Product Information

# VESTAKEEP® i4 G

## IMPLANTABLE GRADE POLYETHER ETHER KETONE RESIN FOR PERMANENT IMPLANTS

**VESTAKEEP® i4 G** is a natural colored, high viscosity polyether ether ketone (PEEK) that is especially designed for long term implantable medical devices. This grade is often used for extrusion processing technologies.

### Proven Biocompatibility of VESTAKEEP® i-Grades

The extra high purity and extended quality measures make VESTAKEEP® i-Grade materials an excellent choice for permanent implants.

For VESTAKEEP® i4 G, biocompatibility has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

VESTAKEEP® i4 G complies ASTM F2026 "Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications".

A summary of biocompatibility test results is available upon request.

**Biocompatibility tests available for i4 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 (90 days) |

### Processing of VESTAKEEP® i-Grades

VESTAKEEP® i4 G can be processed by common melt processing techniques like injection molding and extrusion.

We recommend a melt temperature between 370°C and 380°C during the injection molding process. The mold temperature should be within a range of 160°C to 200°C, preferably 180°C.

Our technical experts would appreciate to give you support regarding the special requirements for the processing of VESTAKEEP® i4 G.

### Delivery of VESTAKEEP® i-Grades

VESTAKEEP® i4 G is supplied as cylindrical pellets in 10 kg boxes with moisture-proof polyethylene liners.

VESTAKEEP®

## Key Features

**Industrial Sector**
Medical Devices

**Processing**
Injection molding, Extrusion

**Delivery form**
Pellets, Granules

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

**Conformity**
Biocompatibility, Medical application

**Additives**
Unfilled

| Mechanical properties ISO | dry | Unit | Test Standard |
|---|---|---|---|
| Tensile modulus | **3500** | MPa | ISO 527 |
| Tensile strength | **94** | MPa | ISO 527 |
| Yield stress | **94** | MPa | ISO 527 |
| Yield strain | **5** | % | ISO 527 |
| Stress at break | **76** | MPa | ISO 527 |
| Strain at break, B | **30** | % | ISO 527 |
| Nominal strain at break, tB | **>50** | % | ISO 527 |
| Charpy impact strength, +23°C | **N** | kJ/m² | ISO 179/1eU |
| Charpy impact strength, -30°C | **N** | kJ/m² | ISO 179/1eU |
| Charpy notched impact strength, +23°C | **9.1** | kJ/m² | ISO 179/1eA |
| Type of failure | **C** | - | - |
| Charpy notched impact strength, -30°C | **6** | kJ/m² | ISO 179/1eA |
| Type of failure | **C** | - | - |

| Thermal properties | dry | Unit | Test Standard |
|---|---|---|---|
| Melting temperature | **338** | °C | ISO 11357-1/-3 |
| Glass transition temperature, DSC | **152** | °C | ISO 11357-1/-2 |
| Temp. of deflection under load A, 1.80 MPa | **150** | °C | ISO 75-1/-2 |

| | | | |
|---|---|---|---|
| Temp. of deflection under load B, 0.45 MPa | **205** | °C | ISO 75-1/-2 |
| Vicat softening temperature A, 10 N, 50 K/h | **335** | °C | ISO 306 |
| Vicat softening temperature B, 50 N, 50 K/h | **305** | °C | ISO 306 |
| Melting Temperature | **338** | °C | ASTM D 3418 |

| **Physical properties** | **dry** | **Unit** | **Test Standard** |
|---|---|---|---|
| Density | **1300** | $kg/m^3$ | ISO 1183 |
| Water absorption | **0.4** | % | Sim. to ISO 62 |
| Humidity absorption | **0.12** | % | Sim. to ISO 62 |
| Density | **1300** | $kg/m^3$ | ASTM D 792 |

| **Optical properties** | **dry** | **Unit** | **Test Standard** |
|---|---|---|---|
| Color L | **61.9** | - | CIE |
| Color a | **2.77** | - | CIE |
| Color b | **8.63** | - | CIE |

| **Rheological properties** | **dry** | **Unit** | **Test Standard** |
|---|---|---|---|
| Melt volume-flow rate, MVR | **12** | $cm^3/10min$ | 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

**Special Characteristics**
Semi-crystalline

**Regulatory**
US Pharmacopeia Class VI conformity

**Color**
Natural color

**Chemical Resistance**
Acid resistance, Alkali resistance, Solvent resistance, Grease resistance, Hydrolytically stable, Oil resistance, Oxidation resistance, General chemical resistance