

Product Information

# VESTAKEEP® i4 G

## IMPLANTABLE GRADE POLYETHER ETHER KETONE RESIN FOR PERMANENT IMPLANTS



**VESTAKEEP® i4 G** is a natural colored, high viscosity polyether ether ketone (PEEK) that is especially designed for long term implantable medical devices. This grade is often used for extrusion processing technologies.

### 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® i4 G, biocompatibility has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

VESTAKEEP® i4 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 i4 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® i4 G can be processed by common melt processing techniques like injection molding and extrusion.

We recommend a melt temperature between 370°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® i4 G.

### Delivery of VESTAKEEP® i-Grades

VESTAKEEP® i4 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

### Resistance to

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

### Conformity

Biocompatibility, Medical application

### Additives

Unfilled

Mechanical properties ISO	dry	Unit	Test Standard
Tensile modulus	<b>3500</b>	MPa	ISO 527
Tensile strength	<b>94</b>	MPa	ISO 527
Yield stress	<b>94</b>	MPa	ISO 527
Yield strain	<b>5</b>	%	ISO 527
Stress at break	<b>76</b>	MPa	ISO 527
Strain at break, B	<b>30</b>	%	ISO 527
Nominal strain at break, tB	<b>&gt;50</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>9.1</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>	-	-

Thermal properties	dry	Unit	Test Standard
Melting temperature	<b>338</b>	°C	ISO 11357-1/-3
Glass transition temperature, DSC	<b>152</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>305</b>	°C	ISO 306
Melting Temperature	<b>338</b>	°C	ASTM D 3418

Physical properties	dry	Unit	Test Standard
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

Optical properties	dry	Unit	Test Standard
Color L	<b>61.9</b>	-	CIE
Color a	<b>2.77</b>	-	CIE
Color b	<b>8.63</b>	-	CIE

Rheological properties	dry	Unit	Test Standard
Melt volume-flow rate, MVR	<b>12</b>	cm <sup>3</sup> /10min	ISO 1133
Temperature	<b>380</b>	°C	-
Load	<b>5</b>	kg	-

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