



# MEDICAL GRADE POLYMERS

13 August 2024

**Michael Wallick**

Regulatory Affairs &  
Product Stewardship Leader, Americas



# AGENDA

- ▶ Overview of Victrex
- ▶ Testing Requirements
- ▶ Change Management
- ▶ Specifications
- ▶ Victrex & Invibio Portfolio

OUR PURPOSE

**We Bring Transformational & Sustainable Solutions  
That Address World Material Challenges Every Day**

SHAPING FUTURE PERFORMANCE™



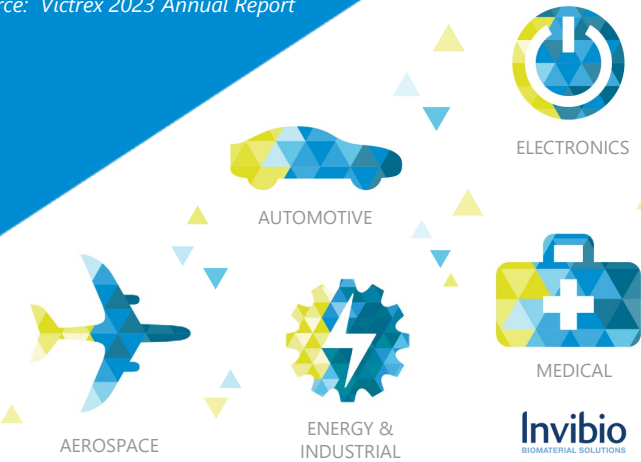
# #1 PEEK EXPERTS

40+ years since the invention of PEEK, with Victrex as the first to commercialise this exceptional thermoplastic



## OUR PURPOSE

**WE BRING TRANSFORMATIONAL & SUSTAINABLE SOLUTIONS THAT ADDRESS WORLD MATERIAL CHALLENGES EVERY DAY**



## POLYMER MANUFACTURING

Delivering the key PEEK & PAEK materials with No.1 manufacturing capacity of 8,000+ tonnes (UK nameplate capacity)



## GLOBAL BUSINESS

**1,000+** Employees    **40+** Countries    **£1.5bn** Market Value

...waking up every day focused on PEEK and delivering innovative & sustainable solutions

... served by Victrex across our markets

- FTSE 250 Company
- £300m+ revenue

## DIFFERENTIATE THROUGH INNOVATION TO CREATE NEW MARKETS



### POLYMER

Pioneering new grades e.g. LMPAEK™ for Composites & Additive Manufacturing (3D Printing)



### PRODUCT FORMS

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



### PARTS

Developing new applications for PEEK, PAEK and Thermoplastic Composites

## A WORLD LEADER IN VALUE CREATION THROUGH PEEK AND PAEK-BASED POLYMER SOLUTIONS

Enabling customers to develop sustainable solutions and overcome complex design & engineering challenges across key markets



## INVESTMENT IN INNOVATION

**Expanded capabilities through Polymers, Forms & Parts**

circa **5-6%** of annual sales invested in R&D

- Polymer Capacity
- Aerospace Parts
- Composite Solutions
- Gear Solutions
- Additive Manufacturing
- Medical Components

\* PEEK = Poly Ether Ether Ketone / PAEK = Poly Aryl Ether Ketone

## Sustainability Strategy

Aligned to UN Sustainable Development Goals 2030



- Ambition of carbon net zero emissions by 2050 aligned to SBTi (Scope 1, 2 & 3)
- Increase the use of our sustainable products which support CO<sub>2</sub> reduction
- Enhance circularity of our products and recycling rates
- Minimise resources (Carbon, Waste and Water) used in our operations
- Increase employee and community engagement on social responsibility



# FOCUSED ON SIX KEY MARKETS

Everyday millions of people rely on products and applications containing our high-performance PAEK polymer solutions



