

DRUG DELIVERY EBOOK

A GUIDE TO PEEK POLYMERS IN DRUG DELIVERY DEVICE DESIGN



A MESSAGE FOR THE INNOVATORS

Drug delivery devices have the potential to lower treatment costs, improve patient outcomes and promote an active lifestyle. Finding ways to improve the device or to develop new solutions is challenging – but with the right high performing materials, that journey can be easier. Victrex is here to help you discover what is possible, and how far you can push the boundaries when inventing with PEEK.

In this eBook, we will introduce you to the science of PEEK and how it can help you meet your objectives when developing a new device:

The main objectives in developing a new device include:

- Positive impact on patients: therapeutic success, easy to use, treatment adherence
- Lower barriers to innovation: reduced costs, speedier time-to-market

Innovation is possible, and there are new solutions waiting to be uncovered – you just need to find them.



John Devine, PhD

Medical Business Director

Victrex and Invibio Biomaterial Solutions



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TRENDS IN DRUG DELIVERY DEVICE ENGINEERING



4 TRENDS IN DRUG DELIVERY DEVICE ENGINEERING

These trends mean that new demands are being placed on the materials of construction for drug delivery devices, because traditional approaches and materials may not be suitable.

TREND 1

Next generation biologics

TREND 2

Patient-centric, wearable solutions

TREND 3

Home-based care

TREND 4

Targeted drug delivery

TREND 1

NEXT GENERATION BIOLOGICS

Many of today's major drugs are delivered by injection and require systems such as infusion pumps, syringes, or on-body or auto injectors. Next generation biologics with larger molecules bring new challenges in their delivery, such as larger dosage volumes of 2.25ml and high viscosity formulations.

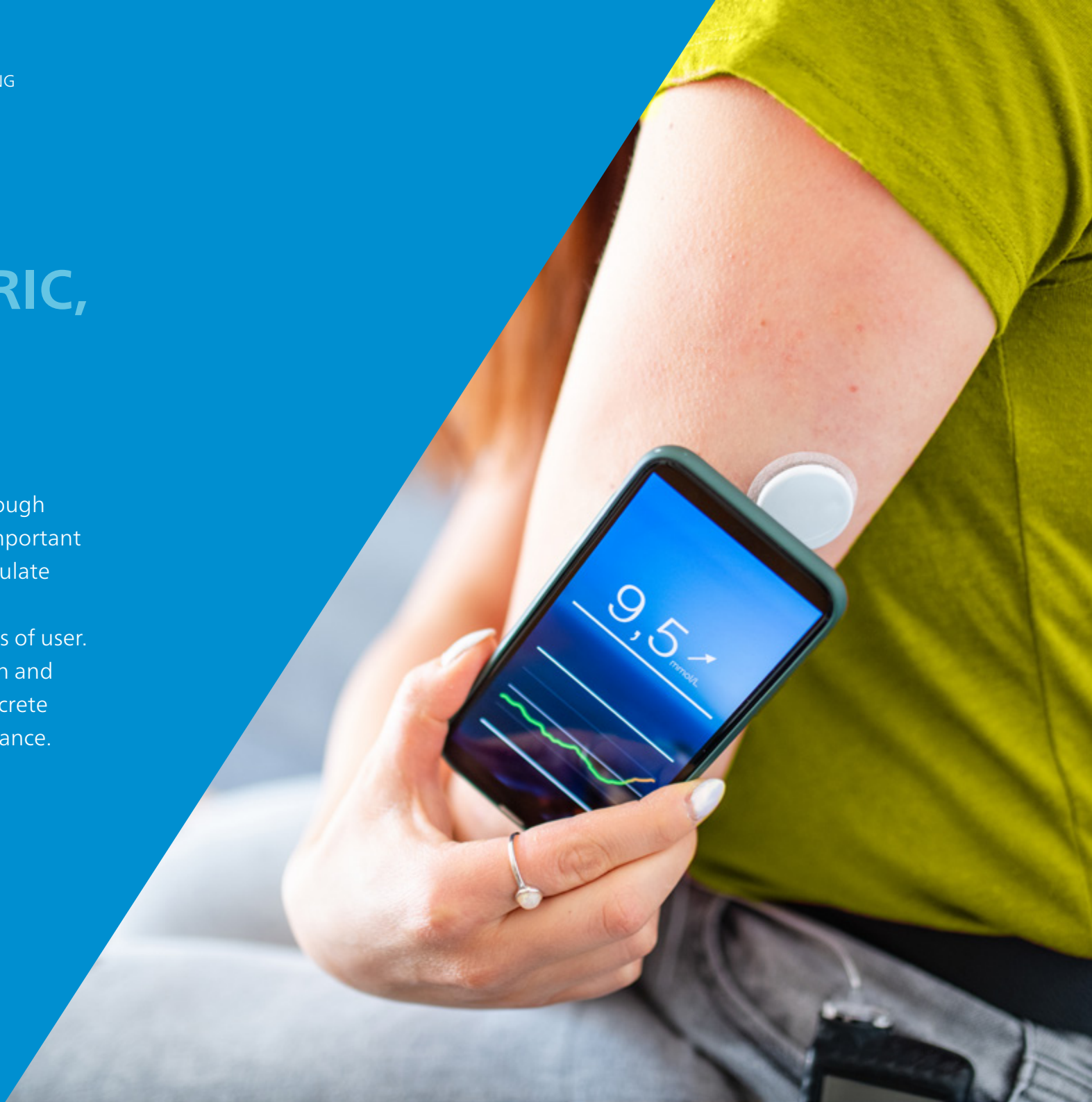
Novel delivery mechanisms and novel Active Pharmaceutical Ingredients (API) can present challenges with drug degradation, poor absorption, local irritation and variability in absorption and the impact on leachables or extractable from materials.



