3DEXPERIENCE® Works

3DEXPERIENCE®

IMPROVING MEDICAL DEVICE DESIGN WITH SIMULATION TECHNOLOGY

White Paper

OVERVIEW

This guide to maximizing productivity gains in the medical design industry provides an overview of the numerous challenges facing medical product designers. Using examples from medical devices already developed, you will learn how a concurrent engineering approach can help you solve design and business challenges and gain assurance of product quality, reliability, and safety.

DASSAULT SYSTEMES

INTRODUCTION

Medical product designers and developers face a number of business and engineering challenges specific to their industry. Patient safety is as important a consideration as efficiency, effectiveness, and cost-containment in the design of such products as implants, drug delivery systems, diagnostic equipment, clinical laboratory instruments, surgical devices, and pharmaceutical packaging.

BUSINESS CHALLENGES

The medical industry is highly volatile and competitive and changes on a daily basis. Not only do medical device organizations have to address normal design challenges, such as time to market, innovation, cost reduction, and global competition, they also have the massive responsibilities of patient safety and following strict regulatory guidelines.

To add a further challenge, increasing regulatory scrutiny is putting medical device manufacturers under the gun on total quality and safety. With the number of FDA (Food & Drug Administration) warning letters issued on the rise, the time and budget medical device manufacturers spend on regulatory activities is climbing. In fact, one-third of medical device R&D job openings are in Quality and Regulatory and one-quarter of the industry's R&D spending goes to regulatory activities.

In spite of investments of time, effort, and regulatory diligence the risk to patients through device failures, and to companies through recalls persists:

- **Between 2009 and 2019 approximately 83,000 patients died as a result of failing devices (ref. FDA).**
- **There were 99M Class II device unit recalls per quarter in the 6 quarters up to July 2019 (Ref. McKinsey).**

A recall typically costs at least a 10% drop in company valuation (Ref. McKinsey). According to the FDA, "Both the time and the cost of medical product development continues to rise for many types of products. We know that the cost of product development can impact how such products are priced, and can be a factor in limiting patients' ability to get timely access to beneficial new treatments and services." The bottom line: Now more than ever, medical device designers have to develop new products quickly, at lower cost, while ensuring consistently high quality and performance.

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For example, when Tensys Medical Inc. developed the first noninvasive, continuous arterial blood pressure management system, the company knew it had a narrow window of opportunity and needed to get the product out to the market quickly. It credits SOLIDWORKS® design validation tools with shortening the design cycle by 60 percent and helping it to create a new medical market space.

The first noninvasive, continuous arterial blood pressure management system, designed by Tensys Medical Inc.

Medical equipment developers also need to comply with government and consumer agency standards and requirements, while simultaneously adapting products to customer demand. When the Kerr Group designs over-the-counter drug packaging, for example, its designers have to balance childproofing needs with the requirements of senior citizens to be able to open the packages with arthritic hands—and do so to the satisfaction of the Consumer Products Safety Commission.

Engineers at the Kerr Group rely upon SOLIDWORKS Simulation to help them find designs that meet such criteria. Product designers who want to compete successfully in the hectic medical products environment have to work hard at reducing development and manufacturing costs and minimizing product liability exposure. SOLIDWORKS software's design validation tools help them do so on a daily basis.

ENGINEERING CHALLENGES

In addition to the challenges posed by the rigorous criteria already mentioned, medical product design challenges include understanding and designing for ergonomic issues that affect operating time and patient trauma. The ever-increasing cost of medical services makes it essential that products be more efficient and user-friendly to meet the goals of reducing operating time and surgery costs. Medical staff has strict aesthetic requirements that designers must meet, along with such functional needs as the range of motion required and the contact force requirements of surgical instruments for specific surgical tasks. Also, the materials used for medical products have become very sophisticated and product engineers need to be educated about their strength and conductivity, as well as the effects of sterilization on their material properties.

