DASSAULT SYSTEMES

SOLIDWORKS

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.

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

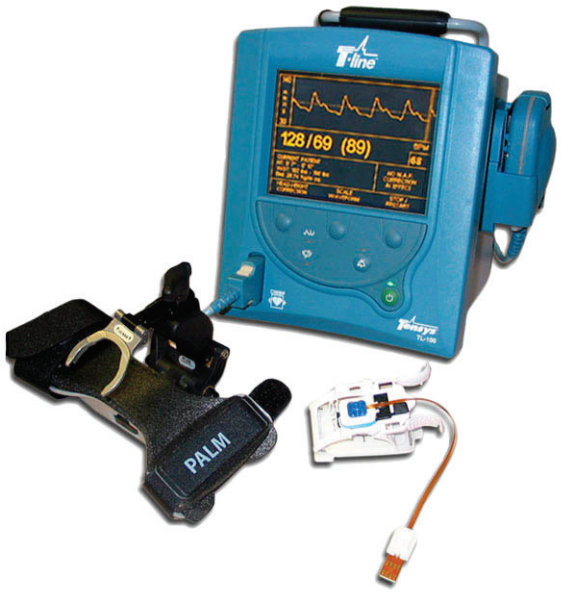
The medical industry is highly volatile and competitive and changes on a daily basis. Not only do medical device organizations have to address normal design challenges, such as time to market, innovation, cost reduction, and global competition, they also have the massive responsibilities of patient safety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

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.

Emergo Group recently conducted the 2015 Medical Device Industry Survey with over 5,400 respondents, where they asked medical device industry senior executives to identify their biggest challenges. It's not a surprise to find traditional regulatory concerns and financial challenges on this list. What is surprising is that new product development ranked equally with these traditional concerns. 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.

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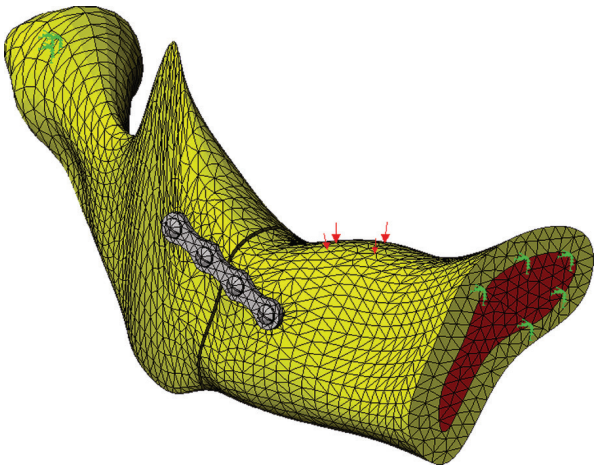
Implanted devices, such as cardiovascular stents, have to be error free because failure can cause fatalities. Orthopedic implants, such as hip and knee replacements, have to function flawlessly to avoid pain and the danger of fracture to patients. Product engineers have to predict the life of implantable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



SOLIDWORKS Simulation helped product designers optimize SOLIDWORKS 3D CAD software models, such as the artificial jaw joints used in this jaw reconstruction.

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.

DESIGN VALIDATION FOR THE MEDICAL DEVICE INDUSTRY

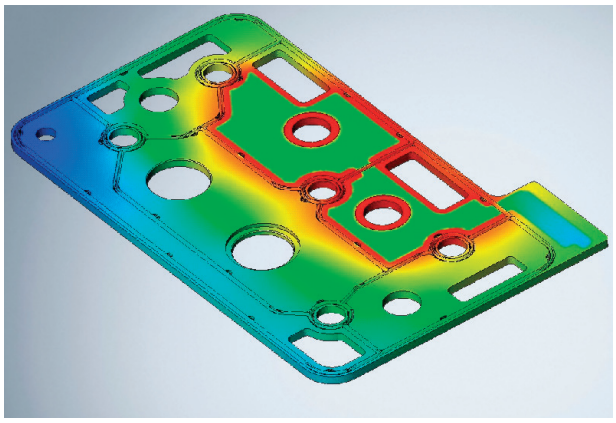
The purposes for which engineers perform design analysis include proof of concept, "what if" studies to identify the best design, design confirmation, and assistance in answering to regulatory requirements. Proof of concept is required early in the development cycle. "What if" studies can include variations 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.

Analysis with SOLIDWORKS Simulation meets the requirements of regulatory agencies for proof of design reliability.

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.