## AUTOMOTIVE

**500+ million**  
VICTREX™ PEEK based applications in use



## AEROSPACE

**20,000+ aircraft**  
have Victrex solutions onboard



## ENERGY

**75+ million VICTREX™ PEEK seals**  
in use today



## MEDICAL

**15+ million implanted devices**  
worldwide use Invibio PEEK-OPTIMA™ polymers



## ELECTRONICS

**4+ billion mobile devices**  
use APTIV™ Acoustic Film



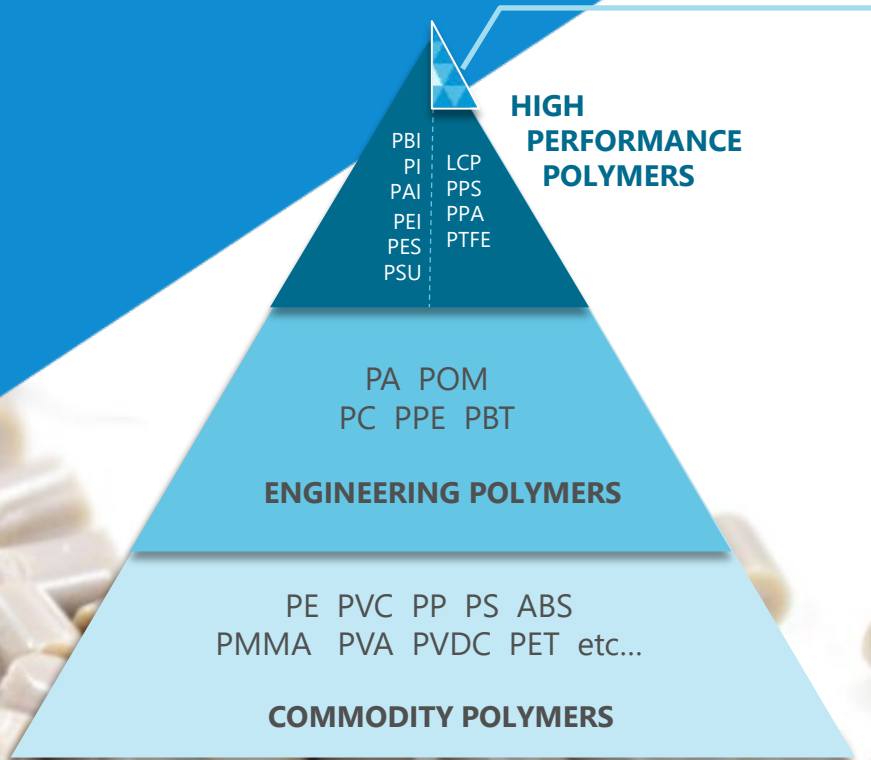
## INDUSTRIAL

**100+ million machines**  
operating with Victrex solutions

VICTREX DIFFERENTIATION

# VICTREX™ PEEK POLYMERS

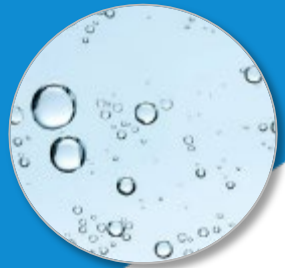
A Multifaceted Solution



VICTREX DIFFERENTIATION

# FROM MONOMERS, POLYMERS, INTO FORMS & PARTS

The only vertically integrated PEEK & PAEK manufacturing in the world contributing to security of supply and a differentiated product



Gears Solutions

AM Solutions

Composites Solutions

Medical Device Solutions

## MONOMERS

- BDF

## POLYMERS

- PEEK
- PAEK (incl. LMPAEK)

## FORMS

- APTIV™ Films
- Coatings (VICOTE™)
- Fibres (ZYEX™)
- Pipes (VICTREX PIPES™)
- Filaments
- Composite UD Tapes

## PARTS

- Gears Solutions
- Additive Manufacturing Solutions
- Composites Solutions
- Medical Device Solutions

**VERTICALLY INTEGRATED PEEK & PAEK MANUFACTURE**



# VICTREX R&D NETWORK



Polymer Innovation Centre (UK)



UK

- PAEK polymer & compounds development
- Application development
- Materials testing
- Medical parts design & manufacturing
- Forms (Film, Pipes, Coatings, Composites, Fibres)



Partnering with academia  
 Heading industry consortium on  
 PAEK additive manufacturing, etc.



JP

- Application development
- Materials testing
- Tribology testing



US

- PAEK Gears Design, Testing, & Manufacturing
- Aerospace composite parts



CN

- Application development
- Materials testing
- Films Thermoforming
- IM Prototyping



# VICTREX MANUFACTURING NETWORK

## UK Sites

### THORNTON-CLEVELEYS

#### POLYMER INNOVATION CENTRE

Dedicated facility to test lab concepts at scale

#### POLYMER

3 independent PAEK Plants with 8,000+<sup>t</sup> nameplate capacity

#### APTIV™ FILM,

2<sup>nd</sup> production line added that doubled capacity (2015)

#### COMPOSITE UD TAPE

Investment of ~£15m on new PAEK composite manufacturing (2016)

#### VICTREX PIPES™

The only company manufacturing composite PEEK pipe.

#### INVIBIO BIOMATERIAL SOLUTIONS

- Clean room injection moulding
- Invibio Trauma plates
- Knee
- JUVORA Dental Disc



#### SEALSANDS ROTHERHAM

#### MONOMER

Upstream integration of key raw material for supply & quality control

#### LEEDS

#### INVIBIO MEDICAL DEVICE DEVELOPMENT CENTRE

#### STONEHOUSE

#### ZYEX™ FIBRES

Added capability following acquisition (2017)

#### PORTSMOUTH

#### MAGMA GLOBAL

Dedicated manufacturing facilities (2018)

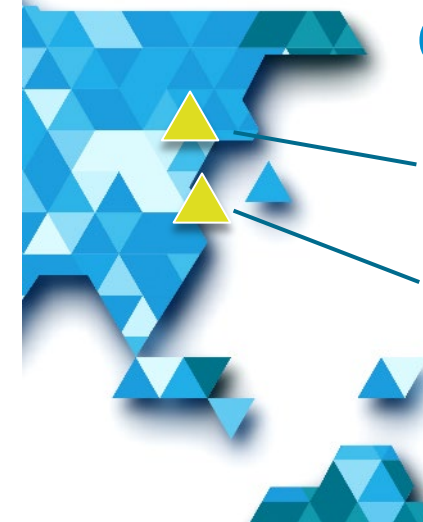
## US Sites



#### GRANTSBURG, WI POLYMER GEARS

#### BRISTOL, RI AERO COMPOSITES

## China Sites



#### PANJIN MANUFACTURING

#### SHANGHAI COMPOUNDING



# PLANET

## AMBITION FOR NET ZERO CARBON EMISSIONS

Full alignment to Net Zero and Science Based Targets Initiative (SBTi) including short-term (2032) & long-term (2050) targets across scopes 1, 2 & 3



## GOVERNANCE

ESG Centre of Excellence

- Increase disclosures and reporting
- Board committee (Corporate Responsibility Committee) with oversight of ESG targets
- Plans & targets submitted to SBTi