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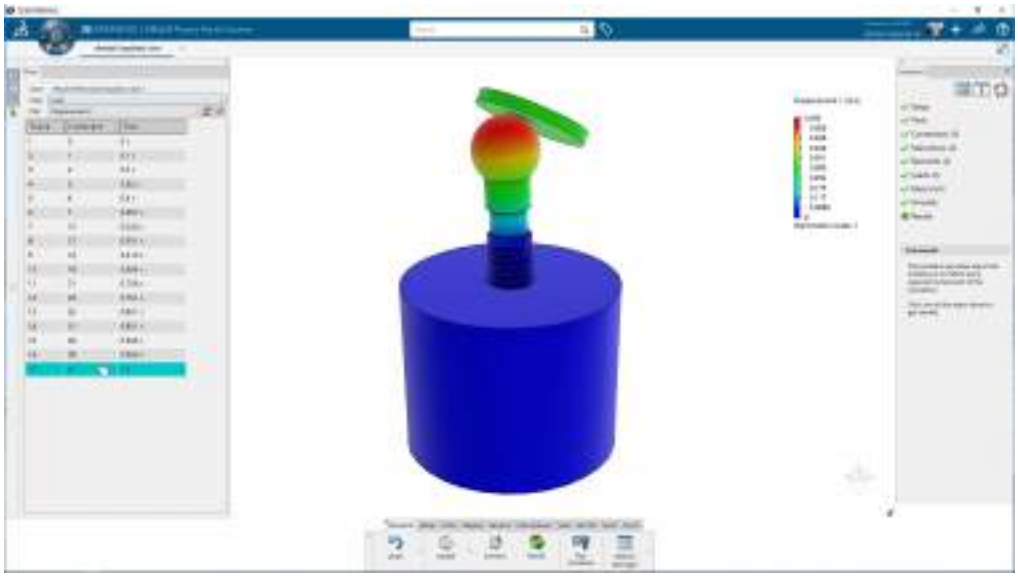
Implanted devices, such as cardiovascular stents, have to be error free because failure can cause fatalities. Orthopedic implants, such as hip and knee replacements, have to function flawlessly to avoid pain and the danger of fracture to patients. Product engineers have to predict the life of implantable devices accurately so that patients can have them removed or replaced in a timely, non-life-threatening manner.

Virtual simulation, with a concurrent engineering approach, helps medical product engineers balance all these simultaneous needs and gain assurance of product quality, reliability, and safety. Specific examples citing medical device user stories are discussed below.



SOLIDWORKS Simulation helped product designers maximize strength and stiffness, identify forces and loads, and verify connectors in this dental implant.

DESIGN VALIDATION FOR THE MEDICAL DEVICE INDUSTRY

Analysis with SOLIDWORKS and **3D**EXPERIENCE Works meets the requirements of regulatory agencies for proof of design reliability.

The purposes for which engineers perform design analysis include proof of concept, "what if" studies to identify the best design, design confirmation, and assistance in answering to regulatory requirements. Proof of concept is required early in the development cycle. "What if" studies can include variations in geometry, types of material, and different operating loads. Design verification can help to test product reliability while reducing the number of costly and time-consuming physical prototypes. Drop tests can be performed to ensure the performance of hand-held devices and home-care equipment. The results of all these tests are generally accepted by regulatory agencies when companies seek approval.

The FDA has three classification levels for medical products:

- **Class I - Passive devices that do not enter the patient's body or contact only the skin**
- **Class II - Active devices or devices that are used to administer fluids to the patient's body**
- **Class III - Implanted devices inside the patient's body**

The FDA is familiar with finite element analysis (FEA) and even expects design validation results to accompany some submissions—particularly of Class II and III devices. The agency expects such analysis results to match those obtained with established experimental methods.

Using SOLIDWORKS Simulation during the design process allowed Myomo to test part interaction and weight issues before going to market with this orthotic device.

SOLIDWORKS SIMULATION SOLUTIONS

SOLIDWORKS software is the 3D CAD program of choice for many manufacturers of diagnostic and clinical equipment, surgical tools, implants, drug delivery systems, and pharmaceutical packaging systems.

Product engineers who use SOLIDWORKS software have to resolve design issues such as portability of equipment that often gets moved from one part of a hospital to another, ease of operation, maneuverability and configurability for use in medical facilities and home care, and—always—safety for consumers and medical personnel.

