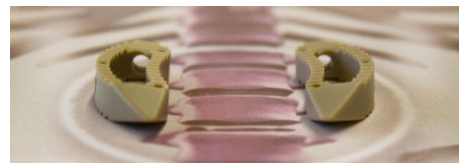


## VESTAKEEP® i4 G



### Implantable grade polyether ether ketone resin for permanent implants

VESTAKEEP® i4 G is a natural colored, high viscosity polyether ether ketone (PEEK) that is especially designed for long term implantable medical devices. This grade is often used for extrusion processing technologies.

### Proven Biocompatibility

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

For VESTAKEEP® i4 G, biocompatibility has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

VESTAKEEP® i4 G complies ASTM F2026 "Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications".

A summary of biocompatibility test results is available upon request.

VESTAKEEP® i4 G is supplied as cylindrical pellets.

### Biocompatibility tests available for i4 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® i4 G

		Test method	Unit	Value
Density	23°C / 50% r.h.	ISO 1183	g/cm <sup>3</sup>	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	96
Strain at yield			%	5.0
Stress at break			MPa	> 70
Strain at break			%	> 20
Tensile modulus		ISO 527-1 ISO 527-2	MPa	3500
CHARPY impact strength	23°C / 50% r.h. -30°C	ISO 179/1eU		
			kJ/m <sup>2</sup>	N <sup>1)</sup>
			kJ/m <sup>2</sup>	N <sup>1)</sup>
CHARPY notched impact strength	23°C / 50% r.h. -30°C	ISO 179/1eA		
			kJ/m <sup>2</sup>	8 C <sup>1)</sup>
			kJ/m <sup>2</sup>	6 C <sup>1)</sup>
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
Melting range		ISO 11357		
DSC	2 <sup>nd</sup> heating		°C	340
Melt volume-flow rate (MVR)	380°C/5kg	ISO 1133	cm <sup>3</sup> /10 min	12

<sup>1)</sup> C = Complete break, incl. hinge break H  
N = No break

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