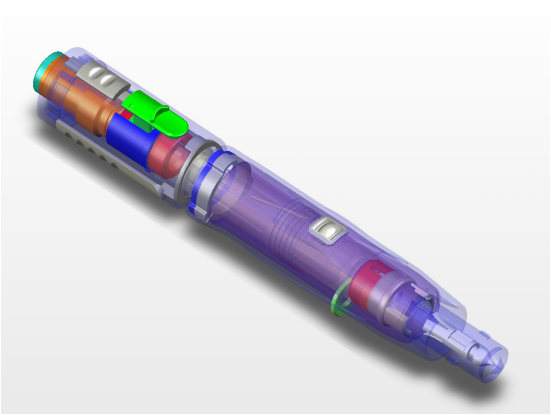
Using SOLIDWORKS Simulation during the redesign of this anesthetic unit, engineers at Dräger Medical, GmbH, reduced the number of prototypes used in the early stages of product development from eight to two.

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 SOLIDWORKS Simulation design validation solutions 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.



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.

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.

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.

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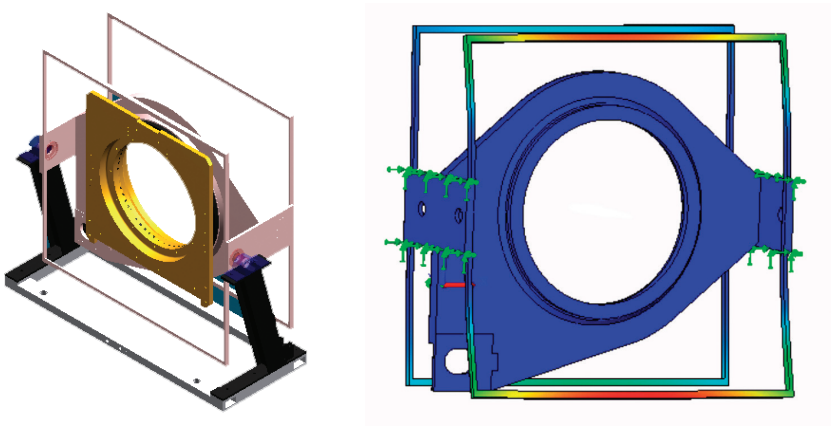
Dräger Medical of Germany, a worldwide leader in critical care equipment, used SOLIDWORKS Simulation linear static and thermal analyses to study the performance of a number of different plastic materials from the viewpoints of performance and meeting statutory regulations when they wanted to change the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

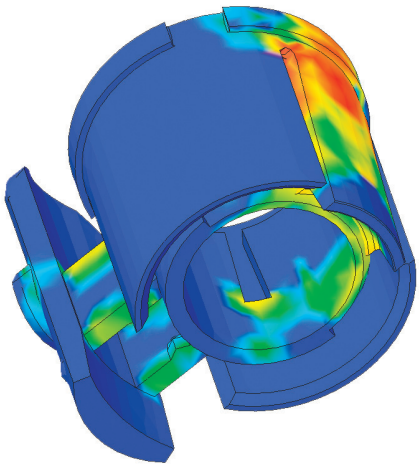


Frequency analysis on a subassembly of a CT scanner

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.

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.



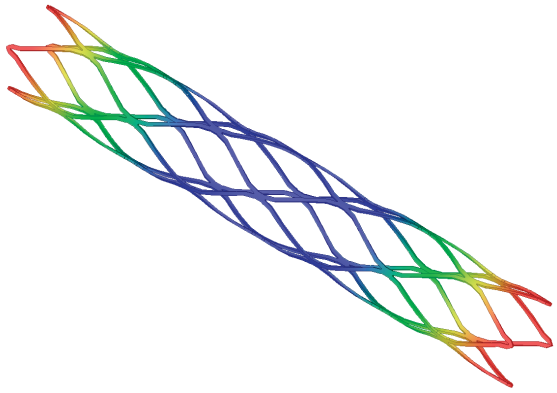
SOLIDWORKS Simulation was used on the injection device's trigger to determine the contact force needed to activate the injection.

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.



Nonlinear analysis of an expanding stent using Nitinol shape memory material.

When designing a new coronary and vascular stent that deforms less on insertion than traditional stents, REVA Medical Inc., working with SOLIDWORKS software, tested the reliability of the device over time with multiple nonlinear analyses. These studies focused primarily upon welded connections that had been designed to be more flexible, fatigue-resistant, and less susceptible to breakage than previous designs. The analyses made it possible to make several design changes that improved performance and to finalize the product design about 50 percent sooner than had been anticipated.