From designing concepts to the detailing and validation phases of product development, the testing during each phase of product development is crucial to understanding how products will work and whether they will behave as desired. Intuitive scalable and powerful design validation solutions from SOLIDWORKS and **3D**EXPERIENCE Works enable SOLIDWORKS 3D CAD software users to perform a variety of simulations and leverage CAD data for engineering purposes during all phases of the design process. Further, since SOLIDWORKS Simulation is embedded within SOLIDWORKS 3D CAD, users can accomplish these studies without switching between multiple interfaces.

Full integration between design and simulation also makes it possible for medical device engineers to perform easy design modifications and configuration-specific studies to enable the manufacture of products customized to individual needs. The complete integration between SOLIDWORKS Simulation and SOLIDWORKS 3D CAD offers multiple benefits for the medical engineer:

- **100 percent associativity between design model and simulation model so any design changes and variations are automatically updated on the simulation model for "what if" scenarios.**
- **Strong 3D CAD data support: design properties become engineering properties for a productive and smooth workflow such as materials properties, fasteners, automatic recognition of fluid domain in CFD, and recognition of the geometry topology for mesh definition.**
- **Shared communication tool with eDrawings allows simulation results to be easily communicated downstream with all stakeholders of the project.**

In addition to that, **3D**EXPERIENCE Works offers scalable and powerful simulations using the industry leading Abaqus technology from SIMULIA. It offers an associative workflow for rapid trade-off studies with SOLIDWORKS 3D CAD models.

Using SOLIDWORKS Simulation during the redesign of this anesthetic unit, engineers at Dräger Medical, GmbH, reduced the number of prototypes used in the early stages of product development from eight to two.

PROVEN SIMULATION SOLUTION

The virtual testing capabilities within SOLIDWORKS Simulation are built on a strong finite element analysis (FEA) foundation. SOLIDWORKS Simulation, together with the CFD capabilities in SOLIDWORKS Flow Simulation, the plastic injection molding tools with SOLIDWORKS Plastics, the sustainability features in SOLIDWORKS Sustainability, and the rigid body motion simulation of SOLIDWORKS Motion have helped users test such medical products as orthopedic implants, cardiovascular stents, heart valve replacements, cancer treatment delivery systems, solution pumps, blood pressure monitors, anesthetic units, open oxygen delivery systems, centrifugal blood separators, needle-free drug delivery systems, and many more.

SOLIDWORKS Simulation solutions bring a unique and new approach to concurrent engineering. The solution, with CAD embedded tools, offers among the highest levels of accuracy, coupled with unique intuitiveness and engineering philosophy.

Associativity between SOLIDWORKS design and simulation tools and **3D**EXPERIENCE Works simulation tools makes it possible for medical product designers to perform easy design modifications and configuration-specific studies, to enable the manufacture of products customized to individual needs.

Analysis capabilities

SOLIDWORKS Simulation solutions offer a complete and consistent engineering suite of tools so medical engineers can perform complete performance tests all within the same solution. They can test against a broad range of parameters during the design process, such as durability, static and dynamic response, assembly motion, heat transfer, fluid dynamics, and plastics injection molding.

Static analysis

SOLIDWORKS Simulation provides a wide range of structural analysis capabilities, including static analysis to determine stresses, strain, and deflections. With the information thus provided, medical product designers can understand product behavior early in the process to either improve design or avoid failure.

This most frequently used of all analysis tools helped Tensys Medical to analyze an actuator that moves a sensor over the wrist of a patient during surgery to find the optimal position to produce continuous waveform indication of the patient's blood pressure by a safe, non-invasive device. The geometry of the actuator is complex and Tensys engineers used SOLIDWORKS Simulation linear stress analysis to locate and then eliminate areas of high stress. The designers then optimized the design for reliability and produced a part with the ability to flex almost indefinitely.

Thermal

Thermal analysis calculates the temperature and heat transfer within and between components in medical design and its environment. This is an important consideration for medical device design, as many products contain materials with temperature dependent properties and because there are possible effects of human body temperatures, as well as heat generated by electronic components embedded in the product. Product safety is also a consideration—if a product or component gets too hot, engineers may have to design a guard over it.

