

Product Information

VESTAKEEP® iC 2630 G

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



VESTAKEEP® iC 2630 G is a black polyether ether ketone (PEEK) resin. It contains 30% carbon fiber to increase stiffness.

Biocompatibility

VESTAKEEP® iC 2630 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 2630 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 2630 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 2630 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 2630 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 | 22700 | MPa | ISO 527 |
| Stress at break | 234 | MPa | ISO 527 |
| Strain at break, B | 1.7 | % | ISO 527 |

Physical properties

| | dry | Unit | Test Standard |
|------------------|-------------|-------------------|----------------|
| Density | 1400 | kg/m ³ | ISO 1183 |
| Water absorption | 0.04 | % | Sim. to ISO 62 |
| Density | 1400 | kg/m ³ | ASTM D 792 |

Rheological properties

| | dry | Unit | Test Standard |
|----------------------------|------------|------------------------|---------------|
| Melt volume-flow rate, MVR | 18 | cm ³ /10min | ISO 1133 |
| Temperature | 400 | °C | - |
| Load | 5 | kg | - |

Characteristics

Applications

Medical implants

Regulatory

US Pharmacopeia Class VI conformity

Delivery form

Cylindrical pellets