SOLIDWORKS Simulation nonlinear analyses made it possible for engineers at the Okayama University Faculty of Dentistry to design an artificial jaw joint for patients with broken jaw joints caused by rheumatoid arthritis or by retreated lower jaws. They analyzed different plate and screw models and materials and with the help of nonlinear analysis, identified a specific plastic material as the most appropriate material for the replacement jaw.

SOLIDWORKS Simulation nonlinear analysis, in conjunction with linear stress and thermal analyses, helped National University Hospital in Copenhagen, Denmark to study titanium spinal implants without resorting to invasive tests on people. Because the implants were intended to last the patient's lifetime, the interaction between the titanium and natural bone—a nonlinear material—was of particular importance. The nonlinear analyses showed the researchers how bone would grow around the implants.

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.

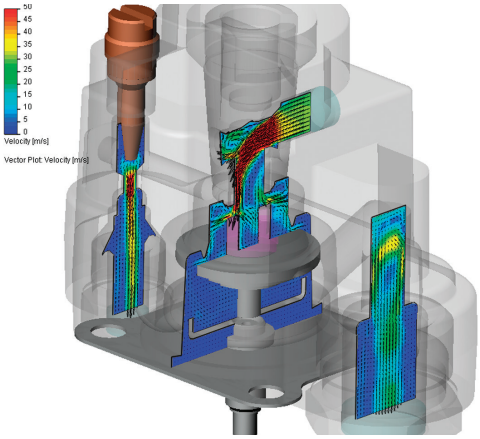
Optimization

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.



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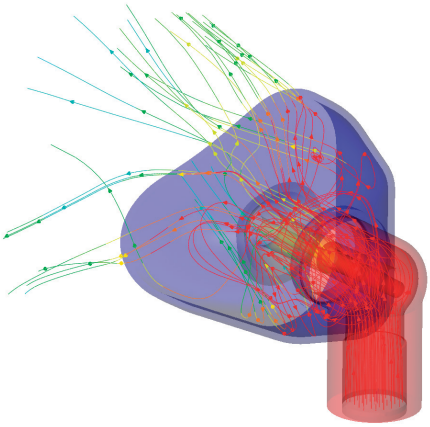
Fully embedded with SOLIDWORKS 3D CAD, SOLIDWORKS Flow Simulation's intuitive CFD tool enables you to simulate liquid flow in real world conditions.

In the case of the Dräger Medical ventilation system, SOLIDWORKS Flow Simulation assisted the designers to study the effects that resulted from changing the position of the gas flow into the ventilation system with the objective of ensuring that patients get enough oxygen. The company reported that use of SOLIDWORKS Flow Simulation along with linear static stress and thermal analyses reduced testing time by about 50 percent and cut the number of physical prototypes needed by 75 percent.

Canadian medical equipment developer Southmedic™ designed the first minimal contact open oxygen delivery system, the OxyArm™ headset. The technology behind the device is based on torch-like or vortex-like flow patterns generated inside a diffuser cup to deliver the correct concentration level of oxygen to the patient at different flow rates. Analysis required a combination of internal and external flows in the process of mixing air and oxygen. SOLIDWORKS Flow Simulation made it possible to perform these complex CFD analyses very easily. By tweaking the design, Southmedic's engineers quickly obtained the desired level of performance in a process invisible to the naked eye—saving time and money.



Southmedic took advantage of CAD embedded simulation benefits to reduce its design cycle by 45 percent.

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.

Sustainability

Leading companies in the Medical Device industry pursue new corporate sustainability strategies to reduce costs and improve profits in a more environmentally sustainable way. The commitment to sustainability in this industry is increasing and has an impact on product development processes. SOLIDWORKS Sustainability provides actionable environmental results by measuring the environmental impacts of individual designs across the product life cycle—including the effects of material, manufacturing, assembly, and transportation.

In addition to helping you reduce production costs and develop greener products, environmental assessment can lower the total cost of ownership (TCO) of your products by evaluating potential transportation, usage, and disposal effects.

Use SOLIDWORKS Sustainability to reduce production costs and develop greener products, while taking advantage of environmental assessment to lower your product's total cost of ownership (TCO) by evaluating potential transportation, usage, and disposal effects.

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, patient safety, and regulatory agencies. 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 unique engineering tools with an embedded Simulation CAD solution. 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. This approach allows them to 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. If you're constantly facing diminishing timelines, competitors in your rearview mirror, and complex regulatory demands, concurrent engineering with CAD and embedded simulation capabilities will enable you to navigate challenges and bring your medical breakthroughs to life faster than ever.

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