VESTAKEEP®

Technical Information

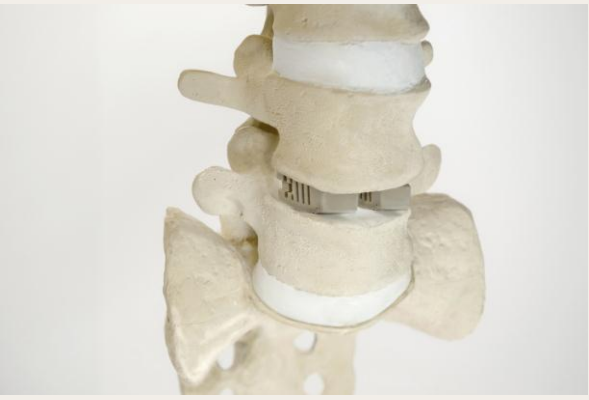
VESTAKEEP® PEEK for medical applications

Evonik markets a line of VESTAKEEP® PEEK resins and stock shapes especially designed for the medical industry.
The material is offered in different grades depending on the duration and the type of contact it will have with the body:
VESTAKEEP®M is used for short term contact, while VESTAKEEP® i is used for long term/ permanent implant contact.

VESTAKEEP® PEEK medical and implant grades

	M-Grades	i-Grades
Implantation time	30 days	Permanent
Biocompatibility testing	Basic	Extensive
Cytotoxicity batch testing	Yes	Yes
Special production		Yes
FDA Masterfiles (MAF)		Yes
„No change“ assurance		Yes

Spinal cages
machined from VESTAKEEP® i4R rods



Comprehensive Supply Chain Control: Quality at its highest stage

Medical companies want a material supplier they can trust and count on for the life of their device. Evonik supply chain security begins at the raw materials and is ensured all the way to the shipment of the final material order, whether powder, resin or extruded stock shape.
By vertically integrating all processes in house, driven by ISO 13485 certifications, our customers can be sure they have the material quality they require for the length of the life of their product.

FDA Masterfile strength

Evonik's Masterfiles (MAF) include extensive in house and independent testing to ensure the latest and most reliable information that our customers require for FDA clearances and approvals on implant devices.
Evonik has established itself an implant PEEK material supplier in many applications for US, Europe and other regions. Multiple medical implants based on VESTAKEEP i-Grade materials already received clearance from the FDA. A combination of superior material performance, quality and Masterfile strength has created the confidence our customers desire when partnering with a supplier of critical materials.

Biocompatibility and Safety

Biocompatibility, biostability and safety are all major criteria when a material is selected for a medical device or a medical implant.
In an extensive testing programme run by independent certified labs biocompatibility has been tested following United States Pharmacopeia (USP 26-Nf 21, 2003) and ISO 10993-1:2003 guidelines. The test reports attest to VESTAKEEP®'s excellent biocompatibility.
In order to ensure a high level of safety, each lot of VESTAKEEP® M and VESTAKEEP® i is tested for cytotoxicity according to ISO 10993-5.
VESTAKEEP's® biocompatibility and biostability are principally attributable to the polymers' high chemical resistance.

VESTAKEEP® i-Grades

VESTAKEEP® i-Grades are Evonik's high end solution for long term implant applications providing utmost safety, quality and reliability. The extra high purity and extended quality measures make VESTAKEEP® i-Grades an ideal material for long-term body contact.
VESTAKEEP® i-Grade resins and stock shapes are compliant with **ASTM F2026** "Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications".

Biocompatibility tests carried out on i4R

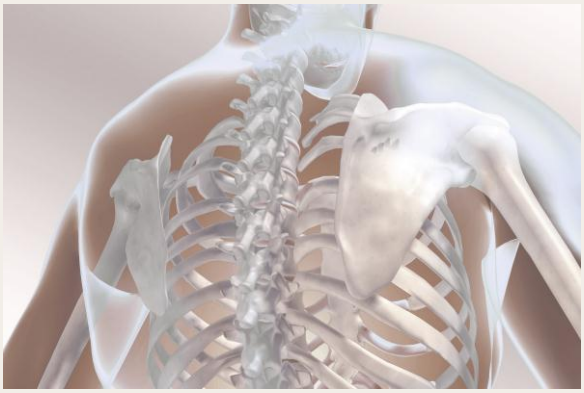
Standard	Description
ISO 10993-3	Genotoxicity: Ames Test
ISO 10993-3	Genotoxicity: Chromosome aberration test
ISO 10993-3	Genotoxicity: Mouse Lymphoma test
ISO 10993-5	Cytotoxicity
ISO 10993-6	Test for local effects after Implantation in bone (90 days)
ISO 10993-10	Sensitization: Maximization test according to Magnusson and Kligman
ISO 10993-10	Irritation: Intracutaneous Reacivity
ISO 10993-11	Subchronic Systemic Toxicity
ISO 10993-18	GC/MS Fingerprint of extractable organic substances
USP Class VI	Acute Systemic Toxicity Intracuteneous Reactivity Muscle Implantation

VESTAKEEP® M-Grades

The good biocompatibility, processability and the option to pigment make the VESTAKEEP® M-Grades an ideal material for the fabrication of medical devices with short time contact to human blood, tissue or bone for up to 30 days.

