Product Information

# VESTAKEEP® iC 4506 R

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

**VESTAKEEP® iC4506 R** is a rod stock based on implantable grade polyether ether ketone resin VESTAKEEP® iC4506 G. It contains 6% barium sulphate to render it X-ray opaque.

### Proven Biocompatibility

VESTAKEEP® iC4506 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 VESTAKEEP® iC4506 R 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® iC4506 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 pyrogenes |

### Delivery of VESTAKEEP® i-Grades

VESTAKEEP® iC4506 R is supplied as stock shapes with 20 mm diameter and a length of 3000 mm and with a diameter of 40 mm and a length of 2000 mm. Other diameters and lengths are possible.

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## 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 | **609000** | psi | ISO 527 |
| Tensile strength | **15800** | psi | ISO 527 |
| Yield stress | **15800** | psi | ISO 527 |
| Yield strain | **4.6** | % | ISO 527 |
| Strain at break, B | **10** | % | ISO 527 |
| Izod Impact notched, 23°C | **2.57** | ftlb/in$^2$ | ISO 180/1A |
| Type of failure | **C** | - | - |
| Flexural modulus, 23°C | **609000** | psi | ISO 178 |
| Flexural strength, 23°C | **24700** | psi | ISO 178 |

| Thermal properties | dry | Unit | Test Standard |
|---|---|---|---|
| Melting temperature | **644** | °F | ISO 11357-1/-3 |
| Glass transition temperature, 2 nd heating, onset | **293** | °F | ISO 11357 |
| Glass transition temperature, 2 nd heating, midpoint | **311** | °F | ISO 11357 |
| Recrystallization temperature, 10 K/min | **545**[e] | °F | ISO 11357 |
| Melting Temperature | **644** | °F | ASTM D 3418 |

e: 20 K/minute

VESTAKEEP®

| Physical properties | dry | Unit | Test Standard |
|---|---|---|---|
| Density | **1.35** | g/cm³ | ISO 1183 |
| Water absorption | **0.4** | % | Sim. to ISO 62 |
| Density | **1.35** | g/cm³ | 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