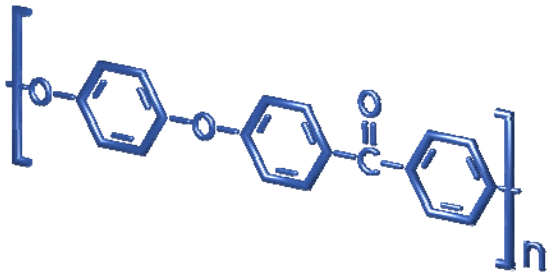
VESTAKEEP® PEEK Polymers for Medical Applications



Evonik has further expanded its technological lead in the high-performance polymers sector with VESTAKEEP® PEEK (polyether ether ketone) polymers. VESTAKEEP®[1] PEEK polymers are suitable for applications with extremely high mechanical, thermal, and chemical requirements.

VESTAKEEP® PEEK polymers are particularly characterized by the following material properties:

- very high heat resistance
- high rigidity
- low water absorption and therefore
- high dimensional stability
- high hardness
- good strength
- excellent sliding friction behavior, minimal abrasion
- good electrical characteristics
- excellent chemical resistance
- excellent hydrolytic stability
- good processability
- low tendency to form stress cracks

VESTAKEEP® PEEK –Quality at the highest stage

Evonik markets its VESTAKEEP® compounds worldwide. A proven quality management system ensures a high level of quality for the products introduced on the market, from development through production, and to quality assurance. Our system is ISO 9001:2000 certified and is continually optimized. A large number of customers have tested this quality system over the years and have attested to its excellence.

Delivery of VESTAKEEP® PEEK for medical applications:

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.

[1] VESTAKEEP® is a registered trademark of Evonik Degussa GmbH

VESTAKEEP® PEEK polymers –the grades for medical applications

We offer two grades of PEEK for medical applications. Which one should be used depends on what kind of contact it will have with the body, and for how long. In our product nomenclature, "M" stands for short-term contact, "i" for long-term contact[2]. Each series is available in medium and high-viscosity grades in granule form, the M grade also in powder form:

VESTAKEEP M2G	VESTAKEEP I2G
VESTAKEEP M4G	VESTAKEEP I4G
VESTAKEEP M4P	

These products have been formulated for high biocompatibility, and batch tests are conducted in vitro to test for cytotoxicity according to DIN EN 10993-5, which ensures a necessary margin of safety.

The following lists the biocompatibility tests that are conducted at the VESTAKEEP® M and I grades by independent qualified laboratories:

United States Pharmacopoeia Testing: <88> "Biological Reactivity Testing In Vivo" Class VI:

- Acute Systemic Toxicity test: 4 different extraction media (70°C/24h);
  no signs of toxicity

- Irritation Test – Intracutaneous Injection test: 4 different extraction media (70°C/24h);
  no signs of erythema, edema or clinical toxicity

- Implantation Test: In Vivo-Implantation test: intramuscular, 7 days;
  no significant signs of hemorrhage, necrosis, discoloration, encapsulation or infection compared with the control sites

United States Pharmacopoeia Testing: <87> "Biological Reactivity Testing In Vitro"

- Cytotoxicity Test: L929 MEM elution, according to ISO 10993-5 (37°C/24h);
  no reactivity (grade 0)

The good biocompatibility, processability and its feasibility to pigmentation make the M grades an ideal material for the fabrication of medical devices with short time contact to human blood, tissue or bone (no longer than 30 days).

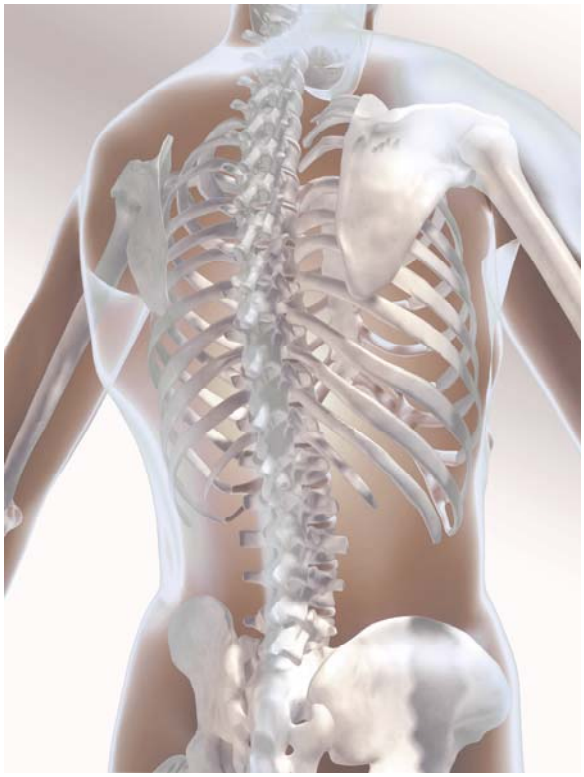
In comparison to VESTAKEEP® M grades the VESTAKEEP® i grades comply with a tighter specification.

They are also compliant with the specifications as specified in 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[2].

