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

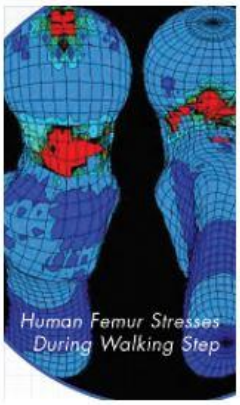
ISO 13485:2016 & ISO 9001:2015 Certified | ISO 17025:2017 Accredited for Several Test Methods
ISTA Certified Testing Laboratory Member

February 2020

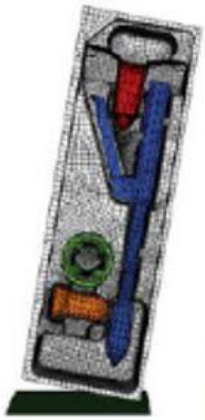
Developing Computational Models for Evaluating Medical Devices

Computational modeling and simulation (CM&S) can transform medical device development by enabling innovation, providing comprehensive understanding of long-term safety and streamlining pre-market device evaluation. The FDA has prioritized development of computational modeling technologies to support regulatory decision making. CM&S based in-silico methods can be used to assess use scenarios that are difficult or not possible using traditional in-vivo and in-vitro methods. The recently published ASME V&V 40 - 2018 standard, which was developed in collaboration with the FDA, provides a risk-informed framework for assessing the credibility of computational models applied to medical devices. The goal of the standard is to promote consistency in the way modeling is performed and reviewed by requiring adequate verification, validation and uncertainty quantification.

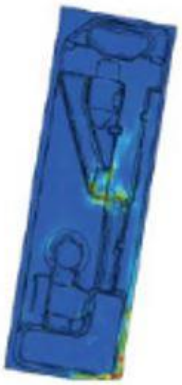
Computational models may focus on the device (to verify requirements are met), the in-vivo or use environment (to validate that user needs are met), the manufacturing process (to ensure quality control), or the shipping and handling process (to verify packaging performance).

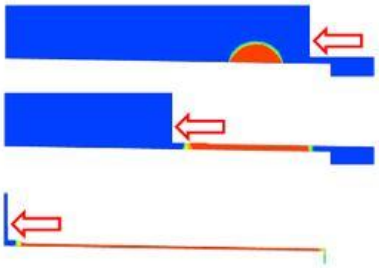


In-Vivo Model

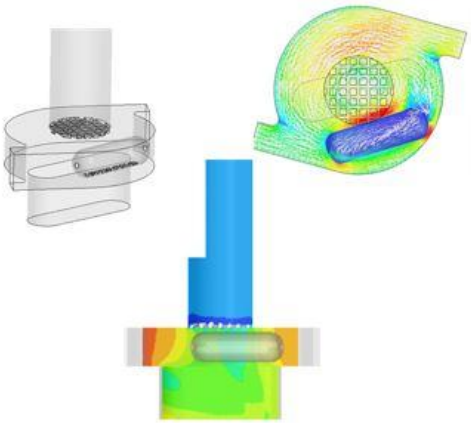


Device Packaging Model

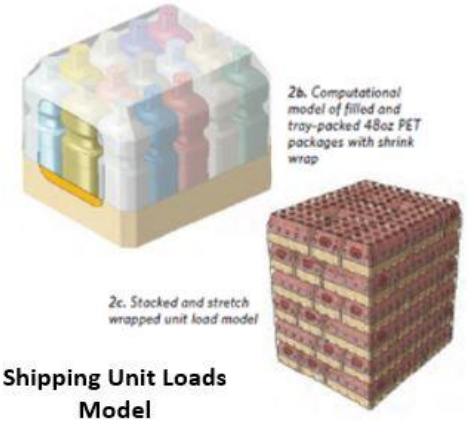




Gluing (Manufacturing) Process



Device Model



Shipping Unit Loads Model

Credible virtual models of the device, i.e. regulatory grade digital twins, can be used through the total product life-cycle supporting non-clinical and clinical activities, including virtual device and process validation. They can provide a flexible platform to determine device performance benchmarks, capture design parameter inter-dependencies, evaluate a wide range of use conditions and facilitate faster response to future policy changes. In silico data obtained from the digital twins can be used as secondary evidence in support of other in-vivo and in-vitro data, and could eventually become the primary evidence in regulatory submissions and approvals.

Stress Engineering Services has more than 30 years of experience developing accurate computational models supporting medical device development and post-market failure analysis. Combined with the extensive test lab with standardized and custom medical device test capabilities that can support model validation, Stress Engineering Services is in a unique position to help our clients develop regulatory grade digital twins and leverage the latest guidance from the FDA.