TREND 2

PATIENT-CENTRIC, WEARABLE SOLUTIONS

Connected devices will gather data through intelligent devices and communicate important information to remotely monitor or regulate a device. Integrated electronics may be customisable to allow for different types of user. Other key factors such as user education and training packages and compact and discrete device design will also help user compliance.



TREND 3

HOME-BASED CARE

Care is trending to move away from hospital-based treatments. This means that drug delivery device design now needs to incorporate more human-centred design factors. This will promote the chances of user adherence and reduce user-related risks. To maximise adherence, designs can consider the users' personal preference on pain reduction, aesthetics or ergonomics. For example, subcutaneous injection systems or fixed dose, prefilled syringes or easier drug reconstitution for easier self-administration using injection devices at home.



TREND 4

TARGETED DRUG DELIVERY

Concentrated activity at a specific body site will continue to be a focus. There will continue to be R&D and IP, especially in areas such as nanomedicine and anti-cancer treatments. These all have new challenges for the delivery systems.



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INSIGHTS FROM DRUG DELIVERY INDUSTRY PEERS



CONNECTED, WEARABLE DEVICES



In our experience, all the pharmaceutical companies that are developing injectable drugs are considering wearable injectors in their device strategies. Anticipating this demand, all established injectable device manufacturers that we are aware of have at least one form of wearable injector in their portfolio... The device concepts which push drug from standard pharmaceutical cartridges are likely to feature strongly in the future marketplace, primarily due to risk aversion by pharmaceutical companies. Alternative devices will have a bright future where they can demonstrate an advantage such as a smaller or more elegant form factor or better usability.



Tom Oakley

*Director of Drug Delivery Science
Springboard*

Citation: Oakley T, "Wearable Injectors, Latest Devices and Recent Trends". ONdrugDelivery, Issue 111 (September 2020), pp 6–9.

PATIENT-FRIENDLY, PRODUCT AESTHETIC AND FEEL FOR TREATMENT ADHERENCE



Patients expect their medical devices to look and behave in the same way that their consumer devices do.

Developments battery charging, connectivity, 5G and miniaturization have the potential to shake up innovation in medical and smart health technology. Advanced materials have a part to play in improving the ergonomics of devices, and providing an experience to patients that supports and encourages medicines adherence.