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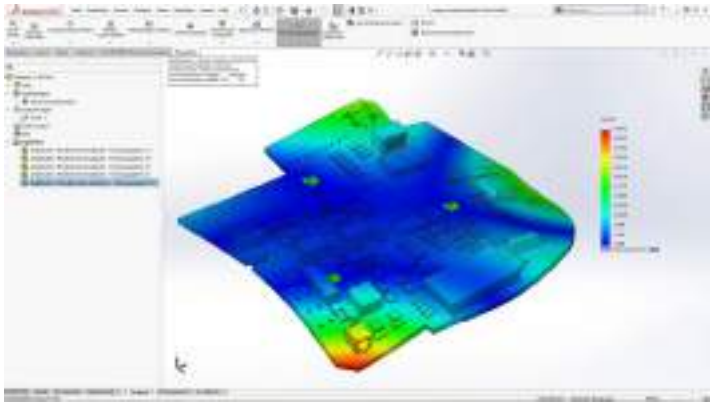
Dräger Medical of Germany, a worldwide leader in critical care equipment, used SOLIDWORKS Simulation linear static and thermal analyses to study the performance of a number of different plastic materials from the viewpoints of performance and meeting statutory regulations when they wanted to change the material used in the respiratory gas unit of a ventilator from aluminum to plastic.

Frequency and vibration

Vibrations that medical devices may experience can reduce performance, shorten product life, or even lead to improper usage of the product.

Frequency analysis was particularly important for one major device firm involved in designing and analyzing a new computerized tomography (CT) scanner. The leading company needed to know the frequency of a key assembly—and they needed the results very quickly. The head of the CAE department reports that the team was able to obtain the required results in 20 minutes on a PC—an analysis that he says would have taken a senior engineer several weeks with other simulation tools.

