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 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.

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/m^2	ISO 179/1eA
Type of failure	**C**	-	-

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

Physical properties	dry	Unit	Test Standard
Density	**1460**	kg/m^3	ISO 1183
Water absorption	**0.4**	%	Sim. to ISO 62

Density	**1460**	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	-

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