Adam Salmen

*Electronics Strategic Marketer
Vixtrex*

EASE OF PROCESSING, INJECTION MOLDED OR MACHINED



Trends continue in automated micro assemblies for cost and quality reasons. Micro-fluidics and high-volume drug delivery markets requiring micro needles, hubs, septum containers are driving the need for micro automated assemblies. The full factorial of multiple components requires a keen review of stack-up tolerances and single micron tolerance components.

As drug delivery parts and assemblies get thinner and smaller, the need for strong materials, such as PEEK, are selected due to its high-performance, semi-crystalline mechanical strength, outstanding chemical resistance, and dimensional stability across a broad temperature range. PEEK is a material that many medical and drug delivery device OEMs reach for because of its prevalence in implants and well-documented acceptance in predicate implantable and surgical devices.



Donna Bibber

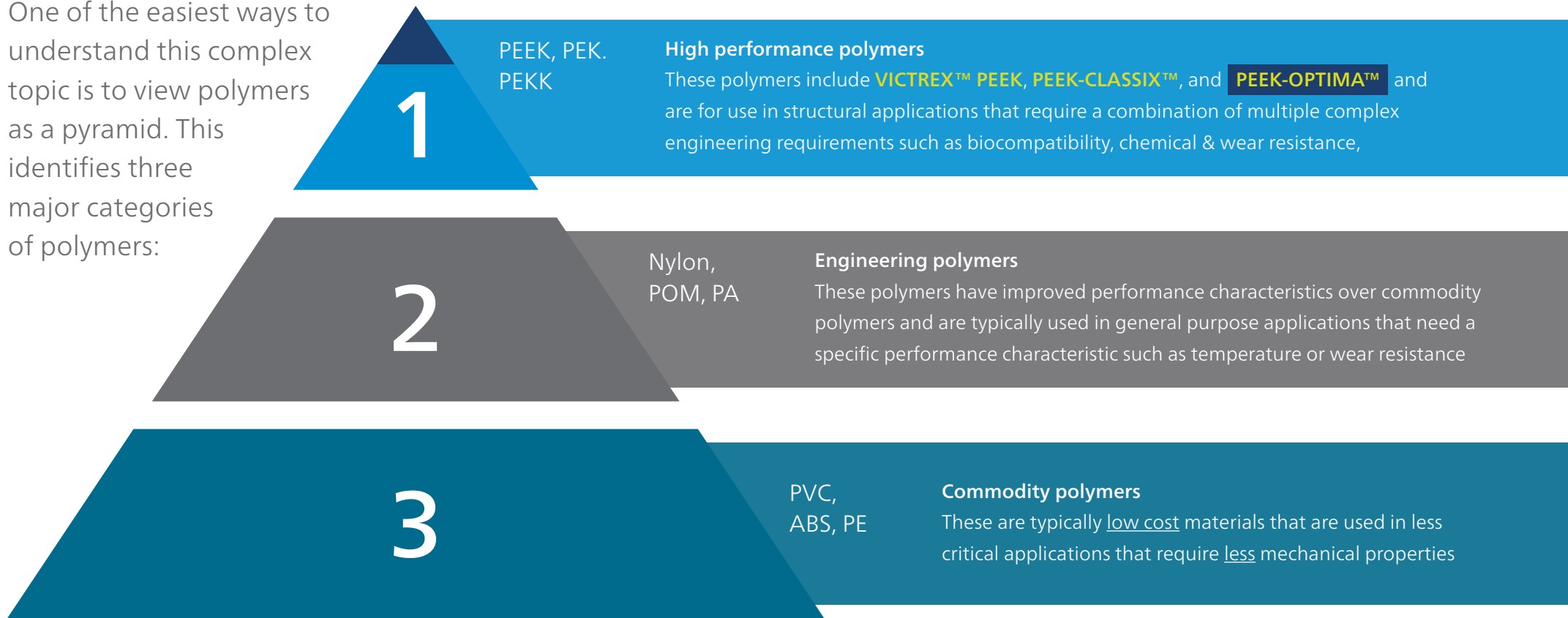
*Miniaturization Subject Matter Expert,
Isometric Micro Molding, Inc.*

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WHAT IS PEEK AND WHY DOES HIGH PERFORMANCE MATTER?



