PEEK

Historical background

PEEK (Polyetheretherketone) was invented in 1978 by ICI. It was originally used in extreme industrial applications because of its exceptional mechanical, thermal and chemical properties. PEEK-OPTIMA® polymer from Invibio® Biomaterial Solutions was developed in 1998 in response to the demand from major medical device manufacturers who wanted a high-performance grade Polymer which could offer all the guarantees for long-term implantation in terms of purity and traceability.

Procedures and manufacturing site

PEEK-OPTIMA is a semicrystalline aromatic polymer of the PAEK (Polyaryletherketone) family. This biocompatible

material is designed for permanent implantation. Invibio manufactures this material in compliance with the most demanding production standards, including ISO 13485 and GMP. Its quality is controlled and certified by Invibio and by the certified independent laboratory NAMAS/UKAS after stringent trials on essential physico-chemical criteria. It is delivered in the form of granules designed for injection moulding or extrusion. Invibio also offers a wide range of semi-finished products, bars and plates intended to be converted by machining.

Our custom solutions department can suggest specific semi-finished products according to clients' requirements.

The range of implantable materials based on PEEK-OPTIMA resin has been complemented by the introduction of BaSO4-charged compounds to make it radio-opaque, or carbon fibres to improve its mechanical and tribological properties. ENDOLIGN®, a composite with extremely high mechanical performance comparable to some metals, was introduced in 2006. Invibio's R&D department is constantly working on the development of future range extensions with new properties.

A grade designed for temporary implantation (30 days), PEEK-CLASSIX®, has been available since 2004.

PEEK OPTIMA polymer devices have been approved by the FDA, the PMDA, the SFDA and of course carry CE marking.

Available biocompatibility data – quality certificates

Invibio offers full biocompatibility data for all grades on the market. PEEK-OPTIMA is thus used worldwide, even in the most demanding countries (Japan, USA, etc.). Biocompatibility dossiers may be adapted to the requirements of the various authorising bodies in each country.

Standard biocompatibility tests include, specifically:

- Genotoxicity ISO 10993-3.
- Haemolysis (Extract) ISO 10993-4.
- Cytotoxicity ISO 10993-5.
- Biostability: Local effects of implantation ISO 10993-6.
- Sensitisation ISO 10993-10.
- Pyrogenicity ISO 10993-11.
- Chemical analysis ISO 10993-18.
- USP Class VI plastics systemic toxicity study.
- USP Class VI plastics intracutaneous toxicity study.

Uses

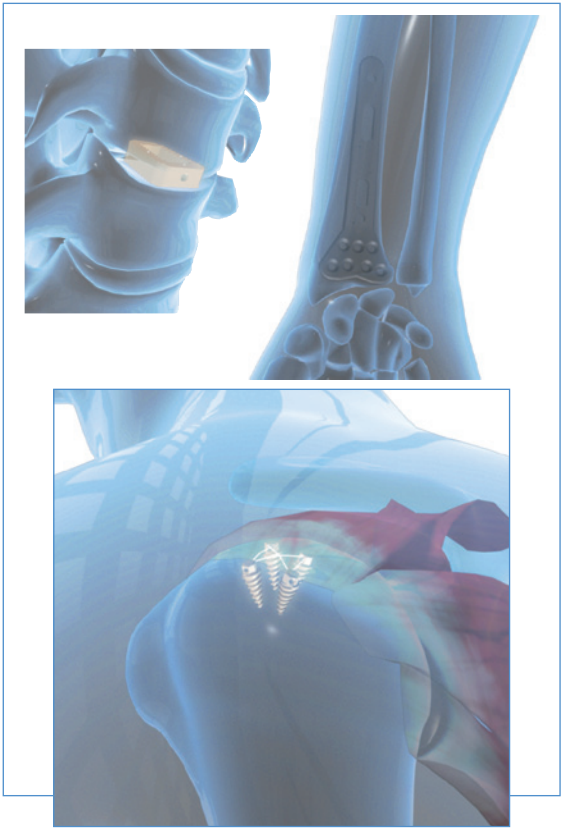
The polymer PEEK-OPTIMA and its derivative compounds and composites have excellent physical and chemical properties:

- Excellent mechanical performance.
- High resistance to wear and tear.
- Possibility of repeated sterilisation by all current techniques without affecting performance.
- Total or partial radiotransparency.
- Biocompatibility.
- "Drug and Device" Masterfile registered with the FDA.

These properties provide a material of choice for manufacturers of all types of long-term implantable devices. Used in the production of interbody fusion cages (spinal) since its launch in 1998, this material has since gained prominence in numerous other spheres of application

- Ligament fixation (suture anchors, interference screws).
- Active implantable devices (neuromodulation, neurostimulation).
- Orthopaedic prostheses.
- Dental (implants, fixed or movable prostheses).
- Cardiovascular.
- Traumatology (ENDOLIGN composite osteosynthesis plates and screws).
- Cranio-maxillary-facial reconstruction.

Property	Unit	PEEK-OPTIMA (LT1 - Unfilled)	PEEK-OPTIMA IC (LT1 6BA)	PEEK-OPTIMA CFR (LT1 CA30)	Motis G	ENDOLIGN Unidirectional	ENDOLIGN Multidirectional
Tensile Strength (Yield)	Mpa	90	85	200	155	2000	900
E-Modulus	Gpa		3	18	15	150	70
Elongation at Break	%	15	15	1.5	2		
Flexural Strength	Mpa	110	110	300	240	1100	
Impact Strength (Notched izod)	Kj/m^2	5	4	8	5.7		



Invibio provides its materials in long-term supply contracts, guaranteeing no alteration in the essential characteristics of the material.

Partner

Invibio Biomaterial Solutions was created in 2001 as a subsidiary of Victrex Plc, with the aim of developing and marketing only those polymer grades designed for human implantation. Invibio directs all operations connected with the manufacture of implantable grades from its base in the north of England, on the former site of ICI, thus guaranteeing that manufacturing procedures validated over many years remain unchanged. R&D activities relating to future grades, as well as technical support and regulatory departments, are located at the same site.

A subsidiary has been created in the United States in order to ensure a commercial and logistical presence in this leading medical device market. Over recent years, Invibio has also been developing strong markets in Asia.

www.invibio.com