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.

VESTAKEEP®

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	**508000**	psi	ISO 527
Tensile strength	**13600**	psi	ISO 527
Yield stress	**13600**	psi	ISO 527
Yield strain	**5**	%	ISO 527
Stress at break	**11000**	psi	ISO 527
Strain at break, B	**30**	%	ISO 527
Nominal strain at break, tB	**>50**	%	ISO 527
Charpy impact strength, +23°C	**N**	ftlb/in^2	ISO 179/1eU
Charpy impact strength, -30°C	**N**	ftlb/in^2	ISO 179/1eU
Charpy notched impact strength, +23°C	**4.33**	ftlb/in^2	ISO 179/1eA
Type of failure	**C**	-	-
Charpy notched impact strength, -30°C	**2.85**	ftlb/in^2	ISO 179/1eA
Type of failure	**C**	-	-

Thermal properties	dry	Unit	Test Standard
Melting temperature	**640**	°F	ISO 11357-1/-3
Glass transition temperature, DSC	**306**	°F	ISO 11357-1/-2
Temp. of deflection under load A, 1.80 MPa	**302**	°F	ISO 75-1/-2

Temp. of deflection under load B, 0.45 MPa	**401**	°F	ISO 75-1/-2
Vicat softening temperature A, 10 N, 50 K/h	**635**	°F	ISO 306
Vicat softening temperature B, 50 N, 50 K/h	**581**	°F	ISO 306
Melting Temperature	**640**	°F	ASTM D 3418

Physical properties	**dry**	**Unit**	**Test Standard**
Density	**1.3**	g/cm^3	ISO 1183
Water absorption	**0.4**	%	Sim. to ISO 62
Humidity absorption	**0.12**	%	Sim. to ISO 62
Density	**1.3**	g/cm^3	ASTM D 792

Optical properties	**dry**	**Unit**	**Test Standard**
Color L	**61.9**	-	CIE
Color a	**2.77**	-	CIE
Color b	**8.63**	-	CIE

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

Test specimen production	**dry**	**Unit**	**Test Standard**
Injection Molding, melt temperature	**716**	°F	ISO 294
Injection Molding, mold temperature	**356**	°F	ISO 294
Injection Molding, injection velocity	**7.87**	in/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