

Solutions to Unique Challenges ...from Design to Manufacturing to Sunsetting

Imperia Engineering Partners Materials Engineering Laboratory offers a range of services that few other engineering consulting firms can. Our broad expertise, industry specific resources, and quality systems, paired with our extensive knowledge of the medical device industry, enable us to provide insights and answers to challenges from across the entire device lifecycle. With over 20 years in the medical device industry, the Materials Engineering Laboratory has developed an unparalleled understanding of the interrelated nature of product design, material selection, and product performance. This understanding enables the Materials Engineering Laboratory to deliver reliable and complex solutions while meeting all regulatory requirements.



Delivering Value & Success

Imperia's expertise in medical devices revolves around several key areas of vital importance to manufacturers throughout the product life cycle:

- *Engineering Investigation*
- *Failure Analysis*
- *Materials Selection*
- *Product Development Support*
- *Reliability Improvement*
- *Production Scale-Up*
- *Process Modification*

Materials Engineering Laboratory – Services

Failure Analysis and Prevention

- *Evaluation of field failures*
- *Life cycle extension*
- *Aging and degradation*
- *Materials selection (Compatibility, wear, etc.)*
- *Defect analysis, performance improvement*

Evaluation

- *Validation of process, fabrication, design and materials (FEA)*
- *Reverse engineering, IP*
- *Development of test methods and customized fixtures*
- *Design of experiment*
- *Assessment of suppliers*
- *Verification of assumptions*

Validation/Qualification

- *Automation*
- *Qualification/Simulation*
- *Prototypes*
- *System and Components*

Imperia Quality Assurance Program

The sophisticated Materials Engineering Laboratory facilities have Quality Assurance Program which complies with the GLP standards set forth in 21 CFR 58.35, OCED Principles of GLP, and Japan Ordinance Nos. 21 and 37. Our QA Program is also compliant with the requirements of 21 CFR 820 (CGMP), ANSI/ISO/ASQC QISO 9001-2000, 10 CFR 50 Appendix B, NQA-1-1994, and 10 CFR 21. The depth of our QA Program allows Imperia to support R&D, Regulatory Submissions, and Quality Control.



Your Solution to Material Challenges

Navigating the Path to Product Lifecycle Success for Medical Devices

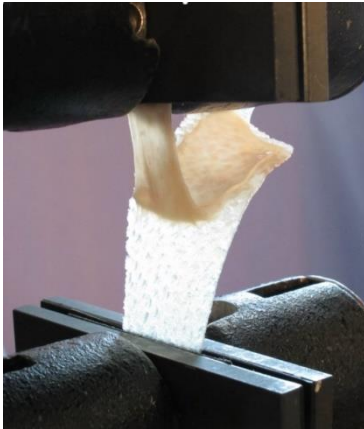
Selected Device & Component Experiences

- Spinal Repair/Fixation
- Catheters
- Stents (Urinary/Cardio)
- Disposable & Implantable
- Artificial Joints
- Biomaterials
- Heart Defibrillator
- Inhalers
- Packaging
- Wearable Drug Delivery System

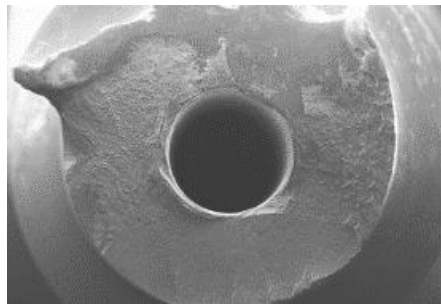
Equipment

- Microscopes with Imaging (for metallurgy, biological applications and more)
- Metallographic Cross Sectioning Equipment
- Cyclic Polarization Analysis for Corrosion Potential of Materials
- Scanning Electron Microscope\Energy Dispersive Spectrometer
- Fourier Transform Infrared Analysis with Microscope
- Differential Scanning Calorimeter
- Fully Equipped Chemical Laboratory
- Mechanical Testing-Custom-Tension, Compression, Peels, Fatigue and more
- Machine Shop – Customized Fixtures

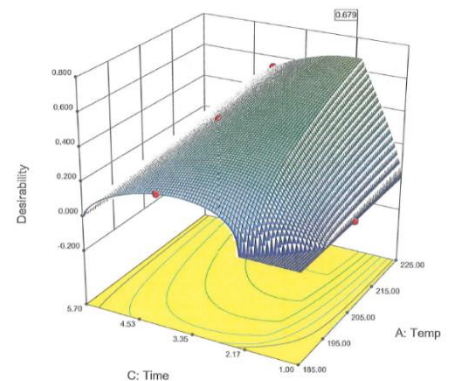
Mechanical Testing



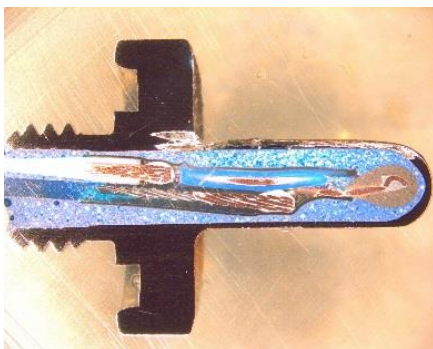
Failure Analysis



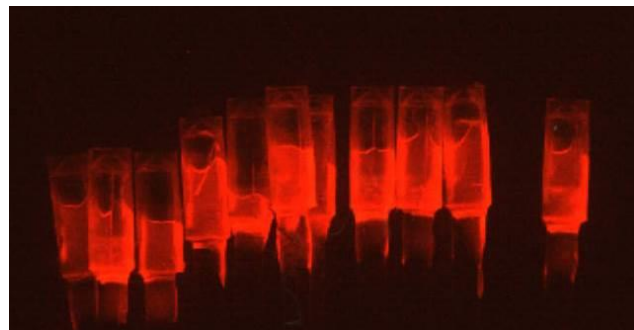
Process Optimization



Material Selection & Qualification



Product Performance



About Imperia

Imperia Engineering Partners (formerly Altran US Corp.) has been a trusted, high-tech engineering and consulting partner of businesses in the Life Sciences, Consumer Products and Energy industries for over 30 years. Our areas of expertise include polymer and chemistry, materials processing, metallurgy, coating and linings, instrumentation & control, mechanical engineering, electrical engineering and failure analysis.

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