

Product Information

VESTAKEEP® i2 G

IMPLANTABLE GRADE POLYETHER ETHER KETONE RESIN FOR PERMANENT IMPLANTS



VESTAKEEP® i2 G is a natural colored, standard viscosity polyether ether ketone (PEEK) that is especially designed for long term implantable medical devices. This grade is often used for injection molding processing technologies due to its good flowability.

Proven Biocompatibility of VESTAKEEP® i-Grades

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

For VESTAKEEP® i2 G, biocompatibility has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

VESTAKEEP® i2 G complies ASTM F2026 "Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications".

A summary of biocompatibility test results is available upon request.

Biocompatibility tests available for i2 G

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

Processing of VESTAKEEP® i-Grades

VESTAKEEP® i2 G can be processed by common melt processing techniques like injection molding and extrusion.

We recommend a melt temperature between 360°C and 380°C during the injection molding process. The mold temperature should be within a range of 160°C to 200°C, preferably 180°C.

Our technical experts would appreciate to give you support regarding the special requirements for the processing of VESTAKEEP® i2 G.

Delivery of VESTAKEEP® i-Grades

VESTAKEEP® i2 G is supplied as cylindrical pellets in 10 kg boxes with moisture-proof polyethylene liners.

The values presented are typical or average values, they do not constitute a specification.

Key Features

Industrial Sector

Medical Devices

Processing

Injection molding, Extrusion

Delivery form

Pellets, Granules

Optics

Opaque

Conformity

Biocompatibility, Medical application

Additives

Unfilled

Mechanical properties ISO

	dry	Unit	Test Standard
Tensile modulus	3700	MPa	ISO 527
Tensile strength	98	MPa	ISO 527
Yield stress	98	MPa	ISO 527
Yield strain	5	%	ISO 527
Stress at break	74	MPa	ISO 527
Nominal strain at break, tB	20	%	ISO 527
Charpy impact strength, +23°C	N	kJ/m ²	ISO 179/1eU
Charpy impact strength, -30°C	N	kJ/m ²	ISO 179/1eU
Charpy notched impact strength, +23°C	6	kJ/m ²	ISO 179/1eA
Type of failure	C	-	-
Charpy notched impact strength, -30°C	6	kJ/m ²	ISO 179/1eA
Type of failure	C	-	-
Flexural modulus, 23°C	3600	MPa	ISO 178
Flexural stress at conv. deflection, 23°C	117	MPa	ISO 178

Thermal properties

	dry	Unit	Test Standard
Melting temperature	342	°C	ISO 11357-1/-3
Glass transition temperature, DSC	150	°C	ISO 11357-1/-2

Temp. of deflection under load A, 1.80 MPa	150	°C	ISO 75-1/-2
Temp. of deflection under load B, 0.45 MPa	205	°C	ISO 75-1/-2
Vicat softening temperature A, 10 N, 50 K/h	335	°C	ISO 306
Vicat softening temperature B, 50 N, 50 K/h	310	°C	ISO 306
Coeff. of linear therm. expansion, 23°C to 55 °C, parallel	60	E-6/K	ISO 11359-1/-2
Melting Temperature	342	°C	ASTM D 3418

Physical properties	dry	Unit	Test Standard
Density	1300	kg/m ³	ISO 1183
Water absorption	0.4	%	Sim. to ISO 62
Humidity absorption	0.12	%	Sim. to ISO 62
Density	1300	kg/m ³	ASTM D 792

Burning Behav.	dry	Unit	Test Standard
Burnin behav. at thickness h	V-0	class	IEC 60695-11-10
Thickness tested	3.2	mm	-
Oxygen index	38	%	ISO 4589-1/-2
Limiting Oxygen Index	38	%	ASTM D 2863

Electrical properties	dry	Unit	Test Standard
Volume resistivity, V	>1E13	Ohm*m	IEC 62631-3-1
Relative permittivity, 100Hz	2.8	-	IEC 62631-2-1
Relative permittivity, 1MHz	2.8	-	IEC 62631-2-1
Dissipation factor, 1MHz	50	E-4	IEC 62631-2-1
Dielectric strength, AC, S20/P50	16	kV/mm	Sim. to IEC 60243-1
CTI, test solution A, 50 drops value	200	-	IEC 60112
Assessment of the insulation group	III a	-	DIN EN 60664-1

Rheological properties

	dry	Unit	Test Standard
Melt volume-flow rate, MVR	68	cm ³ /10min	ISO 1133
Temperature	380	°C	-
Load	5	kg	-
Molding shrinkage, parallel	1.1	%	ISO 294-4, 2577
Molding shrinkage, normal	1.1	%	ISO 294-4, 2577
Mold temperature	180	°C	-
Melt temperature	360	°C	-

Test specimen production

	dry	Unit	Test Standard
Injection Molding, melt temperature	380	°C	ISO 294
Injection Molding, mold temperature	180	°C	ISO 294
Injection Molding, injection velocity	200	mm/s	ISO 294

Characteristics
Special Characteristics

Semi-crystalline

Regulatory

US Pharmacopeia Class VI conformity

Color

Natural color

Chemical Resistance

Acid resistance, Alkali resistance, Solvent resistance, Grease resistance, Hydrolytically stable, Oil resistance, Oxidation resistance, General chemical resistance