VESTAKEEP®
PEEK
BIOMATERIALS
FOR IMPLANT
APPLICATIONS

Evonik
POWER TO CREATE
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Evonik, the creative industrial group from Germany, is one of the world leaders in specialty chemicals. Our activities focus on the key megatrends health, nutrition, resource efficiency and globalization.

Evonik. Power to create.

As a technology leader for high-performance polymers, Evonik supplies polyether ether ketone (PEEK) materials for the medical sector. VESTAKEEP® PEEK for medical applications includes i-Grades for permanent surgical implants, Dental-Grades for temporary and permanent dental applications and Care-Grades for medical devices.

These materials are changing standards for medical technology applications due to their outstanding biocompatibility and biostability.

If implants are to be trusted to perform, the materials they are made from must be both biostable and able to handle mechanical stresses. Historically, this was the exclusive domain of titanium, stainless steel or cobalt-chromium. However, more and more implants are being made of PEEK, which have many advantages over metal. VESTAKEEP® i-Grades have been created to fill these needs.

From its exceptional material properties and performance capabilities, VESTAKEEP® PEEK is the material of choice for medical applications.
SETTING NEW STANDARDS

Customized for the human body

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 according to USP <88> Class VI and following ISO 10993-1:2009 guidelines. These test results attest to VESTAKEEP®’s excellent biocompatibility and biostability, which are principally attributed to the polymers’ high chemical resistance and thermal stability.

VESTAKEEP® PEEK provides convincing advantages like:
- Biocompatibility
- Biostability
- Sterilization compatible
- Resistant to chemicals
- Modulus similar to bone
- Metal-free
- Wear comfort due to light weight and low thermal conductivity
- No x-ray artifacts and/or adjustable opacity
- Injection molding and extrusion compatible
- Low water absorption
- Easy to machine
- Good processability
- Lower stress-shielding effect
### Biocompatibility tests

<table>
<thead>
<tr>
<th>Tests according to ISO 10993 for</th>
<th>VESTAKEEP® i-Grade</th>
<th>VESTAKEEP® Dental-Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>USP Class VI Acute systemic toxicity, Intracutaneous reactivity, Muscle implantation</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>ISO 10993-5 Cytotoxicity</td>
<td>Lot control</td>
<td>Lot control</td>
</tr>
<tr>
<td>ISO 10993-10 Sensitization: maximization test according to Magnusson and Kligman</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>ISO 10993-10 Sensitization: murine local lymph node assay (LLNA)</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>ISO 10993-10 Irritation: intracutaneous reactivity</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>ISO 10993-11 Acute systemic toxicity</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>ISO 10993-11 Subacute/Subchronic systemic toxicity 14d/28d*</td>
<td>14 days</td>
<td>14 days</td>
</tr>
<tr>
<td>ISO 10993-3 Genotoxicity: reverse mutation assay (Ames)</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>ISO 10993-3 Genotoxicity: chromosome aberration test</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>ISO 10993-3 Genotoxicity: mouse lymphoma test</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>ISO 10993-6 Implantation tests Bone 90 days</td>
<td></td>
<td>Muscle 7 days</td>
</tr>
<tr>
<td>ISO 10993-18 GC/MS fingerprint</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

* Tested on VESTAKEEP® i-Grade resin
VESTAKEEP® IMPLANT

1 Cranial-Maxillo-Facial
2 Cardiovascular
3 Pharmacy
4 Spine
5 Orthopaedics
6 Sports medicine
7 Extremities
VESTAKEEP® i-Grades are Evonik’s solution for permanent implants. They are biocompatible, have excellent mechanical properties and are extremely reliable. The extra high purity and extensive quality measures make VESTAKEEP® i-Grades an ideal material for long-term human implants.

The special combination of performance characteristics of VESTAKEEP® i-Grade PEEK polymers makes them the material of choice for implants. They are used for different fields of application such as spine, sports medicine, cardiovascular, cranial-maxillo-facial, orthopaedics, extremities or pharmacy.

X-ray transparency

Traditionally, metals have been the materials of choice for spinal cages and other implants in the human body, but recently the high-performance polymer polyether ether ketone (PEEK) has proven a serious and even more desirable alternative. Metal implants reach their limits when it comes to the imaging methods that physicians use, both during the operation, and to monitor the healing process. Because of their density, metals absorb x-rays and produce artifacts on the radiographic image. PEEK, however, is transparent to x-rays. In cases where the doctor desires to see the implant, x-ray opaque grades of VESTAKEEP® are being developed.

Elasticity

Another weakness of metals is the modulus of elasticity, which is much higher than that of bone.