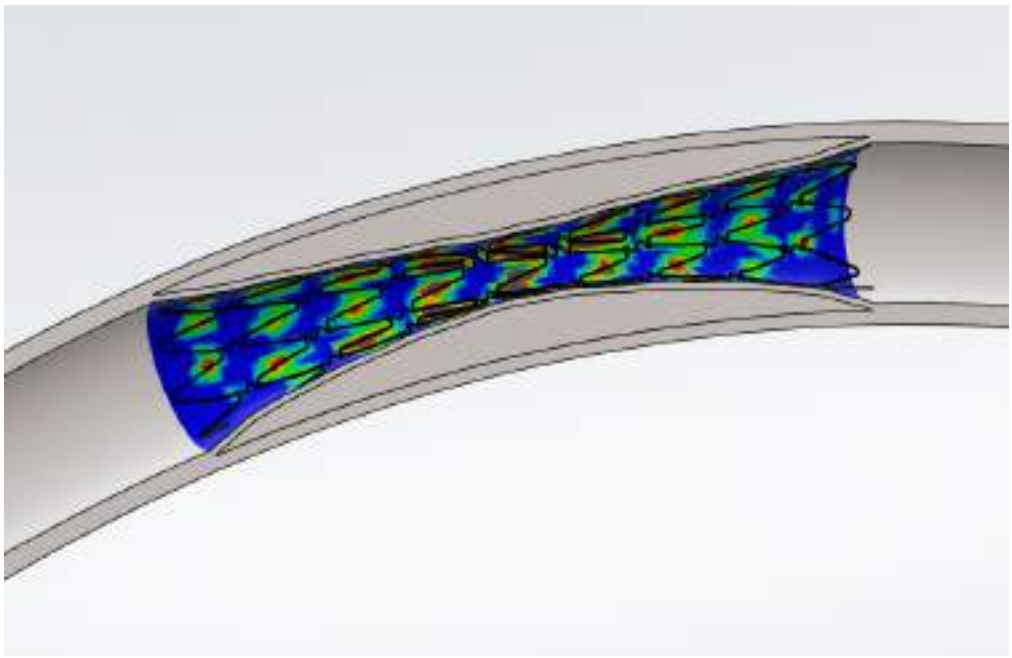


Withstand vibration loading

Contact

Contact analysis is important for assemblies in all products and particularly so in the medical product field where safety is so critical. The same holds true for the ability to determine the desired factor of safety in medical products, where premature failure might cause injuries or deaths. One example comes from a large medical device designer tasked with developing a needle-free injection system. This system was designed to use pressure to create a micro-thin stream of medicine to penetrate the skin and deposit medication into subcutaneous tissue. The company's engineers performed static analysis on the safety mechanism of the device to predict the contact force required to activate it. After several design modifications, SOLIDWORKS Simulation helped them to come up with a final design that exhibited the desired level of activation force required by patients during an emergency.

To solve more complex contact interactions involving friction, large strain, large displacement and large rotation, the Abaqus technology with the most advanced and robust contact capabilities with an associative workflow is available for the SOLIDWORKS users with the **3D**EXPERIENCE Works portfolio.



Special surface capabilities within **3D**EXPERIENCE Simulation tools help to represent stent contact with catheters, balloons and arteries in both straight and curved conditions.

Nonlinear

Nonlinear stress analysis calculates the stresses and deformations of products under the most general loading and material conditions for:

- **Dynamic (time dependent) loads**
- **Large component deformations**
- **Nonlinear materials, such as rubber or metals, beyond their yield point**

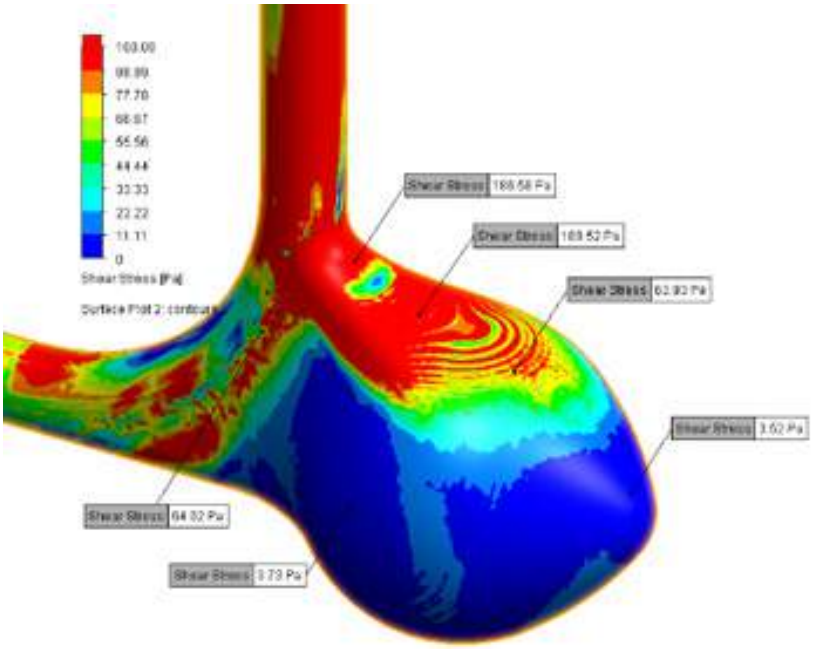
Nonlinear analysis is often critical to medical applications to determine the factors that may cause device issues. The SOLIDWORKS Simulation material database has many nonlinear materials models with predefined properties, including one for Nitinol, a shape memory alloy widely used in medical devices. Nonlinear analysis can be used for such tasks as analyzing a catheter going through an artery to simulate the resistance and torsion caused by resistance from human tissue.

To solve the complete stent applications such as the stent insertion with bending, torsion, extension, the expansion and the deployment of the stent, the Abaqus technology is available for the SOLIDWORKS users within the **3D**EXPERIENCE Works portfolio.

The capabilities include:

- **Special surface capabilities to represent stent contact with catheters, balloons and arteries in both straight and curved conditions.**
- **Material modeling capabilities for common medical grade materials including 304 and 316 stainless and Nitinol.**
- **Complete large strain, large displacement and large rotation capability with contact.**

Tiniko, a small Korea-based company that manufactures innovative medical implants for the treatment of spinal conditions, like fractures or degenerative diseases, added advanced simulation solutions to SOLIDWORKS to reduce the development time, and the duration of clinical trials with better prediction of the behavior of the implants. This was a challenge with the Titanium and Nickel alloy that they use in the implants due to its interesting properties - shape memory and ultra elasticity.