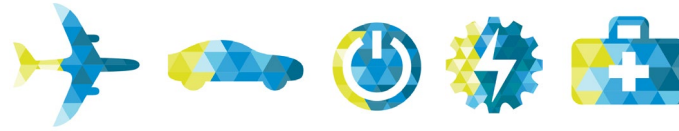
## SUSTAINABILITY VISION

WE BRING TRANSFORMATIONAL & SUSTAINABLE SOLUTIONS THAT ADDRESS WORLD MATERIAL CHALLENGES EVERY DAY



## PRODUCTS

ENABLE ENVIRONMENTAL & SOCIETAL BENEFITS



Develop and deliver sustainable products that provide quantifiable environmental and societal benefits

2023: 55% of revenue  
2030: Goal of 70% of revenue



# PEOPLE

HAVE A POSITIVE IMPACT ON THE COMMUNITIES WHERE WE WORK



## STEM INSPIRATION

Science, Technology, Engineering & Maths

Inspire the next generation: increase annual contacts reached

2023: 3,225 pa  
2030 Goal: 2,500 pa



## COMMUNITY ACTIVITY

Maintain strong community engagement (cumulative hours target 2020-2030)

2023: 14,808  
2030 Goal: 10,000



## FEMALES IN LEADERSHIP ROLES

Enhance diversity, equity & inclusion

2023: 19%  
2030 goal: 40%

## SAFETY, HEALTH & WELLBEING

Strong progress towards achieving a Zero accident & Zero incident culture

|   |               |
|---|---------------|
| <b>Recordable Injury Frequency Rate</b> | Current: 0.2  |
|   | Goal: 0.0     |
|   | Ind. Avg. 1.3 |

## Sustainability Strategy

Aligned to UN Sustainable Development Goals 2030



- Ambition of carbon net zero emissions by 2050 aligned to SBTi (Scope 1, 2 & 3)
- Increase the use of our sustainable products which support CO<sub>2</sub> reduction
- Enhance circularity of our products and recycling rates
- Minimise resources (Carbon, Waste and Water) used in our operations
- Increase employee and community engagement on social responsibility



# TESTING

What's the bid deal...

- ▶ It's not like there's 100's of different applications with different contact types and duration...
- ▶ And it's not like there are different regulations for each region...



Table A.1 — Endpoints to be addressed in a biological risk assessment

| Medical device categorization by        |                                 |                     | Endpoints of biological evaluation |                       |                                      |              |               |   |   |                                      |                                |                                  |                               |                                   |                   |                           |                              |  |                          |
|---|---------------------------------|---------------------|------------------------------------|-----------------------|--------------------------------------|--------------|---------------|---|---|--------------------------------------|--------------------------------|----------------------------------|-------------------------------|-----------------------------------|-------------------|---------------------------|------------------------------|--|--------------------------|
| Category                                | Contact                         | Contact duration    |                                    |                       | Physical and/or chemical information | Cytotoxicity | Sensitization | Irritation or intracutaneous reactivity | Material mediated pyrogenicity <sup>a</sup> | Acute systemic toxicity <sup>b</sup> | Subacute toxicity <sup>b</sup> | Subchronic toxicity <sup>b</sup> | Chronic toxicity <sup>b</sup> | Implantation effects <sup>h</sup> | Hemocompatibility | Genotoxicity <sup>d</sup> | Carcinogenicity <sup>e</sup> | Reproductive/developmental toxicity <sup>f</sup> | Degradation <sup>g</sup> |
|   |                                 | A - limited (≤24 h) | B - prolonged (>24 h to 30 d)      | C - Long term (>30 d) |                                      |              |               |   |   |                                      |                                |                                  |                               |                                   |                   |                           |                              |  |                          |
| Surface medical device                  | Intact skin                     | A                   | X <sup>g</sup>                     | E <sup>h</sup>        | E                                    | E            |               |   |   |                                      |                                |                                  |                               |                                   |                   |                           |                              |  |                          |
|   |                                 | B                   | X                                  | E                     | E                                    | E            |               |   |   |                                      |                                |                                  |                               |                                   |                   |                           |                              |  |                          |
|   |                                 | C                   | X                                  | E                     | E                                    | E            |               |   |   |                                      |                                |                                  |                               |                                   |                   |                           |                              |  |                          |
|   | Mucosal membrane                | A                   | X                                  | E                     | E                                    | E            |               |   |   |                                      |                                |                                  |                               |                                   |                   |                           |                              |  |                          |
|   |                                 | B                   | X                                  | E                     | E                                    | E            |               | E                                       | E   |                                      |                                |                                  |                               | E                                 |                   |                           |                              |  |                          |
|   |                                 | C                   | X                                  | E                     | E                                    | E            |               | E                                       | E   | E                                    | E                              | E                                | E                             | E                                 |                   | E                         |                              |  |                          |
|   | Breached or compromised surface | A                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   |                                      |                                |                                  |                               |                                   |                   |                           |                              |  |                          |
|   |                                 | B                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                 |                   | E                         |                              |  |                          |
|   |                                 | C                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                 |                   | E                         | E                            |  |                          |
| Externally communicating medical device | Blood path, indirect            | A                   | X                                  | E                     | E                                    | E            | E             | E                                       |   |                                      |                                |                                  |                               |                                   | E                 |                           |                              |  |                          |
|   |                                 | B                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   |                                      |                                |                                  |                               | E                                 |                   |                           |                              |  |                          |
|   |                                 | C                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                 |                   | E                         | E                            |  |                          |
|   | Tissue/bone/dentin <sup>i</sup> | A                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   |                                      |                                |                                  |                               |                                   |                   |                           |                              |  |                          |
|   |                                 | B                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   |                                      |                                |                                  |                               | E                                 |                   | E                         |                              |  |                          |
|   |                                 | C                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                 |                   | E                         | E                            |  |                          |
|   | Circulating blood               | A                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   |                                      |                                |                                  |                               |                                   | E                 | E                         |                              |  |                          |
|   |                                 | B                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   |                                      |                                |                                  |                               | E                                 | E                 |                           |                              |  |                          |
|   |                                 | C                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                 |                   | E                         | E                            |  |                          |
| Implant medical device                  | Tissue/bone <sup>i</sup>        | A                   | X                                  | E                     | E                                    | E            | E             | E                                       |   |                                      |                                |                                  |                               |                                   |                   |                           |                              |  |                          |
|   |                                 | B                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   |                                      |                                |                                  |                               | E                                 |                   | E                         |                              |  |                          |
|   |                                 | C                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                 |                   | E                         | E                            |  |                          |
|   | Blood                           | A                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   |                                      |                                |                                  |                               | E                                 | E                 |                           |                              |  |                          |
|   |                                 | B                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   |                                      |                                |                                  |                               | E                                 | E                 |                           |                              |  |                          |
|   |                                 | C                   | X                                  | E                     | E                                    | E            | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                 |                   | E                         | E                            |  |                          |





