

Product Information

VESTAKEEP® iC 4506 G

X-RAY OPAQUE POLYETHER ETHER KETONE FOR LONG TERM IMPLANTABLE MEDICAL DEVICES



VESTAKEEP® iC4506 G is an opaque, natural colored, high viscosity polyether ether ketone (PEEK) resin. It contains 6% barium sulphate to render it X-ray opaque.

Proven Biocompatibility

VESTAKEEP® iC4506 G is especially designed for long term implantable medical devices.

The compound composition is optimised for high biocompatibility and mechanical, thermal and chemical resistance.

Biocompatibility has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

A summary of biocompatibility is available upon request.

Biocompatibility reports available for VESTAKEEP® iC4506 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 | Subchronic Systemic Toxicity |
| ISO 10993-3 | Genotoxicity: Ames Test |
| ISO 10993-3 | Genotoxicity: Chromosome Aberration test |
| ISO 10993-3 | Genotoxicity: Mouse Lymphoma test |
| ISO 10993-6 | Test for local effects after Implantation in bone (180 days) |
| ISO 10993-11 | Material-mediated pyrogenes |

Processing of VESTAKEEP® i-Grades

VESTAKEEP® iC4506 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 of VESTAKEEP® i-Grades

VESTAKEEP® iC4506 G is supplied as cylindrical pellets in hobbcocks 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.

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, UV / light / weathering

Electrical

Insulating

Conformity

Biocompatibility, Medical application

Additives

Mineral fillers

Mechanical properties ISO

| | dry | Unit | Test Standard |
|-------------------------------|-------------|-------------------|----------------------|
| Tensile modulus | 3600 | MPa | ISO 527 |
| Tensile strength | 95 | MPa | ISO 527 |
| Yield stress | 95 | MPa | ISO 527 |
| Yield strain | 5 | % | ISO 527 |
| Strain at break, B | 10 | % | ISO 527 |
| Charpy impact strength, +23°C | 7 | kJ/m ² | ISO 179/1eU |
| 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 | 1350 | kg/m ³ | ISO 1183 |
| Water absorption | 0.4 | % | Sim. to ISO 62 |
| Density | 1350 | kg/m ³ | ASTM D 792 |

| Rheological properties | dry | Unit | Test Standard |
|----------------------------|------------|------------------------|---------------|
| Melt volume-flow rate, MVR | 10 | cm ³ /10min | ISO 1133 |
| Temperature | 380 | °C | - |
| Load | 5 | kg | - |

| Test specimen production | dry | Unit | Test Standard |
|---------------------------------------|------------|------|---------------|
| Injection Molding, melt temperature | 380 | °C | ISO 294 |
| Injection Molding, mold temperature | 180 | °C | ISO 294 |
| Injection Molding, injection velocity | 200 | mm/s | ISO 294 |

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

Natural color

Additives

Inorganic fillers

Chemical Resistance

Acid resistance, Solvent resistance, Oxidation resistance, Radiation resistance, General chemical resistance