Invibio®
biomaterial solutions

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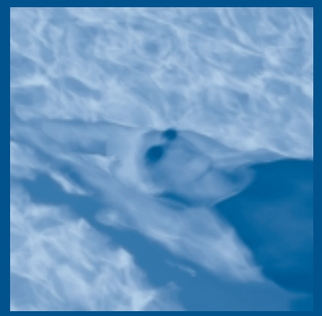
RoSPA 20 02 GOLD MEDAL Award

ISO 9001 SGS

SGS

PEEK-OPTIMA®
POLYMER



Performance Purity Flexibility Endurance

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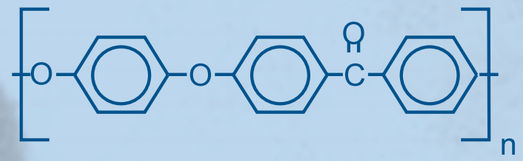
Performance

A Winning Formula

PEEK-OPTIMA® is a polyaromatic semicrystalline thermoplastic based on the basic formula (-C_6H_4-O-C_6H_4-O-C_6H_4-CO-)n and is known generically as polyetheretherketone.



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

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:

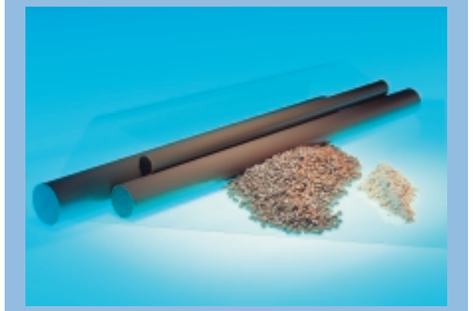
- Excellent mechanical performance
- High wear resistance
- Ability to be repeatedly sterilized without impairing performance
- Biocompatibility
- Drug and Device Master Files lodged with the FDA

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.