One of the easiest ways to understand this complex topic is to view polymers as a pyramid. This identifies three major categories of polymers:



When your drug delivery application demands **multiple** engineering requirements, Victrex high performance polymer solutions can help you to overcome complex design and engineering challenges.

Polyetheretherketones such as VICTREX™ PEEK are ideally suited to extreme and demanding environments. While alternative materials can meet specific needs, PEEK can support multiple requirements. For example the light weight, high strength PEEK polymer provides high resistance to wear, temperature, fatigue and aggressive fluids/chemicals and can contribute to:

- ✔ ENHANCED FUEL EFFICIENCY
- ✔ IMPROVED SAFETY
- ✔ EXTENDED PART LIFE
- ✔ GREATER COMFORT
- ✔ MORE DESIGN FREEDOM
- ✔ PRODUCTION COST EFFICIENCIES

Aligned to global megatrends and fuelled by our product leadership strategy we strive to bring innovative solutions to our focus markets, shaping new materials, forms and parts.

20,000+

Aircraft rely on Victrex solutions.

AEROSPACE SOLUTIONS >

500+ MILLION

VICTREX™ PEEK based parts in automotive applications.

AUTOMOTIVE SOLUTIONS >

4+ BILLION

Mobile devices use APTIV™ acoustic film.

ELECTRONIC SOLUTIONS >

75+ MILLION

VICTREX™ PEEK seals in use today.

ENERGY SOLUTIONS >

100+ MILLION

Machines operate using Victrex solutions.

INDUSTRIAL SOLUTIONS >

13+ MILLION

Implanted devices worldwide use Invibio PEEK-OPTIMA™ polymers.

MEDICAL SOLUTIONS >

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WHERE CAN PEEK BE USED?



TRANSFORMING DRUG DELIVERY WITH PEEK

WEARABLE DEVICES

Biocompatible and safe for skin contact
<30 days, or long-term implantable



INHALERS

High wear and strength, and safe in contact with drugs in respiratory devices with components such as gears, **dosing control**, reservoirs and chambers – with **low moisture absorption**

CONNECTED DEVICES

Insulative, lightweight and low friction for components such as embedded **electronic circuits**, PCB, **battery housing** and **antennae**



AUTO-INJECTOR PENS

Excellent mechanical and fatigue resistance in components such as **springs**, **washers** and **plungers & pistons** which require low friction

TRANSDERMAL PATCHES AND PUMPS

High biocompatibility for components such as **skin ports** or **valves** that need to encounter **blood**, **tissue** or **drugs**

FEATURED CASE STUDY

PATCH PUMP FOR DIABETES

Wear Performance

VICTREX™ PEEK is wear resistant and has little ageing effects. Therefore, Victrex PEEK is suitable for miniature parts that require high accuracy for long term reliability.

Low co-efficient of friction provides wear and abrasion resistance to moving components.

- Micro gear system
- Cam moving rotar system
- Shaft

Electrical Properties

VICTREX™ PEEK is well suited for integration of electronics, this enables use in solutions that offer wireless communication, capacitive sensors and switches .