Tiniko was able to connect their data from SOLIDWORKS to perform multi-step analysis using **3D**EXPERIENCE Works Simulation.

"Clinical trials are very expensive, take months, and are a difficult way to analyze the causes of product problems. For this reason, we adopted **3D**EXPERIENCE Works Simulation solutions. We were able to perform advanced simulation, nonlinear dynamic analysis, multi-step analysis, and many other simulation techniques at a very reasonable price. A great advantage was being able to use existing data created by SOLIDWORKS. With all data connected, our workflows are dramatically improved by **3D**EXPERIENCE Works Simulation," In-Hyuk Heo, Researcher, TiNiKo.

Tiniko implemented the SIMULIA Structural Mechanics Engineer role, part of the **3D**EXPERIENCE Works portfolio, due to its demonstrated high accuracy and reliability. The entire set of simulation data is also available in the cloud which makes it very convenient for sharing the results with researchers and clinicians to analyze the issues and more rapidly come up with a solution. Tiniko is planning to develop new and more advanced devices because they trust their newly acquired ability to accurately simulate the product behavior and meet their objectives.

Fatigue analysis

Fatigue is defined as failure under a repeated or otherwise varying load, which never reaches a level sufficient to cause failure in a single application. Fatigue analysis examines how repeated or random load cycles can cause structural failure. For medical device engineers, understanding how long products and materials perform over the test of time is critical for patient safety and maintaining compliance.

Cardiovascular Systems, Inc. (CSI) is revolutionizing the treatment of vascular disease through the development of a disposable, diamond-coated, catheter-based device. The devices are used in a procedure called orbital atherectomy, which uses centrifugal force to grind away up to 90 percent of arterial plaque obstruction.

CSI is revolutionizing the treatment of vascular disease through the development of products like the PREDATOR 360, a disposable, diamond-coated catheter based device.

While the orbital atherectomy devices that CSI used for its clinical trials were all steel, manufacturing disposable versions that follow FDA approval required an examination of less expensive materials. Using SOLIDWORKS Simulation software, the company's engineers were able to thoroughly analyze the blend of high-strength plastics they utilized to validate performance prior to testing.

"With SOLIDWORKS Simulation, we were able to conduct structural and fatigue analyses to optimize our design and material selection. This type of information was key to controlling costs, ensuring quality, and staying on schedule," said Christopher Narveson, design and engineering services manager, CSI. As a result of these fatigue analyses, CSI was able to reduce development time by 25 percent.

Optimization

One objective of virtual testing during the design phase is to improve product behavior under environmental constraints. Product Engineers can perform structural optimization analysis using CAD-embedded SOLIDWORKS Simulation to reach the best available strength-to-weight, frequency, or stiffness performance for designs.

Design optimization for medical device engineers can increase the value of a product by improving its performance within its operating environment and by reducing the cost of producing it by reducing the amount of material used to make it. By employing optimization, the product engineer will increase his knowledge of his product's behavior and improve upon the design.

Computational fluid dynamics (CFD)

Fluid flow issues are critical in medical applications. Whether for artificial heart valves, solution pumps, oxygen delivery, and a host of other such products, a variety of fluids must move reliably as designed and at prescribed temperatures. SOLIDWORKS Flow Simulation makes it possible to study such issues in a very straightforward manner. Like SOLIDWORKS Simulation, SOLIDWORKS Flow Simulation is fully integrated within SOLIDWORKS 3D CAD.

