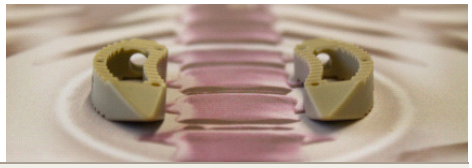
VESTAKEEP®

Technical Information

VESTAKEEP® i5 G



Implantable grade polyether ether ketone resin for permanent implants

VESTAKEEP® i5 G is a natural colored, very high viscosity polyether ether ketone (PEEK) that is especially designed for long term implantable medical devices.

Proven biocompatibility

The extra high purity and extended quality measures make VESTAKEEP® i-grade materials an excellent choice for permanent implants.

For VESTAKEEP® i5 G, biocompatibility has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

VESTAKEEP® i5 G complies to ASTM F2026 “Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications”.

A summary of biocompatibility test results is available upon request.

VESTAKEEP® i5 G is supplied as cylindrical pellets.

Biocompatibility tests available for i5 G

Standard	Description
ISO 10993-3	Genotoxicity: Ames Test
ISO 10993-3	Genotoxicity: Chromosome aberration test
ISO 10993-3	Genotoxicity: Mouse Lymphoma test
ISO 10993-5	Cytotoxicity
ISO 10993-6	Test for local effects after Implantation in bone (90 days)
ISO 10993-10	Sensitization: Maximization test according to Magnusson and Kligman
ISO 10993-10	Irritation: Intracutaneous Reactivity
ISO 10993-11	Subchronic Systemic Toxicity
ISO 10993-12	GC/MS Fingerprint
USP Class VI	Acute Systemic Toxicity Intracutaneous Reactivity Muscle Implantation

Properties of VESTAKEEP® i5 G

		Test method	Unit	Value
Density	23°C / 50% r.h.	ISO 1183	g/cm³	1.30
Water absorption	saturation	ISO 62	%	0.4
Moisture absorption	23°C / 50% r.h.	ISO 62	%	0.12
Tensile test	23°C / 50% r.h.	ISO 527-1 ISO 527-2		
Stress at yield			MPa	95
Strain at yield			%	5.0
Stress at break			MPa	> 70
Strain at break			%	> 40
Tensile modulus		ISO 527-1 ISO 527-2	MPa	3400
CHARPY impact strength		ISO 179/1eU		
	23°C / 50%r.h.		kJ/m²	N[1)]
	-30°C		kJ/m²	N[1)]
CHARPY notched impact strength		ISO 179/1eA		
	23°C / 50% r.h.		kJ/m²	9 C[1)]
	-30°C		kJ/m²	8 C[1)]
Temperature of deflection under load				
Method A	1.8MPa	ISO 75-1	°C	150
Method B	0.45MPa	ISO 75-2	°C	205
Vicat softening temperature		ISO 306		
Method A	10N		°C	335
Method B	50N		°C	305
Differential Scanning Calorimetry (DSC)		ISO 11357		
Recrystallization temperature			°C	285
Glass transition temperature, 2nd heating, onset			°C	145
Glass transition temperature, 2nd heating, midpoint			°C	155
Melting temperature, 2nd heating			°C	340
Melt volume-flow rate (MVR)	380°C/5kg	ISO 1133	cm³/10 min	7

1) C = Complete break, incl. hinge break H
N = No break

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