

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".

**Biocompatibility test reports available for VESTAKEEP® 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)

**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 additive-printing processes, or any other processing, to which the filament is subjected.

Only density and filament diameter apply to VESTAKEEP® Care i4 3DF directly.

**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**

	<b>dry</b>	<b>Unit</b>	<b>Test Standard</b>
Tensile modulus	<b>508000</b>	psi	ISO 527
Tensile strength	<b>13600</b>	psi	ISO 527
Yield stress	<b>13600</b>	psi	ISO 527
Yield strain	<b>5</b>	%	ISO 527
Stress at break	<b>11000</b>	psi	ISO 527
Charpy impact strength, +23°C	<b>N</b>	ftlb/in <sup>2</sup>	ISO 179/1eU
Charpy impact strength, -30°C	<b>N</b>	ftlb/in <sup>2</sup>	ISO 179/1eU
Charpy notched impact strength, +23°C	<b>2.85</b>	ftlb/in <sup>2</sup>	ISO 179/1eA
Type of failure	<b>C</b>	-	-
Charpy notched impact strength, -30°C	<b>4.33</b>	ftlb/in <sup>2</sup>	ISO 179/1eA
Type of failure	<b>C</b>	-	-

**Thermal properties**

	<b>dry</b>	<b>Unit</b>	<b>Test Standard</b>
Melting temperature	<b>640</b>	°F	ISO 11357-1/-3
Glass transition temperature, DSC	<b>306</b>	°F	ISO 11357-1/-2
Temp. of deflection under load A, 1.80 MPa	<b>302</b>	°F	ISO 75-1/-2
Temp. of deflection under load B, 0.45 MPa	<b>401</b>	°F	ISO 75-1/-2
Vicat softening temperature A, 10 N, 50 K/h	<b>635</b>	°F	ISO 306
Vicat softening temperature B, 50 N, 50 K/h	<b>581</b>	°F	ISO 306
Melting Temperature	<b>640</b>	°F	ASTM D 3418

Physical properties	dry	Unit	Test Standard
Density	1.3	g/cm <sup>3</sup>	ISO 1183
Filament Diameter	0.0689	in	-
Density	1.3	g/cm <sup>3</sup>	ASTM D 792

Burning Behav.	dry	Unit	Test Standard
Burnin behav. at thickness h	V-0	class	IEC 60695-11-10
Thickness tested	0.1260	in	-

Rheological properties	dry	Unit	Test Standard
Melt volume-flow rate, MVR	12	cm <sup>3</sup> /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).

