Multimaterial Reinforced Bioactive Polyetherketoneketone Composites for Bone Replacement

IPR Status

Patent Filed in India (2025); Trade Mark filed in India (2025) [**NeoPEKK™**]

Application/Uses

The multifunctional PEKK composites can be used for manufacturing implantable medical devices that require a combination of bioactivity, antibacterial functionality, radiolucency, and mechanical compatibility with bone. Some of important applications include:

- Load-bearing spinal implants, including lumbar, cervical, and thoracic interbody fusion cages and related spinal fixation devices.
- Orthopaedic implants and fixation devices, such as bone plates, screws, wedges, joint reconstruction components, and trauma fixation devices.
- Dental and maxillofacial implants, including dental implants & abutments, bone augmentation devices, and cranio-maxillofacial implants.
- Patient-specific and customized implants manufactured using additive manufacturing (3D printing) or conventional polymer-processing techniques.
- Implant feedstock materials, supplied as pellets, granules, rods, or filaments for subsequent manufacture of biomedical implants using injection moulding, compression moulding, extrusion, machining, or additive manufacturing.
- Next-generation multifunctional implant systems requiring simultaneous osteoconductive, antibacterial, radiolucent, and load-bearing performance for long-term implantation.

Salient Features

1. Novel bulk multifunctional PEKK composite integrating bioactive and antibacterial inorganic fillers in a single material platform that simultaneously promotes bone regeneration, osteointegration, and resistance to bacterial colonization.
2. Retains the inherent advantages of PEKK, including radiolucency, chemical resistance, and suitability for load-bearing applications.
3. Bulk multifunctional architecture with uniform filler dispersion provides reliable, improved long-term implant stability and performance, while eliminating dependence on surface coatings.
4. Optimized filler composition provides an effective balance between biological performance, mechanical strength, industrial scalability and processability.
5. Compatible with conventional manufacturing and additive manufacturing, enabling both standard and patient-specific implants.
6. Scalable, commercially viable platform technology with broad applicability across spinal, orthopaedic, trauma, cranio-maxillofacial, and dental implant markets.

Level/Scale of Development

- **Technology Readiness Level (TRL) 5–6:** Prototype multifunctional PEKK composite successfully developed and validated through comprehensive materials, microstructural, and mechanical characterization.
- **Preclinical validation completed:** In vitro and in vivo studies confirm enhanced osteogenesis, osteointegration, antibacterial efficacy, and mechanical suitability for load-bearing implants.

- **Regulatory testing completed:** ISO 10993 biological safety evaluation (cytotoxicity, skin sensitization, irritation/reactivity, systemic toxicity, genotoxicity) and ASTM E2180 antibacterial testing completed through CDSCO-recognized, NABL/FDA-accredited laboratories.
- **Commercialization ready:** Prepared for pilot-scale manufacturing, prototype implant fabrication, regulatory advancement, and technology licensing to medical device manufacturers.

Line Ministry Mapping

- **Ministry of Health and Family Welfare (MoHFW)** – Implantable medical devices for spinal, orthopaedic, trauma, and dental surgery.
- **Ministry of Chemicals and Fertilizers** – Medical devices, biomaterials, and indigenous manufacturing under the medical devices sector.
- **Ministry of Science and Technology** – Translation and commercialization of advanced biomaterials, polymers, and healthcare technologies.
- **Ministry of Commerce and Industry** – Promotion of indigenous medical device manufacturing, technology transfer, and export-oriented innovation.
- **Ministry of Heavy Industries** – Advanced manufacturing technologies for high-value medical devices and biomedical engineering products.

User Sector

- Indian and global spinal, orthopaedic, trauma, and dental **implant manufacturers**.
- **Medical device companies** manufacturing polymer-based implantable devices.
- **Medical-grade polymer** and biomaterial **manufacturers**.
- **Contract manufacturing organizations** (CMOs/OEMs) for medical devices.
- Hospitals, specialty surgical centres, and academic medical institutions.
- **Technology transfer** organizations, investors, and strategic industry partners for commercialization and licensing.

Multimaterial reinforced bioactive Polyetherketoneketone composite granules, filament, and spinal cage.