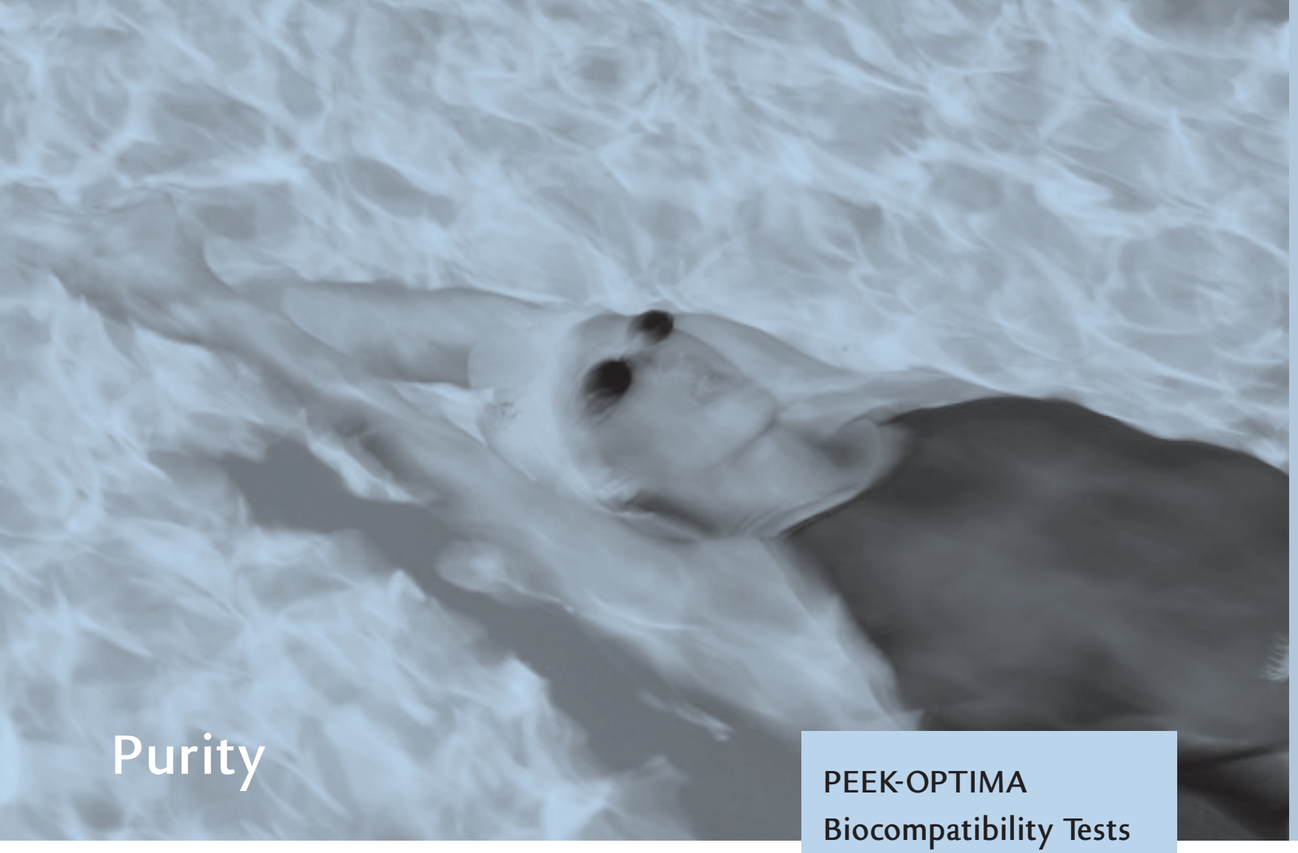
Quality Assured, Every Time

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.



PEEK-OPTIMA Powder, Pellets, Rods & Film



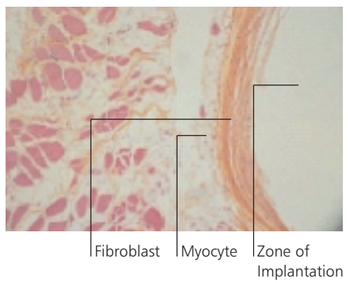
Purity

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.

Tried and Tested

Test material implanted in paravertebral muscle for one year caused virtually no response-mild fibrosis, or in some cases a light fibrous capsule. There was no muscle degeneration, nor necrosis, or any other significant change.



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
- Biostability: 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

