

Product Information

VESTAKEEP® iC 4630 G

CARBON FIBER-REINFORCED, IMPLANTABLE-GRADE POLYETHER ETHER KETONE COMPOUND FOR LONG-TERM IMPLANTS



VESTAKEEP® iC 4630 G is a black, medium viscosity polyether ether ketone (PEEK) resin. It contains 30% carbon fiber to increase stiffness.

Biocompatibility

VESTAKEEP® iC 4630 G is especially designed for long term implantable medical devices. The compound composition is optimized for high biocompatibility and mechanical, thermal and chemical resistance.

VESTAKEEP® iC 4630 G is a development material, biocompatibility testing is planned.

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

Planned biocompatibility tests for VESTAKEEP® iC 4630 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 pyrogenesis

Processing

VESTAKEEP® iC 4630 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 during the injection molding process. The mold temperature should be within a temperature range from 160°C to 200°C, preferably 180°C.

Delivery

VESTAKEEP® iC 4630 G is supplied as cylindrical pellets in hobbcks 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.

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

Key Features
Industrial Sector

Medical Devices

Processing

Injection molding

Delivery form

Pellets, Granules

Optics

Opaque

Resistance to

Heat (thermal stability), Hydrolysis / hot water, Wear / abrasion, Fatigue resistance, Oil / fuels

Conformity

Biocompatibility, Medical application

Additives

Carbon fibers

Mechanical properties ISO

	dry	Unit	Test Standard
Tensile modulus	23000	MPa	ISO 527
Stress at break	235	MPa	ISO 527
Strain at break, B	2	%	ISO 527
Charpy notched impact strength, +23°C	10	kJ/m ²	ISO 179/1eA
Type of failure	C	-	-

Thermal properties

	dry	Unit	Test Standard
Melting temperature	340	°C	ISO 11357-1/-3

Physical properties

	dry	Unit	Test Standard
Density	1390	kg/m ³	ISO 1183
Water absorption	0.4	%	Sim. to ISO 62
Humidity absorption	0.12	%	Sim. to ISO 62

Rheological properties

	dry	Unit	Test Standard
Melt volume-flow rate, MVR	25	cm ³ /10min	ISO 1133
Temperature	400	°C	-
Load	21.6	kg	-

Characteristics

Applications

Medical implants

Special Characteristics

High impact strength, Semi-crystalline, High heat resistant, MRT compatible, Sterilizable

Regulatory

US Pharmacopeia Class VI conformity, Cytotoxicity ISO 10993-5

Color

Black

Delivery form

Cylindrical pellets