

PEEK Polymer, a Good Material Option for Drug Delivery Devices

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Introduction

Medication adherence among patients with chronic diseases averages only 50% in developed countries according to the World Health Organization (WHO).¹ Non-adherence has significant ramifications, both clinically and economically. For patients, it can result in poor health, requiring additional hospitalizations and medical visits. It reduces productivity and compromises quality of life, possibly ending in death. It also significantly burdens healthcare systems², with estimates of avoidable costs ranging up to \$290 billion in the US and €1.25 billion in Europe.³

Implantable infusion pumps and more generally e-drug delivery devices, in contrast, have the potential to lower treatment costs, improve patient outcomes and promote an active lifestyle. Improving devices or developing new solutions is, however, challenging for the industry as strict regulations must be observed for patient safety, leading to long development times.

The main objectives in developing a new device include:

1. **Positive impact on patients:** easy to use, treatment adherence and outcomes
2. **Lower barriers to innovation:** reduced costs, speedier time-to-market

Investigation into high performing materials can help to address these needs, as can partnering with an experienced material-solutions provider as early as possible, i.e. during the design phase.

Material requirements become more demanding

Implantable or wearable drug delivery devices such as insulin pumps, used in the treatment of diabetes, could make a major contribution to the improvement of medication adherence. The current trend for these devices is to become less invasive, with smaller dimensions and parts miniaturized to precise tolerances. This results in reduced weight and greater ease of use. When complex electronic components must be embedded, they too are designed to be compact, with a wall thickness that is as thin as possible.

Thus, the supply chain poses further challenges to the industry. The key question on the materials side, regardless of it being an implantable or non-implantable drug delivery device, is: Can the device be further improved using different, higher performing materials? However

additional sourcing challenges arise when the design specifications require more than three important material properties.

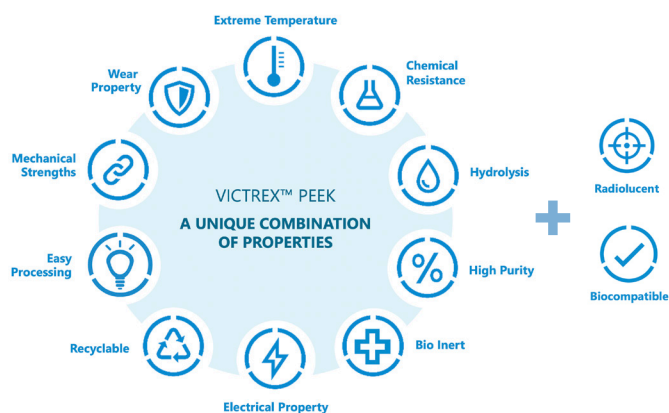


Figure 1: PEEK offers a unique combination of properties meeting demanding material requirements and design specifications.

High performing PEEK polymers, forms, parts – a potential solution?

One of the highest performing polymers, and one that can support multiple key engineering requirements, is PEEK (Polyetheretherketone), available as non-implantable VICTREX™ PEEK and implantable Invibio™ PEEK-OPTIMA™, for example. They are both provided by the Victrex group, which includes Invibio Biomaterial Solutions™ as a subsidiary. PEEK has been used to achieve improved safety and durability, greater design freedom and patient comfort, and increased cost efficiency in the production of medical devices.

Currently, the group supplies its PEEK solutions in the form of pellets, powder, filament, film, and rod and plaque stock shapes, such as composite trauma plates. In addition to natural (unfilled) PEEK, the polymer is also available compounded with fillers, including glass fiber and short and continuous carbon fiber. As a thermoplastic, PEEK can be processed using conventional thermoplastic processing equipment for injection and compression molding, as well as extrusion. Invibio is an ISO-certified manufacturer and provides a comprehensive Master File supporting regulatory submissions for implantable PEEK-OPTIMA polymers.



Figure 2: PEEK polymer available in a wide range of forms for use in different manufacturing processes.

Implantable PEEK – a winning formula

After the first implantable PEEK was introduced by Invibio in 1999, the company continued to pioneer novel materials, and PEEK gained more and more acceptance in the market:

- The medical industry has successfully utilized this unique polymer for long-term implantable devices for spine, trauma, orthopedics, extremities, cranio-maxillofacial (CMF) and dental applications, for example
- More than 500 medical devices made with PEEK-OPTIMA Polymers have gained FDA clearance in the US alone
- More than 13 million devices using PEEK-OPTIMA polymers have been implanted worldwide

It is important to note that the polymer, as well as Invibio's knowledge and support, continue to this day, to serve an active source of innovation.

There are many underlying reasons for the successful use of PEEK in medical devices: The high-performance polymer is biocompatible, which is an absolute requirement for implantable applications. Moreover, PEEK is inherently radiolucent, so medical imaging by X-ray, CT scan and MRI, are artifact-free and therefore facilitate monitoring and diagnosis with unobstructed views. Furthermore, it can be sterilized using standard processes such as gamma and e-beam radiation and steam sterilization.

