

SES Medical Technologies

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

January 2019

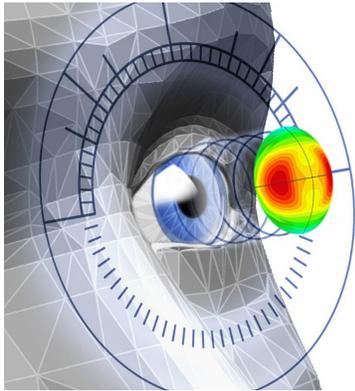
Process Validation

The purpose of process validation is to ensure the intended manufacturing elements are installed properly and inevitable variability in inputs produces product within specification. Stress Engineering Services, Inc. (SES) has the unique ability to leverage its extensive experience and knowledge of equipment and product failure mechanisms to ensure a thorough and robust validation.

We work closely with clients to create master validation plans to ensure efficient execution with predictable performance. Our years of predictive analysis experience in the medical products arena allows us to engage on very short notice and therefore providing a more predictive success in validation efforts. SES routinely works with your equipment suppliers, component suppliers and product development organization to design, lead, and even execute your production validations. We have the unique capacity to work directly within your facility and with your suppliers before components hit your doors. Our engineers have been sent to suppliers aiding in process controls, engineering, and gauging all in support of our clients' process validation success.



With our deep understanding of and experience with the human eye and its function, we have helped solve several challenging problems in the ophthalmology domain. SES has served several businesses in the development of solutions to treat various kinds of eye disorders and diseases, such as refractive errors, cataract, glaucoma, dry eye, macular degeneration, etc.



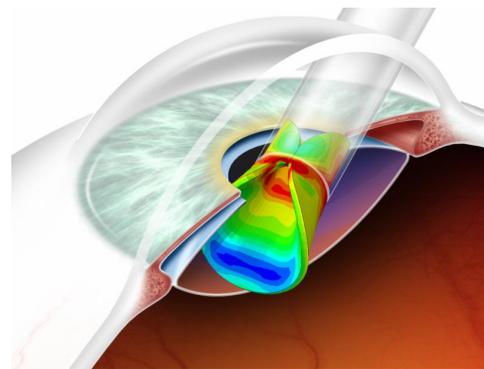
Soft contact lens deformation over an eye with astigmatism

Contact Lenses

Contact lenses are used to treat different kinds of refractive errors such as myopia, hyperopia, presbyopia and astigmatism. SES has built advanced numerical simulations that can help answer questions such as: How does a soft contact lens deform when it is worn? How does the optical power of the lens change due to this deformation? What kinds of lenses are more comfortable to wear? How does a contact lens facilitate oxygen permeation to the cornea? The tools developed by SES have been used extensively in innovation, design development and optimization efforts.

Cataract Surgery

During a cataract surgery, the natural lens of the eye with the cataract is removed and is replaced with an artificial intraocular lens (IOL). The IOL is typically implanted into the eye behind the iris through a delivery system that folds the lens and pushes it through a narrow lumen before it is delivered. The smaller the size of the lumen, the smaller the incision required in the cornea to deliver the lens. Smaller incisions mean reduced post-surgical vision aberrations and speedier recovery. However, a smaller lumen also requires tighter folding of the IOL, which poses significant challenges in terms of larger strains on the IOL, larger stresses on the delivery lumen, higher force to deliver, etc. Advanced numerical simulation based approaches can be used to address some of these questions and to gain a better insight into metrics that cannot be easily measured. SES has a broad experience in applying physics-based computational models and material testing for the design, development and optimization of cataract IOLs and delivery systems.



Delivery of an intraocular lens (IOL) during cataract surgery

Upcoming Events

[SPE Medical Plastics Minitec](#)

Biodegradable/Resorbable Polymers: Recent Themes and Challenges in the Medical Device Industry

Technical Presentation by Rob Klein, Associate II with SES

February 4, 2019 | immediately precedes MD&M West

Sheraton Park Hotel at the Anaheim Resort

[MD&M West 2019](#)

February 5-7, 2019 | Anaheim Convention Center | Anaheim, CA

SES Medical - Booth #2097

Polymer Laboratory at Stress Engineering - Booth #2095

Missed our latest newsletter?

Click [here](#) to read about DHF Remediation and FMEAs.

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.

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

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

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