Vestakeep®

Product Information

VESTAKEEP® iC 4800 3DF

IMPLANTABLE-GRADE POLYETHER ETHER KETONE FILAMENT FOR 3D PRINTING WITH ENHANCED OSSEOINTEGRATION FOR LONG TERM IMPLANTABLE MEDICAL DEVICES



VESTAKEEP^{*} **iC4800 3DF** is an opaque, natural colored, high viscosity polyether ether ketone (PEEK) filament based on VESTAKEEP^{*} iC4800 G resin. It contains calcium phosphates to enhance osseointegration. It therefore belongs to the VESTAKEEP^{*} Fusion product family.

Biocompatibility

The base resin VESTAKEEP* iC4800 G is especially designed for long term implantable medical devices. The compound composition is optimised for high biocompatibility and mechanical, thermal and chemical resistance.

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

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 pyrogenes

Available biocompatibility reports for VESTAKEEP® iC4800 G

Delivery

VESTAKEEP[®] iC4800 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[®] iC4800 G resin used in the manufacture of VESTAKEEP[®] iC4800 3DF. The performance and the purity of any parts manufactured from VESTAKEEP[®] iC4800 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 $\mathsf{VESTAKEEP}^*$ iC4800 3DF directly.

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

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



VESTAKEEP®

Key Features

Industrial Sector Medical Devices, 3D Printing

Processing 3D Printing

Delivery form (Mono)filament

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	4350	MPa	ISO 527
Tensile strength	90	MPa	ISO 527
Yield stress	90	MPa	ISO 527
Yield strain	4	%	ISO 527
Strain at break, B	10	%	ISO 527
Charpy notched impact strength, +23°C	4.7	kJ/m²	ISO 179/1eA
Type of failure	С	-	-
Thermal properties	dry	Unit	Test Standard
Melting temperature	340	°C	ISO 11357-1/-3
Glass transition temperature, 2 nd heating, onset	145	°C	ISO 11357
Glass transition temperature, 2 nd heating, midpoint	155	°C	ISO 11357
Recrystallization temperature, 10 K/min	285 ^[e]	°C	ISO 11357
Melting Temperature	340	°C	ASTM D 3418
20 K/minute			
Physical properties	dry	Unit	Test Standard
Density	1460	kg/m³	ISO 1183
Water absorption	0.4	%	Sim. to ISO 62



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1460	kg/m³	ASTM D 792
dry	Unit	Test Standard
10	cm³/10min	ISO 1133
380	°C	-
5	kg	-
	dry 10 380	dry Unit 10 cm³/10min 380 °C

Characteristics

Applications Medical implants

Processing Fused deposition molding, Additive manufacturing

Special Characteristics Phosphorus-free, PTFE-free, High impact strength, Semicrystalline, High viscosity, Self-extinguishing

Features Low odor, Non-corrosive **Regulatory** US Pharmacopeia Class VI conformity

Color Grey

Additives Inorganic fillers

Chemical Resistance Acid resistance, Solvent resistance, Oxidation resistance, Radiation 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.

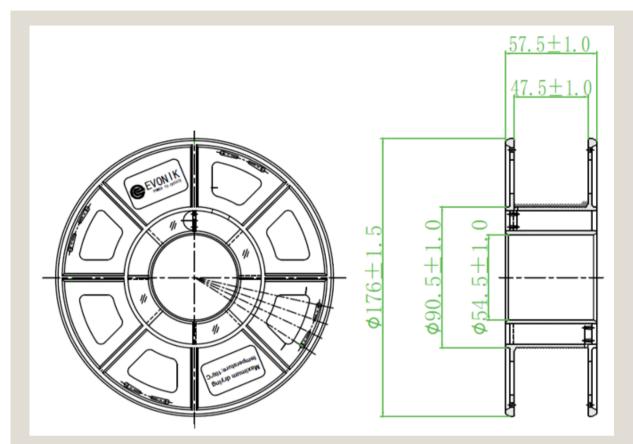
The maximum drying temperature of the filament is 140°C. Please also pay attention to the instructions of your drying device.

Spool dimensions

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



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