Test reports available for VESTAKEEP® M-Grades

Standard	Description
ISO 10993-5	Cytotoxicity
ISO 10993-10	Local Lymph Node Assay
ISO 10993-10	Irritation: Intracutaneous Reacivity
ISO 10993-11	Acute Systemic Toxicity
USP Class VI	Acute Systemic Toxicity Intracuteneous Reactivity Muscle Implantation



Special high-performance grades

Because of their combination of outstanding mechanical properties and their excellent resistance to common cleaning and sterilizing processes, VESTAKEEP® PEEK polymers are opening up new options in the design of next generation medical implants and devices. Key properties are

- Excellent biocompatibility
- Outstanding biostability
- Good resistance to commonly used sterilization methods like autoclaving and others
- Resistance to high-energy radiation such as gamma rays or X-rays
- X-ray transparency, no metal-typical shadows or artefacts in radiographs.
- Good combination of mechanical strength, wear resistance and impact resistance makes PEEK a good choice for high strength medical devices
- Good dimensional stability allows for manufacturing of high-precision parts
- Good electrical properties, especially electrical insulation, is important for medical equipment – for example HF endoscopes

For more information please visit our website www.vestakeep.com

Processing of VESTAKEEP®

VESTAKEEP® PEEK resins can be processed using all conventional melt processing techniques such as injection moulding, extrusion, and compression moulding.
Stock shapes can be machined by all conventional equipment like turning or milling machines.

Availability and Delivery of VESTAKEEP® M and i

We deliver our VESTAKEEP® i-Grade and M-Grade polymers in precisely the form you need as resin granules, stock shapes or as a powder.

Delivery forms VESTAKEEP® PEEK

	M-Grades	i-Grades
Resin grades	M2G, M4G	i2G, i4G
Powder grades	M4P	i4P
Rods	M4R	i4R
Plates		i4PL

VESTAKEEP® M-Grades are available in carton boxes with polyethylene inliners with a content of 25 kg (granules) and 10 kg (powders).

VESTAKEEP® i-Grades (granules) are packed in sealed polypropylene buckets with 10 kg; two specially certified polyethylene inliners contain 5 kg each.

VESTAKEEP® M4R and i4R rods are available in various diameters ranging from 6 mm up to 100 mm. The standard length is 1 m. Please inquire our standard diameters. Other dimensions are also available upon request.

Properties of VESTAKEEP® M- and i-Grades

Property		Test method	Unit	M2G/i2G	M4G/i4G M4P/i4P	i4R
Density	23 °C	ISO 1183	g/cm³	1.30	1.30	1.30
Tensile test		ISO 527				
Tensile modulus			MPa	3600	3500	4000
Stress at yield			MPa	100	95	110
Strain at yield			%	5.0	5.0	4.8
Strain at break			%	>20	>20	>20
CHARPY impact strength	23 °	ISO 179/1eU	kJ/m²	N[1]	N[1]	N[1]
	-30 °C		kJ/m²	N[1]	N[1]	N[1]
CHARPY notched impact strength	23 °C	ISO 179/1eA	kJ/m²	6.0 C	8.0 C	
	-30 °C		kJ/m²	6 C	6 C	
Izod notched impact strength	23 °C	ISO 180	kJ/m²			5.5
VICAT softening temperature	Method A, 10 N	ISO 306	°C	335	335	335
	Method B, 50 N		°C	310	305	305
Linear thermal expansion, longitudinal	23-55°C	ISO 11359	$10^{-4}K^{-1}$	0.6	0.6	0.6
Relative permittivity	50 Hz	IEC 60250		2.8	2.8	2.8
	1 MHz			2.8	2.8	2.8
Electric strength	K20/P50	IEC 60243-1	kV/mm	25	25	25
Comparative tracking index CTI		IEC 60112				
Test solution A				200	200	200
100 drops value				175	175	175
Volume resistivity		IEC 60093	Ohm·cm	10^{15}	10^{15}	10^{15}
Surface resistance		IEC 60093	Ohm	10^{14}	10^{14}	10^{14}
Diff. scanning calorimetry (DSC)		ISO 11357				
Recrystallisation Temp 1st h.			°C	app 285	app 285	app 285
Glass transition 2nd h. onset			°C	app 145	app 145	app 145
Glass transition 2ndh. midpoint			°C	app 155	app 155	app 155
Melting temp. 2nd heating			°C	app 340	app 340	app 340
Melt volume-flow rate (MVR)	380°C/ 5 kg	ISO 1133	cm³/ 10min	70	12	
Flammability acc. UL94	0.8 mm	IEC 60695		V-0	V-1	
	1.6 mm			V-0	V-0	
Mold shrinkage	in flow direction	ISO 294-4	%	0.7	1.1	
	in transverse direction		%	1.2	1.8	

[1] No breakage

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