

Introducing OrthoPEEK™ --- A Premium Implantable Grade PEEK for Medical Devices



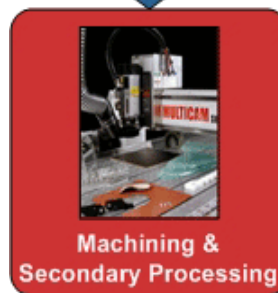
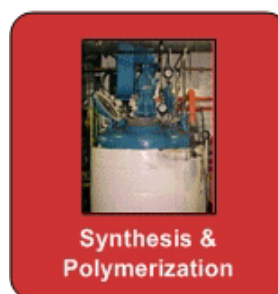
Polymics Ltd.

Founded in 1994 by Dr. Tim Hsu, Polymics is the only company in the world with the expertise and capabilities to take customers needs from high performance material synthesis to final finished parts.

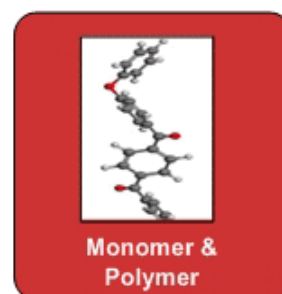
Distinguished by:

- Exclusive focus on high performance polymers for various applications including medical devices
- Vertical production capabilities from raw material synthesis to finished devices
- Truly "Problem to Finished Part Solutions" - working with customers to design and develop ultimate solutions
- Customers including Medtronic and Zimmer

Manufacturing Steps



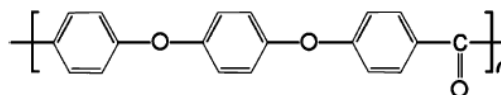
Products



Polymics OrthoPEEK™

--- FDA Registered & Premium Quality Ensured

PEEK --- A Member of Poly Aryl Ether Ketone (PAEK) family materials typically offered with the following grades



Chemical Formula of PEEK

- **Industrial:** Large quantity PEEK materials that are used in industries other than medical device and healthcare related fields. The process & quality control are not compliant with the medical related usage.
- **Medical:** small to medium quantity PEEK materials that are used in medical device industry as instruments for minimum body contact (up to 30 days).
- **Implantable:** very small quantity PEEK materials that are used in human body for long-term implantation applications. The PEEK materials are under strict process and quality control and at least meet the requirements described in ASTM 2026-08.

❖ FDA Device Master File (MAF) Registered

❖ OrthoPEEK™ has passed a variety of biocompatibility tests including, but not limited to

Haemocompatibility	ISO 10993-4
Cytotoxicity	ISO 10993-5
Sensitization	ISO 10993-10
Intracutaneous reactivity	ISO 10993-10
Acute Toxicity	ISO 10993-11

OrthoPEEK™

- An implantable PEEK material provided by Polymics Ltd. offered with a variety of forms – resin, compounds, shaped stocks and final finished OEM devices
- One of the only two implantable PEEK materials available in the world.
- Proprietary synthesis and processing with ISO 9001 certified quality control
- A key material technology platform for a variety of implantable medical device applications (see left figure).



Polymics, Ltd.

High Performance Polymers & Compounds

Polymics OrthoPEEK™

--- Excellent & Proved Material Performances

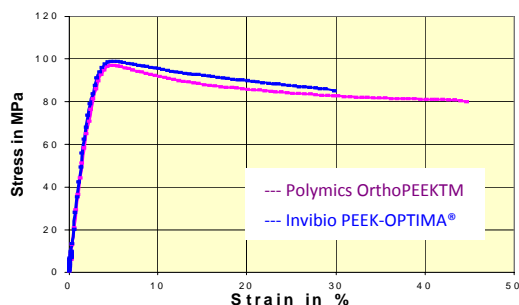
Polymics OrthoPEEK™ major material characteristics:

- Biocompatible
- Chemically stable
- Excellent mechanical & tribological properties
- Modulus similar to bone
- Minimization of stress shielding
- Radiolucence
- Compatible with all sterilization methods

