

# PEEK-OPTIMA® Unfilled

Polyetheretherketone

Invibio Inc.

## Message:

PEEK-OPTIMA® image contrast compounds, from Invibio® Biomaterial Solutions, offer implant manufacturers all the benefits of PEEK-OPTIMA polymer, now with tailored radiopacity. These compounds comprise an image contrast additive at specified levels, providing a broad contrast range for optimal visualization with x-ray, CT and MRI imaging modalities.

PEEK-OPTIMA image contrast grades are safe, biocompatible materials intended for implantable medical and pharmaceutical devices and applications requiring blood, bone or tissue contact of more than 30 days.

These compounds provide a unique combination of features and benefits, including:

- Tailored radiopacity allows implant visibility to be optimized
- PEEK-OPTIMA polymer provides a superior combination of strength, stiffness and toughness, even after sterilization
- Biocompatibility ensures safe, long term implantation
- Processing methods allow broad design and manufacturing flexibility
- US FDA Drug and Device Master files can assist with regulatory requirements

Unlike metals, PEEK-OPTIMA image contrast grades provide the possibility of tailoring the visibility of an implant to suit a particular application. It is therefore possible to achieve an appropriate balance of implant, bone and tissue visualization without artifacts or scatter.

Available in a range of viscosities (standard, medium and low), PEEK-OPTIMA image contrast grades can be processed by conventional methods, including injection molding and extrusion, and can be machined, allowing medical device manufacturers broad design and manufacturing flexibility.

Extensive testing of PEEK-OPTIMA compounds to ISO 10993 standards demonstrated no evidence of cytotoxicity, systemic toxicity or irritation. Results have been lodged with the US FDA and can reduce the time and expense of the approval process.

General Information			
Features	Biocompatible		
	Good Toughness		
	High Purity		
	High Stiffness		
	High Strength		
	Low Toxicity		
	Radiopaque		
Uses	Body Implants		
	Dental Applications		
	Medical/Healthcare Applications		
Agency Ratings	DMF Unspecified Rating		
	FDA Unspecified Rating		
Forms	Granules		
Processing Method	Extrusion		
	Injection Molding		
	Machining		
Physical	Nominal Value	Unit	Test Method
Density	1.30	g/cm <sup>3</sup>	ISO 1183

Mechanical	Nominal Value	Unit	Test Method
Tensile Stress (Yield)	100	MPa	ISO 527-2
Tensile Strain (Break)	20	%	ISO 527-2
Flexural Modulus	4000	MPa	ISO 178
Flexural Stress	170	MPa	ISO 178
Impact	Nominal Value	Unit	Test Method
Notched Izod Impact Strength	7.6	kJ/m <sup>2</sup>	ISO 180

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