

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	<b>22700</b>	MPa	ISO 527
Stress at break	<b>234</b>	MPa	ISO 527
Strain at break, B	<b>1.7</b>	%	ISO 527

#### Physical properties

	dry	Unit	Test Standard
Density	<b>1400</b>	kg/m <sup>3</sup>	ISO 1183
Water absorption	<b>0.04</b>	%	Sim. to ISO 62
Density	<b>1400</b>	kg/m <sup>3</sup>	ASTM D 792

#### Rheological properties

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

### Characteristics

#### Applications

Medical implants

#### Regulatory

US Pharmacopeia Class VI conformity

#### Delivery form

Cylindrical pellets