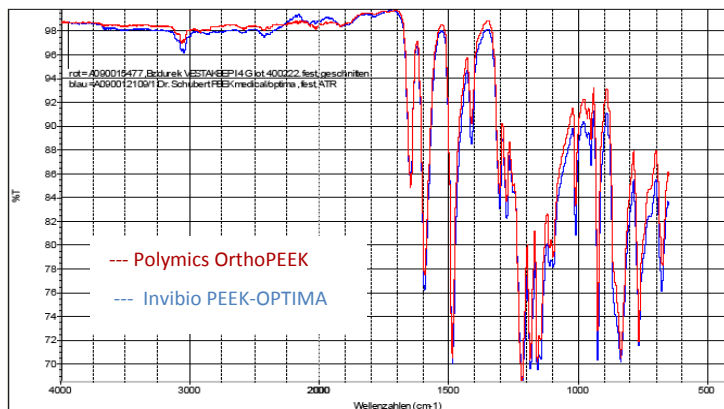
Polymics OrthoPEEK™ equivalent to Invibio PEEK-OPTIMA® in terms of:

- manufacturing process
- chemistry
- physical and mechanical properties
- thermal properties
- meeting ASTM F2026-08
- biocompatibility
- Sterilization

Tensile Stress-Strain Curves of Injection Molded Parts



FTIR Spectra



Chemistry & Composition

	OrthoPEEK	Optima PEEK
Manufacturing process	Nucleophilic route	Nucleophilic route
Organic extractables at 23°C, 24 hours	none	none
Heavy Metals	Below detectable limit (<ppb)	Below detectable limit (<ppb)
FTIR Spectra	Equivalent to Optima PEEK	See spectra

Properties of Extruded PEEK Bars

Properties (Methods, Units)	ASTM 2026-08	Invibio PEEK-OPTIMA	Polymics OrthoPEEK
Density (ISO 1183, g/cm³)	1.28 – 1.32	1.30	1.30
Tensile Strength at Yield (ISO 527, min, MPa)	90	115	110
Tensile Strength at Break (ISO 527, min, MPa)	70	84	80
% Elongation at Break (ISO 527)	5	10	20
Flexural Strength (ISO 178, min, MPa)	110	170	150
Flexural Modulus (ISO 178, min, GPa)	3	4	4
Impact Strength, Notched IZOD, (ISO 180, min, KJ/m²)	4	4.7	5.8
T _g (°C)	125 – 165	143	143
T _m (°C)	320 – 360	340	340
T _c (°C)	260 – 320	292	290
Total heavy Metals as Lead (max, wt%)	0.1	< 0.1	<0.1

❖ More Data are available upon requests



Polymics, Ltd.

High Performance Polymers & Compounds

Polymics OrthoPEEK™

--- Superior Customer Service

Polymics OrthoPEEK™ Offers:

- Reasonable price to medical device manufacturers
- No buy-in fees, royalties or inventory tracking
- No Language barrier in business transaction and customer support
- Pre- and post-sale customer support and technical consulting
- Willingness & capability to work with customers on product development and OEM production
- Agreement to allow customers to develop proprietary grades/devices
- A variety of forms – resin, compounds, shaped stocks and final finished OEM devices

Contacts:

Official website in both English and Chinese (coming soon):

<http://www.polymics.com/orthopeek>

<http://www.orthopeek.com>

Polymics, Ltd. - USA

2215 High Tech Road

State College, PA 16803

Phone: 814.357.5860 | Fax: 1.814.357.5863 |

Email: info@polymics.com

Polymics, Ltd. – Taiwan

Applied Polymer Materials Inc.

#1006, Guangfu Road

Bade City, Taoyuan, 33455

Taiwan, R.O.C

Phone: 866.3.367.1357 | Fax: 866.3.377.1908

| Email: info_apm@polymics.com

Disclaimer: The information contained in this brochure is believed to be an accurate description of the typical characteristics and/or uses of Polymics product(s). However, it is your ultimate responsibility to determine the performance, efficacy and safety of using Polymics 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. Polymics's sole warranty is that its product(s) meet its then current published specifications. Polymics specifically disclaims any other express or implied warranty, including the warranties of merchantability, non-infringement, and of fitness for a particular use or purpose. Polymics 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. Polymics reserves the right to modify products, specifications and/or packaging, as part of a continuous program of product development.

Copyright © 2009 Polymics Ltd.

Polymics™ and the Polymics logo are registered trademarks of Polymics Ltd.

OrthoPEEK™ is a registered trademark of Polymics Ltd.

