

Product Information

VESTAKEEP® iC 4612 3DF

IMPLANTABLE-GRADE POLYETHER ETHER KETONE FILAMENT FOR 3D PRINTING WITH 12% CARBON FIBER FOR LONG TERM IMPLANTABLE MEDICAL DEVICES



VESTAKEEP® iC4612 3DF is an opaque, medium viscosity polyether ether ketone (PEEK) filament. It contains 12% carbon fiber to enhance stiffness.

Biocompatibility

The base resin VESTAKEEP® i4 G is especially designed for long term implantable medical devices. The compound composition is optimised for high biocompatibility and mechanical, thermal and chemical resistance.

VESTAKEEP® iC4612 3DF is a provisional material, biocompatibility testing is ongoing.

The biocompatibility testing program follows ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

Planned biocompatibility reports for VESTAKEEP® iC4612 3DF

| 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 pyrogenesis |

Delivery

VESTAKEEP® iC4612 3DF filament has a diameter of 1.75 mm and is supplied on TROGAMID® spools with 500g or 1000g. The spools are packaged in double bags to facilitate transfer into clean areas.

The properties listed are for information only and only apply to the VESTAKEEP® iC4612 G resin used in the manufacture of VESTAKEEP® iC4612 3DF. The performance and the purity of any parts manufactured from VESTAKEEP® iC4612 3DF are highly dependent on any 3D- or additive-printing processes, or any other processing, to which the filament is subjected. Only density and filament diameter apply to VESTAKEEP® iC4612 3DF directly.

The values presented are typical or average values, they do not constitute a specification.

FOR FURTHER INFORMATION PLEASE CONTACT US AT EVONIK-HP@EVONIK.COM
OR VISIT OUR PRODUCT AT WWW.EVONIK.COM/MEDICAL-TECHNOLOGY

Key Features

Industrial Sector

Medical Devices, 3D Printing

Processing

3D Printing

Delivery form

(Mono)filament

Conformity

Biocompatibility

Additives

Carbon fibers

Mechanical properties ISO

| | dry | Unit | Test Standard |
|--------------------|--------------|------|---------------|
| Tensile modulus | 11500 | MPa | ISO 527 |
| Stress at break | 170 | MPa | ISO 527 |
| Strain at break, B | 2.7 | % | ISO 527 |

Thermal properties

| | dry | Unit | Test Standard |
|---------------------|------------|------|----------------|
| Melting temperature | 340 | °C | ISO 11357-1/-3 |

Physical properties

| | dry | Unit | Test Standard |
|---------|-------------|-------------------|---------------|
| Density | 1330 | kg/m ³ | ISO 1183 |

Rheological properties

| | dry | Unit | Test Standard |
|----------------------------|-------------|------------------------|---------------|
| Melt volume-flow rate, MVR | 62 | cm ³ /10min | ISO 1133 |
| Temperature | 400 | °C | - |
| Load | 21.6 | kg | - |

Characteristics

Applications

Medical implants

Processing

Additive manufacturing

Features

Resistance to steam

Regulatory

US Pharmacopeia Class VI conformity, Cytotoxicity ISO 10993-5

Special Characteristics

High impact strength, Semi-crystalline, High heat resistant, MRT compatible, Sterilizable

Color

Black

Other extrusion

Drying recommendations

We recommend to dry the filament prior to usage to avoid stringing, bubbles, or other defects.

- a) Filament on spool: minimum 12 hours at 80°C to 100°C. 100°C must not be exceeded to avoid distortion of the spool.
- b) Filament removed from spool: minimum 4 hours at 130°C to 140°C.

The maximum drying temperature of the filament is 140°C. Please also pay attention to the instructions of your drying device.

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