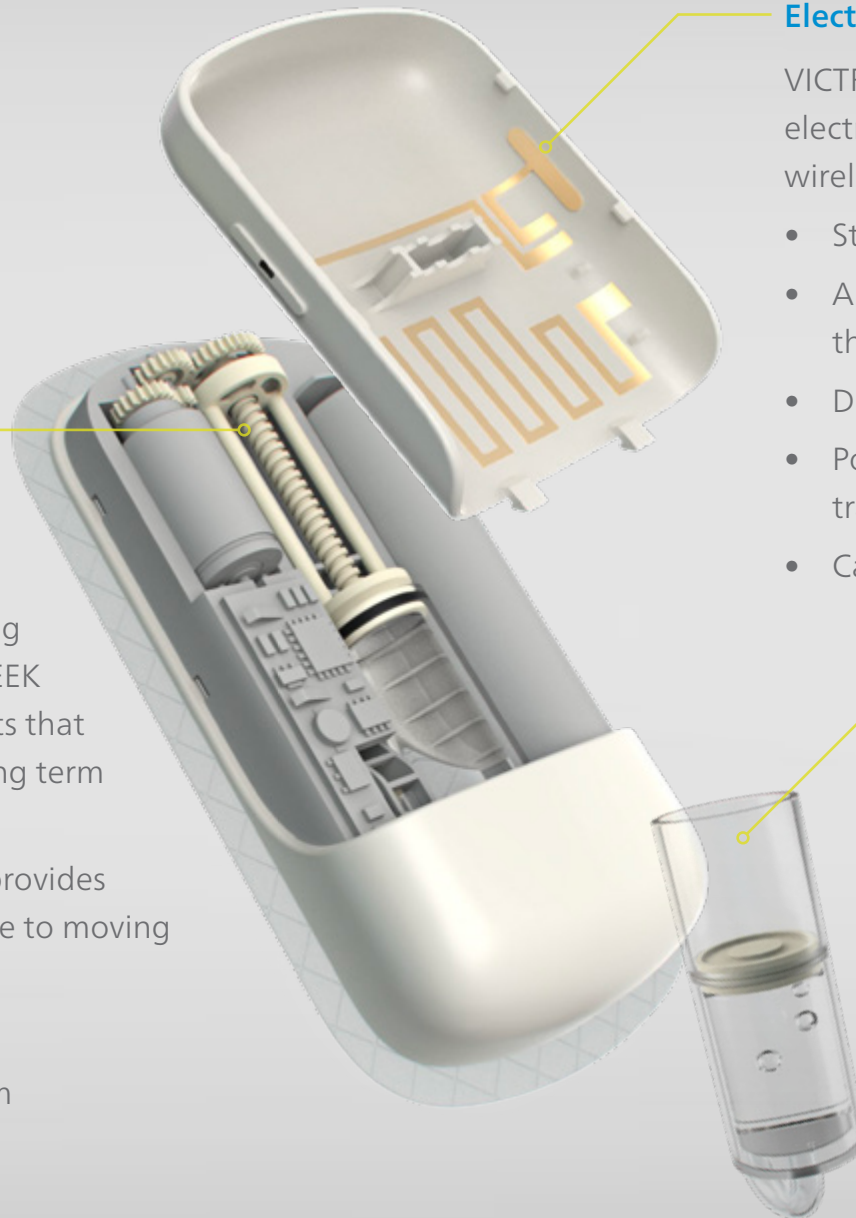
- Structural electronics integrated into PEEK
- Antennae system with no interference from the PEEK to connect with the smartwatch
- Dimensional stability so the casing snap fits closed
- Possible for LED integration to tactile switches with translucent APTIV™ FILM
- Capacitive switch and sensor to control dosage meter

Chemical Resistance

VICTREX™ PEEK retains performance when in contact with chemical or drug concentrates, and during sterilisation.

Low moisture absorption (0.05wt%) means VICTREX™ PEEK components retain dimensions in biological or fluid environments.

- Drug chamber plunger and seal system
- Drug chamber casing



FEATURED CASE STUDY

INHALER FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

Challenge

Boehringer Ingelheim needed to overhaul the materials used within their Respimat® inhaler, to move away from metals. Key to this was reducing the manufacturing costs per unit from machining. They were seeking a solution that enabled more design freedom and easier processing through molding for mass production for very small parts

Solution

VICTREX™ PEEK was selected the material of choice for the newly designed Respimat® re-usable inhaler dosing chamber, because of its:

- Excellent compressive strength and creep resistance
- Very good dimensional stability
- Outstanding chemical resistance
- Purity (does not contain any additives or processing agents)
- Very low level of leachable or extractables, and therefore no interactions with the drug



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SIZE



SPACE OPTIMISATION

In today's competitive world, you want more from an advanced materials supplier than simply materials. Getting the most from high-performance polymers means considering component design hand-in-hand with material selection and optimised processing. This is the key to maximising an application's value in-use and achieving high manufacturing efficiencies at the lowest possible component cost. With design and material selection decided, processing optimisation becomes critical to drive your product quality and manufacturing yields higher.

