

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

VESTAKEEP® iC4800 G is supplied as cylindrical pellets in hobbcocks containing 5 kg or 10kg. Polyethylene bags are used as primary packaging.

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	631000	psi	ISO 527
Tensile strength	13100	psi	ISO 527
Yield stress	13100	psi	ISO 527
Yield strain	4	%	ISO 527
Strain at break, B	10	%	ISO 527
Charpy notched impact strength, +23°C	2.24	ftlb/in ²	ISO 179/1eA
Type of failure	C	-	-

Thermal properties

	dry	Unit	Test Standard
Melting temperature	644	°F	ISO 11357-1/-3
Glass transition temperature, 2 nd heating, onset	293	°F	ISO 11357
Glass transition temperature, 2 nd heating, midpoint	311	°F	ISO 11357
Recrystallization temperature, 10 K/min	545^[e]	°F	ISO 11357
Melting Temperature	644	°F	ASTM D 3418

e: 20 K/minute

Physical properties

	dry	Unit	Test Standard
Density	1.46	g/cm ³	ISO 1183
Water absorption	0.4	%	Sim. to ISO 62

Density	1.46	g/cm ³	ASTM D 792
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Rheological properties	dry	Unit	Test Standard
Melt volume-flow rate, MVR	10	cm ³ /10min	ISO 1133
Temperature	380	°C	-
Load	5	kg	-

Characteristics

Applications

Medical implants

Special Characteristics

Phosphorus-free, PTFE-free, High impact strength, Semi-crystalline, 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