In terms of mechanics, given that the polymer can be processed by injection molding or machining, very small parts with accurate dimensions and tight tolerances can be produced and assembled, making it a competitive option for drug delivery applications. PEEK is also chemically inert, and this stability allows it to be in contact with aggressive chemicals or drugs without interactions, whether PEEK is present in the form of packaging or as a conduit. If mechanical strength is required, then PEEK parts can be designed to meet this key engineering requirement.

Successful PEEK-OPTIMA based drug delivery solutions have been identified for applications that include neuromodulation, oncology and implantable infusion pumps.⁴

Non-implantable PEEK: 40+ years of experience across industries

Like the implantable PEEK from Invibio, the non-implantable VICTREX™ PEEK delivers high mechanical strength, where it exhibits stiffness, along with impact and fatigue resistance, and a low frictional ratio. As well, it is chemically stable at both high and low temperatures, remaining non-leachable and non-extractable. Invented back in 1978, today the high performing material is used across key industries, including medical.

In medical, the potential range of drug delivery applications for non-implantable PEEK is quite broad and includes injection-pen/auto-injector and wearable segments. For these and other devices the solutions must be reliable and safe, and accurately dispense the right amount of drug at the right location at the right time. The requirement to be patient-friendly and low-cost is important for these types of applications, in order to address the challenge of treatment adherence. In terms of processability, it can be machined and injected to precisely accurate dimensions and tolerances. As a result, the number of parts and components that comprise the device can be reduced. Additionally, PEEK is a dielectric, wear and water resistant with low outgassing. Proof points for the success of the multi-talented PEEK beyond the medical field are available in automotive, aerospace, electronics, energy and manufacturing & engineering applications.

Working with a proven partner: benefits for device manufacturers

Specialized support from a material solutions provider helps to rapidly move implantable devices from concept to commercialization. With more than 40 years of experience and success in enabling customers to overcome complex engineering challenges, the Victrex Group offers support at every stage of new product development to fast-track customer design innovations and time-to-market, so that customers can focus on their core strengths.

Value-added services offered by Invibio:

- **Material development** – continuously expanding the product range with innovative solutions, including PEEK-OPTIMA™ HA Enhanced for bone ongrowth and PEEK-OPTIMA™ Ultra-Reinforced for example.
- **Device component manufacturing** – fully integrated PEEK parts development accelerating time-to-market, Invibio works with partners from concept through commercialization to overcome design and

manufacturing challenges, for example, for very small gears.

- **Technical support** – providing guidance for material selection, processing, prototyping and validation, sterilization methods, chemical resistance and troubleshooting as well as support for machining and testing, vendor selection and failure analysis.
- **Regulatory support** – global in reach with region-specific expertise: access to comprehensive MasterFile data; extensive biocompatibility data; including submission support
- **Security of Supply** – All raw material suppliers are selected and qualified from leading manufacturers and are part of an advanced supplier assurance program. Invibio follows a strict corporate risk management process supporting seamless delivery to the market as an ISO-certified manufacturer.

Invibio’s medical-grade PEEK-OPTIMA Natural polymer is a reliable implantable material with:

20+ Years Proven Clinical History

ZERO Material-Related Recalls

EXTENSIVE Clinical Evidence & Demonstrated Beneficial Patient Outcomes

Summary: Proven expertise from start to success pushes boundaries

Whenever a challenging combination of material properties is required, whether in implantable or non-implantable drug delivery devices, high-performing PEEK polymers offer a range of compelling mechanical, chemical and electrical attributes, including biocompatibility, the vital characteristic for implantable applications.

Working together with Victrex and its’ subsidiary Invibio, can push design and engineering boundaries in the creation of solutions that utilize the full potential of PEEK and result in a competitive edge. Detailed knowledge of design synergies and cross-applications acquired by the group over 40 years enables the medical device industry to translate material benefits and advances into innovative connected devices that have the potential to lower treatment costs and improve patient outcomes while promoting an active lifestyle. ▲

ABOUT THE AUTHOR

John Devine, PhD

Dr. John Devine is the Business Director for Invibio Biomaterial Solutions and is responsible for identifying and executing the market strategy for the adoption of Invibio materials and components. His leadership in identifying unmet clinical needs and the creation of new products and business models has contributed greatly to a portfolio of innovations for the device industry. He is a named inventor on a number of patented inventions, is a frequent contributor to papers at key biomaterials and industry conferences and has authored numerous peer reviewed articles. Dr. Devine holds a doctorate in the field of organic polymer synthesis and structure property relationships from the University of St. Andrews, United Kingdom, a Masters degree in Process Technology and Management from the University of Strathclyde, United Kingdom and a degree in Chemistry from the University of Glasgow, Scotland.



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4. Data on file at Invibio Biomaterial Solutions™.

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