

Product Information

**VESTAKEEP® i5 G**

**IMPLANTABLE GRADE POLYETHER ETHER KETONE RESIN FOR PERMANENT IMPLANTS**



**VESTAKEEP® i5 G** is a natural colored, very high viscosity polyether ether ketone (PEEK) that is especially designed for long term implantable medical devices.

**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® i5 G, biocompatibility has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

VESTAKEEP® i5 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 i5 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)

**Delivery of VESTAKEEP® i-Grades**

VESTAKEEP® i5 G is supplied as cylindrical pellets in 10 kg boxes with moisture-proof polyethylene liners.

**Key Features**

**Industrial Sector**

Medical Devices

**Processing**

Extrusion

**Delivery form**

Pellets, Granules

**Resistance to**

Heat (thermal stability), Hydrolysis / hot water, Wear / abrasion, Fatigue resistance, Oil / fuels

**Conformity**

Biocompatibility, Medical application

**Additives**

Unfilled

**Mechanical properties ISO**

	<b>dry</b>	<b>Unit</b>	<b>Test Standard</b>
Tensile modulus	<b>3500</b>	MPa	ISO 527
Tensile strength	<b>95</b>	MPa	ISO 527
Yield stress	<b>95</b>	MPa	ISO 527
Yield strain	<b>5</b>	%	ISO 527
Stress at break	<b>77</b>	MPa	ISO 527
Nominal strain at break, tB	<b>34</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>9.5</b>	kJ/m <sup>2</sup>	ISO 179/1eA
Type of failure	<b>C</b>	-	-
Charpy notched impact strength, -30°C	<b>8</b>	kJ/m <sup>2</sup>	ISO 179/1eA
Type of failure	<b>C</b>	-	-

**Thermal properties**

	<b>dry</b>	<b>Unit</b>	<b>Test Standard</b>
Melting temperature	<b>338</b>	°C	ISO 11357-1/-3
Glass transition temperature, DSC	<b>153</b>	°C	ISO 11357-1/-2
Glass transition temperature, 2 nd heating, onset	<b>145</b>	°C	ISO 11357
Glass transition temperature, 2 nd heating, midpoint	<b>155</b>	°C	ISO 11357
Recrystallization temperature, 10 K/min	<b>285</b>	°C	ISO 11357
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>305</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>338</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>
Oxygen index	<b>36</b>	%	ISO 4589-1/-2
Limiting Oxygen Index	<b>36</b>	%	ASTM D 2863

<b>Rheological properties</b>	<b>dry</b>	<b>Unit</b>	<b>Test Standard</b>
Melt volume-flow rate, MVR	<b>7</b>	cm <sup>3</sup> /10min	ISO 1133
Temperature	<b>380</b>	°C	-
Load	<b>5</b>	kg	-
Molding shrinkage, parallel	<b>0.9</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>380</b>	°C	-

<b>Test specimen production</b>	<b>dry</b>	<b>Unit</b>	<b>Test Standard</b>
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**

High impact strength, 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