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PEEK-OPTIMA® polymer from Invibio® is a high performance biomaterial providing advanced solutions for implant manufacturers. Formulated to meet the most exacting in-vivo criteria, PEEK-OPTIMA is biocompatible, safe and stable.

Manufacturers of cardiovascular, dental, neurological and orthopaedic implants choose PEEK-OPTIMA for its:

• Excellent mechanical performance
• High wear resistance
• Ability to be repeatedly sterilized without impairing performance
• Biocompatibility
• Drug and Device Master Files lodged with the FDA

Invibio offers a ‘no-change’ agreement for the assured long-term supply of PEEK-OPTIMA. This guarantees its specification and production methods over an agreed period of time.

PEEK-OPTIMA® is a polyaromatic semicrystalline thermoplastic based on the basic formula \((-\text{C}_6\text{H}_4\cdot\text{O}\cdot\text{C}_6\text{H}_4\cdot\text{O}\cdot\text{C}_6\text{H}_4\cdot\text{CO})_n\) and is known generically as polyetheretherketone.

A Winning Formula

In compliance with ISO 9000 and ISO 13485 standards, Invibio embraces all the principles of Good Manufacturing Practice in relation to the manufacture of PEEK-OPTIMA unfilled granules, compounds & stock shapes. Enhanced quality control procedures and standards ensure a tight product specification for PEEK-OPTIMA including:

• cGMP
• Complete batch and raw materials traceability
• Accredited independent testing laboratory
• Packaging in double lined, tamper-evident drums suitable for clean-room production.

Performance

Quality Assured, Every Time

Total Hip Plate and Pins Ligament Fixation Washers Spinal Cages Pulmonary Artery Band

PEEK-OPTIMA Powder, Pellets, Rods & Film
Flexibility

The Decision is Simple

PEEK-OPTIMA is an inherently pure, inert material. Extensive biocompatibility testing demonstrated no evidence of cytotoxicity, systemic toxicity, irritation or any macroscopic reaction response. Furthermore, very low levels of residual and extractable metal ions minimize the potential risk of allergic reactions commonly associated with nickel and other metal ions.

DMF and MAF files containing the results of these tests have been lodged with the FDA.

DMF and MAF files containing the results of these tests have been lodged with the FDA.

Unlimited Design Solutions

The PEEK-OPTIMA family, comprising three grades - standard viscosity, medium viscosity and low viscosity - is available in granular form for injection molding and/or extrusion.

PEEK-OPTIMA can be processed by:
- injection molding
- extrusion (e.g. rod, tube, plate, monofilament and film)
- compression molding

Stock shapes are produced in a broad range of diameters for machined components.

Purity

DMF and MAF files containing the results of these tests have been lodged with the FDA.

PEEK-OPTIMA Biocompatibility Tests

- Genotoxicity ISO 10993-3
- Hemolysis (Extract) ISO 10993-4
- Cytotoxicity ISO 10993-5
- Biotransition: Local Effects of Implantation ISO 10993-6
- Sensitization ISO 10993-10
- Pyrogenicity ISO 10993-11
- Chemical Analysis ISO 10993-18
- USP Plastic Class VI Systemic Toxicity Study
- USP Plastic Class VI Intracutaneous Toxicity Study

It’s in the Mix

PEEK-OPTIMA compounds can be formulated using a variety of additives including carbon fiber, barium sulphate and glass fiber to satisfy a complete spectrum of application-specific requirements.

Carbon Fiber for Added Strength

The compounding of PEEK-OPTIMA with short carbon fibers, allows the strength of natural unfilled polymer to be increased significantly to address higher stress demanding applications.

Glass Fiber for Property Enhancement

Glass fibers may be compounded with PEEK-OPTIMA polymer to enhance mechanical properties without substantially changing the color of the base material.

Barium Sulphate for Radiopacity

PEEK-OPTIMA polymer is naturally radiolucent. Adding barium sulphate at varying concentrations, as shown, allows the optical density of devices to be tailored from mild to strong radiopacity.

Composites

In certain applications for which superior mechanical properties are required, PEEK-OPTIMA may be used as the matrix polymer in combination with continuous carbon fibers to form reinforced composite materials.
Resilient and Enduring

Natural, unfilled PEEK-OPTIMA is characterized by its high strength, extreme resistance to hydrolysis and resistance to the effects of ionizing radiation. Therefore, PEEK-OPTIMA can be repeatedly sterilized using conventional gamma irradiation, steam and ethylene oxide without significant deterioration of mechanical properties.

Gamma Sterilization

The resilient chemical structure of PEEK-OPTIMA makes it very tolerant to gamma irradiation. However, gamma irradiation of other polymeric materials induces cross-linking and/or chain scission leading to weakening and embrittlement as shown below.

Steam Sterilization

The chemical structure of PEEK-OPTIMA ensures extreme stability against hydrolysis, even at elevated temperatures. PEEK-OPTIMA can be steam sterilized repeatedly without reduction or deterioration in mechanical properties.

