Cambridge Polymer Group

Cleanliness Assessment of Medical Devices

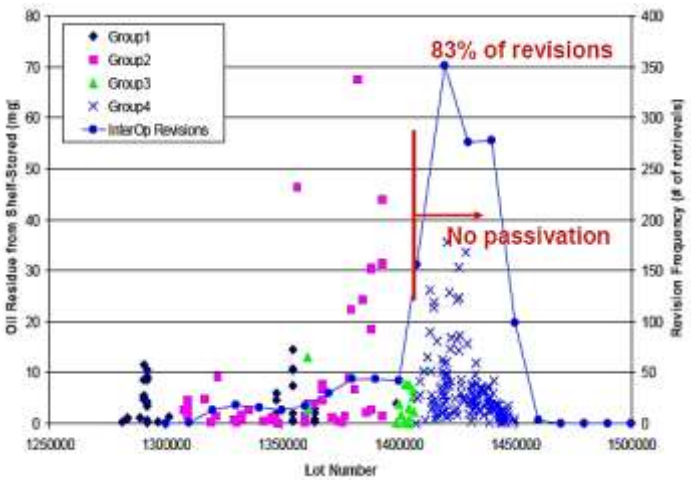
Changes in Manufacturing Processes Can Impact Biocompatibility

Summary

In 2000, a major recall occurred in the orthopaedic industry where evidence suggested thousands of metallic acetabular shells were failing to properly osseointegrate and were therefore loose. Cambridge Polymer Group investigated the reason for these failures and determined that the root cause was related to a combination of residual oil on the implant and the removal of a nitric acid passivation step during manufacturing. CPG helped the manufacturer validate the replacement manufacturing process for this product.

Description

In 2000, Sulzer Orthopedics observed that a large number of their Interop acetabular shells were not sufficiently osseointegrated after several months of implantation. Cambridge Polymer Group was engaged to determine the reasons why. We investigated the manufacturing processes and developed assays for assessing residue content on the parts. Root cause analysis was performed based on the analysis. CPG also developed tests to quantify manufacturing residues on explanted components. As a result of the analyses described here, Sulzer developed a new manufacturing process, which CPG helped to validate through cleanliness assessment.



Analysis

Our investigation showed that Sulzer's manufacturing process was leaving behind a hydrocarbon-based lubricant. The bulk of the acetabular shells that failed clinically had oil on them and were not subjected to a nitric acid passivation wash. It is believed that the passivation step either removed endotoxins that were carried within the lubricant or removed a toxic component from within the lubricant.

Key Points

- This case highlights how changes in manufacturing processes can impact biocompatibility.
- Cambridge Polymer Group is now heavily involved in developing standards for assessing cleanliness within ASTM and the FDA, and regularly consults with companies on medical device cleanliness through verification testing.

Cambridge Polymer Group, Inc. is a contract research laboratory specializing in materials. We partner with our clients to solve the world's toughest polymer problems utilizing our multi-disciplinary research team and full service laboratory.

We work with clients throughout the product life cycle to:

- Develop new materials
- Design prototypes for proof-of-concept studies
- Create and execute experimental design
- Validate and verify manufacturing processes
- Perform root-cause analysis in product failures

Cambridge Polymer Group, Inc. was founded in 1996 to provide a cost-effective resource for testing, research and development to clients who need periodic access to Ph.D.-level scientists and their support structure. We have developed a host of testing methods and materials for our clients, which number more than 1,000.

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