Product Information VESTAKEEP[®] iC 4800 G

POLYETHER ETHER KETONE WITH ENHANCED **OSSEOINTEGRATION FOR LONG TERM IMPLANTABLE MEDICAL** DEVICES

VESTAKEEP* iC4800 G is an opaque, natural colored, high viscosity polyether ether ketone (PEEK) resin. It contains calcium phosphates to enhance osseointegration. It therefore belongs to the VESTAKEEP* Fusion product family.

Biocompatibility The base resin VESTAKEEP* iC4800 G is especially designed for long term implantable medical devices. The compound composition is optimised for high biocompatibility and mechanical, thermal and chemical resistance.

The biocompatibility testing program follows ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

Available biocompatibility reports for VESTAKEEP® iC4800 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	Acute Systemic Toxicity
ISO 10993-3	Genotoxicity: Ames Test
ISO 10993-3	Genotoxicity: Mouse Lymphoma test
ISO 10993-11	Subchronic Systemic Toxicity (28 days)
ISO 10993-6	Test for local effects after Implantation in bone (28, 90, 180 days)
ISO 10993-11	Material-mediated pyrogenes

Processing

VESTAKEEP iC4800 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

Evonik Operations GmbH

VESTAKEEP* iC4800 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.

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



VESTAKEFP®



VESTAKEEP[®]

Key Features

Industrial Sector Medical Devices

Processing Injection molding

Delivery form Pellets, Granules

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	4350	MPa	ISO 527
Tensile strength	90	MPa	ISO 527
Yield stress	90	MPa	ISO 527
Yield strain	4	%	ISO 527
Strain at break, B	10	%	ISO 527
Charpy notched impact strength, +23°C	4.7	kJ/m²	ISO 179/1eA
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
20 K/minute			
Physical properties	dry	Unit	Test Standard
Density	1460	kg/m³	ISO 1183
Water absorption	0.4	%	Sim. to ISO 62



VESTAKEEP®

dry	Unit	Test Over level
dry	Unit	Tank Charles Jacob
		Test Standard
10	cm³/10min	ISO 1133
380	°C	-
5	kg	-
	380	380 °C

Characteristics

Applications Medical implants

Special Characteristics

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

Features Low odor, Non-corrosive Color Grey

Additives Inorganic fillers

Chemical Resistance

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

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