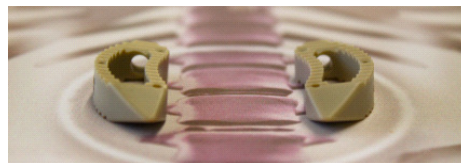


VESTAKEEP® i4 PL



Implantable grade polyether ether ketone plates for permanent implants

VESTAKEEP® i4 PL are plates based on implantable grade VESTAKEEP® i4 G neat polyether ether ketone resin.

Proven Biocompatibility

The extra high purity and extended quality measures make VESTAKEEP® i-Grade materials an excellent choice for permanent implants.

For VESTAKEEP® i4 PL, biocompatibility has been tested according to ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

VESTAKEEP® i4 PL complies ASTM F2026 "Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications".

A summary of biocompatibility test results is available upon request.

Dimensions of VESTAKEEP® i4 PL

Thickness up to 60mm

Width up to 600mm

Biocompatibility tests available for i4 PL

Standard	Description
ISO 10993-3	Genotoxicity: Ames Test
ISO 10993-3	Genotoxicity: Chromosome aberration test
ISO 10993-3	Genotoxicity: Mouse Lymphoma test
ISO 10993-5	Cytotoxicity
ISO 10993-6	Test for local effects after Implantation in bone (90 days)
ISO 10993-10	Sensitization: Maximization test according to Magnusson and Kligman
ISO 10993-10	Irritation: Intracutaneous Reactivity
ISO 10993-11	Subchronic Systemic Toxicity
ISO 10993-12	GC/MS Fingerprint
USP Class VI	Acute Systemic Toxicity Intracutaneous Reactivity Muscle Implantation

Properties of VESTAKEEP® i4 PL

		Test method	Unit	Value
Density	23°C / 50% r.h.	ISO 1183	g/cm ³	1.30
Water absorption	saturation	ISO 62	%	0.4
Moisture absorption	23°C / 50% r.h.	ISO 62	%	0.12
Tensile test	23°C / 50% r.h.	ISO 527-1 ISO 527-2		
Stress at yield			MPa	109
Strain at yield			%	4.8
Stress at break			MPa	> 70
Strain at break			%	> 20
Tensile modulus		ISO 527-1 ISO 527-2	MPa	4000
Flexural Test		ISO 178		
Flexural Modulus			MPa	4050
Flexural Strength			MPa	165
Izod notched impact strength	23°C / 50% r.h.	ISO 180/1eA	kJ/m ²	5.5
Temperature of deflection under load				
Method A	1.8MPa	ISO 75-1	°C	155
Method B	0.45MPa	ISO 75-2	°C	205
Differential Scanning Calorimetry (DSC)		ISO 11357		
Recrystallization temperature			°C	285
Glass transition temperature, 2 nd heating, onset			°C	145
Glass transition temperature, 2 nd heating, midpoint			°C	155
Melting temperature, 2 nd heating			°C	340
Relative permittivity	50 Hz 10 kHz	IEC 60250		2.8 2.8
Dielectric strength	K20/K20	IEC 60423-1	kV/mm	21

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Evonik Resource Efficiency GmbH

Kirschenallee, 64293 Darmstadt, Germany

Phone +49 2365 49-9227 e-mail evonik-hp@evonik.com