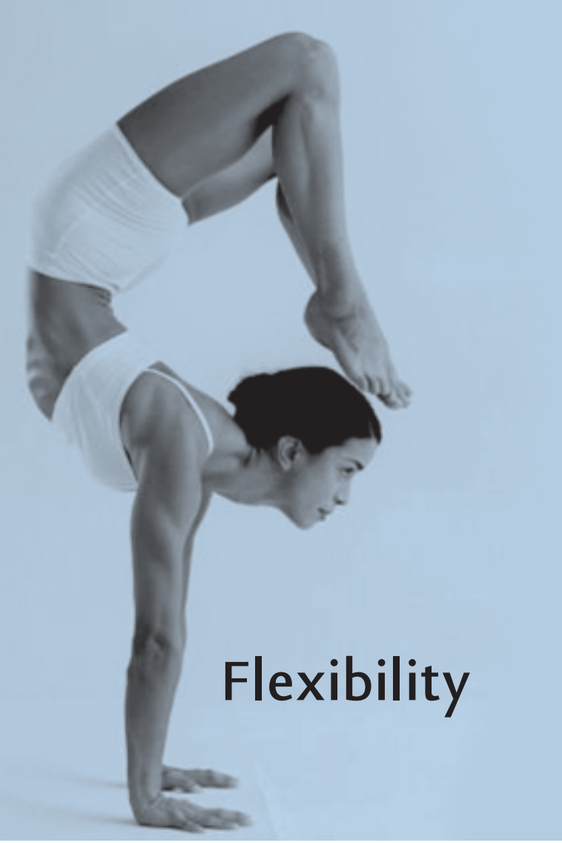
Unlimited Design Solutions

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

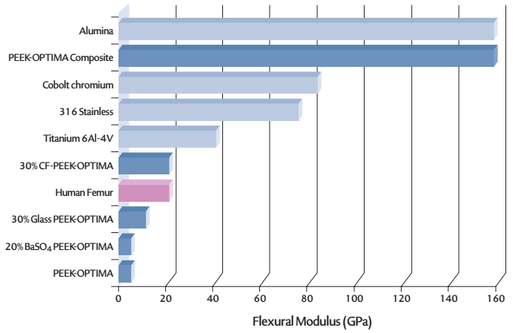
Stock shapes are produced in a broad range of diameters for machined components.



Flexibility

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

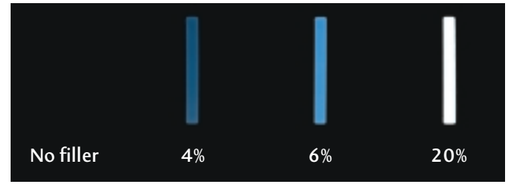
The compounding of PEEK-OPTIMA with short carbon fibers, allows the strength of natural unfilled polymer to be increased significantly to address higher stress demanding applications.

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.

Endurance

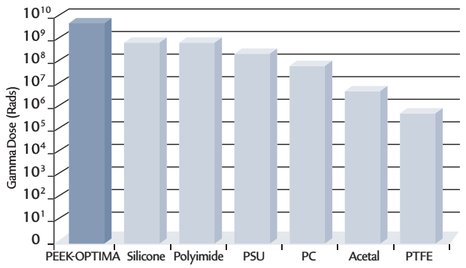
Resilient and Enduring

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.

The Oxidative Gamma Dose at Which a Slight Deterioration in Flexural Properties Occurs



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.

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

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.

PEEK-OPTIMA®

Typical Material Properties (Granular)

Property		Method	Units	PEEK-OPTIMA®
Density		ASTM D792	g cm^{-3}	1.29
Tensile Strength	(Yield)	ISO 527 Type 1B @ 50mm min^{-1}	ksi (MPa)	14.5 (100)
Tensile Elongation	(Break)	ISO 527 Type 1B @ 50mm min^{-1}	%	20
Flexural Modulus		ISO 178	ksi (GPa)	580 (4)
Flexural Strength		ISO 178	ksi (MPa)	24.7 (170)
Shear Strength		ASTM D3846	ksi (MPa)	7.7 (53)
Shear Modulus		ASTM D3846	ksi (GPa)	188.5 (1.3)
Compressive Strength		ASTM D695	ksi (MPa)	17.1 (118)
Poisson's Ratio		ASTM D638	N/A	0.4
Rockwell Hardness		ASTM D785	M scale	99
Unnotched Izod Impact		ASTM D256	ft-lb/in (J/m)	no break
Notched Izod Impact		ASTM D256	ft-lb/in (J/m)	1.18 (63)
Heat Distortion Temperature		ISO 75	°F (°C)	306 (152)
Relative Thermal Index		UL 746 B	°F (°C)	500 (260)
24-Hour Water Absorption		ISO 62	Wt. %	0.5
Coefficient of Thermal Expansion				
	Below T_g	ASTM D696	10^{-5} °F^{-1}(10^{-5} °C^{-1})	2.6 (4.7)
	Above T_g	ASTM D696	10^{-5} °F^{-1}(10^{-5} °C^{-1})	6.0 (10.8)
Melt Temperature		DSC	°F (°C)	644 (340)
Shrinkage LT1				
(0.118 in (3mm) thick plaque, 170°C/338°F mold)				
Flow			%	1.2
Color				Natural
FDA DMF and MAF Available				Yes
USP Class VI Certification				Yes
ISO 10993 Data Available				Yes
No Change Manufacturing Agreement				Yes
Custom Reinforced Compounds Available				Yes
Stock Shapes Available				Yes