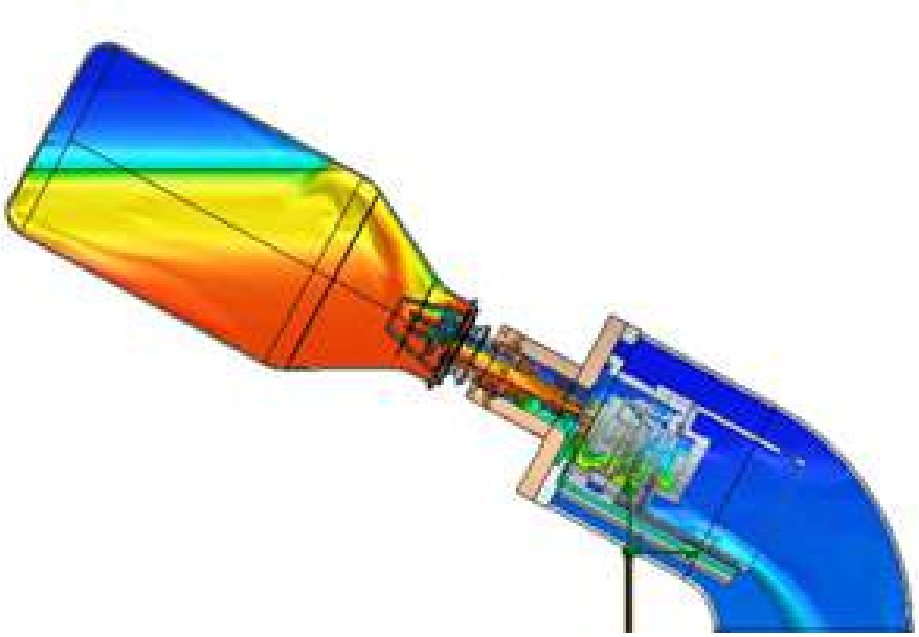
SOLIDWORKS Flow Simulation can simulate the flow of fluids, including non-Newtonian liquids, mixing of fluids, conjugate heat transfer with fluid flow, and external/internal flow. Blood flow provides a good example of a non-Newtonian fluid.

Medical devices often incorporate mechanisms to transport fluids, from simple pre-filled syringes to complex peristaltic pumps to administer large-molecule therapeutics for extended durations. Accurately modeling the fluid velocities and pressures is critical to understanding and optimizing the drug delivery process. It is also important to understand the effect of the fluid on the surrounding structures to minimize leakage and enhance durability.

GE Healthcare's Anesthesia and Respiratory Care Group leverages simulation to make every design decision for its innovative products with a combination of SOLIDWORKS Flow Simulation and **3D**EXPERIENCE Works Structural Performance Engineer. SOLIDWORKS Flow Simulation is an intuitive computational fluid dynamics (CFD) solution embedded within SOLIDWORKS 3D CAD that enables the analysis of liquid and gas flows through and around designs to calculate product performance and capabilities.

"I have a ballpark idea of how our designs will work, but how do I make it right the first time? Simulation lets us test our work so we can be right out of the gate. When we go to do our testing and verification, it needs to be a check-the-box exercise. We cannot find surprises right before we launch. **3D**EXPERIENCE Works Simulation removes this uncertainty and helps us push the envelope with our products. I'm very impressed with its capabilities," Dr. Joseph Lacey, Principal Engineer, GE Healthcare.

3DEXPERIENCE Works Structural Performance Engineer provides structural simulation with advanced linear, non-linear static, transient and modal dynamic, quasi-static, frequency, buckling, thermal simulation, and thermal-structural simulation capabilities. Together, these simulation tools help GE Healthcare to reduce physical prototypes, optimize liquid and gas exchange paths, and speed up product development.



GE Healthcare optimized the liquid and gas exchange paths when transferring an anesthesia agent from a sealed bottle to its vaporizer using the free surface capabilities in SOLIDWORKS Flow Simulation

Motion simulation

SOLIDWORKS Motion Simulation allows medical engineers to ensure equipment and instruments move smoothly, with no spikes in their motion and load behavior. Load data results of motion simulation can also be transferred to SOLIDWORKS Simulation to check the strength of parts, playing an important role in optimizing medical product design.