# TESTING

- ▶ 1. What specific testing is required?
  - Different testing for different applications AND regions
  - Based on contact type and duration
  - ISO 10993 vs. USP Class VI
  - What's the minimum amount
  - Baseline the material, but final finished device is typically required...
  - Is there a worst case that covers all medical non-implantable
  
- ▶ 2. What frequency of testing is required?
  - Once off "type" testing on initial batch (more on this later... change)
  - Annual testing each year
  - Individual batch testing... This can be costly
  
- ▶ Cost and timing of Chemical analysis testing and TRA
  - Can be 100k and take up to 6 months
  
- ▶ And let's not forget, what about Shelf-life, sterilization and aging...?



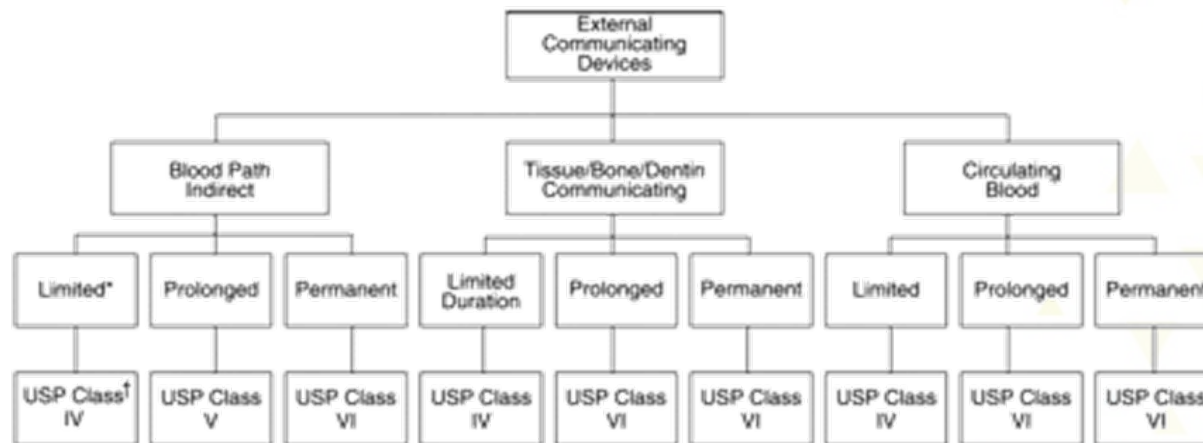


# TESTING

## Medical Device vs. Pharmaceutical & Drug Delivery

Table A.1 — Endpoints to be addressed in a biological risk assessment

| Medical device categorization by        |                                 |   | Endpoints of biological evaluation   |                |               |   |   |                                      |                                |                                  |                               |                                    |                   |                           |                              |   |                          |  |
|---|---------------------------------|---|--------------------------------------|----------------|---------------|---|---|--------------------------------------|--------------------------------|----------------------------------|-------------------------------|------------------------------------|-------------------|---------------------------|------------------------------|---|--------------------------|--|
| Nature of body contact                  |                                 | Contact duration  | Physical and/or chemical information | Cytotoxicity   | Sensitization | Irritation or intracutaneous reactivity | Material mediated pyrogenicity <sup>a</sup> | Acute systemic toxicity <sup>b</sup> | Subacute toxicity <sup>b</sup> | Subchronic toxicity <sup>b</sup> | Chronic toxicity <sup>b</sup> | Implantation effects <sup>bc</sup> | Hemocompatibility | Genotoxicity <sup>d</sup> | Carcinogenicity <sup>d</sup> | Reproductive/developmental toxicity <sup>de</sup> | Degradation <sup>f</sup> |  |
| Category                                | Contact                         | A - limited (<24 h)<br>B - prolonged (>24 h to 30 d)<br>C - Long term (>30 d) |                                      |                |               |   |   |                                      |                                |                                  |                               |                                    |                   |                           |                              |   |                          |  |
| Surface medical device                  | Intact skin                     | A   | X <sup>e</sup>                       | E <sup>h</sup> | E             | E                                       |   |                                      |                                |                                  |                               |                                    |                   |                           |                              |   |                          |  |
|   |                                 | B   | X                                    | E              | E             | E                                       |   |                                      |                                |                                  |                               |                                    |                   |                           |                              |   |                          |  |
|   |                                 | C   | X                                    | E              | E             | E                                       |   |                                      |                                |                                  |                               |                                    |                   |                           |                              |   |                          |  |
|   | Mucosal membrane                | A   | X                                    | E              | E             | E                                       |   |                                      |                                |                                  |                               |                                    |                   |                           |                              |   |                          |  |
|   |                                 | B   | X                                    | E              | E             | E                                       |   | E                                    | E                              |                                  |                               | E                                  |                   |                           |                              |   |                          |  |
|   |                                 | C   | X                                    | E              | E             | E                                       |   | E                                    | E                              | E                                | E                             | E                                  |                   | E                         |                              |   |                          |  |
|   | Breached or compromised surface | A   | X                                    | E              | E             | E                                       | E   | E                                    |                                |                                  |                               |                                    |                   |                           |                              |   |                          |  |
|   |                                 | B   | X                                    | E              | E             | E                                       | E   | E                                    | E                              |                                  |                               | E                                  |                   |                           |                              |   |                          |  |
|   |                                 | C   | X                                    | E              | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                  |                   | E                         | E                            |   |                          |  |