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?



MINIATURIZED PARTS

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 miniaturised to precise tolerances. This results in reduced weight and greater ease of use.

As a thermoplastic, PEEK can be processed using conventional thermoplastic processing equipment for injection and compression moulding as well as extrusion machined, or injection moulded. This means products can be made to tight engineering tolerances, promoting safe and miniaturised medical devices. The suitability for precision engineering boosts the range of applications – whether that is PEEK-based solutions in non-implantable drug-delivery devices or future connected e-devices. When complex electronic components must be embedded, they too are designed to be compact, with a wall thickness that is as thin as possible.



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PERFORMANCE



PERFORMANCE

What are the key engineering requirements that matter the most to you? The list of key engineering requirements defined by designers is often lengthy and complex, and the more requirements, the shorter the list of materials able to meet all of them. Increasingly, designers are looking to high-performance polymers (HPPs) for answers.

An HPP such as PEEK offers many important properties required by drug delivery devices. Without a doubt, PEEK is one of the highest performing polymers, and one that can support multiple key engineering requirements. 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.

When your drug delivery application demands multiple engineering requirements, Victrex high performance polymer solutions can help you to overcome complex design and engineering challenges.



WHY USE PEEK FOR DRUG DELIVERY DEVICES?

Safe in contact with the human body biologics

Masterfile of **biocompatibility** and clinical evidence, demonstrates **no leachables** or extractables when exposed to a wide range of body tissue types,

Safe in contact with drugs

Retains performance when in contact with chemical or **drug concentrates**, and during sterilisation.

Lightweight & durable

Lightweight and durable to resist impact, and for continued use over time, even in **miniaturised parts** under load.

Electrical performance

Electrical **insulative properties** enable outstanding thermal, environmental resistance and mechanical performance for **connected devices**.

Withstands high temperatures

Can be used near **parts that generate heat** over time.

Longevity & performance over time

Low co-efficient of friction provides wear and abrasion resistance to moving components.

No moisture absorption

Low moisture absorption (0.05wt%) means components retain dimensions in biological or **fluid environments**.

Regulatory approved

Compliant with medical device and food contact standards including **FDA, REACH**, and many others.

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COMPLIANCE



COMPLIANCE

Considerations for ensuring your PEEK device is EU Medical Device Regulation (MDR) compliant

The fundamentals of EU MDR calls for medical device manufacturers to look at all the materials used in devices, their composition and hazardous substances. You need to disclose all raw materials used to manufacture a device:

- Each substance/material up to 0.1% (1000 ppm)
- All hazardous materials

Post-market clinical evidence – are you ready?

There is now an increased requirement for clinical evidence to demonstrate safety and performance of medical devices, which could pose a significant cost burden and resource constraints to drug delivery device manufacturers.

Material considerations

- How do materials evolve through manufacturing processes and clinical use?
- Do they remain stable, and does their reactivity change?
- What is the impact of shelf-life and ageing in finished medical devices?

Victrex has taken steps to make it easy for you to answer these questions more easily, and to have information available to support you through your development:

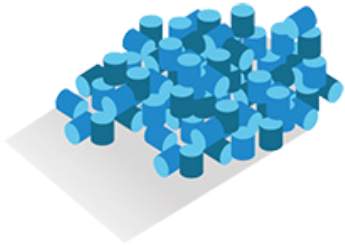
- Long clinical history of implantable PEEK, with more than 9 million devices implanted worldwide
- Proven stability and biocompatibility
- Non-hazardous
- Zero material-related recalls
- Clinical evaluation report support, with 20 years of proven clinical history available in a single evaluation
- Manufactured within a secure, integrated supply chain, from monomer to specifier
- ISO 13485:2016 certification

