

PEEK-OPTIMA™ Polymers

A Proven History of Biocompatibility and Implantation

CLINICAL HISTORY

- ▶ Invibio Biomaterial Solutions™ introduced the first implantable PEEK polymer, PEEK-OPTIMA, more than 20 years ago, setting the industry standard for PEEK biomaterial biocompatibility and quality. Since then, PEEK-OPTIMA polymers have been used in more than 13 million implanted devices¹ across a wide range of medical applications, including spinal fusion where it has become a leading implant material with both surgeons and patients relying on it.
 - Extensive clinical evidence
 - Beneficial patient outcomes¹

REGULATORY HISTORY

- ▶ PEEK-OPTIMA polymers offer exceptional product purity, quality control and testing. Their proven biocompatibility and biostability is supported by Comprehensive Master Files and are used in thousands of regulatory body-cleared implantable devices, worldwide. No other implantable PEEK is used as extensively in such clearances.
 - Comprehensive Master Files
 - Zero material-related recalls
 - ISO-certified manufacturer
 - Used in medical devices cleared globally¹
 - US FDA 510(k), CE-marked and other regulatory bodies

PRODUCT FEATURES

- ▶ The PEEK-OPTIMA family of products is available in a wide variety of forms, including granules, pellets, fibers and films, making it one of the most versatile biomaterial solutions available to medical device designers. All PEEK-OPTIMA polymers and compounds are engineered for:
 - High chemical resistance
 - Ability to be repeatedly sterilized using steam, ethylene oxide (EtO) or gamma sterilization / irradiation without degradation in mechanical properties or biocompatibility
 - Compatibility with X-ray, CT and MRI for artifact-free imaging

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- Extremely low levels of extractables and leachables
- Excellent mechanical properties such as stiffness, toughness and durability
- Ease of Manufacturing including precision machining, injection molding and extrusion

PRODUCT BENEFITS

- ▶ As a metal-free alternative, the effectiveness of PEEK-OPTIMA polymer solutions and the potential to improve treatment is demonstrated through enhanced research and clinical evidence.
 - Biocompatibility
 - Broad regulatory clearances globally
 - Modulus similar to bone
 - Reduced stress shielding
 - Artifact-free imaging
 - Eliminates the risk of allergies from metal
 - Lightweight and warmer compared to metal
 - Strong, durable and highly resistant to creep² and fatigue
 - No metal after-taste when used in dental implant prosthetics

CLINICAL APPLICATIONS

- ▶ PEEK-OPTIMA polymers and compounds are available in a range of grades and forms that offer nearly unlimited medical design and manufacturing flexibility across highly diverse applications requiring implantation or blood, bone and tissue contact for greater than 30 days:
 - Spinal interbody fusion
 - Spinal rods for dynamic stabilization and motion preservation
 - Trauma plates for fracture fixation
 - Hammertoe and wedges for foot and ankle applications
 - Cranio-maxillofacial (CMF) patient-specific implants
 - Suture anchors

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- Femoral implants
- Dental implant prosthetics
- Total and partial joint replacement
- Cardiovascular implants including artificial heart
- Drug Delivery systems

REFERENCES

1. Supporting information available upon request.
2. Ferguson SJ, et al. The long-term mechanical integrity of non-reinforced PEEK-OPTIMA polymer for demanding spinal applications experimental and finite-element analysis. *Eur Spine J.* 2006;15(2):149-156.



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