Product Information

VESTAKEEP® i4 P

IMPLANT GRADE VESTAKEEP® POWDER

VESTAKEEP® i4P is a high-viscosity polyether ether ketone (PEEK) powder that is designed for long term human implant applications.

Proven Biocompatibility of VESTAKEEP® i-Grades

VESTAKEEP® i4 P is compliant with ASTM F2026 "Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications". The extra high purity and extended quality measures make the i-grades an ideal material for long term body contact.

A summary of biocompatibility tests is available upon request.

Biocompatibility tests available for i4 P

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

As a powder, VESTAKEEP® i4 P can be used for compounding, compression molding and other melt processing.

For information about processing of VESTAKEEP®powders, please follow the general recommendations in our brochure "VESTAKEEP® Polyether Ether Ketone Powder".

Delivery of VESTAKEEP® i-Grades

VESTAKEEP® i4 P is supplied as powder in boxes with moisture-proof polyethylene liners.

VESTAKEEP®

Key Features

Industrial Sector
Medical Devices

Delivery form
Powder

Optics
X-ray transparent

Resistance to
Heat (thermal stability), Hydrolysis / hot water, UV / light / weathering, Wear / abrasion, Fatigue resistance

Conformity
Biocompatibility, Medical application

Additives
Unfilled

Mechanical properties ISO	dry	Unit	Test Standard
Tensile modulus	**508000**	psi	ISO 527
Tensile strength	**13800**	psi	ISO 527
Yield stress	**13800**	psi	ISO 527
Yield strain	**5**	%	ISO 527
Stress at break	**11000**	psi	ISO 527
Strain at break, B	**30**	%	ISO 527
Nominal strain at break, tB	**>50**	%	ISO 527
Charpy impact strength, +23°C	**N**	ftlb/in²	ISO 179/1eU
Charpy impact strength, -30°C	**N**	ftlb/in²	ISO 179/1eU
Charpy notched impact strength, +23°C	**3.33**	ftlb/in²	ISO 179/1eA
Type of failure	**C**	-	-
Charpy notched impact strength, -30°C	**2.85**	ftlb/in²	ISO 179/1eA
Type of failure	**C**	-	-

Thermal properties	dry	Unit	Test Standard
Temp. of deflection under load A, 1.80 MPa	**302**	°F	ISO 75-1/-2
Temp. of deflection under load B, 0.45 MPa	**401**	°F	ISO 75-1/-2
Vicat softening temperature A, 10 N, 50 K/h	**635**	°F	ISO 306
Vicat softening temperature B, 50 N, 50 K/h	**581**	°F	ISO 306

Physical properties	dry	Unit	Test Standard
Density	**1.3**	g/cm³	ISO 1183
Density	**1.3**	g/cm³	ASTM D 792

Rheological properties	dry	Unit	Test Standard
Melt volume-flow rate, MVR	**11**	cm³/10min	ISO 1133
Temperature	**380**	°C	-
Load	**5**	kg	-

Test specimen production	dry	Unit	Test Standard
Injection Molding, melt temperature	**716**	°F	ISO 294
Injection Molding, mold temperature	**356**	°F	ISO 294
Injection Molding, injection velocity	**7.87**	in/s	ISO 294

Characteristics

Regulatory
US Pharmacopeia Class VI conformity

Chemical Resistance
General chemical resistance