

PEEK-OPTIMA® Polymer in the Implantable Medical Device Industry

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PEEK AND THE MEDICAL INDUSTRY

Polyetheretherketone, or PEEK polymer is an exceptionally strong engineering thermoplastic that retains its mechanical properties even at very high temperatures. The material is tough and abrasion resistant with high impact strength and excellent flexural and tensile properties. It has a low coefficient of friction and resists attack by a wide range of organic and inorganic chemicals and solvents.

Because of its unique properties, PEEK polymer has been used to develop a variety of components for the medical market, including applications for implantable medical devices – or “in vivo” devices – used within the human body.

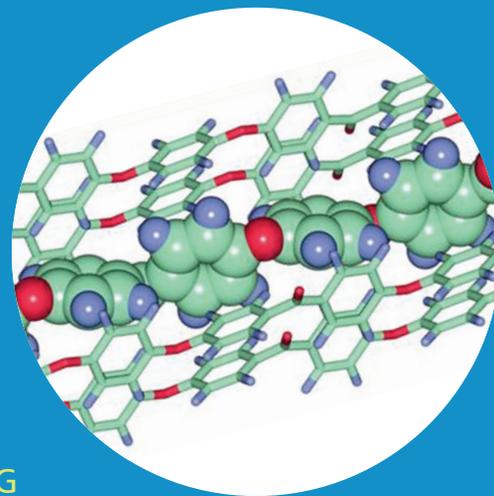
The most important attributes for a thermoplastic designed for in vivo use is biocompatibility – the suitability of a material for exposure to the body or bodily fluids, and biostability – the ability of a material to maintain its physical and chemical integrity after implantation in living tissue.

PEEK-OPTIMA: MATERIAL OF CHOICE

Formulated to meet the most demanding in vivo criteria, PEEK-OPTIMA – a PEEK polymer manufactured and marketed by Invibio® – is a safe, biocompatible and stable polymer, available in a range of forms that offer virtually unlimited design solutions.

PEEK-OPTIMA polymer exhibits a superior combination of strength, stiffness and toughness, together with extensive biocompatibility, making it ideally suited for in vivo medical device applications. The polymer can be processed through conventional techniques including injection molding, extrusion or machining, allowing medical device manufacturer’s broad design and manufacturing flexibility.

Since its introduction to the market in 1999, PEEK-OPTIMA polymer has quickly gained the confidence and acceptance of the medical community as a highly reliable, implantable material.



IDEAL IMAGING

PEEK-OPTIMA polymer offers exceptional imaging versatility by being inherently radiolucent and capable of being easily modified to be radiopaque.

Additional radiographic qualities include the elimination of imaging artifacts and scatter generated from metallic implants which prevent a complete inspection of tissue and bone growth when using conventional imaging techniques such as X-rays, MRI and Computer Tomography (CT).

OPTIMAL MODULUS

The modulus (degree of elasticity or stiffness) of PEEK-OPTIMA polymer may be adapted to closely match that of cortical bone. This is significant as bone requires stimulus from mechanical stress to maintain its structure.

Metallic implants, with a substantially higher modulus than cortical bone, can cause a phenomenon known as “stress shielding”, which is commonly thought to lead to bone mass loss and the loosening and subsequent failure of some metallic orthopaedic implants. PEEK-OPTIMA polymer compounds, with a similar modulus to cortical bone, help mitigate this stress shielding.

PEEK-OPTIMA polymer can be tailored by adding reinforcing fibres that significantly increase the mechanical properties of the material in order to satisfy applications requiring very high strength.

CHEMICAL RESISTANCE

PEEK-OPTIMA polymer is one of the most chemically resistant polymers available. It displays excellent chemical resistance, confirmed by 30-day exposure to simulated body fluid environments, utilizing sodium chloride solutions, glycerol, vegetable oil and an alcohol, with no adverse influence on the material's mechanical properties.

STERILIZATION

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

CERTIFIED BIOCOMPATIBILITY AND QUALITY

The development of PEEK-OPTIMA polymer has been achieved using enhanced manufacturing procedures, supported by physical, chemical and mechanical testing conducted at key stages of production. Independent laboratories have performed biocompatibility and biostability testing relevant to ISO 10993 and USP Class VI procedures, which have shown excellent results.

The material is manufactured to the highest level of purity with complete material history traceability. Device (MAF) and Drug (DMF) Master Files containing these results, as well as additional testing and extensive data concerning the polymer and its manufacturing methods, are lodged with the FDA.

In addition, the material is cGMP certified meaning Invibio embraces all the principles of "Good Manufacturing Practice" in relation to the manufacturing of unfilled granules, compounds and stock shapes.

AN IDEAL BIOMATERIAL SOLUTION

Medical device manufacturers rely on advanced polymeric biomaterials such as PEEK-OPTIMA polymer for their unique combination of biocompatibility, ideal imaging properties, optimum modulus and excellent chemical resistance.

Because of its versatility, PEEK-OPTIMA polymer devices are being investigated and developed in nearly every application area for implants. Device manufacturers have used the material in the development of spinal-fusion cages, finger joints, hip and femoral bone replacements, bone screws and pins, components for implanted cardiac pumps and dental posts and caps.

Invibio's PEEK-OPTIMA polymer presents an ideal biomaterial solution for the implantable medical device industry, and remains the material of choice for the development of long-term medical implant applications.

If you would like more information about PEEK-OPTIMA polymer or other Invibio solutions, please visit our website at www.invibio.com or call us at 866-INVIBIO or +44 (0) 1253 898000.

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