Product Information VESTAKEEP[®] iC 4506 G

X-RAY OPAQUE POLYETHER ETHER KETONE FOR LONG TERM IMPLANTABLE MEDICAL DEVICES

VESTAKEEP* iC4506 G is an opaque, natural colored, high viscosity polyether ether ketone (PEEK) resin. It contains 6% barium sulphate to render it X-ray opaque.

Proven Biocompatibility VESTAKEEP* iC4506 G is especially designed for long term implantable medical devices.

The compound composition is optimised for high biocompatibility and mechanical, thermal and chemical resistance.

Biocompatibility has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

A summary of biocompatibility is available upon request.

Biocompatibility reports available for VESTAKEEP® iC4506 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 (180 days)
ISO 10993-11	Material-mediated pyrogenes

Processing of VESTAKEEP® i-Grades VESTAKEEP® iC4506 G can be processed by common melt processing techniques like injection molding and extrusion. For injection molding, we recommend a melt temperature between 380°C and 400°C. The mold temperature should be within a temperature range from 160°C to 200°C, preferably 180°C.

Delivery of VESTAKEEP® i-Grades

VESTAKEEP* iC4506 G is supplied as cylindrical pellets in hobbocks containing 5 kg or 10kg. Polyethylene bags are used as primary packaging.

The results shown have been generated from a low number of production lots. Therefore, they are preliminary and not yet the result of a statistical evaluation. Therefore they must not be used to establish specifications.

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





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FOR FURTHER INFORMATION PLEASE CONTACT US AT <u>EVONIK-HP@EVONIK.COM</u> OR VISIT OUR PRODUCT AT <u>WWW.EVONIK.COM/MEDICAL-TECHNOLOGY</u>

Key Features

Industrial Sector Medical Devices

Processing Injection molding

Delivery form Pellets, Granules

Optics Opaque Resistance to Heat (thermal stability), Hydrolysis / hot water, UV / light / weathering

Electrical Insulating

Conformity Biocompatibility, Medical application

Additives Mineral fillers

Mechanical properties ISO	dry	Unit	Test Standard
Tensile modulus	3600	MPa	ISO 527
Tensile strength	95	MPa	ISO 527
Yield stress	95	MPa	ISO 527
Yield strain	5	%	ISO 527
Strain at break, B	10	%	ISO 527
Charpy impact strength, +23°C	7	kJ/m²	ISO 179/1eU
Type of failure	с	-	-
Thermal properties	dry	Unit	Test Standard
Melting temperature	340	°C	ISO 11357-1/-3
Glass transition temperature, 2 nd heating, onset	145	°C	ISO 11357
Glass transition temperature, 2 nd heating, midpoint	155	°C	ISO 11357
Recrystallization temperature, 10 K/min	285 ^[e]	°C	ISO 11357
Melting Temperature	340	°C	ASTM D 3418

e: 20 K/minute



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Physical properties	dry	Unit	Test Standard
Density	1350	kg/m³	ISO 1183
Water absorption	0.4	%	Sim. to ISO 62
Density	1350	kg/m³	ASTM D 792
Rheological properties	dry	Unit	Test Standard
Melt volume-flow rate, MVR	10	cm³/10min	ISO 1133
Temperature	380	°C	-
Load	5	kg	-
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

Applications Medical implants

Special Characteristics Phosphorus-free, PTFE-free, High impact strength, Semicrystalline, High viscosity, Self-extinguishing

Features Low odor, Non-corrosive **Color** Natural color

Additives Inorganic fillers

Chemical Resistance

Acid resistance, Solvent resistance, Oxidation resistance, Radiation resistance, General chemical resistance



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