

PEEK-CLASSIX™

PEEK-CLASSIX™ polymer from Invibio® is a high performance, biocompatible thermoplastic designed for medical device applications requiring blood or tissue contact of less than 30 days. A polyaryletherketone, PEEK-CLASSIX polymer is one of the most chemically resistant polymers available and exhibits a superior combination of strength, stiffness and toughness making it ideally suited for medical device applications.

The polymer can be processed through conventional techniques including injection molding, extrusion, machining and compression molding allowing medical device manufacturers broad design and manufacturing flexibility.

Key Features

- Meets US Pharmacopoeia Class VI / ISO 10993 Standards
- Able to withstand repeat autoclaving
- Superior chemical resistance
- Mechanical strength
- Dimensional stability
- Excellent wear and impact resistance
- Thin wall section processability
- Available in custom colors and compounds

PEEK-CLASSIX polymer is designed for use in medical devices that require short term contact with blood or tissue of less than 30 days. It is not for use in devices designed for long term implantation or requiring contact with blood or tissue of greater than 30 days.

Applications

- Catheters
- Tubing
- Drug Delivery
- Blood Management
- Laparoscopes
- Surgical Instruments
- Endoscopes
- Analytical Equipment

Certifications

- US Pharmacopoeia Class VI
- ISO 10993-1 Guidance
- ISO 10993-5 Cytotoxicity
- ISO 10993-10 Sensitization



Invibio is a global leader in high performance biomaterial solutions for the medical device market. Invibio produces PEEK-CLASSIX polymer at its headquarters and manufacturing facility in the United Kingdom and has offices in the USA and Europe.

Typical Properties

Property	(Units)	Method	PEEK-CLASSIX Polymer Grades	
			BC1 WHITE	BC1 BLACK
Tensile Strength	(MPa)	ISO 527	95	95
Tensile Elongation at Break	(%)	ISO 527	>25	>25
Flexural Strength	(MPa)	ISO 178	160	154
Flexural Modulus	(GPa)	ISO 178	4.2	4.0
Notched Izod Impact Strength	(KJ/m ²)	ISO 180	7.6	7.2
Density	(g/cc)	ASTM D792	1.38	1.30

The PEEK-CLASSIX polymer family comprises standard, medium and low melt viscosity formulations designated BC1, BC2 and BC3 respectively. Data sheets are available on request.

PEEK-CLASSIX polymer is available in pellet form for injection molding and/or extrusion. Additionally, PEEK-CLASSIX polymer compounds can be formulated using a variety of additives including carbon fiber, barium sulfate and glass fiber to satisfy a complete spectrum of application-specific requirements.

PEEK-CLASSIX polymer can be repeatedly sterilized using conventional sterilization methods including steam, gamma radiation and ethylene oxide processes without the degradation of its mechanical properties. It is characterized by extreme hydrolytic resistance, even at elevated temperatures.

Fig 1. Sterilization – Comparative polymer performance

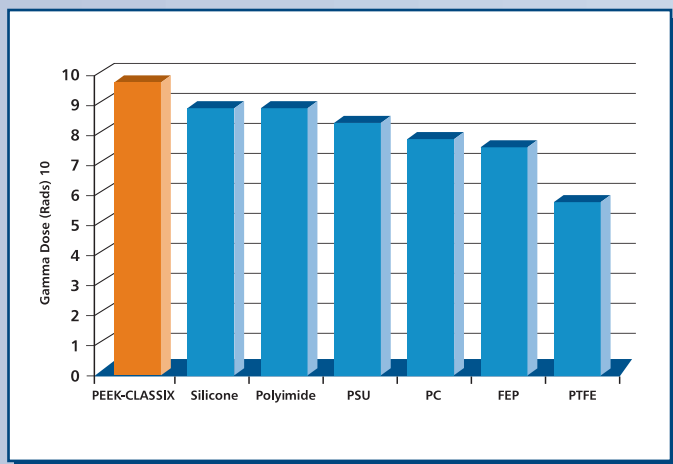
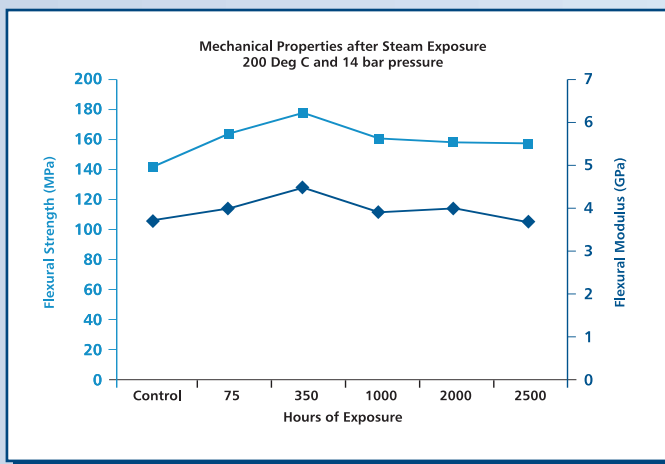


Fig 2. Sterilization – PEEK-CLASSIX mechanical performance



Invio Inc.

3A Caledon Court, Greenville, SC 29615 USA
Tel: 866-INVIBIO (866-468-4246) Fax: (864) 672-7328

Invio Ltd.

Technology Centre, Hillhouse International
Thornton Cleveleys, Lancashire FY5 4QD UK
Tel: +44 (0)1253 866812 Fax: +44 (0)1253 851458
info@invio.com

www.peek-classix.com

Copyright © 2003 Invio Ltd

Disclaimer

PEEK-CLASSIX™ is not for use in devices designed for long term implantation or requiring contact with blood or tissue of greater than 30 days.

The information contained in this brochure is believed to be an accurate description of the typical characteristics and/or uses of Invio® product(s). However, it is your ultimate responsibility to determine the performance, efficacy and safety of using Invio product(s) for a specific application. Suggestions of uses should not be taken as inducements to infringe any particular patent or as a representation that the product is suitable for such uses.

Invio's sole warranty is that its product(s) meet its then current published specifications. Invio specifically disclaims any other express or implied warranty, including the warranties of merchantability, non-infringement, and of fitness for a particular use or purpose.

Invio shall not be liable for any direct, indirect, incidental, special, or consequential damages, in contract, tort, or otherwise, arising out of the use of its product(s) or in connection with the information contained herein. The information and data contained herein are based on information believed reliable. Mention of a product in this documentation is not a guarantee of availability. Invio reserves the right to modify products, specifications and/or packaging, as part of a continuous program of product development.

Invio®, PEEK-CLASSIX™ and the Invio logo are trademarks of Invio Ltd.