

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.

**Key Features**

**Industrial Sector**  
Medical Devices

**Processing**  
Injection molding, Extrusion

**Delivery form**  
Pellets, Granules

**Optics**  
Opaque

**Conformity**  
Biocompatibility, Medical application

**Additives**  
Unfilled

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

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

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

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

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

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

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

Test specimen production	dry	Unit	Test Standard
Injection Molding, melt temperature	<b>380</b>	°C	ISO 294
Injection Molding, mold temperature	<b>180</b>	°C	ISO 294
Injection Molding, injection velocity	<b>200</b>	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