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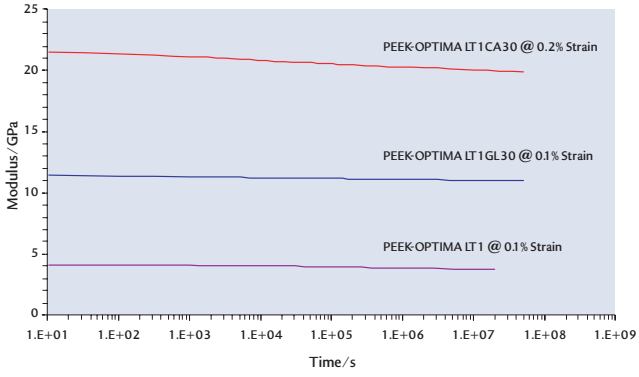
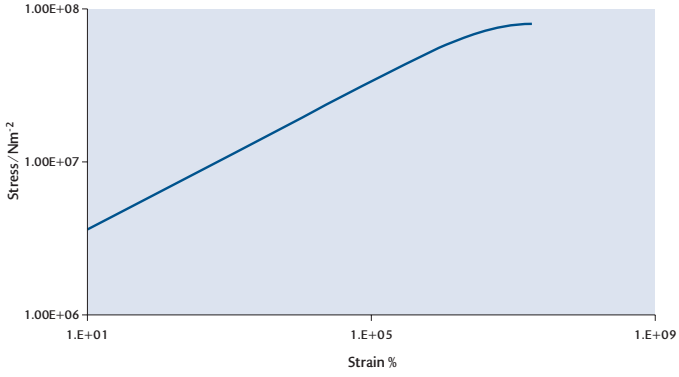
PEEK-OPTIMA®

Creep

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

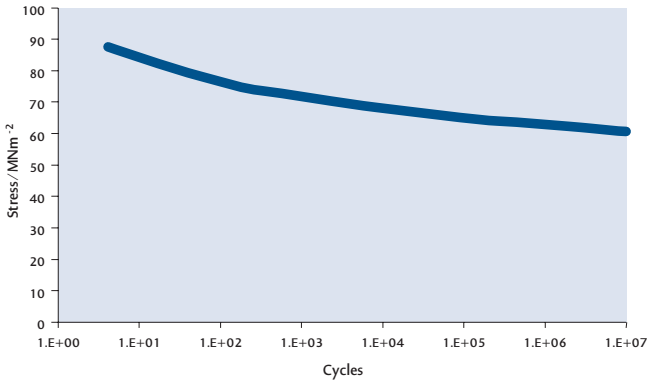


100s Isochronous Data PEEK-OPTIMA LT1 @ 23˚C

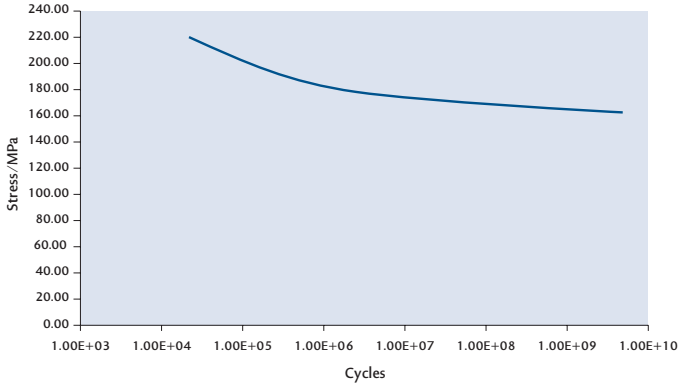


Fatigue

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



Flex Fatigue for PEEK-OPTIMA LT1 CA30 23˚C 0.5 Hz



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