Product Information

VESTAKEEP® i2 UFP10

ULTRA-FINE POLYETHER ETHER KETONE (PEEK) POWDER FOR PERMANENT IMPLANTS

VESTAKEEP® i2 UFP10 is an unreinforced, medium-viscosity, natural colored polyether ether ketone (PEEK) ultra-fine powder.

VESTAKEEP® i2 UFP10 is especially designed for long term implantable medical devices.

The semi-crystalline polymer is designed for high biocompatibility and superior mechanical, thermal and chemical resistance.

Proven Biocompatibility of VESTAKEEP® i-Grades

The biocompatibility of VESTAKEEP® i2 UFP10 has been tested following ISO 10993 recommendations for permanent tissue/bone contact. The material complies USP Class VI.

VESTAKEEP® i2 UFP10 is compliant with ASTM F2026 "Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications".

A summary of biocompatibility tests is available upon request.

Biocompatibility test reports available for i2 UFP10

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)
ISO 10993-4	Haemocompatibility

In addition to the body contact period the suitability of the material depends on further criteria, for example the nature of the contact, the processing, or the surface. In any case the suitability has to be verified for the end product.

Processing of VESTAKEEP® i-Grades

For information about processing of VESTAKEEP® i2 UFP10, please follow the general recommendations in our brochure "High Performance in Powder Form - Polyether Ether Ketone Powders".

Delivery of VESTAKEEP® i-Grades

VESTAKEEP® i2 UFP10 is supplied as a powder in 15 kg boxes or 5 kg buckets with moisture-proof polyethylene liners.

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

Processing
Press and sintering, Coating

Delivery form
Powder

Optics
X-ray transparent

Resistance to
Heat (thermal stability), Hydrolysis / hot water

Conformity
Biocompatibility, Medical application

Additives
Unfilled

Mechanical properties ISO	dry	Unit	Test Standard
Tensile modulus	**3700**	MPa	ISO 527
Yield stress	**100**	MPa	ISO 527
Yield strain	**5**	%	ISO 527
Stress at break	**80**	MPa	ISO 527
Nominal strain at break, tB	**30**	%	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	**6**	kJ/m²	ISO 179/1eA
Type of failure	**C**	-	-

Thermal properties	dry	Unit	Test Standard
Melting temperature	**340**	°C	ISO 11357-1/-3
Temp. of deflection under load A, 1.80 MPa	**155**	°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	**310**	°C	ISO 306
Melting Temperature	**340**	°C	ASTM D 3418

Physical properties	**dry**	**Unit**	**Test Standard**
Density	**1300**	kg/m³	ISO 1183
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	**70**	cm³/10min	ISO 1133
Temperature	**380**	°C	-
Load	**5**	kg	-

Powder properties	**dry**	**Unit**	**Test Standard**
Bulk density, powder	**230**	g/l	EN ISO 60
Particle size, Max.	**55**	µm	ISO 13320, DIN ISO 8130-13
Particle size, D(50)	**11**	µm	ISO 13320, DIN ISO 8130-13

Characteristics

Special Characteristics
Semi-crystalline, Low viscosity, Sterilizable

Regulatory
US Pharmacopeia Class VI conformity

Color
Natural color

Delivery form
Ultrafine powder (UFP)

Chemical Resistance
Acid resistance, Alkali resistance, Solvent resistance, Grease resistance, Hydrolytically stable, Oil resistance, Oxidation resistance, General chemical resistance

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