

Product Information

VESTAKEEP® iC 4520 R

STOCK SHAPES BASED ON X-RAY OPAQUE POLYETHER ETHER KETONE FOR LONG TERM IMPLANTABLE MEDICAL DEVICES



VESTAKEEP® iC4520 R is a rod stock based on implantable grade polyether ether ketone resin VESTAKEEP® iC4520 G. It contains 20% barium sulphate to render it X-ray opaque.

Proven Biocompatibility

VESTAKEEP® iC4520 R is especially designed for long term implantable medical devices.

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

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

A summary of biocompatibility test results is available upon request.

Biocompatibility reports available for VESTAKEEP® iC4520 R

| 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 pyrogens |

Delivery of VESTAKEEP® i-Grades

VESTAKEEP® iC4520 R is supplied as stock shapes with 10 mm and 20 mm diameter and a length of 30000 mm. Other diameters and lengths are possible.

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

Machining

Delivery form

Stock shape (rods and plates)

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 | 4800 | MPa | ISO 527 |
| Yield stress | 110 | MPa | ISO 527 |
| Yield strain | 4.2 | % | ISO 527 |
| Strain at break, B | 10 | % | ISO 527 |
| Izod Impact notched, 23°C | 5.2 | kJ/m ² | ISO 180/1A |
| Type of failure | C | - | - |
| Flexural modulus, 23°C | 4700 | MPa | ISO 178 |
| Flexural strength, 23°C | 170 | MPa | ISO 178 |

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 | 1500 | kg/m ³ | ISO 1183 |

| | | | |
|------------------|-------------|-------------------|----------------|
| Water absorption | 0.4 | % | Sim. to ISO 62 |
| Density | 1500 | kg/m ³ | ASTM D 792 |

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