

MATERIAL SAFETY

Material composition and hazardous substances requirement¹

- ▶ Disclose all raw materials used to manufacture a device:
- ▶ Each substance/material up to 0.1% (1000 ppm)
- ▶ All hazardous materials

Material considerations

- ▶ How do materials evolve through manufacturing processes and clinical use?
 - Do they remain stable?
 - Does their reactivity change?

Finished medical device considerations

- ▶ Expect more focus on testing for:
 - Shelf-life
 - Ageing

PEEK-OPTIMA polymers allow these questions to be answered more easily

- ▶ Long clinical history in spine and orthopedics
- ▶ Proven stability and biocompatibility
- ▶ Non-hazardous
- ▶ Zero material-related recalls

SUPPLY CHAIN TRACEABILITY

PEEK-OPTIMA polymers are manufactured

- ▶ Under the **full control** of Invibio Biomaterial Solutions™
- ▶ Within a **secure**, integrated supply chain
- ▶ From monomer to specifier
- ▶ Under ISO 13485:2016 certification

Monomer Manufacturing



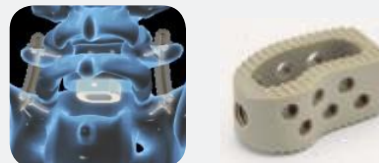
Polymer Manufacturing



Downstream Manufacturing



Finished Components*



*These products are not cleared for implantation or distribution.

POST-MARKET SURVEILLANCE

Post-market clinical evidence – are you ready?

- ▶ Increased requirement for clinical evidence to demonstrate safety and performance of medical devices under MDR
- ▶ Poses significant cost burden and resource constraints to spine medical device manufacturers

Invibio will manage selected clinical studies for medical device manufacturers

- ▶ Opportunity to collect quality clinical data
- ▶ Objective to generate marketing collateral and clinical publications on PEEK-materials and technologies

CLINICAL EVALUATION REPORTS (CER)

PEEK-OPTIMA Technical Dossier

- ▶ **20 years** - proven clinical history captured in a single evaluation
- ▶ **~9M devices implanted worldwide** – large volume of data and many references available for use
- ▶ **Focused** on spine indications including:
 - Literature search – protocol filters 5 year review (2012-2107)
 - Filters down to 44 relevant papers with 3,000 cases
 - To be updated annually

~9M PEEK-OPTIMA Devices Implanted Worldwide

20 Years of Clinical History

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REFERENCES

1. (EU) 2017/745 Annex I, Chapter 2, Section 10.4.1 Design and manufacture of devices.

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