



Failure Analysis in Catheters

Root Cause Analysis of Manufacturing Processes

Summary

A client presented catheter hubs that appeared to be cracking during their manufacturing process. The hubs were compound structures with polycarbonate embedding electronics and the catheter itself. A detailed understanding the interaction between the materials and the processes in use was vital to allow determination of the cause of failure. Cambridge Polymer Group isolated the root-cause and proposed an alternative manufacturing strategy that the client adopted.

Description

The client was utilizing proven sterilization technologies to provide terminal sterilization of their components. E-beam sterilization is routinely used in the biomedical industry but has a severe drawback in some materials. The high flux and beam energies cause rapid charge build up on components. If uncompensated, this charge can arc between the charged surface and metal contacts resulting in fracture of the insulating polymer. CPG determined this process as the root-cause of the issues and devised an alternative sterilization strategy utilizing the gamma radiation process allowing the client to meet their process requirements with virtually no other changes.



Analysis

The spectacular dendritic discharge patterns formed in a dielectric by electrical discharge are known as “Lichtenberg figures” and result from breakdown of the polymer dielectric when excessive charge is built up during the high-flux electron beam radiation process. This process is analogous to the discharge that occurs during a lightning storm and can cause catastrophic failure of components if not adequately controlled. Lower energy, or non-irradiative sterilization circumvents this issue.

Key Points

- Routine processes can cause unexpected issues
- Understanding materials and processing conditions is vital
- Interdisciplinary approach is critical for modern systems and products

ANALYTICAL TESTING
BIOMEDICAL MATERIALS
MATERIALS CONSULTATION
RESEARCH & DEVELOPMENT



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.

100 TradeCenter Drive, Suite 200, Woburn, Massachusetts 01801
P: 617-629-4400 • F: 617-629-9100 • info@campoly.com • www.campoly.com
ISO 17025 Accredited #3930.01 & ISO 9001 Certified #000912-1-US-1-QMS
DEA Licensed #RC0548606 & FDA Registered #3005793482

