

Description:

ZFUZE® therapeutic biomaterial offers an unmatched combination of benefits for implantable orthopedic devices. Formulated from PEEK and zeolites, it promotes early healing and its osteoconductivity supports fast and effective bone cell growth. Other benefits are its radiolucency and its bone-like flexural modulus.

How ZFUZE® Biomaterial Works:

- Uniformly integrated zeolites create a hydrophilic and negatively charged surface on the PEEK matrix.
- This creates an ideal electrostatic interface for bonding positively charged RGD peptides.
- The bioactive interface recruits bone-forming cells to the surface of implants and accelerates osteointegration.
- In addition, the biomaterial facilitates a rapid M1-to-M2 transition that mitigates fibrous encapsulation and enables faster healing and cell growth.

ZFUZE® Biomaterial Properties and Biocompatibility Tests

PROPERTIES ¹ (20mm Extruded Rod)	ASTM METHOD	METRIC	IMPERIAL
Density	D792	1.33 g/cc	0.048 lbs/in ³
Flexural Modulus	D790	5.00 GPa	725,000 psi
Flexural Strength	D790	183 MPa	26,535 psi
Tensile Strength	D638	97.6 MPa	14,152 psi
Elongation @ break	D638	12.48%	12.48%
Glass Transition Temp. (T _g) (softening point)	D3418	150°C	302°F

ISO 10993 BIOCOMPATIBILITY TESTS ²	ISO 10993 METHOD
Chemical Characterization (comprehensive extractions)	ISO 10993-18
Cytotoxicity	ISO 10993-5
Dermal Sensitization	ISO 10993-10
Intracutaneous Reactivity	ISO 10993-10
Acute Systemic Toxicity	ISO 10993-11
Material-Mediated Pyrogenicity	ISO 10993-11
Genotoxicity	ISO 10993-3
Brain Implant Study	ISO 10993-6
Hemolysis	ISO 10993-4
Bacterial Reverse Mutation	ISO 10993-3
Toxicological Evaluation	ISO 10993-17

¹Source: Genesis Medical Plastics. Typical values are based on testing standard ASTM test bars machined from ZFUZE biomaterial rod extruded by Genesis. Because properties may vary due to processing methods and/or the application environment, users are advised to validate performance of parts and devices by testing under actual end-use conditions.

²Source: DiFusion Therapeutic Biomaterials