| Externally communicating medical device | Blood path, indirect            | A   | X                                    | E              | E             | E                                       | E   | E                                    |                                |                                  |                               |                                    |                   |                           | E                            |   |                          |  |
|   |                                 | B   | X                                    | E              | E             | E                                       | E   | E                                    |                                |                                  |                               |                                    |                   | E                         |                              |   |                          |  |
|   |                                 | C   | X                                    | E              | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                  |                   | E                         | E                            |   |                          |  |
|   | Tissue/bone/dentin <sup>i</sup> | A   | X                                    | E              | E             | E                                       | E   | E                                    |                                |                                  |                               |                                    |                   |                           |                              |   |                          |  |
|   |                                 | B   | X                                    | E              | E             | E                                       | E   | E                                    |                                |                                  |                               |                                    |                   |                           | E                            |   |                          |  |
|   |                                 | C   | X                                    | E              | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                  |                   | E                         | E                            |   |                          |  |
|   | Circulating blood               | A   | X                                    | E              | E             | E                                       | E   | E                                    |                                |                                  |                               |                                    |                   |                           | E                            | E <sup>i</sup>                                    |                          |  |
|   |                                 | B   | X                                    | E              | E             | E                                       | E   | E                                    | E                              |                                  |                               |                                    |                   |                           | E                            | E   |                          |  |
|   |                                 | C   | X                                    | E              | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                  |                   | E                         | E                            | E   |                          |  |
| Implant medical device                  | Tissue/bone <sup>i</sup>        | A   | X                                    | E              | E             | E                                       | E   | E                                    |                                |                                  |                               |                                    |                   |                           |                              |   |                          |  |
|   |                                 | B   | X                                    | E              | E             | E                                       | E   | E                                    |                                |                                  |                               |                                    |                   |                           | E                            |   |                          |  |
|   |                                 | C   | X                                    | E              | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                  |                   | E                         | E                            | E   |                          |  |
|   | Blood                           | A   | X                                    | E              | E             | E                                       | E   | E                                    |                                |                                  |                               |                                    |                   |                           | E                            | E   |                          |  |
|   |                                 | B   | X                                    | E              | E             | E                                       | E   | E                                    |                                |                                  |                               |                                    |                   |                           | E                            | E   |                          |  |
|   |                                 | C   | X                                    | E              | E             | E                                       | E   | E                                    | E                              | E                                | E                             | E                                  |                   | E                         | E                            | E   |                          |  |





# CHANGE

- ▶ Management of change, notifications of change, no change agreements...
- ▶ How do you manage change for patient contact grades/formulations?
- ▶ What constitutes a change or significant change...?
  - For example if we changed one of the monomer suppliers, and the levels of impurities in the specification stays the same, but they could be different impurities... what then?
- ▶ How far back in the supply chain...
- ▶ Raw material supplier controls...what about changes in their raw goods or their contact materials during manufacturing, handling, packaging, etc...
- ▶ Understand basic chemistry of the material, and the impact...
  - Bio-mass balance for example...







# CHANGE

## USP <1031>

- ▶ New material consideration
- ▶ Replacement material
- ▶ Dual source
- ▶ What is "the same"...
  - PP, PE, PEEK from different suppliers... are they the same???