EtO Sterilization

EtO residues are within the limits specified in ISO 10993-7, even following three repeated sterilization cycles.

Endurance

Invibio® provides biomaterial solutions for the implantable medical device market. Headquartered in the UK with offices in the USA and Europe it is the sole world-wide manufacturer and distributor of PEEK-OPTIMA® polymer, an advanced biomaterial suitable for long term implantation. The data provided is for evaluative purposes only. Actual PEEK-OPTIMA material specifications must be agreed to by Invibio and customer.

For further information please visit our website at www.invibio.com or call us toll free at 866-INVIBIO or +44 (0)1253 866812.
## Typical Material Properties (Granular)

<table>
<thead>
<tr>
<th>Property</th>
<th>Method</th>
<th>Units</th>
<th>PEEK-OPTIMA®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density</td>
<td>ASTM D792</td>
<td>g cm⁻³</td>
<td>1.29</td>
</tr>
<tr>
<td>Tensile Strength (Yield)</td>
<td>ISO 527 Type 1B @ 50mm min⁻¹</td>
<td>ksi (MPa)</td>
<td>14.5 (100)</td>
</tr>
<tr>
<td>Tensile Elongation (Break)</td>
<td>ISO 527 Type 1B @ 50mm min⁻¹</td>
<td>%</td>
<td>20</td>
</tr>
<tr>
<td>Flexural Modulus</td>
<td>ISO 178</td>
<td>ksi (GPa)</td>
<td>580 (4)</td>
</tr>
<tr>
<td>Flexural Strength</td>
<td>ISO 178</td>
<td>ksi (MPa)</td>
<td>24.7 (170)</td>
</tr>
<tr>
<td>Shear Strength</td>
<td>ASTM D3846</td>
<td>ksi (MPa)</td>
<td>7.7 (53)</td>
</tr>
<tr>
<td>Shear Modulus</td>
<td>ASTM D3846</td>
<td>ksi (GPa)</td>
<td>188.5 (1.3)</td>
</tr>
<tr>
<td>Compressive Strength</td>
<td>ASTM D695</td>
<td>ksi (MPa)</td>
<td>17.1 (118)</td>
</tr>
<tr>
<td>Poisson’s Ratio</td>
<td>ASTM D638</td>
<td>N/A</td>
<td>0.4</td>
</tr>
<tr>
<td>Rockwell Hardness</td>
<td>ASTM D785</td>
<td>M scale</td>
<td>99</td>
</tr>
<tr>
<td>Unnotched Izod Impact</td>
<td>ASTM D256</td>
<td>ft-lb/in (J/m)</td>
<td>no break</td>
</tr>
<tr>
<td>Notched Izod Impact</td>
<td>ASTM D256</td>
<td>ft-lb/in (J/m)</td>
<td>1.18 (63)</td>
</tr>
<tr>
<td>Heat Distortion Temperature</td>
<td>ISO 75</td>
<td>°F (°C)</td>
<td>306 (152)</td>
</tr>
<tr>
<td>Relative Thermal Index</td>
<td>UL 746 B</td>
<td>°F (°C)</td>
<td>500 (260)</td>
</tr>
<tr>
<td>24-Hour Water Absorption</td>
<td>ISO 62</td>
<td>Wt. %</td>
<td>0.5</td>
</tr>
<tr>
<td>Coefficient of Thermal Expansion Below Tg</td>
<td>ASTM D696</td>
<td>10⁻⁶ °F⁻¹(10⁻³ °C⁻¹)</td>
<td>2.6 (4.7)</td>
</tr>
<tr>
<td>Above Tg</td>
<td>ASTM D696</td>
<td>10⁻⁶ °F⁻¹(10⁻³ °C⁻¹)</td>
<td>6.0 (10.8)</td>
</tr>
<tr>
<td>Melt Temperature</td>
<td>DSC</td>
<td>°F (°C)</td>
<td>644 (340)</td>
</tr>
<tr>
<td>Shrinkage LT1</td>
<td></td>
<td></td>
<td>1.2</td>
</tr>
<tr>
<td>(0.118 in (3mm) thick plaque, 170°C/338°F mold)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flow</td>
<td></td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td></td>
<td>Natural</td>
<td></td>
</tr>
<tr>
<td>FDA DMF and MAF Available</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>USP Class VI Certification</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>ISO 10993 Data Available</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No Change Manufacturing Agreement</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Custom Reinforced Compounds Available</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Stock Shapes Available</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

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**Creep**

Creep Modulus vs. Time for PEEK-OPTIMA and Compounds at 23°C

**Fatigue**

Tensile Fatigue for PEEK-OPTIMA LT1 at 23°C 0.5Hz

Flex Fatigue for PEEK-OPTIMA LT1CA30 23°C 0.5 Hz

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