# VESTAKEEP®

### **Product Information VESTAKEEP® i4 3DF**

### **IMPLANTABLE-GRADE POLYETHER ETHER KETONE FILAMENT** FOR PERMANENT SURGICAL IMPLANTS



VESTAKEEP\* i4 3DF is a filament extruded from natural colored, high viscosity VESTAKEEP\* i4 G polyether ether ketone (PEEK) resin. The material is especially designed for long term implantable medical devices.

**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.

The biocompatibility of the base resin VESTAKEEP\* i4 G 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.

VESTAKEEP\* i4 3DF filaments are compliant to ASTM F2026 "Standard Specification for Polyether ether ketone (PEEK) Polymers for Surgical Implant Applications".

| 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)           |

#### Biocompatibility test reports available for VESTAKEEP® i4 G

#### **Delivery of VESTAKEEP® i4 3DF**

VESTAKEEP\* i4 3DF filament has a diameter of 1.75 mm (+/- 0.02 mm\*) and is supplied on TROGAMID\* spools with 250g or 500g. 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® i4 G resin used in the manufacture of VESTAKEEP® i4 3DF. The performance and the purity of any parts manufactured from VESTAKEEP® i4 3DF are highly dependent on any 3D- or additiveprinting processes, or any other processing, to which the filament is subjected. Only density and filament diameter apply to VESTAKEEP® Care i4 3DF directly.

\*Diameters are tested by a multi-axis laser gauge. The diameter is the average of these axis.

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

# VESTAKEEP®

#### **Key Features**

Industrial Sector Medical Devices, 3D Printing

Processing 3D Printing

**Delivery form** (Mono)filament Resistance to Heat (thermal stability), Hydrolysis / hot water, Wear / abrasion

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        |
| 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       | 6    | kJ/m² | ISO 179/1eA    |
| Type of failure                             | с    | -     | -              |
| Charpy notched impact strength, -30°C       | 9.1  | kJ/m² | ISO 179/1eA    |
| Type of failure                             | с    | -     | -              |
|   |      |       |                |
| 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    |
|   |      |       |                |



# **VESTAKEEP®**

| Physical properties          | dry  | Unit      | Test Standard   |
|------------------------------|------|-----------|-----------------|
| Density                      | 1300 | kg/m³     | ISO 1183        |
| Filament Diameter            | 1.75 | mm        | -               |
| Density                      | 1300 | kg/m³     | ASTM D 792      |
|                              |      |           |                 |
| Burning Behav.               | dry  | Unit      | Test Standard   |
| Burnin behav. at thickness h | V-0  | class     | IEC 60695-11-10 |
| Thickness tested             | 3.2  | mm        | -               |
|                              |      |           |                 |
| Rheological properties       | dry  | Unit      | Test Standard   |
| Melt volume-flow rate, MVR   | 12   | cm³/10min | ISO 1133        |
| Temperature                  | 380  | °C        | -               |
| Load                         | 5    | kg        | -               |
|                              |      |           |                 |

#### Characteristics

Applications Monofilament

**Processing** Fused deposition molding

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, General chemical resistance

#### **Other extrusion**

#### Drying recommendations

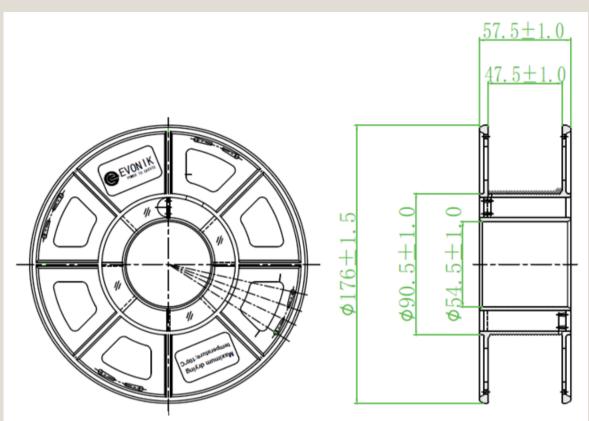
We recommend to dry the filament prior to usage to avoid stringing, bubbles, or other defects.

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.

### **Spool dimensions**





For dimensions of the spool, please see drawing below. All dimensions are given in millimeter (mm).

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