | 189 psi | ASTM D412-06 (A) |
| Elongation at Break | 150% | | ASTM D412-06 (A) |
| Tear Strength [4] | 11 kN/m | 60.8 lb/in | ASTM D624-00 |
| Shore Hardness | 50A | | ASTM 2240 |
| Compression Set 23 °C for 22 hours | 8% | | ASTM D395-03 (B) |
| Compression Set 70 °C for 22 hours | 11% | | ASTM D395-03 (B) |
| Bayshore Resilience | 15% | | ASTM D2632 |
| **Thermal Properties** | METRIC [1] | IMPERIAL [1] | METHOD |
| Glass transition temperature (Tg) | -36 °C | -32.8 °F | DMA |

| Disinfection Compatibility | |
|---|---|
| Chemical Disinfection | 70% Isopropyl Alcohol for 5 minutes |

Samples printed with BioMed Elastic 50A Resin have been evaluated in accordance with the following biocompatibility endpoints:

| ISO Standard | Description [3] |
|---|---|
| ISO 10993-5:2009 | Met requirements of test |
| ISO 10993-23:2021 | Met requirements of test |
| ISO 10993-10:2021 | Met requirements of test |
| 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 can vary with part geometry, print orientation, print settings and temperature.

[2] Data was obtained from parts printed using Form 3B, 100 µm, BioMed Elastic 50A settings, and using the BioMed Elastic 50A MFG guide.

[3] Tensile testing was performed after 3+ hours at 23 °C, using a Die C specimen cut from sheets.

[4] Tear testing was performed after 3+ hours at 23 °C, using a Die C tear specimen directly printed

**SOLVENT COMPATIBILITY**

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% | 1.5 | Isooctane (aka gasoline) | 15.6 |
| Acetone | 43.4 | Mineral oil (light) | 0.7 |
| Isopropyl Alcohol | 39.2 | Mineral oil (Heavy) | 0.4 |
| Bleach ~5% NaOCl | 0.6 | Salt Water (3.5% NaCl) | 0.6 |
| Butyl Acetate | 133.1 | Sodium Hydroxide solution (0.025% PH 10) | 0.7 |
| Diesel Fuel | 7.9 | Water | 0.7 |
| Diethyl Glycol Monomethyl Ether | 31.4 | Xylene | 163.9 |
| Hydraulic Oil | 3.9 | Strong Acid (HCl conc) | 45.6 |
| Skydrol 5 | 41.2 | Tripropylene Glycol Methyl Ether (TPM) | 43.6 |
| Hydrogen peroxide (3%) | 0.9 | | |