The implant assumes a large share of the mechanical load, thereby reducing the stress on the bone. This stress-shielding effect can have far-reaching consequences: Bones need the mechanical stress to be regenerated in the healing process and also remain strong. Elimination of stress may slow down the healing process, and over the years, weaken the bone, resulting in greater susceptibility to bone deterioration and breakage. The elasticity of VESTAKEEP® i-Grade PEEK is closer to the cortical bone and has a higher elasticity than metals. This deters the stress-shielding effect on bone and allows for a longer, healthier life.

Applications

- Spinal cages
- Stents
- Heart valves
- Facial implants for facial bone fractures
- Access ports
- Suture anchors
- Interference screws
- Small joints
VESTAKEEP® Filament for medical 3D printing

**Medical 3D printing grade**

VESTAKEEP® i4 3DF is perfectly suitable for additive manufacturing using fused filament fabrication (FFF) technology.

Advantages of using VESTAKEEP® Filament for additive manufacturing include:

- Patient specific design and geometry of implants
- New design opportunities, e.g. porous or hollow structures
- Less material consumption

The filament is extruded from natural colored, implantable-grade VESTAKEEP® i4 G resin.

The extra high purity and extended quality measures make VESTAKEEP® i-Grade materials an excellent choice for permanent implants. The biocompatibility of VESTAKEEP® i-Grade materials has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

Potential applications for the materials include cranio-maxillo-facial (CMF), spinal implants, and sports medicine.

**Test & development grade**

VESTAKEEP® i4 3DF-T PEEK Filaments for FFF technology are additionally offered as a cost-efficient testing grade for research and process development purposes. 3DF-T and the implantable-grade 3DF are equivalent in terms of processing and mechanical properties. Only for 3DF the documentation and support needed for the regulatory approval of medical device applications is available.
VESTAKEEP® i4 3DF and VESTAKEEP® i4 3DF-T filaments are supplied on spools with 250g or 500g and have a diameter of 1.75mm. The spools are based on medical grade plastic TROGAMID®. The spools are packaged in double bags to facilitate transfer into clean areas.

VESTAKEEP® i2 UFP10 powder is an unreinforced, medium-viscosity polyether ketone ultra-fine powder. The powder is supplied in 15 kg boxes with moisture-proof polyethylene liners or 5 kg buckets with moisture-proof polyethylene liners. VESTAKEEP i2F UFP10 powder can be processed by compression molding or other technologies and is suitable for fiber composites, unidirectional carbon fiber layouts. The material is designed for long term implantable medical devices. The biocompatibility of VESTAKEEP® i-Grade materials has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

VESTAKEEP® iC4506 – For applications that need X-Ray visible implants the PEEK technology offers a radiopaque plastic material based on implantable-grade VESTAKEEP resin and pharmaceutical-grade barium sulfate. This product type provides radiographic contrast without the disadvantage of artifact formation as can be the case with other popular materials for implant technology.
In dental technology PEEK provides a metal-free solution for outstanding wear comfort. Potential applications of VESTAKEEP® Dental in medical devices are for example crowns, bridges, and removable and permanent dentures alike. PEEK is one of the high level innovative materials in dental technology.

VESTAKEEP® Dental PEEK products are available in a wide range of natural colors including white pigmented, tooth-colored and gingiva-colored. The selection of colors allows aesthetic solutions.

**X-ray opacity**

As most other plastics polyetheretherketones exhibit an X-ray absorption close to human tissue. Therefore the materials lack contrast and are invisible in X-ray examinations. Its barium sulphate content renders white VESTAKEEP® Dental DC4430 X-ray opaque. Unlike metals, the material does not generate X-ray artifacts and it is MRT-compatible.

**Potential applications**

- Crowns/bridges
- Cervical gingiva formers
- Temporary and permanent abutments
- Attachment restorations
- Partial dentures/transversal connectors
- Occlusal splints
- Inlay bridges
- Telescopic crowns
- Dentures (basis)
- Healing caps
## VESTAKEEP® PRODUCTS

### VESTAKEEP® Implant

<table>
<thead>
<tr>
<th>Stock shapes</th>
<th>Resins</th>
<th>Color</th>
<th>Description</th>
</tr>
</thead>
</table>
| —            | VESTAKEEP® i2 G  
VESTAKEEP® i2 P 
VESTAKEEP® i2 UFP10 | natural | • standard viscosity |
| VESTAKEEP® i4 3DF  
VESTAKEEP® i4 3DF-T  
VESTAKEEP® i4 PL  
VESTAKEEP® i4 R  
VESTAKEEP® iC4506 R | VESTAKEEP® i4 G  
VESTAKEEP® i4 P  
VESTAKEEP® iC4506 G | natural | • high viscosity |
| VESTAKEEP® i5 R  
VESTAKEEP® i5 G | natural | • very high viscosity |

