

PHARMACEUTICAL | SURGICAL DEVICES | DRUG DELIVERY | MEDICAL EQUIPMENT
 OCULAR | IMPLANTS | DENTAL | DIAGNOSTIC DEVICES | ENT | VETERINARY | VASCULAR



SES Medical
Technologies

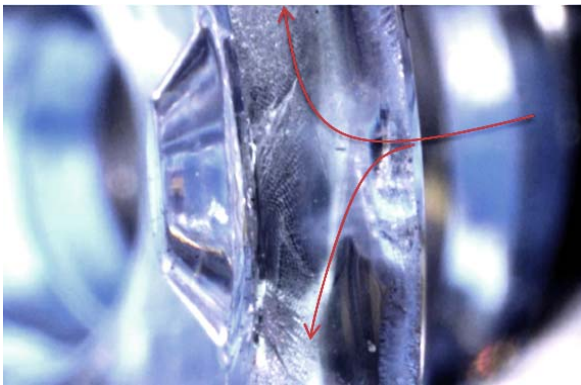
ISO 13485:2016 & ISO 9001:2015 Certified | ISO 17025:2005 Accredited for Several Test Methods
 ISTA Certified Testing Laboratory Member

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SES's Materials Expertise and Capabilities for Enhanced Failure Analysis

The technique of failure analysis involves carefully reviewing the background information (part drawings and specifications, frequency of the failure, timing of the failure, conditions preceding the failure, etc.), inspecting the specimen for the mode of failure (preferably relative to an undamaged specimen), performing testing to characterize the material (preferably relative to an undamaged material), and then, if possible, attempting to replicate the failure. From this information, hypotheses about the likely root causes can be developed and proven or disproven. For those rare situations when it is not possible to identify the root causes with 100% certainty, by narrowing down the possibilities, the end-user can be guided towards product improvements.

SES has extensive material experience and capabilities, and we incorporate material review and testing into nearly all failure analyses that we perform. By capturing Material issues as well as Mechanical and Manufacturing issues, we can understand the full situation and provide our clients with the insights necessary to take remedial action.



Crack surface showing propagation pattern near gate

As one example of a failure analysis that relied heavily on materials expertise, the image on the left shows the crack surface of a rigid plastic medical component that failed while in service. SES performed a detailed failure analysis that included inspection, material testing, and review of the mechanical and environmental factors which influenced the formation and propagation of the crack. SES was able to determine that the process of component failure included three root causes leading to failure: (1) residual stresses near the gate during molding; (2) poor design where a thick region of the part was adjacent to a thin region, leading to additional mechanical and molding residual stresses; and (3) exposure of the exterior to hospital cleaning chemicals that led to an Environmental Stress Cracking (ESC) initiation site.

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Lab Feature - Storage Stability Testing

SES's Cincinnati facility includes a Storage Stability Testing area. Currently SES offers a combination of 9 temperature and humidity controlled chambers. Careful thought has been given to planning of this facility, including:

- Back-up power generation to ensure uninterrupted aging
- Continuous remote monitoring of environmental conditions
- Annual calibration and preventive maintenance
- Internal racking to allow airflow around the product and easy access for product sampling



Upcoming Events



Mark Burchnell, Senior Associate at Stress Engineering Services, will be speaking on *How to take Advantage of New FDA Guidelines for Healthcare Robotics Systems Development*.

While you're at the Healthcare Robotics and Device Talks forum, visit us at booth #302. More details to come soon!

Please join us at **MD&M West in Anaheim, CA February 11-13** and learn more about how Stress Engineering Services can help you with your engineering needs.



Missed our latest newsletter?

Click [here](#) to learn more about our FDA Guidelines and Robotic Systems Development.

Stress Engineering Services Inc. provides expert engineering consulting services for:

- New Product Development
- Material Science & Engineering (Full Polymer & Metallurgical Labs)
- Systems Engineering
- Risk Assessment
- Human Factors
- Sustaining Engineering
- Failure Analysis
- Package Development
- Verification Testing
- Equipment Validation & Development

Our services help clients achieve not only technical success in avoidance or remediation of failures, but also commercial success in removing costs, risk and time from their process and product designs.

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To learn more about Stress Engineering Services Inc., visit our [website](#) or contact us at 513-336-6701.

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