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 follows 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 pyrogenes

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 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.

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

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

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/m²	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/m³	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**	cm³/10min	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

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