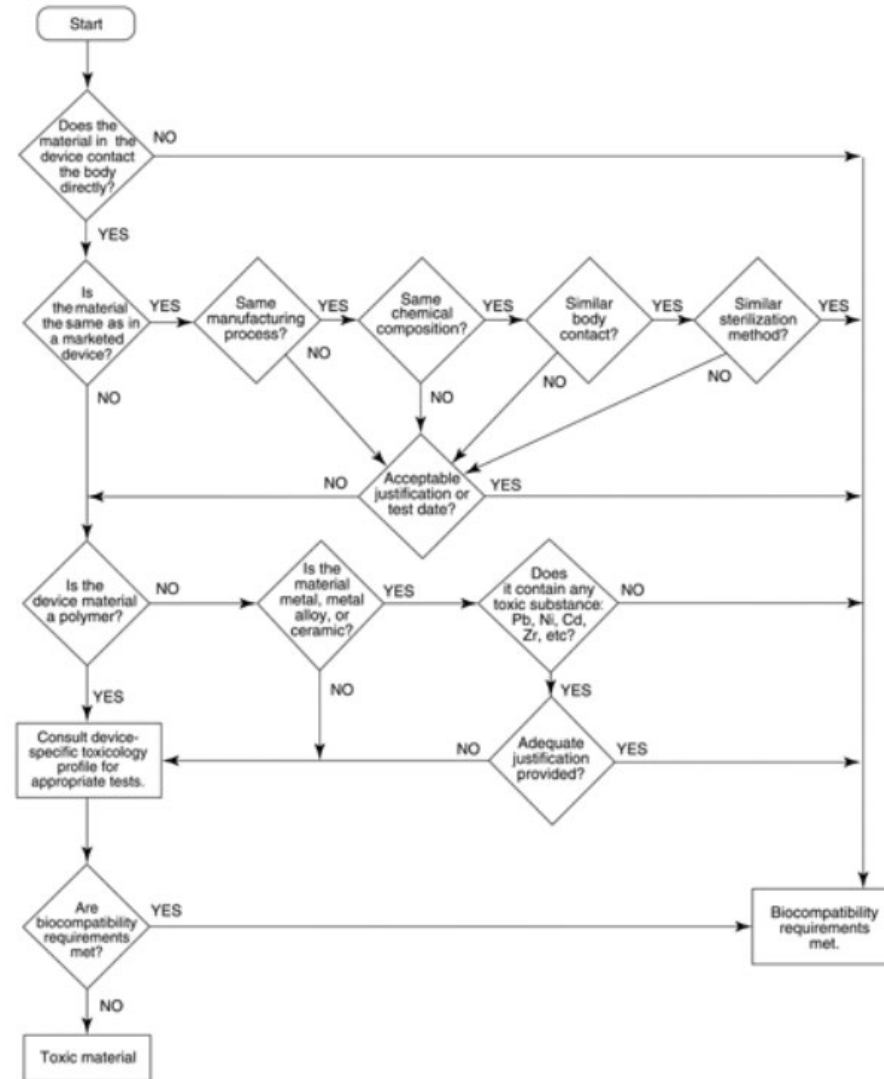


Fig. 1. Biocompatibility flowchart



# CHANGE

10993-1:2020

The selection of materials plays a crucial role in evaluating the biological safety and, when approached in a systematic way, allows the collection of relevant data. In line with ISO 13485 and ISO 14971, criteria to define the acceptable biological risk should be established at the start of the design process. Because starting material, formulation and processing variations including packaging, transportation and aging could impact final product biocompatibility; these considerations should also be incorporated into the risk assessment. The biological evaluation should be designed and performed to demonstrate



# SPECIFICATIONS

Be Specific

- ▶ Device manufacturer internal specification for raw material
- ▶ Reference on prints/drawings
- ▶ Reference in 510(k) if applicable
- ▶ Be grade specific



|   |             |                                    |             |                          |  |          |               |  |
|---|-------------|------------------------------------|-------------|--------------------------|--|----------|---------------|--|
| UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN MILLIMETERS |             | NAME                               | SIGNATURE   | DATE                     | WERK24   |          | <b>WERK24</b> |  |
| ANGULAR = ± °   |             | DRAWN                              | MATHEW WADE | 2021-12-02               | TITLE<br>SHEET METAL SERVO BRACKET   |          |               |  |
| SURFACE FINISH  |             | CHECKED                            | JOHN KYLE   | 2021-12-03               |  |          |               |  |
| DO NOT SCALE DRAWING                                      |             | APPROVED                           | JOHN KYLE   | 2021-12-03               |  |          |               |  |
| BREAK ALL SHARP EDGES AND REMOVE BURRS                    |             |                                    |             |                          | SF. <b>A3</b> DWG NO. <b>01WK00000312</b> REV. <b>01</b><br>SCALE <b>2:1</b> WEIGHT <b>0.65 kg</b> SHEET <b>1 of 1</b> |          |               |  |
| FIRST ANGLE PROJECTION                                    |             | MATERIAL<br>DC07 COLD ROLLED STEEL |             | FINISH<br>POWDER COATING |  |          |               |  |
| TOLERANCE STANDARD  | ISO 2768-mk |                                    |             |                          |  |          |               |  |
| <b>4</b>  |             | <b>3</b>                           |             | <b>2</b>                 |  | <b>1</b> |               |  |





# Medtech Material Application Questionnaire / Design Form



# SPECIFICATIONS

Requested By:

Date Requested:  Date Needed:

| Company Information* |                      |
|----------------------|----------------------|
| Supplier Name:       | <input type="text"/> |
| Supplier Company:    | <input type="text"/> |
| Address:             | <input type="text"/> |
| Phone:               | <input type="text"/> |
| Email:               | <input type="text"/> |

| Customer Information* |                      |
|-----------------------|----------------------|
| Customer Name:        | <input type="text"/> |
| Customer Company:     | <input type="text"/> |
| Division:             | <input type="text"/> |
| Address:              | <input type="text"/> |
| Phone:                | <input type="text"/> |
| Email:                | <input type="text"/> |

| Material Information |                      |
|----------------------|----------------------|
| Project Name:        | <input type="text"/> |
| Material Trade Name: | <input type="text"/> |
| Color:               | <input type="text"/> |
| Compound:            | <input type="text"/> |