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VERSATILE PROCESSING



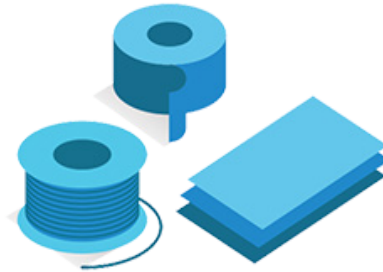
VICTREX™ PEEK PRODUCTS HAVE PROVEN PERFORMANCE IN MANY FORMS:



Polymers

Victrex focuses on PEEK & PAEK polymers, considered the world's highest performing thermoplastics

[LEARN MORE >](#)



PEEK Forms

Manufacturing product forms: Pipes, Films, Fibres and Composite tapes

[LEARN MORE >](#)



PEEK Parts

Developing new applications for PEEK, PAEK and Thermoplastic Composites

[LEARN MORE >](#)

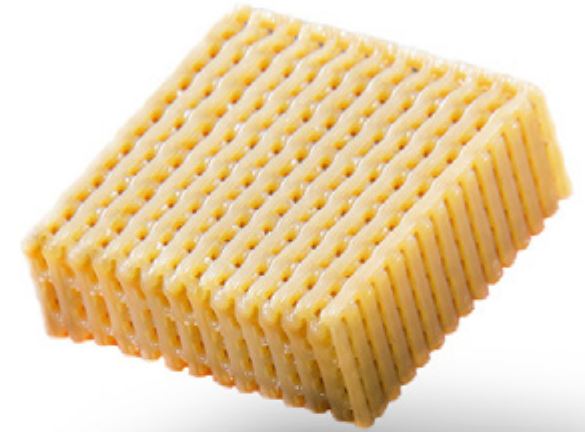


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[DOWNLOAD OUR PEEK PROCESSING GUIDE >](#)

THE BENEFITS OF USING VICTREX PEEK POLYMER FOR 3D PRINTING

Improved technologies for 3D printing of VICTREX™ PEEK and PAEK-based polymers can open up a range of possibilities for design engineers. Potential benefits include



Greater design freedom

enabling the production of highly complex, customised components.



Accelerated speed to market

with digital design and fabrication of PAEK parts for rapid prototyping.



Improved economics

from reduced machining waste, assembly steps, and capital intensity.



High performance

All the benefits high-performance PAEK polymer combined with the benefits of additive manufacturing.



Stronger parts

New AM optimised materials and advancing machine technology both contribute to stronger parts.



Improved printing

with polymers offering less warp in filament fusion than traditional PEEK polymers.

[LEARN MORE ABOUT OPTIMISING HIGH-PERFORMANCE THERMOPLASTICS FOR 3D PRINTING >](#)

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#1 PEEK EXPERTS

Victrex is typically involved at early stages of the development cycle, in the material selection phase. Here we can bring our expertise from a materials point of view, and couple that together with the application development and parts design.

Tony Whitehead explains in this video:

WATCH THE VIDEO



QUESTION TEMPLATE

FACTORS TO CONSIDER WHEN CONSIDERING A MATERIAL CHANGE

Now is the time to consider how embedding high-performance polymers into your products. Ask yourself these questions to kick-start the process:

- 
1. Do the materials in my product require regulatory certifications or clinical evidence?
 2. How could glass, metals and non-biocompatible materials be eradicated from my product design?
 3. Which polymer technology could effectively and economically be integrated into my product design?
 4. What mechanical or electrical requirements or obstacles may impact my choice of polymer?
 5. If more than 3 key engineering requirements are needed for my design to succeed, have I considered PEEK?
 6. How do materials evolve through manufacturing processes and clinical use?
 7. Is my material supplier able to support with detailed design engineering guidance specific to my product, and can they provide processing support?

LET'S TALK

READY TO CREATE THE NEXT GENERATION OF DRUG DELIVERY DEVICE?

Contact us to start the conversation

LET'S TALK



WHAT TO READ NEXT?

PEEK MATTERS

Sharing expertise in PEEK



3 key factors to consider for drug delivery materials

[READ MORE >](#)



Drug delivery devices: How everyone wins when patient compliance is achieved

[READ MORE >](#)



Polymer Crystallinity – HPP Explained (part 3)

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