When Super High Precision Measurements Are Needed

Stress Engineering Services (SES) has a long history using laser sensor systems for many projects, and has recently developed a new laboratory approach using a con-focal laser. This laser system has the ability to measure sub-micron scale

distances on any surface, and, in connection with SES's depth of testing and measuring experience, allows our engineers to develop customized testing services to fit your unique needs.

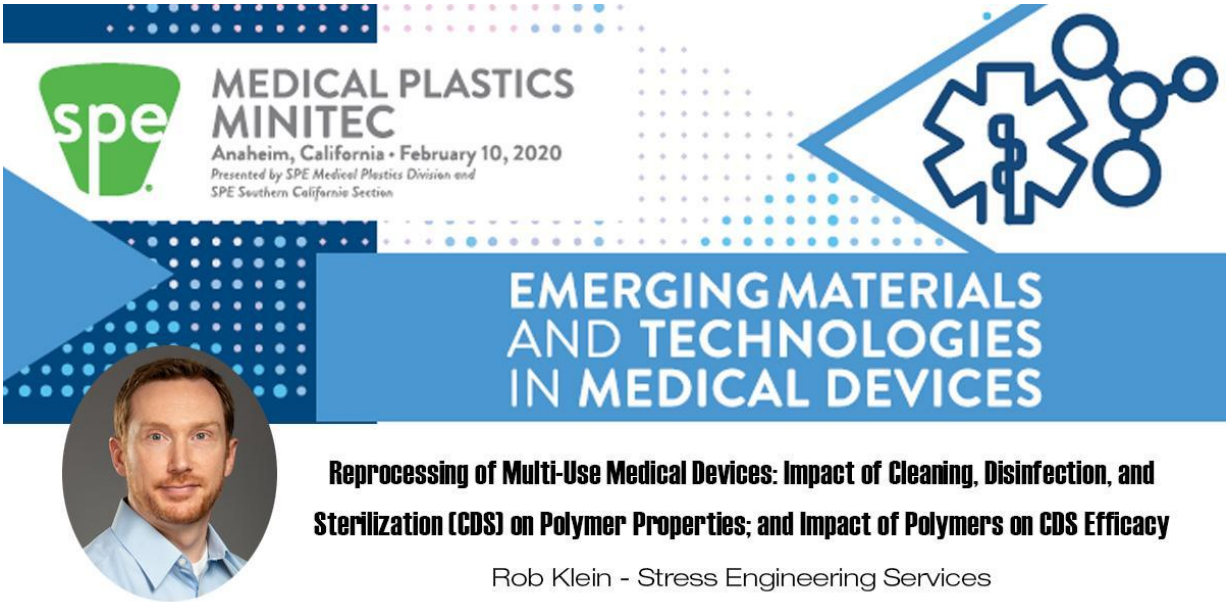
The con-focal method measures transparent glass and polymers, curved surfaces, rough surfaces - all of which can be difficult or impossible to measure with traditional laser displacement sensors. The system is highly insensitive to shock, vibration, and environmental conditions, allowing the sensor head to be mounted on moving components or in industrial environments. Coupled with a stage, the system acts as a sub-micron scale profilometer. The laser can also directly measure the thickness of the component layers in multi-layer transparent or translucent films, with little to no sample preparation providing our engineers with more dynamic information and data on a finite level.

Contact the testing experts at Stress Engineering Services today to discuss how this con-focal laser displacement system can help solve your toughest measurement challenges!

SES Keyence CL-PT010 Con-focal Laser Sensor

Upcoming Events

Stress Engineering Services' Rob Klein is presenting at Medical Plastics Minitec February 10. Please join us in attending his presentation on polymer properties and their effects on reprocessing multi-use medical devices. For the Minitec agenda, click here.



Click here to visit the MD&M West website and register for a free expo pass.

PDA

2020 PDA EUROPE

Parenteral Packaging Conference

25 - 26 February 2020 | Basel,Switzerland

Please join us in attending Jeremy Hemingway's presentation on how Stress Engineering Services' Incremental Computational Approach can help evaluate the seal integrity of Cryogenic Container Closure Systems.
To visit the 2020 PDA Europe Parenteral Packaging Conference site, click here.

BIOMEDevice FEATURING Design & Manufacturing NEW ENGLAND

Click here to visit the BIOMEDevice site.

May 6-7, 2020
Boston Convention and Exhibition Center
Booth#562

Missed our latest newsletter?

Click here to learn more about the European Medical Device Regulation and our Metallurgical Laboratory capabilities.

Find out what's new and visit our blog for insights into how we can help you with your toughest engineering needs!

Click here to visit our BLOG

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 problem avoidance or remediation of failures, but also commercial success in reducing or removing costs, risk and time from their development 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.

9001:2015 Certified
13485:2016 Certified
17025:2005 Accredited for Several Test Methods

HOUSTON | CINCINNATI | NEW ORLEANS | CALGARY | SINGAPORE