| Application Classification*                           |                              |
|---|------------------------------|
| Packaging:  | NA <input type="checkbox"/>  |
| Packaging Type:                                       | NA <input type="checkbox"/>  |
| Type of Administration:                               | NA <input type="checkbox"/>  |
| Oral Type:  | NA <input type="checkbox"/>  |
| Usage Method:   | NA <input type="checkbox"/>  |
| IVD:  | NA <input type="checkbox"/>  |
| FDA Medical Device Classification:                    | NA <input type="checkbox"/>  |
| FDA Medical Device Classification, (please complete): | 21 CFR: <input type="text"/> |
| Contact Duration:                                     | NA <input type="checkbox"/>  |
| Nature of Body Contact:                               | NA <input type="checkbox"/>  |
| EU MDR Class:   | NA <input type="checkbox"/>  |
| Certification:  | NA <input type="checkbox"/>  |

| Process Information*                               |  |
|--|--|
| Process to Be Used:                                | NA <input type="checkbox"/>  |
| If Other:  | <input type="text"/>   |
| Region for Production:                             | NA <input type="checkbox"/>  |
| In which countries will the final product be used: | <input type="text"/>   |
| Is the part a medical device according to:         |  |
| a. FDA (USA)                                       | NA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| b. European Medical Device Directive (MDD)         | NA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Life cycle of device made from requested material? | NA <input type="checkbox"/>  |
| Regulatory Requirements:                           | NA <input type="checkbox"/>  |
| Asia Regulatory: List Below:                       | <input type="text"/>   |

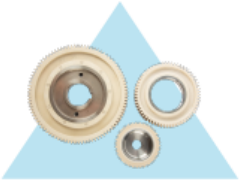
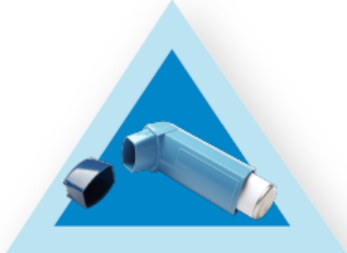











| Application Information*  |  |
|---|--|
| Application   | NA <input type="checkbox"/>  |
| Product End Use   | <input type="text"/>   |
| Contact Type  | NA <input type="checkbox"/>  |
| Drug Form   | NA <input type="checkbox"/>  |
| Duration of Patient Contact   | NA <input type="checkbox"/>  |
| Laser Marking   | NA <input type="checkbox"/>  |
| Laser Marking Depth   | NA <input type="checkbox"/>  |
| Laser Welding   | NA <input type="checkbox"/>  |
| Radiopacity   | NA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Antistatic  | NA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Barrier Oxygen/Water  | NA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| UV Vis Blocking   | NA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Nucleation  | NA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Other   | <input type="text"/>   |
| Sterilization   | NA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Sterilization Method Used   | <input type="text"/>   |
| If Others   | <input type="text"/>   |
| <sup>1</sup> If you chose Sterilization type Gamma or E-Beam, please indicate the total dose: | <input type="text"/>   |
| <sup>2</sup> If you chose Sterilization type Steam, please indicate the temp/time:            | <input type="text"/>   |
| Critical Requirements   | <input type="text"/>   |
| Additional Information / Comments:  | <input type="text"/>   |

**VICTREX PC™**  
**PHARMACEUTICAL  
CONTACT**



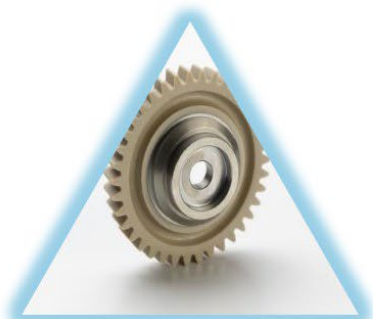


# PRODUCT PORTFOLIO

|   | <br>VICTREX INDUSTRIAL | <br>VICTREX PC™ 101 | <br>INVIBIO PEEK-CLASSIX™ | <br>INVIBIO PEEK-OPTIMA™ |
|---|--|--|--|---|
|  <b>OUR GRADE</b><br>(INCREASING VALUE-ADD)                          |  |  |  |   |
|  <b>APPROPRIATE APPLICATIONS</b>                                     | Indirect contact/instrumentation   | Non-implantable<br>Pharmaceutical contact  | Implantable / prolonged<br>duration (>24hours to 30days)   | Implantable / permanent<br>contact duration >30 days  |
|  <b>ADDITIONAL BIOCOMPATIBILITY TEST DATA</b>                        | N/A  | USP Class VI and USP 661   | ISO 10993-5, 10993-10, 10993-11,<br>10993-12, USP Class VI, USP <88>   | Comprehensive ISO 10993<br>biocompatibility safety and<br>performance studies.                              |
|  <b>QUALITY MANAGEMENT SYSTEM CERTIFICATIONS</b>                     | ISO9001  | ISO9001  | ISO13485   | ISO13485  |
|  <b>FORMS AVAILABLE</b>  | Granules, Film,<br>Powder, UD Tape   | Granules, Film   | Granules   | Granules, Rod, Film,<br>Powder, AM Filament,<br>UD Tape   |
|  <b>PERMITTED IMPLANTATION USAGE (SUBJECT TO CONTRACT)</b>          | No human implantation  | No human implantation  | Limited human implantation upto<br>30 days duration  | Long term human implantation  |
|  <b>MAX BLOOD OR TISSUE CONTACT DURATION (SUBJECT TO CONTRACT)</b> | No human blood<br>or tissue contact  | Human blood or tissue contact<br>for less than 24hour duration   | Human blood or tissue contact for upto<br>30 days duration / 180 days dental                                 | Long term human blood<br>or tissue contact  |
|  <b>PERMITTED PHARMACEUTICAL CONTACT</b>                           | No pharmaceutical contact  | Pharmaceutical contact   | Pharmaceutical contact   | Pharmaceutical contact  |
|  <b>VICTREX GRADES</b>   | Grades available on request  | VICTREX PC™ 101 GRANULES<br>PC™ 101 FILM   | Grades available on request  | Grades available on request   |