For example, a manufacturer of surgical instruments and devices for minimally invasive surgery was required to check load profiles for components such as staplers, fasteners, and retrievers. To determine this information, the company wanted to optimize the force needed for firing and retracting the mechanism of an instrument that holds human tissue during surgery. The designers used SOLIDWORKS Simulation to obtain the force data from motion simulation and then used it to change the design. After just a few iterations, they had optimized the final design, one that was easy for surgeons to use while causing the least possible damage to the patient.

Electromagnetics

As medical devices become increasingly IoT-enabled and deployed for 24/7 monitoring, it is critical to validate a device's electromagnetic performance under all possible operating conditions. Using electromagnetic simulation, you can easily explore and optimize the design and location of the onboard antenna and electronic circuitry to maximize performance and reduce the likelihood of electromagnetic interference. It also allows engineers to minimize the electromagnetic compatibility (EMC) risks and the exposure of the human body to electromagnetic fields, to ensure the device passes the certification tests required by the legal standards.

In addition, electromagnetic solutions within the **3D**EXPERIENCE Works portfolio provide powerful methods such as the unique finite integration technique (FIT), the classical finite element method (FEM) and the transmission line matrix method (TLM), even for hybrid simulations, to deliver an unprecedented simulation reliability through cross-verification and to avoid device malfunctions, warranty claims.

Plastics

Most small medical devices are manufactured with plastics. SOLIDWORKS Plastics brings easy-to-use injection molding simulation directly to the designers of plastic parts and injection molds, as well as advanced CAE analysis. It simulates how melted plastic flows during the injection molding process to predict manufacturing-related defects on parts and molds. You can quickly evaluate manufacturability while you design to eliminate costly mold rework, improve part quality, and accelerate time to market.

For Strong Arm Technologies, makers of the award-winning Strong Arm Ergoskeleton, SOLIDWORKS Plastics played a critical role in ensuring that its lifting system design was optimized for manufacturability. Vice President of Engineering Michael Kim explains his experience: "We need to ensure that we can cost-effectively produce and assemble the product's many parts without impacting performance. SOLIDWORKS analysis, design for manufacturability, and injection-molding tools let us affordably produce a high-performing product that will last.

"For example, SOLIDWORKS Plastics allows us to run our parts through a virtual injection molding process, so we can spot potential draft angle or filling issues before investing in tooling," Kim continues. "With SOLIDWORKS design for manufacturability solutions, we will save time and money working with our manufacturing partners by streamlining the entire process."

Using SOLIDWORKS Simulation tools, Strong Arm Technologies conducted design performance studies that allowed the company to optimize load distribution, resulting in a lighter, stronger, and more effective product.

CONCLUSION

Designers of medical products have to meet the needs of physicians, insure patient safety, and address regulatory requirements. They can never compromise on quality because lives may depend on product performance. To be certain that they meet all these requirements, medical product designers now have access to advanced Simulation tools with associativity with SOLIDWORKS CAD for rapid trade-off studies. The **3D**EXPERIENCE Works Simulation solutions provide a powerful and realistic set of applications based on the Abaqus technology, leader in the structural simulation industry. This offers them the capability to test very early during the design process the performance of their design for improvement of concepts, optimization of design, and failure detection. With this approach, engineers can meet high regulations for quality while keeping within cost restraints. The result is faster innovation of compliant products that are ready to become medical breakthroughs. Adding a connection to the cloud enables time and hardware cost savings with remote high performance computing. For faster and data-driven decision making, simulation lightweight results are easy to share.

A CASE IN POINT...

Saving time and money via simulation

Synaptive Medical utilizes SOLIDWORKS Simulation Professional software to optimize and validate design performance, which minimizes prototyping cycles, saving time and reducing costs. "Our BrightMatter Drive product features a cantilevered robotic arm that is suspended over the patient," Mechanical Engineer Mark Morreale explains. "We used SOLIDWORKS Simulation Professional software to ensure that our design satisfied the safety factors for stress and strength required by the IEC [International Electrotechnical Commission] 60601 standard for all medical electrical equipment.

"We're still required to test everything, but SOLIDWORKS simulation tools help us to reduce testing cycles and mitigate risk," Morreale stresses. "We also use SOLIDWORKS Simulation Professional software to conduct fatigue and drop test studies, and design testing apparatus with SOLIDWORKS."

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