In addition the following biocompatibility tests for VESTAKEEP® i grades were carried out:

- ISO 10993-3: Genotoxicity: Ames test
- ISO 10993-3: Genotoxicity: Chromosome aberration test
- ISO 10993-3: Genotoxicity: Mouse Lymphoma test
- ISO 10993-4: Haemocompatibility
- ISO 10993-6: Subcutaneous implantation 12 weeks
- ISO 10993-10: Intracutaneous reactivity
- ISO 10993-10: Sensitization
- ISO 10993-11: Acute systemic toxicity
- ISO 10993-11: Subchronic systemic toxicity
- ISO 10993-18: Investigation of extractable organic substances

An independent accredited laboratory for medical material investigations evaluated the test results for the VESTAKEEP® i series. A master file has been registered at the FDA to support the registration process for medical devices of our customers utilising VESTAKEEP® i grades.



[2] 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.

Photo: Sebastian Kaulitzki / Fotolia.de

VESTAKEEP® PEEK polymers–Special high-performance grades

Because of a combination of mechanical properties and an excellent resistance to common cleaning and sterilizing processes, VESTAKEEP® PEEK polymers are opening up new options in the field of medicine.

In general, PEEK is used in medical products to improve their usefulness: lighter weight, more freedom of design, and better functional integration. It is also an inexpensive alternative to metals and other materials.

In medical applications, the performance of VESTAKEEP® PEEK products is distinguished by the following:

- PEEK's **biocompatibility**, as described earlier, makes it ideal for many medical applications.
- Because of its high **chemical resistance** to commonly used cleaning materials, among others, it can be used in many different ways.
- Owing to its outstanding resistance to **hot steam sterilization,** VESTAKEEP® PEEK polymers are excellently suited for re-usable medical products, too. One example is the grips on operating instruments. Compared to the plastics used today, this high-performance polymer features improved sterilizability, and therefore a longer life. In addition the easy colorability qualifies for a color coding.
- VESTAKEEP® PEEK polymers are resistant to high-energy radiation such as **gamma rays or X-rays**.
- Good **X-ray transparency** makes VESTAKEEP® PEEK polymers an interesting proposition in the operating room. In the case of fixators, for example, VESTAKEEP® PEEK polymers prevent artifacts from appearing in X-ray images.
- Since VESTAKEEP® PEEK polymers possess both high **mechanical strength and wear and impact resistances,** it is also an interesting choice in athletics for the disabled, where it is used in prosthetic devices.
- High-precision parts can be manufactured, thanks to its **good dimensional stability.** In addition VESTAKEEP® M and i grades have **good electrical insulation** properties. Often, this combination of features is especially important in medical equipment, for example in HF endoscopy.
- VESTAKEEP® PEEK polymers feature **good hydrolysis resistance** to water, solvents, and chemicals.

Even though VESTAKEEP® PEEK products have only recently been used in medical applications, the extensive property profile of the material predestines it for a number of interesting applications, like surgical instruments, endoscopes, applications in the in vitro-diagnostic, orthopedic, spinal, and dental fields, analytical equipment, and medical dosing.

We would be glad to work together with you on developing new solutions for your products. Our dedicated team offers you support in all stages of material development. If you are interested, please get in touch with our market development representatives.

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Important properties of VESTAKEEP® M and VESTAKEEP® I grades

Property	Test method	Unit	VESTAKEEP® M2G/i2G	VESTAKEEP® M4G/i4G	VESTAKEEP® M4P
Density 23 °C	ISO 1183	g/cm³	1.3	1.3	1.3
Tensile test	ISO 527				
Stress at yield		MPa	100	95	95
Strain at yield		%	5	5	5
Strain at break		%	30	30	30
Tensile modulus	ISO 527	MPa	3600	3400	3400
CHARPY 23 °C	ISO 179/1eU	kJ/m²	N	N	N
impact strength −30 °C		kJ/m²	N	N	N
CHARPY notched 23 °C	ISO 179/1eA	kJ/m²	6 C	7 C	8 C
impact strength −30 °C		kJ/m²	6 C	6 C	6 C
VICAT softening temperature	ISO 306				
Method A 10 N		°C	335	335	335
Method B 50 N			310	305	305
Linear thermal expansion	ISO 11359				
longitudinal 23–55°C		$10^{-4}K^{-1}$	0.6	0.6	
Relative permittivity 50 Hz	IEC 60250		2.8	2.8	
1 MHz			2.8	2.8	
Electric strength K20/P50	IEC 60243-1	kV/mm	25	25	
Comparative tracking index	IEC 60112				
Test solution A CTI			200	200	
100 drops value			175	175	
Volume resistivity	IEC 60093	Ohm · cm	10^{15}	10^{15}	
Surface resistance	IEC 60093	Ohm	10^{14}	10^{14}	
Melting range	ISO 11357				
DSC 2nd heating		°C	approx. 340	approx. 340	approx. 340
Melt volume-flow rate (MVR)	ISO 1133				
380°C/ 5 kg		cm³/10 min	70	12	12
380°C/ 10 kg					35
Flammability acc. UL94	IEC 60695				
0.8 mm			V-0	V-1	V-1
1.6 mm			V-0	V-0	V-0
Glow wire test	IEC 60695-2-12/13				
GWIT 2 mm		°C	875	875	
GWFI 2 mm		°C	960	960	
Mold shrinkage	ISO 294-4				
in flow direction		%	0.7	1.1	
in transverse direction		%	1.2	1.8	

N = no break

C = complete break

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