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ADDITIVE X

MEDICAL RESIN

# BioMed Elastic 50A

## 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** * May not be available in all regions

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## MATERIAL PROPERTIES DATA **BioMed Elastic 50A**

| | METRIC [1] | IMPERIAL [1] | METHOD |
|---|---|---|---|
| | Post-Cured [2] | Post-Cured [2] | |
| **Mechanical Properties** | | | |
| Ultimate Tensile Strength [3] | 2.3 | 339 | ASTM D 412-06 (A) |
| Stress at 50% Elongation | 1 | 145 | ASTM D 412-06 (A) |
| Stress at 100% Elongation | 1.3 | 189 | ASTM D 412-06 (A) |
| Elongation at Break | 150% | 150% | ASTM D 412-06 (A) |
| Tear Strength [4] | 11 | 60.8 | ASTM D 624-00 |
| Shore Hardness | 50A | 50A | ASTM 2240 |
| Compression Set 23 °C for 22 hours | 8% | 8% | ASTM D 395-03 (B) |
| Compression Set 70 °C for 22 hours | 11% | 11% | ASTM D 395-03 (B) |
| Bayshore Resilience | 15% | 15% | ASTM D2632 |
| **Thermal Properties** | | | |
| Glass transistion tempreature (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 |

## 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 | | |