### VESTAKEEP® Dental

<table>
<thead>
<tr>
<th>Stock shapes</th>
<th>Resins</th>
<th>Color</th>
<th>Description</th>
</tr>
</thead>
</table>
| VESTAKEEP® D4 R  
VESTAKEEP® D4 G | natural | • high viscosity |
| VESTAKEEP® DC4420 R  
VESTAKEEP® DC4420 G | white | • high viscosity |
| VESTAKEEP® DC4430 R  
VESTAKEEP® DC4430 G | white, X-ray opaque | • high viscosity |
| VESTAKEEP® DC4450 R  
VESTAKEEP® DC4450 G | tooth-colored | • high viscosity |
| VESTAKEEP® DC4470 R  
VESTAKEEP® DC4470 G | gingiva-colored | • high viscosity |

VESTAKEEP® PEEK can be processed using all techniques such as injection molding, extrusion and the compression molding. Combined, this means maximum freedom for the client and the best product for the patient for extreme mechanical, thermal and chemical requirements.
### Processing

- injection molding
- compounding and compression molding
- extrusion
- compounding and compression molding

### Delivery forms stock shapes

<table>
<thead>
<tr>
<th>VESTAKEEP® rods</th>
<th>diameter</th>
<th>standard lengths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6 - 20 mm</td>
<td>3000 mm</td>
</tr>
<tr>
<td></td>
<td>25 - 60 mm</td>
<td>2000 mm</td>
</tr>
<tr>
<td></td>
<td>70 - 100 mm</td>
<td>1000 mm</td>
</tr>
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<table>
<thead>
<tr>
<th>VESTAKEEP® plates</th>
<th>available in different dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• thickness up to 60 mm</td>
</tr>
<tr>
<td></td>
<td>• standard dimension 500 x 1000 mm</td>
</tr>
</tbody>
</table>

### Delivery forms resins

<table>
<thead>
<tr>
<th>granules</th>
<th>• supplied in 1kg, 5kg or 10kg hobboks with polyethylene liners</th>
</tr>
</thead>
<tbody>
<tr>
<td>powders</td>
<td>• supplied in 10kg hobboks with polyethylene liners</td>
</tr>
</tbody>
</table>

<table>
<thead>
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<th>VESTAKEEP® rods</th>
<th>diameter</th>
<th>standard lengths</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>6 mm</td>
<td>3000 mm</td>
</tr>
<tr>
<td></td>
<td>8 mm</td>
<td>3000 mm</td>
</tr>
<tr>
<td></td>
<td>100 mm</td>
<td>1000 mm</td>
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<tr>
<td></td>
<td>• standard dimension 500 x 1000 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VESTAKEEP® discs</th>
<th>available in different dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• diameter 98.4 mm (with step)</td>
</tr>
<tr>
<td></td>
<td>• diameter 99.5 mm (without step)</td>
</tr>
<tr>
<td></td>
<td>• diameter 84.5 mm (without step)</td>
</tr>
<tr>
<td></td>
<td>• thickness 12 - 30 mm</td>
</tr>
</tbody>
</table>

Other dimensions are available on request.

- D = discs
- F = filament
- G = granules
- PL = plates
- P = powder
- R = rods

(2 x 12.5kg)
In addition to the attributes of the VESTAKEEP® product, Evonik provides a comprehensive service for the development and implementation of polymer technologies. We support our customers from start to finish in their search for new areas of innovative applications.

**Standard**
Customer uses VESTAKEEP® PEEK standard portfolio to develop e.g. spinal implant applications.

**Customized solution**
Customer asks for customized geometries/colors.

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We offer a wide standard portfolio but also help our customers with our material competence to develop the next generation medical implant applications.

We support you from start to finish.
Quality and masterfiles

The service we offer includes:
- Research expertise from decades of experience
- Advice on materials selection, new material development
- Support and guidance in processing
- Technical service for optimizing the manufacturing process

Quality Management

VESTAKEEP stock shapes are produced under an ISO 13485 certified quality management system. The material is reliably supplied at a consistent and quality. All production is fully traceable all its way back to the raw materials used for the resin polymerization.

VESTAKEEP® PEEK resins and stock shapes for medical applications have thoroughly been tested for biocompatibility and toxicity based on ISO 10993 and USP <88> Class VI.

VESTAKEEP® Implant grades are ASTM F2026 compliant.

Masterfile strength

Manufacturers require quick and predictable regulatory approval of their medical devices. Evonik filed master access files (MAF) for both the VESTAKEEP® Implant grade resins and stock shapes. The MAFs contain comprehensive data generated in house and also at independent test laboratories. MAFs are updated regularly as new products are developed and additional data on existing materials are obtained.
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