Invibio
BIOMATERIAL SOLUTIONS

European Union Medical Device Regulation (MDR)

Compliance with PEEK-OPTIMA™ polymer implantable devices

MATERIAL SAFETY

Material composition and hazardous substances requirement[1]

- 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

~9M PEEK-OPTIMA Devices Implanted Worldwide

20 Years of Clinical History

SUPPLY CHAIN TRACEABILITY

PEEK-OPTIMA polymers are manufactured

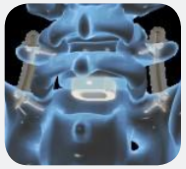
- Under the **full control** of Invibio Biomaterial Solutions™
- Within a **secure,** integrated supply chain
- From monomer to specifier
- Under ISO 13485:2016 certification

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

Invibio
BIOMATERIAL SOLUTIONS

Invibio Ltd.
Technology Centre,
Hillhouse International
Thornton Cleveleys,
Lancashire FY5 4QD
United Kingdom

Tel: +44 (0) 1253 898000
FAX: +44 (0) 1253 898001

Invibio Inc.
300 Conshohocken State Rd
West Conshohocken, PA USA

866-INVIBIO (468 4246)
Tel: +484 342 6004
FAX: +484 342 6005

For further information call us toll free at 866-INVIBIO or +44 (0)1253 898000 or please visit our website at:

Invibio.com

REFERENCES

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

S-MS-PN-E-0214-A (9/2019)