- ▶ **The Problem to Solve** - Customers wanting PEEK to increase their design and performance boundaries have the risk and inconvenience of making sure industrial grade materials are compliant, but they don't need the entire raft of tests that come with medical grades.
- ▶ **The Solution** is to use **VICTREX PC™** which are a range of pre-tested grades of PEEK that sit between our Industrial and Medical grades and meets the industry standards for **direct contact** with pharmaceuticals.
- ▶ **Which Result** in our customers knowing the material will pass any downstream tests, without the risk, time or cost of performing their own tests on the raw material.



Non-implantable medical/  
General industrial

VICTREX PEEK



Non-implantable medical / Limited  
blood/tissue contact / Pharmaceutical  
Contact

All properties of VICTREX PEEK with USP Class VI, USP 87 and USP661 compliance for direct pharma contact applications

**VICTREX PC™**  
**PHARMACEUTICAL**  
**CONTACT**



Implantable medical

PEEK-OPTIMA™





# VICTREX PC™

## Biocompatibility Testing

- **USP Class VI** from the General Chapter USP <88> for materials used in medical devices.
  - The most rigorous and through designation
  - **USP <88>** for Biological Reactivity
  - Uses *in-vivo* biological tests to ascertain the absence of toxic chemical that may migrate out of a material and cause any deleterious health effects.
  - Acute Systemic Toxicity (Systemic Injection) Test: Measures toxicity and irritation when a sample of the compound is administered orally, applied to the skin, and inhaled.
  - Intracutaneous Test: Measures toxicity and localized irritation when the sample is in contact with live subdermal tissue (specifically, the tissue that the medical device is intended to contact).
  - Implantation Test: Measures toxicity, infection, and irritation of an intramuscular implantation of the compound into a test animal over several days.
- **USP <87>** for Cytotoxicity
  - Uses *in-vitro* biological tests
- **USP <661.1>** Plastic Packaging Systems and Their Materials of Construction
  - Tests for the suitability of polymers used in packaging systems for pharmaceutical and drug products.
- **PFAS-free\***
  - \*have not been intentionally added, used or generated as by-products in the manufacturing processes.



# VICTREX PC™

## Additional Regulation Compliance

| <u>Regulation</u>   | <u>Compliance</u>   |
|---|---|
| MDR (EU 2017/745)   | No CMRs or Endocrine Disruptors*                              |
| EU-REACH (EC 1907/2006) and UK-REACH  | No SVHC, No restricted list or authorisation list substances* |
| TSCA, China-REACH, K-REACH, Japan IHSL / CSCL   | No substances on restricted list*                             |
| RoHS (EU 2011/65)   | No restricted substances**                                    |
| BSE TSE (EU 528/2012)   | No biocidal substances*                                       |
| NIAS (Non-Intentionally Added Substances)<br><i>BPA, BPS, Latex, Melamine, Nitrosamines, etc.</i> | No restricted substances*                                     |
| California Proposition 65   | No substances on restricted list*                             |
| Halogens (IEC-61249-2-21)   | No restricted substances**                                    |
| <b>PFAS (EU REACH restriction proposal)</b>   | <b>PFAS Free*</b>   |

\*have not been intentionally added, used or generated as by-products in the manufacturing processes

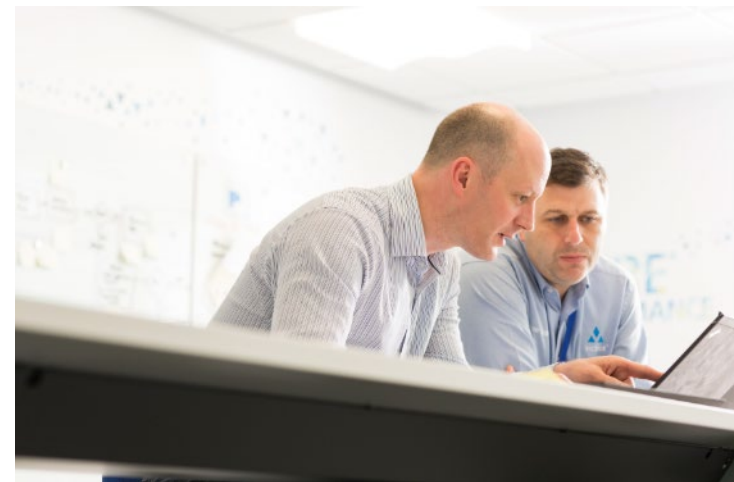
\*\* does not contain the restricted substances at concentrations above the maximum specified values



# REGULATORY SUPPORT

From Victrex

- ▶ Experienced Global Regulatory Team
- ▶ Up to date compliance with applicable regulations and industry standards
- ▶ Support and advice on regulatory strategy and pathways to regulatory clearance
- ▶ Access to material master data to support regulatory submissions





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# SHAPING FUTURE PERFORMANCE™

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