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

Diocompanismity test reports evaluable for VID1744211 11 C				
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 250q or 500q. 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.

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 <u>WWW.EVONIK.COM/MEDICAL-TECHNOLOGY</u>



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

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	c	-	-
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	$cm^3/10min$	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 .

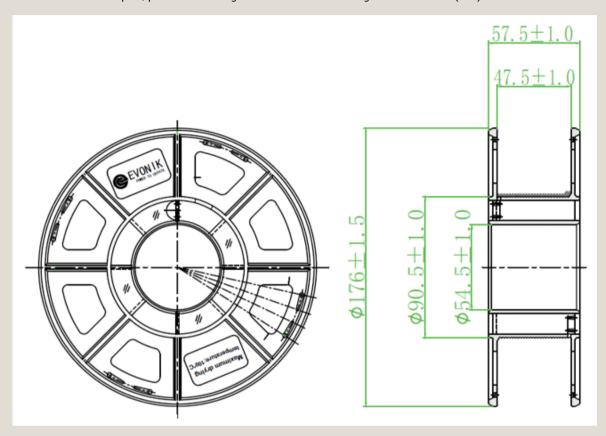
The maximum drying temperature of the filament is 140°C. Please also pay attention to the instructions of your drying device.

Spool dimensions



VESTAKEEP®

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



This information and all technical and other advice are based on Evonik's present knowledge and experience. However, Evonik assumes no liability for such information or advice, including the extent to which such information or advice may relate to third party intellectual property rights. Evonik reserves the right to make any changes to information or advice at any time, without prior or subsequent notice. Evonik disclaims all representations and warranties, whether express or implied, and shall have no liability for, merchantability of the product or its fitness for a particular purpose (even if Evonik is aware of such purpose), or otherwise. EVONIK SHALL NOT BE RESPONSIBLE FOR CONSEQUENTIAL, INDIRECT OR INCIDENTAL DAMAGES (INCLUDING LOSS OF PROFITS) OF ANY KIND. It is the customer's sole responsibility to arrange for inspection and testing of all products by qualified experts. Reference to trade names used by other companies is neither a recommendation nor an endorsement of the corresponding product, and does not imply that similar products could

* is a registered trademark of Evonik Industries AG or one of its subsidiaries

Evonik Operations GmbH Smart Materials High Performance Polymers 45772 Marl / Germany Tel: +49 2365 49-9878 evonik-hp@evonik.com

www.plastics-database.com

